Transfusion-transmissible infections in Australia

2018 Surveillance Report

Australian Red Cross BLOOD SERVICE

UNSW SYDNEY

Kirby Institute

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in collaboration with

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Foreword

This report is jointly produced by the Australian Red Cross Blood Service (Blood Service) and the Kirby Institute via the Surveillance, Evaluation and Research Program, which is responsible for monitoring the pattern of transmission of HIV, viral hepatitis, and specific sexually transmissible infections in Australia. This is the eighth report that summarises donation testing data, and incidence and prevalence trends for transfusion-transmissible infections (TTIs) among Australian blood donors. While it is an important Blood Service resource, it is also intended to be a reference document for organisations and individuals interested in the occurrence of transfusion-transmissible infections in Australia and the effectiveness of the Blood Service's infectious disease blood safety strategy. The data in the report is current at the time of publication and all efforts have been undertaken to confirm its accuracy, however subsequent data updates may occur, and users must consider this.

Ensuring donations do not transmit infectious diseases is a key priority of the Blood Service. Blood donors are required to complete a questionnaire every time they donate to assess their risk of exposure to significant TTIs. The questionnaire for first-time donors includes basic demographic information, as well as questions regarding lifetime exposures to certain risk events. Repeat donors within a two-year time frame are required to complete a shorter questionnaire. The questionnaire is reviewed and those assessed as being at high risk of recent exposure are deferred from donating. Subsequent to satisfactorily completing the assessment process, donors proceed to donate. The current regulatory standard applicable in Australia requires each blood donation to be tested for significant TTIs which can potentially cause infection in the donation recipient (see Supporting Information for details). A timeline of introduction of specific screening tests for Australian blood donors is provided in Supplementary Table 1. If a TTI is detected, the blood donation is removed from the donor pool and the donor undergoes a post-donation interview.

For the purpose of this report the term TTI refers to infections for which there is mandatory blood donation testing. Mandatory tests differ between donations for fresh blood components (i.e. HIV, HBV, HCV, HTLV, syphilis) and plasmapheresis donations, which are exclusively sent for fractionation (i.e. HIV, HCV and HBV only). Consistent with previous years, the overall number of TTIs detected remained very low in 2017 (n=145), the lowest number recorded in the ten-year period, 2008-2017. Of these, 91% were either hepatitis B (HBV) or hepatitis C (HCV) virus. Reflecting the effectiveness of donor screening strategies, the prevalence of infection in first-time donors in 2017 continues to be substantially (15-51 times) lower than the estimated national population prevalence. Only three (2.1%) of all infections in 2017 were determined to be incident (newly acquired) based on a past negative test within the last twelve months for the same TTI. Incident infections are the most concerning from a blood safety perspective, as in contrast to prevalent infections they are more likely to be in the so-called testing 'window period' making them undetectable by the screening test(s). Notably, there was no significant trend observed for incidence rates of any of the TTIs for the five-year study period, 2013-2017.

Given window period infections cannot be detected by testing but can be prevented if the donor discloses risk behaviour leading to deferral from donation, the Blood Service is highly reliant on donor truthfulness. Of the TTIs detected in 2017, 21% had risk factors identified in their post-donation interview which were not disclosed in their initial donation interview (termed 'noncompliance'). While this rate has been fairly stable in the past decade, there has been a fluctuating trend in recent years. As minimising noncompliance is an organisational imperative, the Blood Service continually reviews the donor assessment process for potential improvements. Internationally, electronic (computer-assisted) interviews have demonstrated the capability to provide improved compliance. Accordingly, the Blood Service has successfully piloted an electronic donor questionnaire (PeDQ) for regular plasmapheresis donors at several plasma collection sites with plans to expand this process to other collection sites.

Contents

Glossary

Active syphilis
Defined by reactivity on treponemal and nontreponemal syphilis testing, with or without clinically apparent infection (i.e. excluding past treated infections). This definition is no longer in use (see 'Potentially infectious syphilis') but is included as previous reports and trend data used this definition.

Apheresis
The collection procedure for plasma and/or platelets which separates whole blood into its components and returns remaining components to the donor, using automated separation technology.

First time donor
A donor who has not previously donated blood or blood products in Australia.

Hepatitis B virus (HBV) positive:
The person has either tested positive to hepatitis B surface antigen, hepatitis B DNA or to both:

Hepatitis B surface antigen (HBsAg) positive: HBsAg is a HBV protein and a positive result indicates the presence of HBV in the blood. This means the person is currently infected with HBV and can pass the infection to others (infectious). Most adults who acquire HBV clear the virus within a few months, and their HBsAg test result will be negative after that time. Some people remain infected and continue to test positive for HBsAg. If, after 6 months, the person still tests positive for HBsAg, the infection is considered chronic.

Hepatitis B deoxyribonucleic acid (HBV DNA) positive: HBV DNA assays are used to monitor response to treatment, assess the likelihood of maternal-to-child transmission of HBV, and to detect the presence of occult hepatitis B virus infection (i.e. infection in someone who tests HBsAg negative). If positive, it could either mean:

- The virus is multiplying in a person's body and he or she is highly contagious.
- In case of chronic HBV infection, the presence of viral DNA means that a person is possibly at increased risk of liver damage.

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

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

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

Intravenous drug user
Defined in the context of blood donation as; ever "used drugs" by injection or been injected, even once, with drugs not prescribed by a doctor or a dentist.

Incidence
The rate of newly acquired infection among repeat donors.

Incident donor
A positive repeat donor whose last 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 definitions on page 7).

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

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

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

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

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

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

Positive donor
A donor confirmed (by additional testing as necessary) to have the relevant transfusion-transmissible infection.

Potentially infectious syphilis (PIS)
This is a blood safety specific surveillance definition designed to capture donors who are at theoretical risk of transmitting syphilis by blood transfusion. PIS includes repeat donors if they had seroconverted within the last two years (TPHA negative to positive) with a positive confirmatory result, or had a history of syphilis treatment since their last TPHA non-reactive donation and infectious syphilis cannot be conclusively ruled out at the time of that donation, or were previously known to have past treated syphilis and subsequently had possible reinfection (four-fold RPR titre rise). PIS includes first time donors if screening and confirmatory tests for treponemal antibodies were positive, in addition to RPR titre >8 or clinical evidence (signs of syphilis) or recent contact with a confirmed case.

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

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

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

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

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

Summary of the main findings

General characteristics of blood donors in Australia

1. Over the ten-year period 2008-2017, there were over 13 million blood donations in Australia with an average of 1.3 million donations per year. Over the past ten years, 2008-2017, there has been no significant change in the total number of donations (see Methodological Notes for details). Total blood donations in 2017 increased by 2% (representing 27 824 more donations) compared to 2016, most of which were plasma donations.
2. Of the 'age-eligible' Australian population (aged between 16-80 years), 2.4% donated blood during 2017.
3. First-time and repeat donors comprised 15.3% and 84.7% of all blood donors in Australia over the period 2008-2017, respectively. As in previous years, this ratio remained relatively stable nationally and across all states and territories. Male donors constitute 49.3% of all donors in 2017, which is almost identical to their proportional representation of 49.5% among the Australian general population aged 16-80 years.

Trends in transfusion-transmissible infections in Australian blood donors

A blood donation which is found to be positive for one of the TTIs which the Blood Service tests for is discarded and the donor is counselled and referred for medical follow-up.

1. In 2017, a total of 145 blood donors were detected as having a TTI for which testing is in place, namely, hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus (HIV), human T-lymphotropic virus (HTLV), or potentially infectious syphilis. In the ten-year period 2008-2017 a total of 2 005 TTI-positive donors were detected. In 2017, no donor was infected by more than one TTI.
2. Consistent with the long-term pattern, the most common TTI was HBV, followed by HCV. Of all the donations positive for a TTI in 2017, 91% were positive for either HBV or HCV, a slight increase from 87% in 2016.
3. Overall HTLV was the least common infection among all donors in 2017, with just two donors testing positive. In the ten-year period 2008-2017, HTLV was the least common infection among all donors (43 positive donors); and HIV was the least common infection in the first-time donors (21 positive donors).
4. Although representing only 13.6% of the donor population, first-time blood donors contributed approximately 77% of TTIs in Australia in 2017. This ratio has remained relatively stable since 2008 with the exception of 2014 where first-time blood donors contributed to a record low of 67% of the total TTIs; this decline was due to an increase in the proportion of repeat donors during 2014 who had made their last donation prior to 1990 (the year HCV testing was commenced) and therefore they had not previously been tested for HCV.
5. No transfusion-transmitted HIV, HCV, HTLV or syphilis infections were reported in Australia during 2008-2017.
6. Consistent with previous years, in 2017, the prevalence of TTIs was substantially lower among first-time blood donors (15 to 51 times) compared with national prevalence estimates for 2017.

HBV infection among Australian blood donors

1. There were 75 HBV infections detected among all donations in 2017 (63 in first-time donors and 12 in repeat donors).
2. Of all TTIs detected, HBV continued to have the highest prevalence among first-time donors.
3. The prevalence of HBV infection among first-time donors in 2017 was comparable to that observed in 2016, 68.6 versus 64.7 per 100 000 donations, respectively. This equates to 0.07% of the total first-time donations in 2017, which is 15 times lower than the estimated 1.0% reported in national HBV surveillance data.
4. Among the 75 HBV infections, 14 (3 first-time and 11 repeat donors) were classified as occult HBV infection (OBI) based on the detection of HBV DNA without HBsAg. Most donors with OBI in 2017 were males and had an average age of 54 years. Unlike 2016 where donors with OBI were predominantly born in Asia, the majority of donors (50%) with OBI in 2017 were born in Oceanian countries (Australia inclusive).
5. Incident HBV donors continue to be rare with only one recorded nationally in 2017, giving an incidence rate of 0.3 per 100 000 donor-years of observation, identical to that reported in 2016. Overall, there was no temporal trend in HBV donor incidence nationally or in any state/territory during the ten-year study period 2008-2017.
6. In 2017, HBV positive donors were slightly younger as compared to all donors (41 years versus the mean age 42.9 years), more likely to be male (84% in hepatitis B positive donors versus 49.3% in all donors) and more likely to be born in the Asia-Pacific Region. 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, 2013-2017, was ethnicity/country of birth (81%). In Australia 38% of people living with hepatitis B were born in the Northeast/Southeast Asia.[1]
8. No transfusion-transmitted HBV infections were recorded in 2017. Three probable cases were reported in the 2008-2015 period (see Transfusion-transmissible infections in Australia 2017 Surveillance Report for details).

HCV infection among Australian blood donors

1. There were 48 HCV infections detected among all donors in 2017 (38 in first-time donors and 10 in repeat donors). The proportion of HCV RNA positive (potentially infectious) donors was 40%, a figure that has incrementally declined from around 75% when HCV RNA donation testing was introduced in 2000.
2. HCV was the second most common infection found in first-time blood donors after HBV.
3. During 2008-2017, there has been a significant decrease in HCV prevalence in first-time donors in Australia, from 0.07% of the total first-time donations in 2008 to 0.04% in 2017. This translates into a decrease of 40% from 69.1 per 100 000 first-time donations in 2008 to 41 per 100 000 first-time donations in 2017. The 0.04% first-time donor prevalence in 2017 is 18 times lower than the 0.7% reported for HCV national surveillance data. This decreasing trend is consistent with national HCV new-diagnoses notification rate (from 53 per 100 000 in 2008 to 43 per 100 000 in 2017).
4. In 2017, there were 10 repeat donors who tested positive but only one met the incidence definition. The average incidence rate of HCV among previously negative repeat donors during 2013-2017 was very low at 0.75 per 100 000 donor-years of observation (see Methodological Notes for details). HCV incidence has shown no significant trend during the study period, 2013-2017.
5. In 2017, the mean age of HCV positive donors was 48 years compared to 42.9 years for all donors. Like HBV, HCV positive donors were more likely to be male as compared to all donors (73% versus 49.3%) but in contrast to HBV, the majority (77%) were born in Australia.
6. The most common putative risk factor reported by donors with HCV infection during 2013-2017 was injecting drug use and a history of tattoo/piercing (each 22%). Note this reporting does not confirm causation and background tattoo prevalence should be considered. In comparison, injecting drug use (82.7%) and country of birth/ethnicity and other blood to blood contact (each 2.4%) were the three most dominant routes of exposure in cases of newly acquired hepatitis C infection reported in national notification data in 2017.[1]
7. No transfusion-transmitted HCV infections were reported in Australia during 2008-2017.

HIV infection among Australian blood donors

1. There were three HIV infections detected among all donations in 2017 (two first-time and one repeat donor).
2. The prevalence of HIV infection among first-time donors during 2008-2017 remained very low at 1.8 per 100 000 donations (or 0.002% of the total first-time donations) and comparatively much lower than hepatitis B (77.9 per 100 000 donations) and hepatitis C (51.3 per 100 000 donations). However, no significant trend was observed for incidence rates for HIV infection during this time. The 0.002% HIV prevalence in first-time donor is 51 times lower than the 0.1% prevalence reported for HIV national surveillance data.
3. The incidence of HIV infection per 100 000 donor-years of observation among previously negative repeat donors remained low over time; 0.2 in 2013, 0.0 in 2015, and 0.3 in 2017.
4. In 2017, the mean age of HIV positive donors (n=3) was 36 years as compared to 42.9 years for all donors. Like HBV and HCV, HIV positive donors were more likely to be male as compared to all donors (67% vs 49.3%) but unlike HBV, most (67%) were Australian-born.
5. The two most common reported routes of exposure for donors with HIV infection during 2013-2017 were male-to-male sex and heterosexual sex partners with known risk factors or known to be HIV positive (32%, each), followed by 16% of those where the possible route of exposure remains unknown. This compares to the new HIV diagnoses notification data in Australia where men who have sex with men accounted for 63% of new HIV diagnoses in Australia in 2017, followed by heterosexual sex (25%).[1]
6. No transfusion-transmitted HIV infections were reported in Australia during 2008-2017.

HTLV infection among Australian blood donors

1. There were two HTLV infections detected among all donations in 2017 (both in first-time donors).
2. The prevalence of HTLV infection among first-time donors during 2008-2017 has remained low at 3.7 per 100 000 donations and has shown no significant trend. Population prevalence for HTLV is unknown; therefore, comparison of prevalence rates among first-time donors and the general population is not possible.
3. The HTLV incidence among repeat Australian donors in 2017 was zero as it was for the five-year period 2013-2017.
4. In 2017, the mean age of the two donors with HTLV infection was 54 years; 1 was male and both were born overseas.
5. The most common putative risk factor for donors with HTLV infection during 2013-2017 was ethnicity or country of birth (71%). There are no data to compare risk factors in the general population.
6. No transfusion-transmitted HTLV infections were reported in Australia during 2008-2017.

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

1. There were 17 potentially infectious syphilis infections (7 first-time and 10 repeat donors) detected in 2017, the highest number recorded in the past ten years, 2008-2017.
2. Despite a marked recent increase, the prevalence of active/potentially infectious syphilis in first-time donors has shown no significant change over time in the past ten years, 2008-2017; however, in the past five years, 2013-2017, there is a significant upward trend. In first-time donors the prevalence was 2.1 per 100 000 first-time donations in 2008, 0.8 per 100 000 first-time donations in 2012 and 7.6 per 100 000 first-time donations in 2017.
3. The mean age of potentially infectious syphilis positive donors in 2017 was 30 years (compared to 42.9 years for all donors); and they were more likely to be male as compared to all donors (71% versus 49.3%).
4. The most common reported route of exposure by donors with active/potentially infectious syphilis during 2014-2017 period (risk factor data on donors positive for active/potentially infectious syphilis is only available from 2014) was having a partner with an unspecified risk (43%).

* see ‘Potentially infectious syphilis’ definition in the Glossary section

Donor compliance

1. Of the TTI-positive donors in 2013-2017, 17% (153 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 were over represented accounting for 69% (106 donors).
2. The non-compliance rate of all TTI-positive donors has fluctuated in the last five years between 14.8 and 25%. The non-compliance rate among TTI-negative donors is not determined on a regular basis; however, results from a large national survey from 2012-13 showed a comparatively much lower rate of non-compliance (in the range of 0.05-0.29%). See Additional information section for more information.

Malaria testing

1. In 2017, a total 106 863 donations were tested for malaria antibody of which 1 425 (1.3%) were repeatedly reactive for malaria antibodies. None of these repeatedly reactive donors had detectable malaria DNA, suggesting past infection in the donors.
2. There were no reported cases of transfusion-transmitted malaria during 2017, with the last reported Australian case occurring in 1991.

Bacterial pre-release testing for platelets

1. In 2017, 131 (0.11%) of a total 123 741 screened platelet units had confirmed bacterial contamination.
2. The most frequently-isolated species (114 isolates) was *Cutibacterium (Propionibacterium) acnes*, a commensal skin organism of low pathogenicity which is rarely (if ever) associated with septic transfusion reactions [2].
3. The majority of the remaining confirmed positives were coagulase-negative staphylococci, which along with the propionibacteria are usually considered skin contaminants. Potential pathogens included single isolates of *Klebsiella pneumoniae, Staphylococcus aureus, Streptococcus agalactiae, Streptococcus dysgalactiae, Streptococcus pneumoniae* and *Streptococcus pyogenes*.
4. During 2017 no septic transfusion reactions were identified.

Emerging infections

1. Along with the ongoing risk from local dengue virus outbreaks and seasonal WNV outbreaks in Europe, outbreaks of Ebola virus, MERS-CoV and Zika virus have also been monitored during 2017-2018.
2. The risk to the blood supply posed by donors returning from Ebola virus and Zika virus outbreak areas is managed by deferring donors (Ebola) or restricting donations to plasma sent for fractionation for an appropriate period (Zika).

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Abbreviations

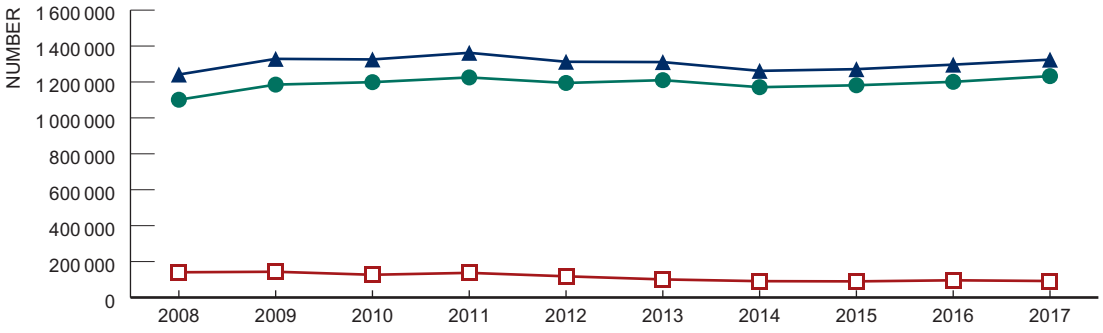
anti-HBc	antibody to hepatitis B core antigen
anti-HBe	antibody to hepatitis B e antigen
anti-HBs	antibody to hepatitis B surface antigen
anti-HeV	antibody to Hendra virus
A(H7N9)	avian influenza H7N9 virus
HBsAg	hepatitis B surface antigen
Blood Service	Australian Red Cross Blood Service
EVD	Ebola virus disease
HBeAg	hepatitis B e antigen
HBsAg	hepatitis B surface antigen
HBV	hepatitis B virus
HCV	hepatitis C virus
HeV	Hendra virus
HIV	human immunodeficiency virus
HTLV	human T-lymphotropic virus
IDU	intravenous drug user
MERS-CoV	Middle East respiratory syndrome coronavirus
NAT	nucleic acid testing
OBI	occult hepatitis B virus infection
SARS-CoV	severe acute respiratory syndrome-related coronavirus
STIs	sexually-transmissible infections
TTIs	transfusion-transmissible infections
WNV	West Nile virus
WP	window period
YFV	yellow fever virus
YF	yellow fever
ZIKV	Zika virus

Main Findings

Blood donors in Australia

Over 13 million donations were tested for TTIs in Australia during the ten-year period 2008-2017 with an average of 1.3 million donations per year. The number of donations increased from 1.2 in 2008 to 1.3 million in 2010 and remained steady at around 1.3 million from 2010 to 2013, with a slight decline to around 1.2 million from 2014 to 2016. In 2017, the number of donations has increased by 2% as compared to 2016 reaching over 1.3 million donations. The majority of this increase reflects an expansion in plasma collections to meet increasing demand for fractionated plasma products. Over the entire ten-year period there was no significant trend in numbers of donations (Figure 1) (see Methodological Notes for details). Notably, from September 2016, in accordance with regulatory requirements, plasma donations from repeat donors collected solely for the manufacture of fractionated plasma products were no longer tested for HTLV or syphilis resulting in differing total test numbers. A total of 0.79 million donations were tested for HTLV and syphilis in 2017, as compared to 1.32 million for HBV, HCV and HIV.

Figure 1 Number of blood donations in Australia by year of donation, 2008-2017



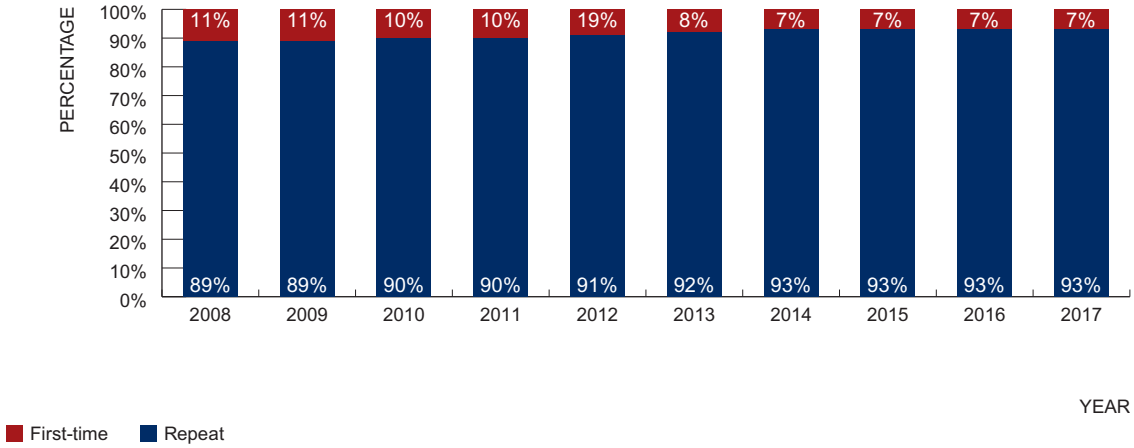
	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
▲ Total	1.24 M	1.33 M	1.33 M	1.36 M	1.31 M	1.31 M	1.26 M	1.27 M	1.30 M	1.32 M
□ First-time	0.14 M	0.14 M	0.13 M	0.14 M	0.12 M	0.10 M	0.09 M	0.09 M	0.10 M	0.09 M
● Repeat	1.10 M	1.19 M	1.20 M	1.23 M	1.19 M	1.21 M	1.17 M	1.18 M	1.20 M	1.23 M

In 2017, 2.4% of the general population who were aged between 16-80 years (age-eligible to donate) donated blood in Australia. Together, New South Wales, Queensland and Victoria accounted for more than 75% of all blood donations. The jurisdictions where the greatest proportion (nearly 4%) of the age-eligible local population donated blood in 2017 were the Australian Capital Territory and Tasmania (Figure 2).

Figure 2 Percentage of age eligible general population who donated blood in 2017, by state/territory

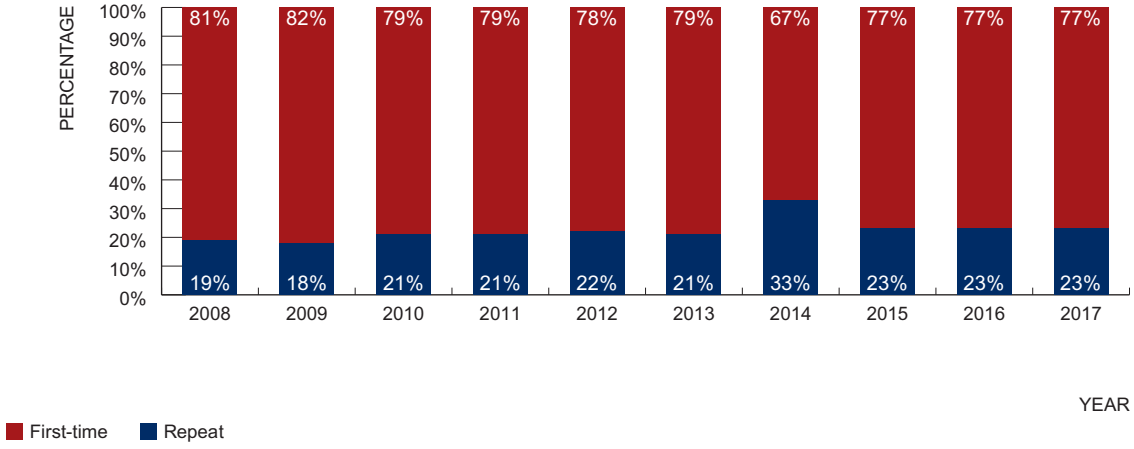
As in previous years, more than 90% of all donations in 2017 were from repeat donors (Figure 3). While first-time blood donors represented only 13.6% of the donor population, and 6.9% of the total donations, they contributed the majority (75%) of TTIs in Australian blood donors in 2017, reflecting detection of prevalent infections rather than incident infections (Figure 4).

Figure 3 Percentage of donations made by first time and repeat donors among all blood donations in Australia, 2008-2017



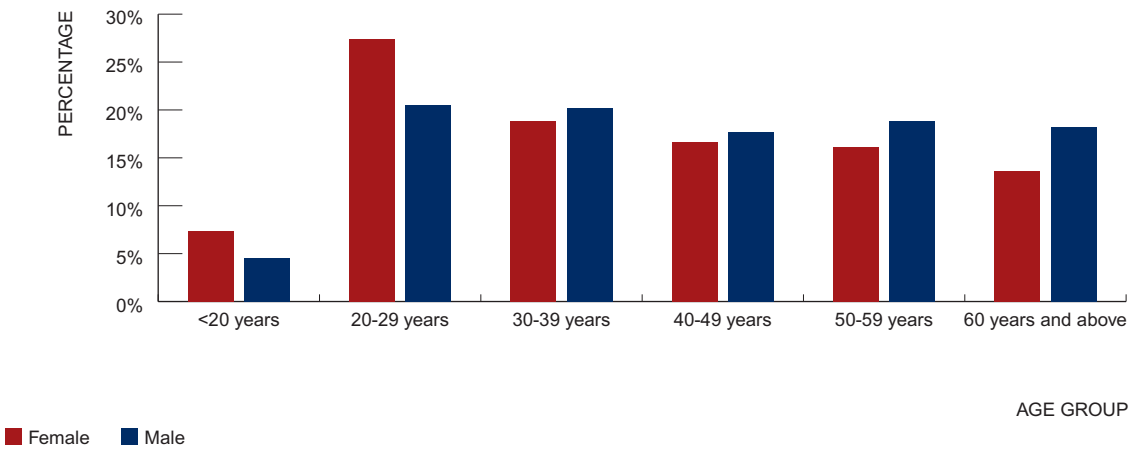
Overall in the past ten years, there has been a steady increase in the proportion of repeat donors among all TTI-positive blood donations in Australia, from 19% in 2008 to 22% in 2012 to 23% in 2017 (Figure 4). The increase in 2014 is explained by an anomaly in the rate of returning 'lapsed' donors, who had made their last donation prior to 1990, undergoing HCV testing for the first time (HCV testing was implemented in 1990). The increase in the TTI-positive repeat donor proportion in the past ten years is probably multi-factorial and influenced by the declining HCV prevalence among first-time donors, and the implementation of HBV DNA testing in 2010 which detected a cohort of previously unidentified repeat donors with occult HBV infection. Importantly, the proportional increase in TTI-positive repeat donors is not reflective of an increase in TTI incidence, which has been stable or declining.

Figure 4 Percentage of first time and repeat donations among all TTI-positive blood donations in Australia, 2008-2017



Among all blood donors who donated in 2017, an approximately equal proportion of males and females contributed donations (50.7% females versus 49.3% males). There was a higher proportion of females among younger age groups (less than 20 years and 20-29 years), and a higher proportion of males in donors 30 years and above (Figure 5). Over 33% of donors were aged 50 years and above; the median age of male and female donors was 42 and 38 years, respectively.

Figure 5 Distribution of blood donors in Australia by age group and sex, 2017



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

This section focuses on the trends in prevalence and incidence of TTIs during the ten-year period 2008-2017 overall in Australia, and trends observed in state/territory jurisdictions. In addition, association of demographic characteristics with presence of TTIs for the year 2017 and the five-year period 2013-2017 will be discussed. Putative risk factors associated with positive blood donors in Australia are also reported for the five-year period, 2013-2017. The findings are presented in respective sections by infection.

Blood donors are a subset of the general population, so to provide a context for the report the epidemiology of each relevant TTI in Australia is also discussed in respective sections. This includes a brief description of the number of people living with TTIs in Australia by the end of 2017, trends in the last ten years, notifications of newly diagnosed TTIs in Australia, and risk exposure categories associated with respective infections. The information is drawn from the HIV, viral hepatitis and sexually transmissible infections in Australia: Annual Surveillance Report 2018.[1]

Of note, prevalence is defined as the frequency and proportion of infection among all blood donors, and first-time blood donors, separately; whereas incidence is the rate of newly acquired infection among repeat donors. It is important to note that given the low donor incidence rates nationally and in all jurisdictions, individual year variation should be interpreted with caution. This is particularly relevant to the 2014-17 incidence data where a stricter definition (negative test within the past 12 months) applies. Poisson regression analysis was used to calculate incidence rate ratios (IRRs) and their 95% confidence intervals. A p-value of less than 0.05 was considered statistically significant.

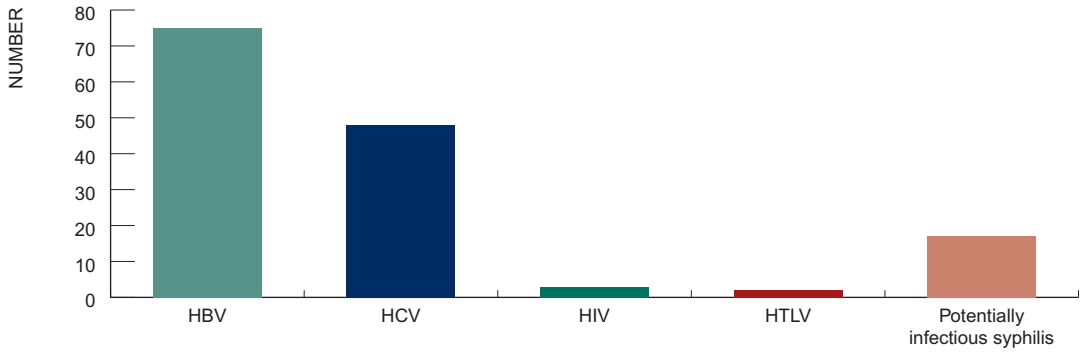
The Blood Service assesses the incidence rate of newly acquired infection in donors since this correlates directly with the risk of transmission. Incident donors (formerly 'seroconverters') are defined as 'positive repeat donors whose last donation tested negative for the same TTI within the last twelve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

During the past ten years, 2008-2017, a total of 2 005 donations (1 568 in first-time and 436 in repeat donations) were positive for at least one of the TTIs subject to mandatory donation testing. Of these, 1 883 were positive for HBV, HCV and HIV (14.4 per 100 000 donations), and 122 (0.9 per 100 000 donations) were positive for active/potentially infectious syphilis and HTLV. As noted above, due to a different total number of donations tested for these infections during the last ten years 2008-2017, (13.0 million donations for HBV, HCV and HIV, as opposed to 12.3 million donations tested for HTLV and syphilis), these data are presented separately (Table 1A and 1B). Of these, 91.4% of the donations were positive for either HBV or HCV. As noted above, overall in the past ten years, there has been a steady increase in the proportion of repeat donors among all positive blood donations in Australia, from 19% in 2008 to 22% in 2012 to 23% in 2017 (Figure 4).

In 2017, a total of 145 donors were found positive for at least one of the TTIs subject to mandatory donation testing. Overall, HBV and HCV were the two most frequent TTIs identified in Australian blood donors in 2017, together contributing 85% of all infections (Figure 6). This proportion has decreased by a relative 3% as compared to 87% in 2016, suggesting a declining trend in the prevalence of HBV and HCV in all donors. HBV and HCV were also the most frequent TTIs in both first-time and repeat donors.

Of note, the method for calculating incidence has been modified in this year's report due to a change in the process for calculating the donor-years of observation (DYO) and includes the inter-donation intervals from 2017 only. Previous reports used two years of inter-donation interval data. Therefore, the incidence calculations cannot be directly compared to previous reports (see Methodological notes for details). For this reason, updated data are presented for a five-year period, 2013-2017 which retrospectively apply the updated DYO calculation method. During 2013-2017, a total of 27 incident donors were identified, nine for HBV, 12 for HCV and six for HIV. In 2017, a total of three incident infections were detected, one each for HBV, HCV and HIV.

Figure 6 Number of blood donors with transfusion-transmissible infections in Australia, in 2017, by infection



	HBV	HCV	HIV	HTLV	Potentially infectious syphilis
Positive donations 2017	75	48	3	2	17

Data on the demographic characteristics (sex, age group, state/territory and year of donation) for all blood donors was analysed (see Methodological Notes for details) to determine any association between demographic factors and presence of any TTI among Australian blood donors in 2017, and the five-year period, 2013-2017 (with the exception of active/potentially infectious syphilis), separately. Standardised national data on demographic factors associated with syphilis infected donors are available on only 37 donors (3 from 2014, 5 from 2015, 12 from 2016 and 17 from 2017), therefore analyses are presented for 2017, and the four-year period, 2014-2017.

Standardised national data on reported putative risk factors associated with donors infected with HBV, HCV, HIV and HTLV are available since 1999. Importantly, assessing the strength of association of disclosed risk factors is complex and this must be borne in mind when interpreting the data. Risk varies based on a number of variables including the timing and location of the risk event. For instance, tattooing performed in some settings (e.g. in Australian prisons or high risk countries) is a recognised risk for HCV transmission, in contrast to tattooing currently performed in Australian commercial tattooing parlours, where the risk is very low.[3]

This report presents risk factor data for the five-year period 2013 to 2017. A total of 798 positive donors with at least one of the TTIs were observed over the period 2013-2017. Among them, 44 donors were positive for active/potentially infectious syphilis, of which only 37 have standardised risk factor data available (3 from 2014, 5 from 2015, 12 from 2016 and 17 from 2017); therefore, data for 2014-2017 period only is presented on donors positive for syphilis. The data on the remaining 754 donors who were positive for any of the other TTIs (HBV, HCV, HIV and HTLV) during 2013-2017 were analysed to determine the key characteristics of blood donors with transfusion-transmissible infections, stratified by year of donation, and findings are presented in the respective infection sections.

Table 1 The number and prevalence rate of transfusion-transmissible infections in Australia, by state/territory, 2008-2017

1A: HBV, HCV and HIV in Australia, by state/territory, 2008-2017

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	394 875	3 657 248	4 052 123	311	39	350	227	81	308	8	6	14	546	126	672
Number *(Number per 100 000 donations)*				*78.76*	*1.07*	*8.64*	*57.49*	*2.21*	*7.60*	*2.03*	*0.16*	*0.35*	*138.27*	*3.45*	*16.58*
NT	8 055	98 891	106 946	9	2	11	7	4	11	0	1	1	16	7	23
Number *(Number per 100 000 donations)*				*111.73*	*2.02*	*10.29*	*86.9*	*4.04*	*10.29*	*0.00*	*1.01*	*0.94*	*198.63*	*7.08*	*21.51*
QLD	239 457	2 423 124	2 662 581	134	22	156	119	62	181	7	9	16	260	93	353
Number *(Number per 100 000 donations)*				*55.96*	*0.91*	*5.86*	*49.7*	*2.56*	*6.80*	*2.92*	*0.37*	*0.60*	*108.58*	*3.84*	*13.26*
SA	87 535	1 196 983	1 284 518	48	11	59	46	18	64	0	1	1	93	30	123
Number *(Number per 100 000 donations)*				*54.84*	*0.92*	*4.59*	*52.55*	*1.50*	*4.98*	*0.00*	*0.08*	*0.08*	*106.24*	*2.51*	*9.58*
TAS	32 618	442 192	474 810	8	2	10	17	10	27	0	0	0	25	12	37
Number *(Number per 100 000 donations)*				*24.53*	*0.45*	*2.11*	*52.12*	*2.26*	*5.69*	*0.00*	*0.00*	*0.00*	*76.64*	*2.71*	*7.79*
VIC	271 734	2 886 410	3 158 144	284	41	325	128	37	165	5	10	15	417	88	505
Number *(Number per 100 000 donations)*				*104.51*	*1.42*	*10.29*	*47.1*	*1.28*	*5.22*	*1.84*	*0.35*	*0.47*	*153.46*	*3.05*	*15.99*
WA	99 894	1 195 913	1 295 807	90	23	113	39	15	54	1	1	2	130	39	169
Number *(Number per 100 000 donations)*				*90.1*	*1.92*	*8.72*	*39.04*	*1.25*	*4.17*	*1.00*	*0.08*	*0.15*	*130.14*	*3.26*	*13.04*
National	1 134 168	11 900 761	13 034 929	884	140	1 024	583	227	810	21	28	49	1 488	395	1 883
Number *(Number per 100 000 donations)*				*77.94*	*1.18*	*7.86*	*51.4*	*1.91*	*6.21*	*1.85*	*0.24*	*0.38*	*131.2*	*3.32*	*14.44*

1B: HTLV and active/potentially infectious syphilis in Australia, by state/territory, 2008-2017

State/Territory of donation	All accepted donations			HTLV			Active/Potentially infectious syphilis			Total positive donations		
	First time	Repeat	All	First time	Repeat	All	First time	Repeat	All	First time	Repeat	All
NSW/ACT	394 875	3 476 999	3 871 874	10	1	11	4	17	21	14	18	32
Number *(Number per 100 000 donations)*				*2.53*	*0.03*	*0.27*	*1.01*	*0.46*	*0.52*	*3.55*	*0.52*	*0.83*
NT	8 055	91 500	99 555	0	0	0	4	3	7	4	3	7
Number *(Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*	*49.66*	*3.03*	*6.55*	*49.66*	*3.28*	*7.03*
QLD	239 457	2 283 100	2 522 557	5	0	5	9	6	15	14	6	20
Number *(Number per 100 000 donations)*				*2.09*	*0.00*	*0.19*	*3.76*	*0.25*	*0.56*	*5.85*	*0.26*	*0.79*
SA	87 535	1 121 900	1 209 435	3	0	3	5	0	5	8	0	8
Number *(Number per 100 000 donations)*				*3.43*	*0.00*	*0.23*	*5.71*	*0.00*	*0.39*	*9.14*	*0.00*	*0.66*
TAS	32 618	409 746	442 364	1	0	1	0	1	1	1	1	2
Number *(Number per 100 000 donations)*				*3.07*	*0.00*	*0.21*	*0.00*	*0.23*	*0.21*	*3.07*	*0.24*	*0.45*
VIC	271 734	2 715 216	2 986 950	18	0	18	8	9	17	26	9	35
Number *(Number per 100 000 donations)*				*6.62*	*0.00*	*0.57*	*2.94*	*0.31*	*0.54*	*9.57*	*0.33*	*1.17*
WA	99 894	1 111 452	1 211 346	5	0	5	9	4	13	14	4	18
Number *(Number per 100 000 donations)*				*5.01*	*0.00*	*0.39*	*9.01*	*0.33*	*1.00*	*14.01*	*0.36*	*1.49*
National	1 134 168	11 209 913	12 344 081	42	1	43	39	40	79	81	41	122
Number *(Number per 100 000 donations)*				*3.70*	*0.01*	*0.33*	*3.44*	*0.34*	*0.61*	*7.14*	*0.37*	*0.99*

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Hepatitis B Virus (HBV)

Epidemiology of HBV in Australia

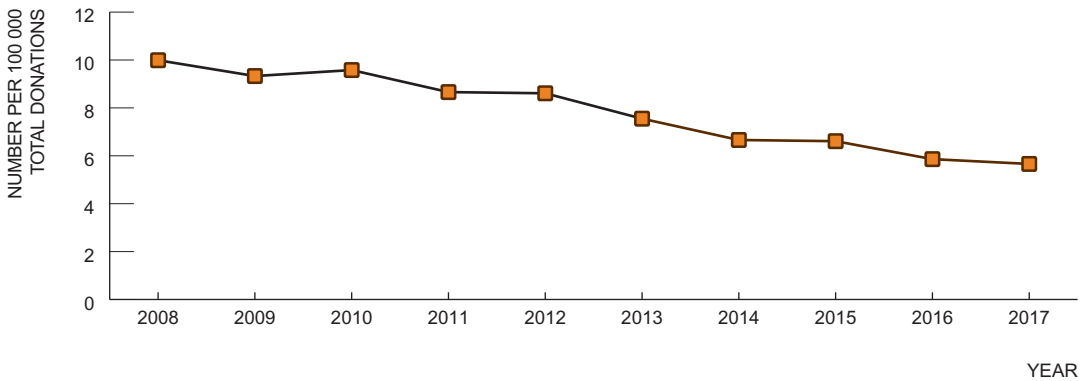
At the end of 2017, an estimated 248 536 people were living with chronic HBV infection in Australia, of whom an estimated 61% were diagnosed with chronic hepatitis B, 21% and 17% were born in the Northeast and Southeast Asia, respectively, and 11% were among Aboriginal and Torres Strait Islander peoples. In total, there were 6 102 notifications of newly diagnosed HBV infection in Australia in 2017; of these, over half (53%) were males, and 90% were people aged 25 years and above. Australia has a concentrated hepatitis B epidemic among key populations: migrants from high prevalence countries, particularly Southeast Asia; men who have sex with men; Aboriginal and Torres Strait Islander peoples; and people who inject drugs. Over the past ten years, 2008-2017, the population rate of diagnosis of HBV infection in Australia has declined in younger age groups: 25 – 29 years (from 69 to 45 per 100 000); 20 – 24 years (from 48 to 22 per 100 000); and 15 – 19 years (from 19 to 8 per 100 000). This decline could be attributable to the successful implementation of immunisation programs for HBV and high levels of vaccine coverage in the younger age groups. In addition, there has been a decline in the rate of newly acquired HBV cases (acquired in the past 2 years) in the past ten years by 50% from 1.2 per 100 000 in 2008 to 0.6 per 100 000 in 2017. The estimated prevalence of chronic HBV infection among people living in Australia is 0.9%, which is higher than for people living in the United Kingdom (<0.5%) but lower than many other countries in South East Asia and the Pacific.[1]

Trends in prevalence

All donations:

In the past ten years, 2008-2017, a total of 1 024 HBV positive donors have been detected (884 first-time donors & 140 repeat donors) (Table 1A). During this period, the prevalence of HBV infection among all donations has declined significantly (IRR 0.93; 95% CI: 0.91-0.95). There has been an overall reduction of 43% from 2008 to 2017, from 9.9 to 5.6 per 100 000 total donations (Figure 7). This significant decline does not appear to be explained by a declining first-time donor prevalence or a decline in incident donors. Predominantly, it reflects the incremental identification and deferral of repeat donors (n=137) with occult HBV infection (OBI) since HBV NAT commenced in 2010 (see OBI section below). Donors with OBI characteristically have very low HBV viral loads (<200 IU/mL) which are often close to the limit of detection of the most sensitive HBV DNA tests.[4] For detail on the number and prevalence rate of HBV infections among all donations for 2017, see Supplementary Table 2.

Figure 7 Prevalence of HBV infection in all blood donations in Australia, 2008-2017

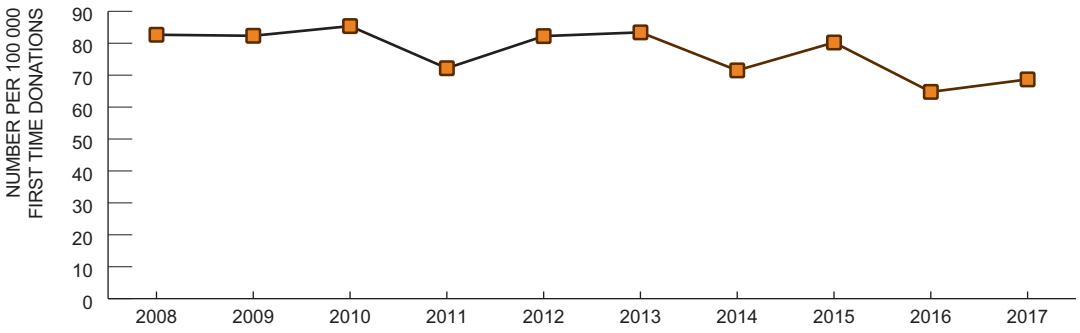


	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Prevalence in all donations	9.99	9.33	9.58	8.66	8.61	7.55	6.66	6.61	5.86	5.66

First-time donors:

Over the ten-year period 2008-2017, no significant annual trend was observed in the prevalence of HBV infection among first-time donors (Figure 8) (IRR: 0.97; 95% CI: 0.95-1.00). However, the average rate dropped to 77.9 per 100 000 donations (0.08% of the total first-time donations) for the period 2008-2017 (Table 1A), as compared to 81.6 and 80.4 per 100 000 first-time donations for periods 2006-2015 and 2007-2016, respectively. Similarly, this trend is reflected in the Australian general population with the notification rate showing a slight downward trend in the past ten years, at 30 per 100 000 in 2008, 29 per 100 000 in 2011, and 25 per 100 000 in 2017.[1]

Figure 8 Prevalence of HBV infection in first time blood donors in Australia, 2008-2017

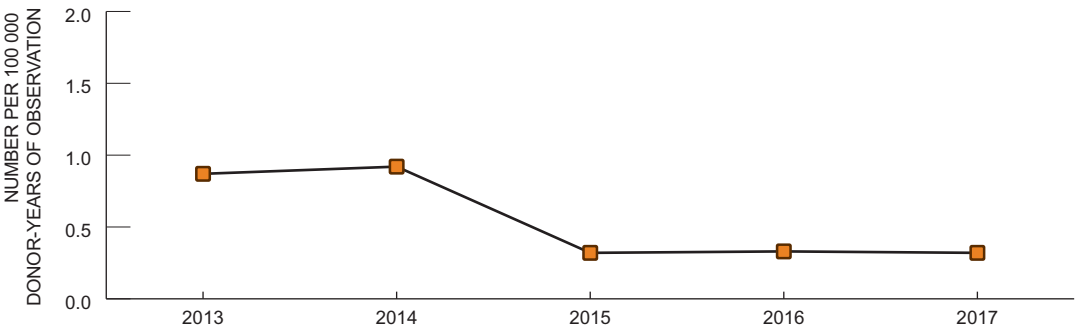


	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Prevalence in first-time donors	82.65	82.33	85.37	72.17	82.23	83.40	71.49	80.23	64.76	68.67

Trends in incidence

Due to change in the methodology for calculating incidence, updated data are presented for a five-year period, 2013-2017 (see Methodological Notes for detail). For the five-year period 2013-2017, there were a total of nine incident donors detected for HBV infection with no statistically significant trend observed for incidence rates (between 0.3 and 0.9 per 100 000 donor-years of observation; IRR: 0.72; 95% CI: 0.44-1.19) (Figure 9). In 2017, only one incident infection was detected for HBV.

Figure 9 Incidence of HBV in repeat blood donors in Australia, 2013-2017



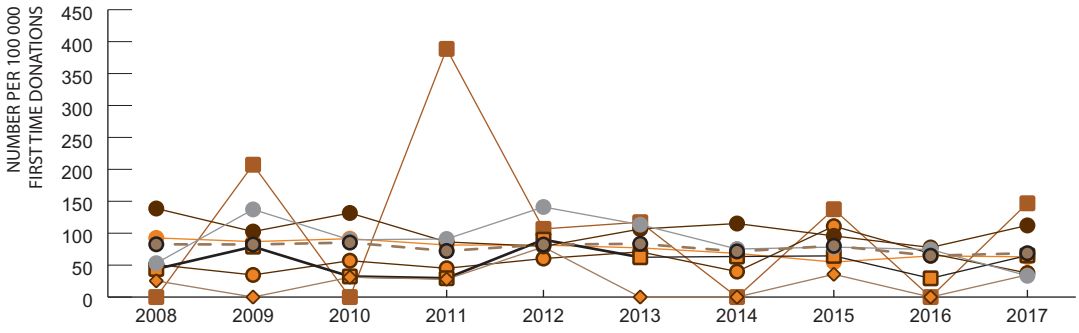
	2013	2014	2015	2016	2017
Incidence	0.87	0.92	0.32	0.33	0.32

No transfusion-transmitted HBV infections were reported in 2017. Three probable cases were reported in the 2008-2014 period, two in 2009 associated with the same donor and one further case in 2011. For details on these cases, see Transfusion-transmissible infections in Australia, 2017 Surveillance Report.

Trends in HBV infection by state/territory

Consistent with previous TTI-surveillance reports, the prevalence of HBV infection among first-time donors varied by jurisdiction in 2017. While the national prevalence was 68.6 per 100 000 donations, this ranged from 33.3 to 146.8 per 100 000 donations across jurisdictions (Figure 10). In 2017, the Northern Territory recorded the highest prevalence of HBV infection among first-time donors as compared to the other states (146.8 per 100 000 donations); however, given this rate equates to only one positive new donation, caution should be taken in interpretation. For the ten-year period 2008-2017, the highest average prevalence rate of HBV infection among first-time donors was observed in the Northern Territory at 111.74 per 100 000 donations, followed by Victoria at 104.5 per 100 000 donations; however, no significant trend was observed during this period in the Northern Territory and Victoria, and given the small number of positive donors, which ranged between 0-3 and 1-8 per year for the Northern Territory and Victoria, respectively, this should be interpreted with caution. A significant declining annual prevalence trend was observed in New South Wales between 2008 and 2017 (IRR: 0.95; 95% CI: 0.91-0.99); from 92.5 per 100 000 donations in 2008, to 81.38 per 100 000 donations in 2012 and 62.9 per 100 000 donations in 2017. No significant annual trend was observed in the prevalence of HBV infection among first-time donors in the past ten years in any other state.

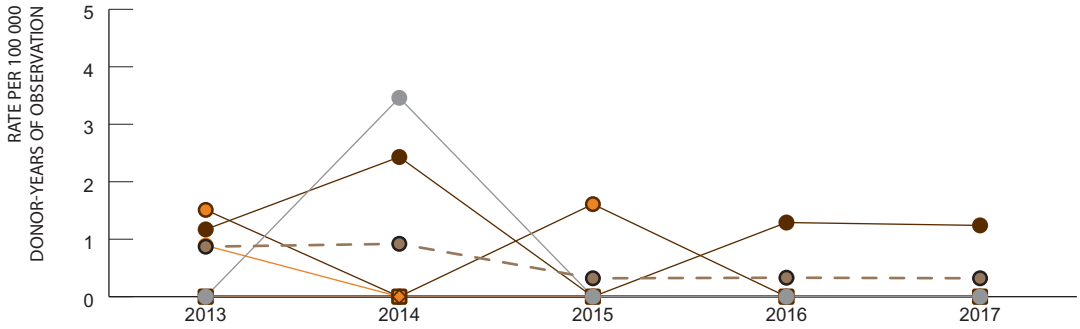
Figure 10 Prevalence of HBV infection among first time donors by state/territory and year of donation, 2008-2017



	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
NSW/ACT	92.58	86.84	91.42	81.51	81.38	77.01	68.41	54.83	64.44	62.97
NT	0.00	207.25	0.00	388.60	106.72	117.23	0.00	137.55	0.00	146.84
QLD	50.85	34.62	56.95	45.08	60.29	70.82	39.91	111.03	68.25	37.63
SA	44.00	78.95	32.31	29.52	89.89	62.33	63.53	64.50	29.31	65.15
TAS	25.41	0.00	31.04	27.88	78.47	0.00	0.00	35.63	0.00	34.79
VIC	138.68	102.54	131.68	86.30	79.37	106.58	115.15	95.79	77.63	112.18
WA	53.06	137.24	89.69	90.98	141.06	113.44	75.26	78.28	74.48	33.31
National	82.65	82.33	85.37	72.17	82.23	83.40	71.49	80.23	64.76	68.67

Incident HBV infection continues to be rare with only one incident donor recorded nationally in 2017. Overall, there was no obvious trend in HBV incidence in any state/territory during the five-year study period 2013-2017 (Figure 11). Among donors in the Northern Territory, South Australia and Tasmania, HBV incidence has been zero since 2013.

Figure 11 Trend in incidence of HBV infection among repeat donors by state/territory and year of donation, 2013-2017



	2013	2014	2015	2016	2017
NSW/ACT	0.89	0.00	0.00	0.00	0.00
NT	0.00	0.00	0.00	0.00	0.00
QLD	1.51	0.00	1.61	0.00	0.00
SA	0.00	0.00	0.00	0.00	0.00
TAS	0.00	0.00	0.00	0.00	0.00
VIC	1.17	2.43	0.00	1.29	1.24
WA	0.00	3.46	0.00	0.00	0.00
National	0.87	0.92	0.32	0.33	0.32

Occult HBV infection

As noted, the implementation of HBV DNA testing for all Australian donors from 2010 has facilitated the identification of OBI among the donor population.[4] To the end of 2017, 134 donors with OBI have been detected, counselled and referred for external clinical assessment reducing the residual risk of HBV infection. Fourteen of the 75 HBV positive donors detected in 2017 were classified as OBI. Most (11/14) were repeat donors and over half (8/14) were males with an average age of 54 years. Unlike last year where donors with OBI were predominantly born in Asia, the majority of donors with OBI in 2017 were born in Oceanian countries (Australia - 4, other Oceanian countries - 3).

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

This section presents a comparison of prevalence of HBV infections among first-time blood donors and the general population for a combined period of 2008-2017, and then 2017 separately. Following this, a discussion is presented on the prevalence reduction in first-time donors as compared to the general population.

The prevalence of HBV is much higher in the general population than in blood donors (Table 2), which is consistent with a previous Blood Service study for the period 2000-2006[5] and expected, based on effective donor selection/education. Prevalence of HBV infection is substantially lower in blood donors than the estimated prevalence in the general population, with a 12 times lower prevalence in first-time donors during the period 2008-2017, and 15 times lower prevalence for the year 2017. Given blood donors are drawn from the general population, the lower prevalence observed in first-time donors is interpreted to predominantly reflect the combined effectiveness of donor education and donor selection policies.

Table 2 Comparison of prevalence of HBV infection in blood donors with population prevalence, 2008-2017

Infection	Estimated population prevalence* (per 100 000 people)		Prevalence in first time blood donors (per 100 000 donations)		Comparison of HBV prevalence in first time blood donors with population prevalence	
	2008-2017	2017	2008-2017	2017	2008-2017	2017
HBV	926	1010	77.94	68.67	12	15

* The 2017 HBV prevalence in the general population was calculated by taking the estimated number of people living with chronic HBV[1], and dividing it by the estimated mid-year resident Australian population in 2017 as reported by the Australian Bureau of Statistics. For the period 2008-2017, an average of the ten years' prevalence rates was calculated.

Demographic factors associated with HBV infections in blood donors

Data on the demographic characteristics (sex, age group, state/territory and year of donation) for all blood donors were analysed (see Methodological Notes for details) to determine any association between demographic factors and presence of HBV infections among Australian blood donors in 2017, and the five-year period, 2013-2017, 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 2017, female donors were 42% less likely to be HBV positive, and donors from Victoria and the Northern Territory were two times more likely to be HBV positive as compared to the reference group (Supplementary Table 4). In 2017, there was no significant association between the age group of the donor and HBV infection status.

In the five-year period, 2013-2017, female donors, donors over 50 years of age, and donors from Tasmania were significantly less likely to be HBV positive as compared to the reference groups described above. Donors from Victoria had a significantly greater rate for HBV positivity (1.5 times, see Supplementary Table 5). In comparison, over the past ten years, the notification rates of HBV infections in Australia have been consistently higher in males than females, have declined in younger age groups (aged under 30 years), with little or no variation in those aged 30+ years, and has consistently been highest in the Northern Territory (88 per 100 000 in 2008 to 41 per 100 000 in 2017). In most other jurisdictions the rate of HBV diagnosis has fluctuated over the last ten years, with a small decline observed in recent years in New South Wales (33 in 2008 to 30 in 2017), Victoria (37 in 2008 to 28 in 2017), and Western Australia (30 in 2008 to 25 in 2017).[1]

Risk factors associated with HBV infected donors

Of the 418 HBV positive donors during 2013-2017, 83% were first-time donors, 70% were male, and the mean age was 39 years (Table 3). Most (87%) of the HBV positive donors were born overseas, which reflects the epidemiology of hepatitis B in the general population. Ethnicity or country of birth (81%) was the most frequent risk factor for HBV positivity, with 32% born in North & South-East Asia in 2017 (Figure 12), followed by having a sexual partner with known risk or known to be positive for HBV infection, and family history/household contact (4% each). There were only 9 incident hepatitis B blood donors in the last five years, consistent with a low incidence rate.

Table 3 Characteristics of donors positive for HBV infection by year of donation, 2013-2017

Characteristics	2013	2014	2015	2016	2017	2013-2017
Number of positive donors	99	84	84	76	75	418
Number of positive first-time donors (%)	85 (86%)	67 (80%)	72 (86%)	62 (82%)	63 (84%)	349 (83%)
% male	72 (73%)	55 (65%)	58 (69%)	60 (79%)	47 (63%)	292 (70%)
Mean age (range) in years	36 (16 to 73)	42 (16-69)	37 (16-67)	40 (16-68)	41 (17-78)	39 (16-78)
Number of incident donors	3	3	1	1	1	9
% born in Australia	14 (14%)	15 (18%)	8 (10%)	5 (7%)	14 (19%)	56 (13%)
Main reported risk factor	Ethnicity/COB[1] 59%	Ethnicity/COB[1] 77%	Ethnicity/COB[1] 93%	Ethnicity/COB[1] 97%*	Ethnicity/COB[1] 87%*	Ethnicity/COB[1] 81%
Second reported risk factor	FH/HC[2] 11%	PRP[3] 8%	PRP[3], Other each 2%	Other, Unknown each 1%	FH/HC[2], PRP[3], OR[4], EHS[5] 3%	PRP[3], FH/HC[2] 4%

1 COB= Country of birth
2 FH/HC= Family history/Household contact
3 PRP= Partner with known risk/known to be positive
4 OR=Occupational risk
5 EHS=Exposure in health setting
* 4 out of 5, and 7 out 14 donors born in Australia had Ethnicity as their major risk factor in 2016 and 2017, respectively.

Figure 12 Donors with HBV infection by country/region of birth, 2017 (n=75)

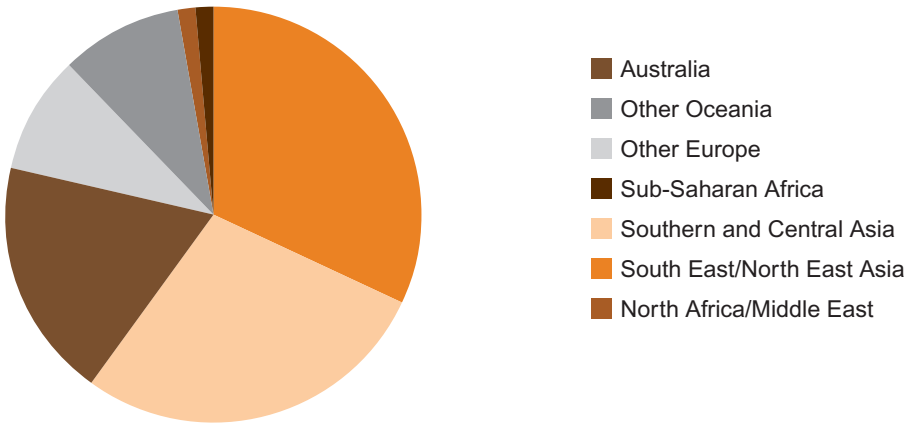
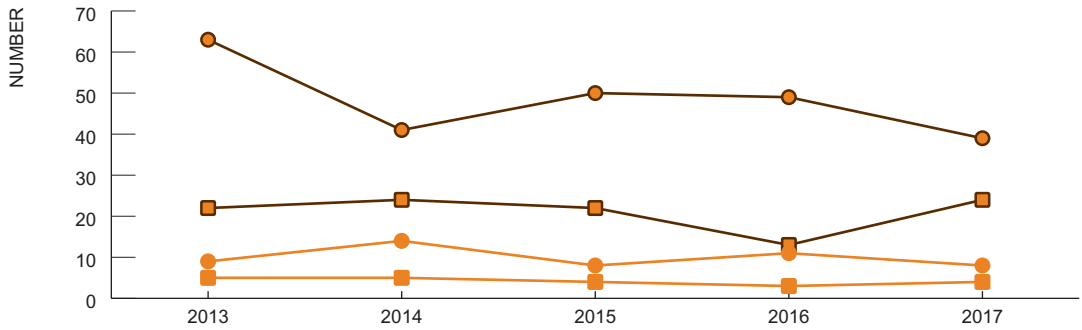


Figure 13 Donors with hepatitis B infection by sex and donor status, 2013-2017



	2013	2014	2015	2016	2017
Male (first-time)	63	41	50	49	39
Male (repeat)	9	14	8	11	8
Female (first-time)	22	24	22	13	24
Female (repeat)	5	5	4	3	4

Since 2013, there has been a declining trend in the number of HBV positive first-time donors in males, with a 38% reduction; no trend has been observed in female HBV positive first-time donors. The number of HBV positive repeat donors remained relatively stable in both sexes during the same period of time (Figure 13). In comparison, there have been small declines in HBV notification rates in males and females in the past ten years, 2008-2017 from 33 to 27 per 100 000 population and 27 to 23 per 100 000 population in males and females, respectively.[1] Of note, caution must be applied in comparing the trends by sex between blood donors and general population as they are numbers in the former versus rates in the latter.

For more information on the number and percentage of donors with HBV infection by sex, age group, donor status, country of birth and exposure category for the year 2017 and the period 2013-2017, see Supplementary Tables 7-13.

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

A comparison of major exposure categories between blood donors positive for HBV infection and the general population was conducted to determine if any unique source of infection exists for Australian donors (Table 4). The comparison should be interpreted with caution as blood donors are asked about multiple potential sources of infection. In the absence of another declared risk factor, e.g. if the blood donor reports they had an operation, then this will be listed as a potential health care exposure risk despite the fact that this may be a very unlikely route of infection. This classification system likely accounts for the much lower proportion of blood donors who have an undetermined risk factor.

Consistent with previous years, the most frequent risk factor for HBV infection in donors was ethnicity or country of birth which accounted for 86.7% of the HBV positive donors in 2017.This proportion has decreased by 11% from 97.4% observed in 2016. This finding also parallels the general population data that shows that country of birth is the strongest risk factor for chronic HBV infection in Australia.[6-8]

Nationally, enhanced information on potential risk categories is collected for the newly acquired infections only. For the newly acquired HBV infection in the general population, 8.8% had country of birth as a major risk factor; importantly, for 37.4% of the newly acquired HBV infection in general population the risk category was undetermined[1] (Table 4) (newly acquired HBV is defined as newly diagnosed HBV infection with evidence of acquisition in the 24 months prior to diagnosis - laboratory or clinical evidence). Caution should be used in comparing the exposure risk categories in blood donors with the general population using newly acquired HBV notification data as the vast majority of HBV positive cases in blood donors have chronic HBV infection as opposed to acute infection.

Table 4 Comparison between HBV positive blood donors and general population in Australia by infection and major potential risk categories, 2017

	HBV[1]	
Major risk category	**General population (%)**	**Blood donors (%)**
Intravenous drug use	26.4	0.0
Country of birth/Ethnicity[2]	8.8	86.7
Sexual contact[3]	6.6	2.7
Blood or tissue recipient	0.0	0.0
Tattoo or body piercing	6.6	1.3
Exposure in health care setting	7.7	2.7
Household contact	2.2	2.7
Other blood to blood contact	1.1	0
Other/undetermined/unknown	37.4	1.3
Imprisonment	2.2	0.0
Occupational risk	0.0	2.7
No risk factor identified	1.1	0.0

1 Includes exposure categories for newly acquired HBV infections only in general population
2 includes 7 out of 14 hepatitis B positive donors born in Australia that had Ethnicity as their major risk factor
3 Includes three sub-groups: Male-to-male sexual contact, Partner with known risk or known to be positive and Engaged in sex work
Of note, in general population, risk factors are not reported for newly acquired HBV cases from QLD

Conclusion

- The prevalence of HBV infection in first time blood donors has shown no significant trend since 2008 and is substantially lower (12 times) than in the general population estimates for the period 2008-2017.
- The incidence of newly acquired HBV infection is much lower than estimates from specific at-risk populations in Australia. This supports the general effectiveness of the donor questionnaire and specifically that repeat donors understand what constitutes 'risk behaviour' for acquiring transfusion-transmissible infections.
- Screening for HBV DNA continues to identify donors with occult HBV (14 of the 75 HBV infections in 2017).
- Putative risk factors identified in blood donors with HBV infection closely parallel those for the general population with no 'unique' risk factors identified to date among blood donors.

Hepatitis C Virus (HCV)

Epidemiology of HCV in Australia

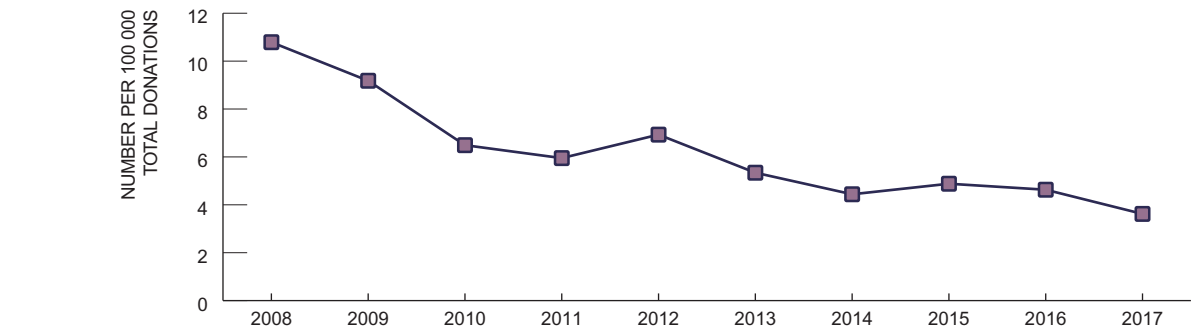
To the end of 2017, an estimated 182 283 (128 981 – 193 119) people were living with chronic hepatitis C in Australia, of which an estimated 80% or 145 838 (114 314 – 181 735) were diagnosed with chronic hepatitis C. Australia has a concentrated chronic hepatitis C epidemic among key populations; people who inject drugs, prisoners, and people from high prevalence countries and HIV positive men who have sex with men. The rate of diagnosis of HCV infection in 2017 was 43 per 100 000 which indicates a decrease from 2016. However, between 2012-2016 the rate increased by 10% from 44 per 100 000 to 47 per 100 000 in 2016. This increase in notification rates may reflect a higher number of people coming forward for testing because of the availability of new treatment options. In general, there has been a 18% decline in the rate of notification of hepatitis C over the ten-year period, 2008-2017, from 53 per 100 000 to 43 per 100 000. The rate of diagnosis in those aged less than 25 years has declined by 30% in the past ten years, 2008-2017. In contrast, the rate of hepatitis C notification in the Aboriginal and Torres Strait Islander population increased by 15% in the five past years, from 146 per 100 000 in 2013 to 168 per 100 000 in 2017. The 2017 rate is 4 times greater than in the non-Indigenous population (38 per 100 000). Most cases (69%) of newly diagnosed HCV infection were in males and 77% were in people aged 30 years and above. [1, 9]

Trends in prevalence

All donations:

In the past ten years, 2008-2017, a total of 810 HCV positive donors have been detected (583 first-time donors & 227 repeat donors) (Table 1A). During the last ten years, the prevalence of HCV infection among all donations has declined significantly (IRR: 0.89; 95% CI: 0.87-0.91). There has been an overall reduction of 66% from 2008 to 2017, from 10.7 per 100 000 donations to 3.6 per 100 000 donations (Figure 14). For detail on number and prevalence rate of HCV infections among all donations for 2017, see Supplementary Table 2.

Figure 14 Prevalence of HCV infection in all blood donations in Australia, 2008-2017, by year of donation

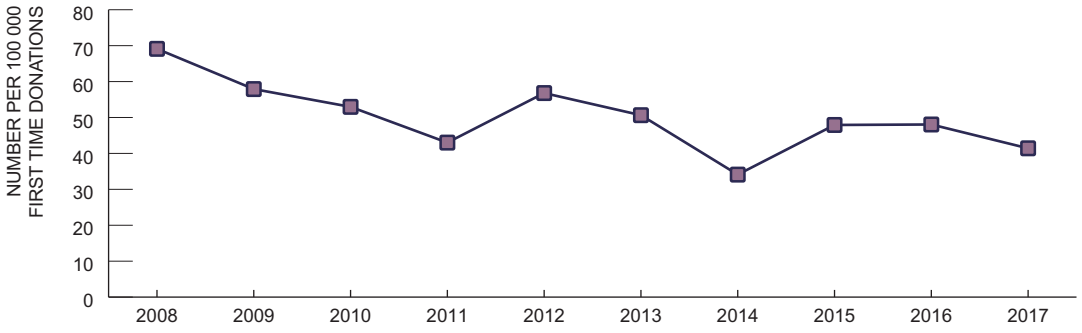


	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Prevalence in all donations	10.79	9.18	6.49	5.95	6.93	5.34	4.44	4.88	4.63	3.62

First-time donors:

During 2008-2017, there has been a significant decrease in HCV prevalence in first-time donors in Australia (IRR: 0.95; 95% CI: 0.92-0.98); from 69.1 per 100 000 donations in 2008, to 56.8 per 100 000 donations in 2012 and 41.40 per 100 000 donations in 2017 (Figure 15). This translates into a decrease from 0.07% of the total first-time donations in 2008 to 0.04% of the total first-time donations in 2017. This trend is consistent with the rate of diagnosis of HCV infection reported through the Australian National Notifiable Disease Surveillance System, where the rate of diagnosis of HCV infection declined from 53 per 100 000 in 2008 to 43 per 100 000 in 2017.[1] In addition, there has also been a decrease in prevalence of hepatitis C antibody among people seen at needle and syringe programs from 62% in 2008 to 49% in 2017, whilst the rates of receptive needle and syringe sharing in the same period remained stable at an average of 16%, highlighting the importance of sustaining and enhancing harm reduction services.[1]

Figure 15 Prevalence of HCV infection in first time blood donors in Australia, 2008-2017, by year of donation

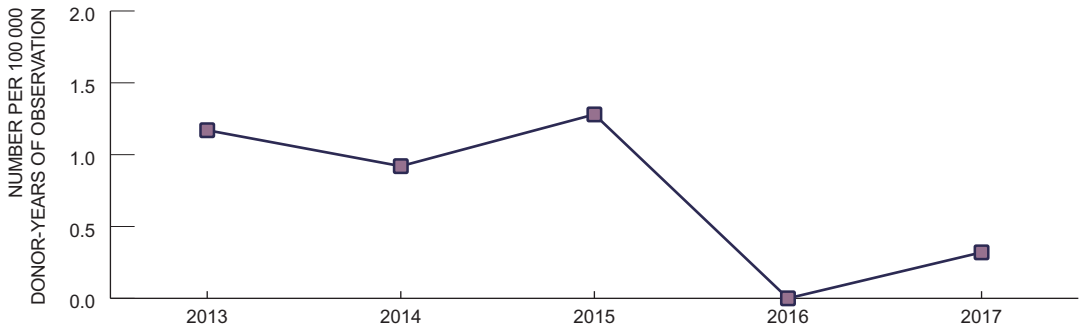


	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Prevalence in first-time donors	69.11	57.91	52.96	43.01	56.80	50.64	34.10	47.92	48.05	41.42

Trends in incidence

Due to a change in the methodology for calculating incidence, updated data are presented for a five-year period (see Methodological Notes for detail). Over the five-year period 2013-2017, a total of 12 incident HCV infections in donors were detected with no statistically significant trend observed for incidence rates (between 0.0 and 1.2 per 100 000 donor-years of observation; IRR: 0.69; 95% CI: 0.44-1.07) (Figure 16). Only one HCV incident donor was identified in 2017, equating to an incidence rate of 0.3 per 100 000 donor-years of observation (Figure 16). Similarly, no significant annual trend was observed for incidence of HCV infection over a five-year study period (2013-2017) among people who inject drugs attending the Kirketon Road Centre, a primary care clinic in central Sydney. The incidence fluctuated between 2.6 and 15.8 per 100 persons-years, with lowest in 2016 at 2.6.[1]

Figure 16 Incidence of HCV in repeat blood donors in Australia, 2013-2017



	2013	2014	2015	2016	2017
Incidence	1.17	0.92	1.28	0.00	0.32

No transfusion-transmitted HCV infections were reported in Australia during 2013-2017.

HCV RNA detection rate in donors

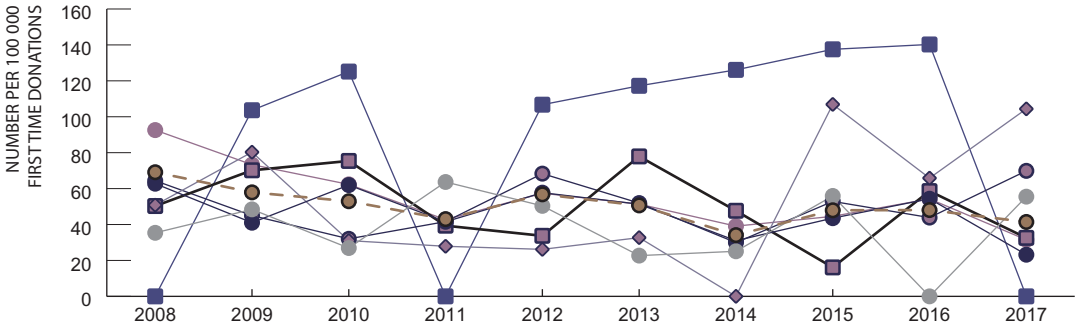
It is generally considered that blood components sourced from HCV antibody positive donors without detectable HCV RNA pose a negligible risk of transfusion-transmission. These donors are presumed to have past resolved infection, however as they meet the public health HCV notification criteria, the Blood Service continues to counsel and refer them for medical follow-up. Notably, there has been a steady decline in the proportion of HCV RNA positive (infectious) donors, which was ~40% in 2017 as compared to 48% in 2016, 68% in 2008 and around 75% when HCV RNA donation testing was introduced in 2000.

Examining 2008 and 2017 data, the decline is significantly associated with a decrease in the rate of RNA positive donors among first-time donors (or those not previously HCV tested), from 60 per 100 000 in 2008 to 15 per 100 000 new donations in 2017. This mirrors the falling HCV incidence (peak seroconversion in 1999)[10] and falling prevalence in the general population. Assuming a continuing incidence decline in the general population (consistent with the Australian Government aim of treating HCV infected individuals with direct acting anti-viral medications as outlined in the Fourth National Hepatitis C strategy[11]), then a continuing decline in HCV prevalence among first-time donors is predicted, as well as a declining proportion of RNA positive donors.

Trends in HCV infection by state/territory

Similar to patterns in previous years' TTI surveillance reports, the prevalence of HCV infection among first-time donors varied by jurisdiction in 2017, ranging from 0.0 to 104.3 per 100 000 donations. Nationally, the prevalence of HCV infection in first-time donors has shown a significant declining trend throughout the ten-year period 2008-2017. However, a significant decrease was observed in the annual trend in the prevalence of HCV infection only among first-time donors in New South Wales/Australian Capital Territory (IRR: 0.91; 95% CI: 0.86-0.95) (Figure 17), from 92.5 in 2008, to 57.4 in 2012, and 31.4 in 2017 (Table 16). In 2017, Tasmania recorded the highest prevalence of HCV infection among first-time donors as compared to other states at 104.3 per 100 000 donations; caution should be taken in interpretation of these rates given the small number of positive donors. On the other hand, in 2017, the Northern Territory observed the lowest rate of 0.0 per 100 000 donations. National notifications data indicate the notification rate of hepatitis C infection in Australia in 2017 was highest in the Northern Territory (57 per 100 000) and Queensland (49 per 100 000).[1] The fluctuating trend in the prevalence of HCV infection in the first-time donors in the Northern Territory over the past ten years should be interpreted with caution due to small number of positive donors (ranging between zero and one).

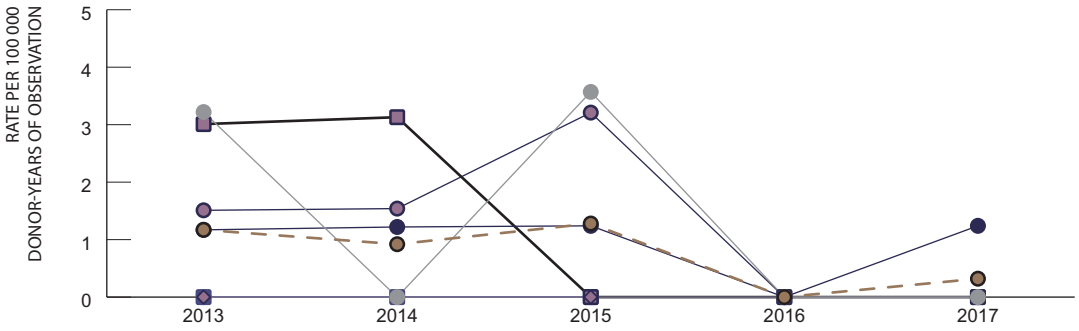
Figure 17 Prevalence of HCV infection among first time donors by state/territory and year of donation, 2008-2017



	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
NSW/ACT	92.58	73.33	62.33	42.70	57.44	51.34	39.09	44.55	54.26	31.48
NT	0.00	103.63	125.16	0.00	106.72	117.23	126.10	137.55	140.25	0.00
QLD	64.41	45.00	32.03	41.61	68.33	51.93	29.94	52.87	43.87	69.88
SA	50.29	70.18	75.40	39.35	33.71	77.92	47.65	16.12	58.62	32.57
TAS	50.81	80.30	31.04	27.88	26.16	32.70	0.00	106.88	65.85	104.38
VIC	62.74	41.02	61.97	41.55	57.72	51.32	31.00	43.54	54.34	23.21
WA	35.38	48.44	26.91	63.68	50.38	22.69	25.09	55.92	0.00	55.51
National	69.11	57.91	52.96	43.01	56.80	50.64	34.10	47.92	48.05	41.42

There was no significant annual trend observed for the HCV incidence in repeat donors nationally during the 2013-2017 study period (IRR: 0.69; 95% CI: 0.44-1.07). Generally, the incidence of HCV infection in repeat donors has remained very low across all Australian jurisdictions during the past five years (Figure 18); however, no significant decrease was observed for any state or territory. Notably, in New South Wales/Australian Capital Territory, Tasmania and Northern Territory, HCV incidence has remained zero since 2013.

Figure 18 Incidence of HCV infection among repeat donors by state/territory and year of donation, 2013-2017



	2013	2014	2015	2016	2017
NSW/ACT	0.00	0.00	0.00	0.00	0.00
NT	0.00	0.00	0.00	0.00	0.00
QLD	1.51	1.54	3.21	0.00	0.00
SA	3.01	3.13	0.00	0.00	0.00
TAS	0.00	0.00	0.00	0.00	0.00
VIC	1.17	1.22	1.24	0.00	1.24
WA	3.22	0.00	3.57	0.00	0.00
National	1.17	0.92	1.28	0.00	0.32

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

This section presents a comparison of prevalence of HCV infections among first-time blood donors and the general population for a combined period of 2008-2017, and then 2017 separately. Subsequently, a discussion is presented on the prevalence reduction in first-time donors as compared to the general population.

The prevalence of HCV infection is much higher in the general population than in blood donors, which is consistent with a previous Blood Service study for the period 2000-2006.[5] There was a 20 and 18 times lower prevalence in first-time donors for the period 2008-2017, and for year 2017, respectively, as compared to the prevalence in general population (Table 5). Given blood donors are drawn from the general population, the prevalence reduction observed in first-time donors is interpreted to reflect the combined effectiveness of donor education and donor selection policies.

Table 5 Comparison of prevalence of HCV infection in blood donors with population prevalence by infection, 2008-2017

Infection	Estimated population prevalence* (per 100 000 people)		Prevalence in first time blood donors (per 100 000 donations)		Comparison of HCV prevalence in first time blood donors with population prevalence	
	2008-2017	**2017**	**2008-2017**	**2017**	**2008-2017**	**2017**
HCV	1026	741	51.32	41.42	20	18

* The 2017 HCV prevalence in the general population was calculated by taking the estimated number of people living with chronic HCV[1], and dividing it by the estimated mid-year resident Australian population in 2017 reported by the Australian Bureau of Statistics. For the period 2008-2017, an average of the ten years' prevalence rates was calculated.

Demographic factors associated with HCV infections in blood donors

Data on the demographic characteristics (sex, age group, state/territory and year of donation) for all blood donors were analysed (see Methodological Notes for details) to determine the association between demographic factors and presence of HCV infection among Australian blood donors in 2017, and the five-year period, 2013-2017, 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 2017, like HBV, female donors were 61% less likely to be HCV positive. Donors over 50 years of age were nearly four times more likely to be HCV positive (Supplementary Table 4). In 2017, there was no significant association between state/territory and HCV infection status.

During the five-year period, 2012-2017, female donors were significantly less likely to be HCV positive (45%) compared to male donors. There was a significantly greater risk of HCV infection among donors aged 40 years or above, and among donors from the Northern Territory and Queensland as compared to the reference groups noted above (Supplementary Table 5).

Risk factors associated with HCV infected donors

Of the 296 HCV positive donors during 2013-2017, 73% were first-time donors and 66% were male. Over the last five years, the mean age was 46 years with a wide range (16-71) (Table 6). Unlike HBV where birth overseas predominated, the majority (69%) of HCV positive donors during 2013-2017 were born in Australia, and 77% in 2017 (Figure 19). Overall, the main reported putative risk factor for HCV positivity during 2013-2017 was intravenous drug use (22%), followed by tattoo or body piercing (21%). It should be noted that there is no significant evidence that tattooing and body piercing performed in licensed premises is associated with an increased risk of acquiring HCV.[3] In contrast, tattooing performed in prison settings, or in some overseas countries is associated with an increased risk of HCV. Given the increasing rate of tattooing among Australians, the 21% of HCV positive donors reporting tattooing or body piercing should be interpreted with caution and this may reflect association rather than causation and non-disclosure of another risk factor. A joint Blood Service and Kirby Institute study has recently been conducted to further investigate the risk of tattooing in the context of blood donation (manuscript in preparation), noting that blood donors with recent tattoos are currently temporarily deferred from donation. Highlighting the continuing relative importance of HCV to blood safety, there were 12 incident HCV infections in blood donors in the last five years, the highest among all TTIs.

Table 6 Characteristics of donors positive for HCV infection by year of donation, 2013-2017

Characteristics	2013	2014	2015	2016	2017	2013-2017
Number of positive donors	70	56	62	60	48	296
Number of positive first-time donors (%)	52 (74%)	38 (68%)	43 (69%)	46 (77%)	38 (79%)	217 (73%)
% male	43 (61%)	37 (66%)	39 (63%)	40 (67%)	35 (73%)	194 (66%)
Mean age (range) in years	45 (23 to 66)	48 (18 to 71)	44.27 (16-67)	48 (22-67)	48 (23-67)	46 (16 to71)
Number of incident donors	4	3	4	0	1	12
% born in Australia	41 (59%)	44 (79%)	43 (69%)	40 (67%)	37 (77%)	205 (69%)
Main reported risk factor	TBP[1] 34%	IDU 30%	TBP[1] 29%	IDU[2] 27%	TBP[1]; IDU[2] 23% each	IDU[2] 22%
Second reported risk factor	IDU[2] 19%	TBP[1], BTR[3] each 13%	IDU[2] 23%	TBP[1] 20%	Other 10%	TBP[1] 21%

1 TBP= Tattoo/Body piercing
2 IDU= Intravenous drug use
3 BTR= Blood/tissue recipient

Figure 19 Donors with HCV infection by country/region of birth, 2017 (n=48)

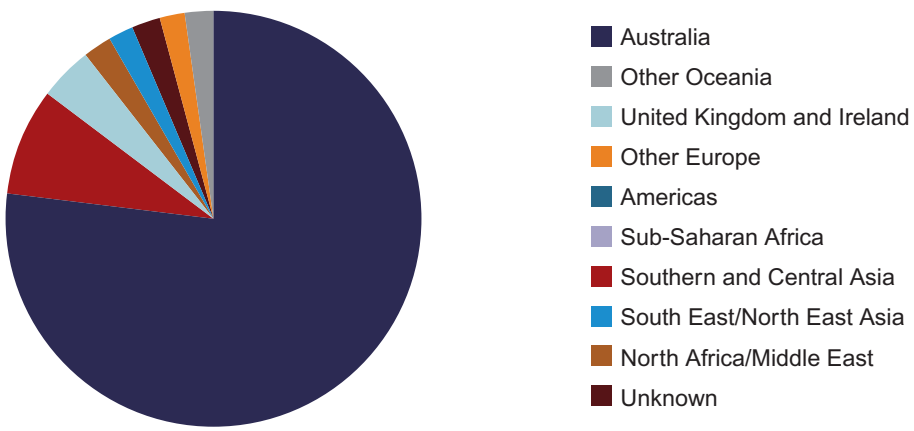
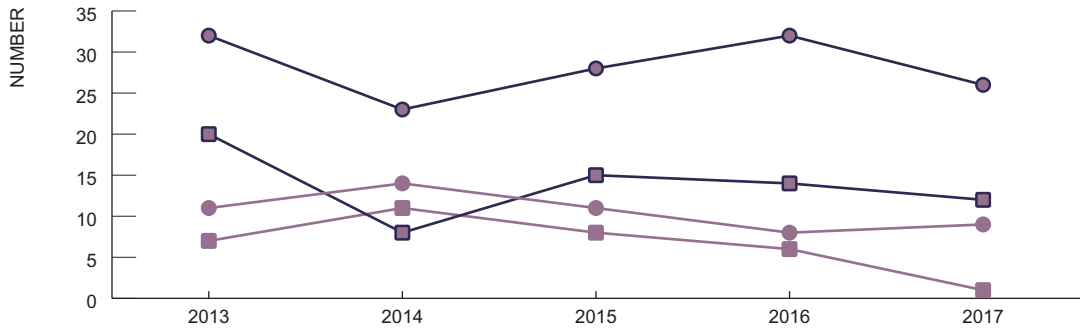


Figure 20 Donors with HCV infection by sex and donor status, 2013-2017



	2013	2014	2015	2016	2017
Male (first-time)	32	23	28	32	26
Male (repeat)	11	14	11	8	9
Female (first-time)	20	8	15	14	12
Female (repeat)	7	11	8	6	1

Over the past five years, 2013-2017, there has been a downward trend in the number of HCV positive first-time and repeat donors in both genders (Figure 20). For more information on the number and percentage of donors with HCV infection by sex, age group, donor status, country of birth and exposure category for the year 2017 and the period 2013-2017, see Supplementary Tables 7-13. Of note, caution must be applied in comparing the trends by sex between blood donors and general population as they are numbers in the former versus rates in the latter.

HCV - Comparison of major exposure categories between blood donors and the general population, 2017

A comparison of major exposure categories between blood donors positive for HCV infection and the general population was conducted to determine if any unique source of infection exists for Australian donors (Table 7). As mentioned above in the HBV section, the comparison should be interpreted with caution as blood donors are asked about multiple potential sources of infection. 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 intravenous drug use (IDU) in a post donation interview. In addition, because blood donor infections are generally prevalent infections, the risk factor exposure is not time limited and therefore common events in the population (tattoos, medical procedures) are more likely to be noted when compared to the newly acquired general population data. Therefore, the utility of the comparison between the two is acknowledged as limited.

The most frequent risk factor reported for HCV infection in blood donors in 2017 was intravenous drug use and tattoo or body piercing (22.9% each). In comparison, intravenous drug use was the most common risk factor for newly acquired HCV infection in the general population in 2017 (82.7%) (newly acquired HCV is defined as newly diagnosed hepatitis C infection with laboratory or clinical evidence of acquisition in the 24 months prior to diagnosis).[1]

Table 7 Comparison between HCV positive blood donors and general population in Australia by major potential risk categories, 2017

		HCV[1]
Major risk category	**General population (%)**	**Blood donors (%)**
Intravenous drug use	82.7	22.9
Country of birth/Ethnicity	2.4	0.0
Sexual contact[2]	2.0	8.3
Blood or tissue recipient	0.4	6.3
Tattoo or body piercing	1.2	22.9
Exposure in health care setting	1.6	8.3
Household contact	0.4	2.1
Other blood to blood contact	2.4	0.0
Other/undetermined/unknown	5.5	20.8
Imprisonment	1.2	8.3
No risk factor identified	0.4	0.0

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

Conclusion

- Supporting the effectiveness of the donor questionnaire, donor education and selection, the prevalence of HCV infection among first-time donors has shown a significant declining trend since 2008 and was 18 and 20 times lower among first-time blood donors than the general population estimate in 2017, and for the period 2008-2017, respectively.
- The incidence of HCV has not shown a significant trend in the five-year study period 2013-2017. However, it is much lower than incidence estimates from specific at-risk populations in Australia. This supports the general effectiveness of the donor questionnaire and specifically that repeat donors understand what constitutes 'risk behaviour' for acquiring transfusion-transmissible infections.
- There is a declining trend in the proportion of HCV positive first-time donors (or previously untested) with detectable RNA and this reflects declining incidence in the general population.
- Putative risk factors identified in blood donors with HCV infection in 2017 likely parallels those for the general population with no 'unique' risk factors identified to date among blood donors.

Human Immunodeficiency Virus (HIV)

Epidemiology of HIV in Australia

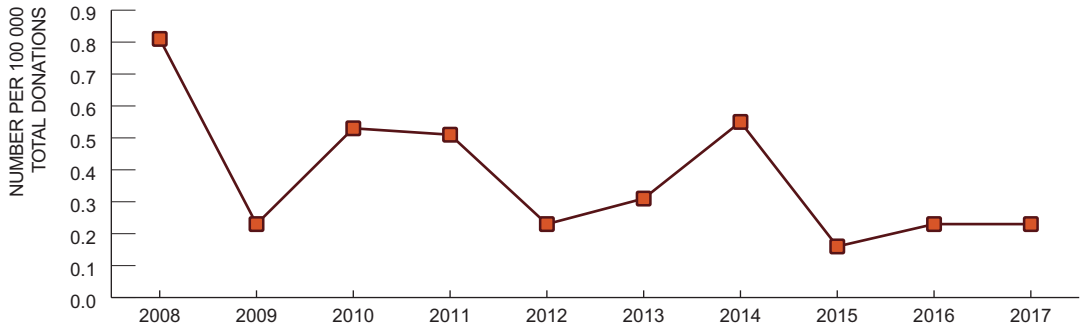
During 2017, an estimated 27 545 (24 141 – 31 126) people were living with HIV and an estimated majority (89%) or 24 646 were diagnosed (21 850 – 27 477). Transmission of HIV in Australia continues to occur primarily through sexual contact between men, with 84% of newly acquired cases of HIV infection in Australia in the period 2008 to 2017 involving men who reported sexual contact with men. The annual number of new HIV diagnoses has gradually increased by 6% over the past 10 years, from 901 diagnoses in 2008 to 963 in 2017. Of these newly diagnosed HIV infections in 2017, 88% were in males, 63% occurred among men who have sex with men, 6% due to male-to-male sex and injecting drug use, 25% were attributed to heterosexual sex, and 3% to injecting drug use. At 0.1%, the prevalence or overall proportion of people in Australia who have HIV is lower than other comparable high income countries, and countries in the region.[1]

Trends in prevalence

All donations:

In the past ten years, 2008-2017, a total of 49 HIV positive donors have been detected (21 first-time donors & 28 repeat donors) (Table 1A). During this period, the prevalence of HIV infection among all donations has shown a statistically significant downward trend (IRR: 0.89; 95% CI: 0.80-0.99). There has been an overall reduction of 72% from 2008 to 2017, from 0.8 per 100 000 donations in 2008 to 0.2 per 100 000 donations in 2017 (Figure 21). For detail on the number and prevalence rate of HIV infections among all donations for year 2017, see Supplementary Table 2.

Figure 21 Prevalence of HIV infection in all blood donations in Australia, 2008-2017, by year of donation



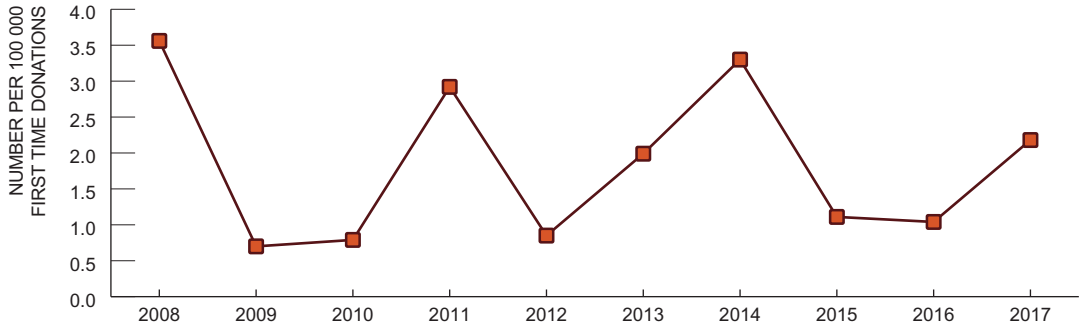
	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Prevalence in all donations	0.81	0.23	0.53	0.51	0.23	0.31	0.55	0.16	0.23	0.23

First-time donors:

The overall HIV prevalence in first-time donors remained very low at 1.8 per 100 000 over the ten-year period 2008-2017 (Table 1A); it peaked in 2008 at 3.5 per 100 000 donations followed by a sharp fall in 2009-10 to 0.7 per 100 000 donations. Since 2011, it fluctuated between 0.8 and 3.3 per 100 000 donations, and was 2.1 per 100 000 donations in 2017 (Figure 22). Overall, no significant trends were observed in the prevalence of HIV infection among first-time donors in the past ten years (IRR: 0.97; 95% CI: 0.83-1.13).

The very low prevalence (0.002%) of HIV infection among first-time donors during 2008-2017 is encouraging given that the number of newly diagnosed HIV infections in the general Australian population increased steadily in the past decade by 6%, from 901 diagnoses in 2008 to 963 cases of newly diagnosed HIV infection in Australia in 2017.[1]

Figure 22 Prevalence of HIV infection in first-time blood donors in Australia, 2008-2017, by year of donation

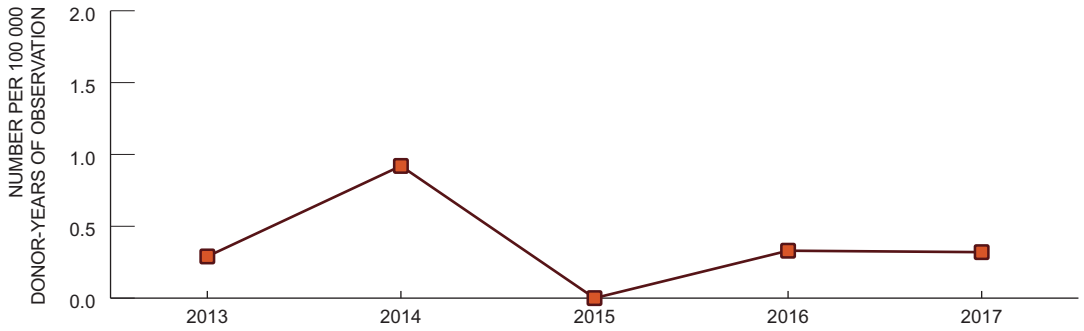


	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Prevalence in first-time donors	3.56	0.70	0.79	2.92	0.85	1.99	3.30	1.11	1.04	2.18

Trends in incidence

Due to a change in the methodology for calculating incidence, updated data are presented for a five-year period (see Methodological Notes for detail). In 2017, one incident infection was detected for HIV. For the five-year period 2013-2017, there were a total of six incident donors identified for HIV, and no significant trend was observed for incidence rates for HIV infection during this time (IRR: 0.86; 95% CI: 0.49-1.54) (ranged between 0.0 and 0.9 per 100, 000 donor-years of observation) (Figure 23). Likewise, no significant trend was observed for the incidence of HIV in a five-year study period (2012-2016) among gay and bisexual men attending sexual health services; the incidence remained less than 0.1 per 100 persons years (fluctuating between 0.58 per 100 persons years to 0.85 per 100 persons years).[12]

Figure 23 Incidence of HIV in repeat blood donors in Australia, 2013-2017, by year of donation



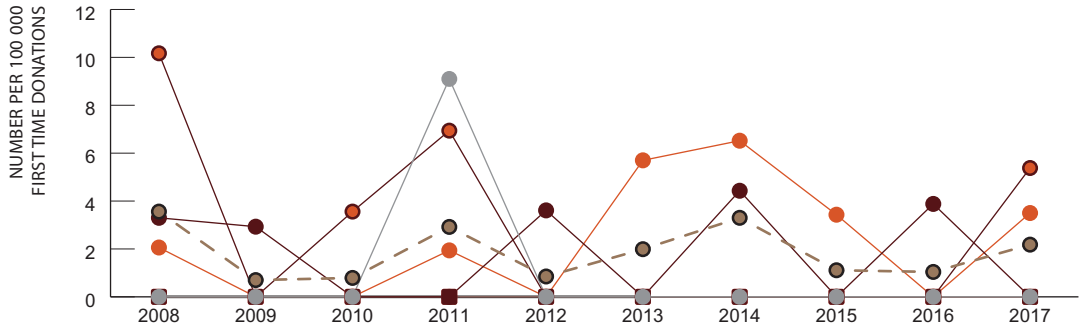
	2013	2014	2015	2016	2017
Incidence	0.29	0.92	0.00	0.33	0.32

No transfusion-transmitted HIV infections were reported in Australia during 2008-2017.

Trends in HIV infection by state/territory

The prevalence of HIV infection in first-time donors remained substantially lower than for hepatitis B and hepatitis C throughout the 2008-2017 period, with an average national prevalence of 1.8 per 100 000 donations (Table 1A). No significant annual trend was observed during the 2008-2017 period in any jurisdiction (Figure 24). In 2017, Queensland observed the highest HIV prevalence in first-time donors at the rate of 5.3 per 100 000 donations (Figure 24); this rate equates to only one positive first-time donor and therefore caution should be taken in interpretation. During 2008-2017, HIV prevalence in the first-time donors was zero in the Northern Territory, South Australia and Tasmania (Table 1A).

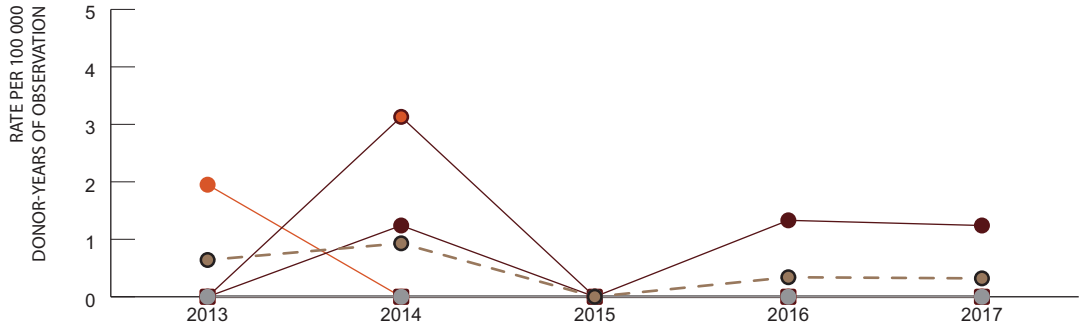
Figure 24 Prevalence of HIV infection among first time donors by state/territory and year of donation, 2008-2017



	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
NSW/ACT	2.06	0.00	0.00	1.94	0.00	5.70	6.52	3.43	0.00	3.50
NT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
QLD	10.17	0.00	3.56	6.94	0.00	0.00	0.00	0.00	0.00	5.38
SA	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
TAS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
VIC	3.30	2.93	0.00	0.00	3.61	0.00	4.43	0.00	3.88	0.00
WA	0.00	0.00	0.00	9.10	0.00	0.00	0.00	0.00	0.00	0.00
National	3.56	0.70	0.79	2.92	0.85	1.99	3.30	1.11	1.04	2.18

Incident HIV infections in blood donors continue to be a rare occurrence with only one incident donor (from Victoria) identified in 2017. No incident HIV donors were recorded in South Australia, Tasmania, Western Australia or the Northern Territory in the past five years, 2013-2017 (Figure 25). No significant annual trend was observed in any jurisdiction during 2013-2017.

Figure 25 Incidence of HIV infection among repeat donors by state/territory and year of donation, 2013-2017



	2013	2014	2015	2016	2017
NSW/ACT	1.95	0.00	0.00	0.00	0.00
NT	0.00	0.00	0.00	0.00	0.00
QLD	0.00	3.13	0.00	0.00	0.00
SA	0.00	0.00	0.00	0.00	0.00
TAS	0.00	0.00	0.00	0.00	0.00
VIC	0.00	1.24	0.00	1.33	1.24
WA	0.00	0.00	0.00	0.00	0.00
National	0.64	0.93	0.00	0.34	0.32

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

This section presents a comparison of prevalence of HIV infections among first-time blood donors and the general population for a combined period of 2008-2017, and then 2017 separately. Subsequently, a discussion is presented on the prevalence reduction in first-time donors as compared to the general population.

The prevalence of HIV is much higher in the general population than in blood donors, which is consistent with a previous Blood Service study for the period 2000-2006.[5] There was a 59 times lower prevalence in first-time donors for the period 2008-2017, and a 51 times lower prevalence in 2017 as compared to the general population (Table 8). Given blood donors are drawn from the general population, the prevalence reduction observed in first-time donors is interpreted to reflect the combined effectiveness of donor education and donor selection policies.

Table 8 Comparison of prevalence of HIV infection in blood donors with population prevalence by infection, 2008-2017

Infection	Estimated population prevalence (per 100 000 people)		Prevalence in first time blood donors (per 100 000 donations)		Comparison of HIV prevalence in first time blood donors with population prevalence	
	2008-2017	2017	2008-2017	2017	2008-2017	2017
HIV	109	112	1.85	2.18	59	51

Demographic factors associated with HIV infections in blood donors

Data on the demographic characteristics (sex, age group, state/territory and year of donation) for all blood donors were analysed (see Methodological Notes for details) to determine the association between demographic factors and presence of HIV infection among Australian blood donors in 2017, and the five-year period, 2013-2017, 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 2017, unlike HBV, there was no significant association between gender and HIV infection status. Given the small number of donors with HIV in 2017, no meaningful analysis was possible for association between HIV positivity and donors' age group or location (Supplementary Table 4).

During the five-year period, 2013-2017, female donors were significantly less likely (66%) compared to male donors to be HIV positive. There was no association between HIV positivity and donor's age group for the period 2013-2017. Similarly, there was no association with state/territory of the donors and HIV infection among Australian blood donors during this period (Supplementary Table 5).

Risk factors associated with HIV infected donors

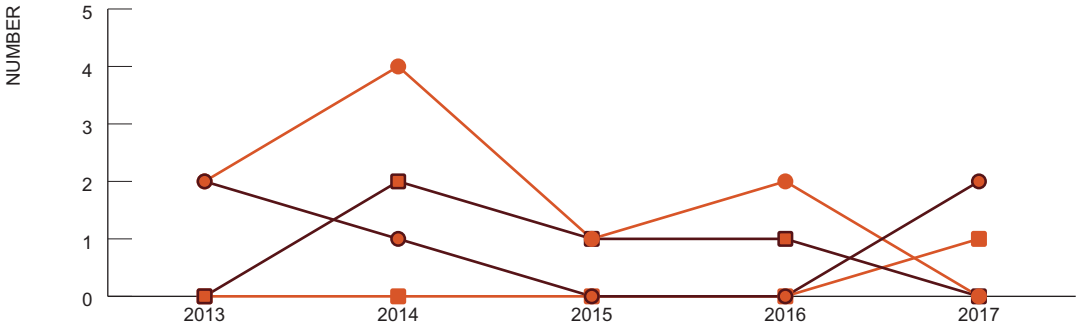
In contrast to HBV and HCV infected donors, the majority of HIV infected donors during 2013-2017 were repeat donors (58%) (Table 9). Most were male (74%) with a mean age of 39 years. Male-to-male sexual contact and having a sexual partner with known risk or known to be positive for HIV infection were the two most common reported risk factors for HIV positivity in blood donors during 2013-2017 (32%, each). Similarly, male-to-male sexual contact and heterosexual contact accounted for 63% and 25% of the new HIV diagnoses in the general population in 2017, respectively.[1] Of 19 HIV positive donors in the five-year period 2013-2017, six were incident HIV infections.

Table 9 Characteristics of donors positive for HIV infection by year of donation, 2013-2017

Characteristics	2013	2014	2015	2016	2017	2013-2017
Number of positive donors	4	7	2	3	3	19
Number of positive first-time donors (%)	2 (50%)	2 (29%)	1 (50%)	1 (33%)	2 (67%)	8 (42%)
% male	4 (100%)	5 (71%)	1 (50%)	2 (67%)	2 (67%)	14 (74)
Mean age (range) in years	47 (28 to 65)	36 (26 to 56)	30 (26-33)	46 (30-56)	36 (24-57)	39 (24 to 65)
Number of incident donors	1	3	0	1	1	6
% born in Australia	3 (75%)	3 (43%)	1 (50%)	2 (67%)	2 (67%)	11 (58%)
Main reported risk factor	MSM[1] contact	MSM[1] contact	Other, Unknown each	PRP[2], MSM[1] contact, Unknown each	PRP[2]	MSM[1] contact; PRP[2] each
	75%	43%	50%	33%	100%	32%
Second reported risk factor	Ethnicity/COB	PRP[2], BTR[3], Unknown each	…	…	…	Unknown
	25%	14%				16%

1 MSM= Male to male contact
2 PRP= Partner with known risk/known to be positive
3 BTR= Blood/tissue recipient (note: receipt of blood/tissue overseas, so does not indicate transmission through blood products in Australia)

Figure 26 Donors with HIV infection by sex and donor status, 2013-2017



	2013	2014	2015	2016	2017
Male (first-time)	2	1	0	0	2
Male (repeat)	2	4	1	2	0
Female (first-time)	0	2	1	1	0
Female (repeat)	0	0	0	0	1

Over the past five years, 2013-2017, there has been no discernible overall trend in repeat and first-time male and female donors (Figure 26). For more information on the number and percentage of donors with HIV infection by sex, age group, donor status, country of birth and exposure category for period 2013-2017, see Supplementary Tables 7-13.

HIV - Comparison of major exposure categories between blood donors and the general population, 2017

A comparison of major exposure categories between blood donors positive for HIV infection and the general population was conducted to determine if any unique source of infection exists for Australian donors (Table 10). The comparison should be interpreted with caution as blood donors are asked about multiple potential sources of infection. In the absence of another declared risk factor, e.g. if the blood donor reports they had an operation, then this will be listed as a potential health care exposure risk despite the fact that this may be an unlikely route of infection. This classification system likely accounts for the much lower proportion of blood donors who have an undetermined risk factor. In addition, as discussed in the HCV section, the risk factor reporting for blood donors should be interpreted with caution given donors are informed of penalties if they knowingly provide misleading information.

As in previous years, the majority of the newly diagnosed HIV infection in the general population was attributed to sexual contact (93%).[1] This was consistent with the findings among blood donors, where sexual contact was identified as the primary risk factor for all three positive donors (100%).

Table 10 Comparison between HIV positive blood donors and general population in Australia by major potential risk categories, 2017

		HIV[1]
Major risk category	**General population (%)**	**Blood donors (%)**
Intravenous drug use	3.4	0.0
Country of birth/Ethnicity	0.0	0.0
Sexual contact[2]	93.3	100.0
Blood or tissue recipient	0.0	0.0
Tattoo or body piercing	0.0	0.0
Exposure in health care setting	0.0	0.0
Household contact	0.0	0.0
Other blood to blood contact	0.0	0.0
Other/undetermined/unknown	3.3	0.0
Imprisonment	0.0	0.0
No risk factor identified	0.0	0.0

1 Includes exposure categories for new HIV diagnoses only in general population
2 Includes three sub-groups: Male-to-male sexual contact, Partner with known risk or known to be positive and Engaged in sex work

Conclusion

- The prevalence of HIV infection is 51 times lower among first-time blood donors than in the general population in 2017, and 59 times lower for the period 2008-2017.
- The incidence of newly acquired HIV infection measured by the rate of incident donors is also much lower than incidence estimates from specific at-risk populations in Australia.
- There was no unique putative risk factor identified in blood donors with HIV infection in 2017.

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Human T-Lymphotropic Virus (HTLV)

Epidemiology of HTLV in Australia

HTLV is not a notifiable infection in Australia except in the Northern Territory, and very few studies have examined the epidemiology in Australia. The international literature focuses on HTLV-1 as this is more pathogenic than HTLV-2, with disease outcomes including HTLV-1-associated myelopathy and adult T-cell leukaemia/lymphoma.[13, 14] The HTLV-1 prevalence in Australia reported in published studies varies considerably, from 1.7% among Aboriginal and Torres Strait Islander adults in the Northern Territory as a whole to 51.7% among adults in the Anangu Pitjantjatjara Lands of South Australia.[15-17] A recent HTLV-1 seroprevalence study conducted in a remote Indigenous community of Northern Territory reported 31 of 97 (32.0%) participants being anti-HTLV-1 positive, including 30 of 74 (40.5%) adults and 1 of 23 (4.3%) children <15 years.[18]

Trends in prevalence

All donations:

In the past ten years, 2008-2017, a total of 43 HTLV positive donors have been detected (42 first-time donors & one repeat donor) (Table 1B). During the period 2008-2017, the overall prevalence of HTLV infection among all donations was 0.3 per 100 000 donations (Table 1B) and has shown no statistically significant trend (IRR: 0.94; 95% CI: 0.84-1.05) (Figure 27). For detail on the number and prevalence rate of HTLV infections among all donations for year 2017, see Supplementary Table 3.

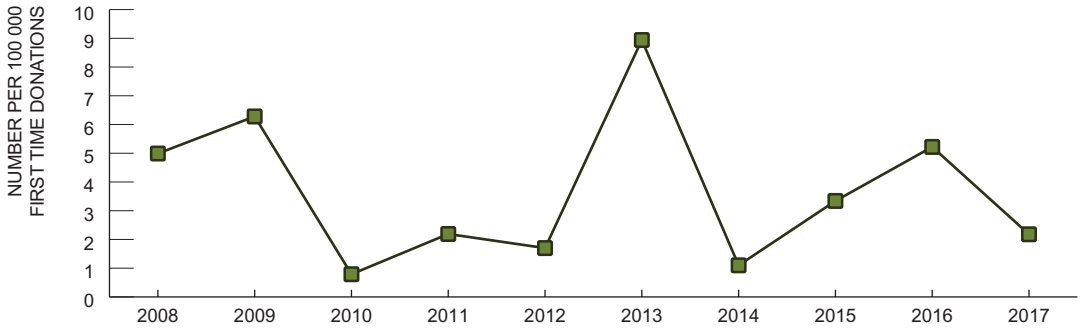
Figure 27 Prevalence of HTLV infection in all blood donations in Australia, 2008-2017, by year of donation

	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Prevalence in all donations	0.56	0.68	0.08	0.22	0.15	0.69	0.08	0.31	0.44	0.25

First-time donors:

The prevalence of HTLV infection in first-time donors remained very low over the past ten years, 2008-2017 with an overall rate of 3.7 per 100 000 donations and has shown no significant trend (Table 1B) (IRR: 0.96; 95% CI: 0.87-1.07). The prevalence rate fluctuated between 0.7 and 8.9 per 100 000 donations during this period (Figure 29). Although the prevalence of HTLV infection in the first-time donors in 2017 decreased by over 55% (2.1 per 100 000 donations) as compared to 2016 (5.2 per 100 000 donations), it is not unexpected given that low numbers can cause baseline fluctuation (Figure 28).

Figure 28 Prevalence of HTLV infection in first time blood donors in Australia, 2008-2017, by year of donation



	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Prevalence in first-time donors	4.99	6.28	0.79	2.19	1.70	8.94	1.10	3.34	5.22	2.18

Trends in incidence

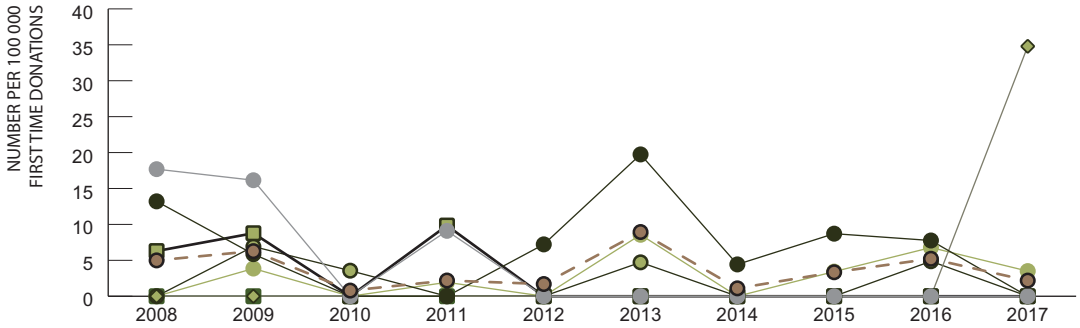
HTLV incidence among repeat Australian donors in 2017 was zero, as it was for the averaged ten-year period 2008-2017. Of note, one lapsed donor from 2007 seroconverted in 2015; however, this case did not meet the definition for an incident donor which is a positive repeat donor whose last donation was within the last 12 months and tested negative for the same TTI. No transfusion-transmitted HTLV infections were reported in Australia during 2008-2017.

Trends in HTLV infection by state/territory

In 2017, HTLV prevalence in first-time donors was zero in most jurisdictions except New South Wales/Australian Capital Territory and Tasmania where the prevalence was 3.5, and 34.7 per 100 000 donations, respectively (Figure 29); caution should be taken in interpretation of HTLV prevalence in first-time donors in Tasmania as this rate equates to only one positive donor (first ever HTLV positive donor in Tasmania in the ten-year period 2008-2017). No significant trend was observed for prevalence in first-time donors during the period 2008-2017 in any jurisdiction, except Western Australia where a significant downward trend was observed (IRR: 0.51; 95% CI: 0.27-0.99). The prevalence of HTLV infection in first-time donors has remained zero in the Northern Territory during the ten-year study period, 2008-2017 (Figure 29).

No incident HTLV infected donors were reported during 2017, and HTLV incidence has remained zero in the ten-year period 2008-2017 with the last incident donor identified in 2004.

Figure 29 Prevalence of HTLV infection among first time donors by state/territory and year of donation, 2008-2017



	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
NSW/ACT	0.00	3.86	0.00	1.94	0.00	8.56	0.00	3.43	6.78	3.50
NT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
QLD	0.00	6.92	3.56	0.00	0.00	4.72	0.00	0.00	4.87	0.00
SA	6.29	8.77	0.00	9.84	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	34.79
VIC	13.21	5.86	0.00	0.00	7.22	19.74	4.43	8.71	7.76	0.00
WA	17.69	16.15	0.00	9.10	0.00	0.00	0.00	0.00	0.00	0.00
National	4.99	6.28	0.79	2.19	1.70	8.94	1.10	3.34	5.22	2.18

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

As noted above, prevalence of HTLV infection in the first-time donors in 2017, and the ten-year study period 2008-2017 was 2.1 and 3.7 per 100 000 donations, respectively. However, population prevalence for HTLV infection is largely unknown with only the NT requiring formal notification; therefore, it is not possible to compare the prevalence of HTLV infection among Australian blood donors and the general population.

Demographic factors associated with HTLV infections in blood donors

Data on the demographic characteristics (sex, age group, state/territory and year of donation) for all blood donors was analysed* to determine the association between demographic factors and presence of HTLV infection among Australian blood donors in 2017, and the five-year period, 2013-2017, 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 2017, there was no significant association between gender, donors' age group or location and HTLV infection status (Supplementary Table 4).

Similarly, during the five-year period, 2013-2017, there was no significant association between gender, age & donor location and HTLV infection status (Supplementary Table 5).

* see Methodological Notes for details

Risk factors associated with HTLV infected donors

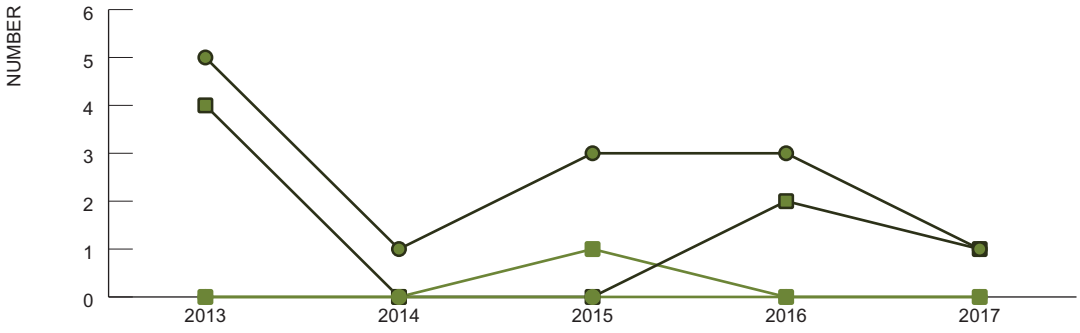
Only 21 donors were positive for HTLV infection during the 2013-2017 period; 20 were first-time donors, the only repeat positive donor was identified in 2015; 62% were male, and the mean age was 42 years with a wide range (20-68 years) (Table 11). The majority of the HTLV positive donors (86%) were born overseas. Ethnicity or country of birth (71%) was the most common risk factor for HTLV infection in blood donors in Australia during the study period, followed by partner with known risk or known to be positive for any TTI (14%). As noted, comparison data were not available for risk factors in the general population. There were no incident HTLV infections in donors during the five-year period 2013-2017.

Table 11 Characteristics of donors positive for HTLV infection by year of donation, 2013-2017

Characteristics	2013	2014	2015	2016	2017	2013-2017
Number of positive donors	9	1	4	5	2	21
Number of positive first-time donors (%)	9 (100%)	1 (100%)	3 (75%)	5 (100%)	2 (100%)	20 (95%)
% male	5 (56%)	1 (100%)	3 (75%)	3 (60%)	1 (50%)	13 (62%)
Mean age (range) in years	45 (30 to 58)	68	33(30-40)	32 (20-45)	54 (44-64)	42 (20 to 68)
Number of incident donors	0	0	0	0	0	0
% born in Australia	2 (22%)	0 (0%)	1(25%)	0 (0%)	1 (50%)	3 (14%)
Main reported risk factor	Ethnicity/COB[1] 78%	Ethnicity/COB[1] 100%	Ethnicity/COB[1] 75%	Ethnicity/COB[1] 80%	Ethnicity/COB[1] 50%	Ethnicity/COB[1] 71%
Second reported risk factor	PRP[2] 22%		PRP[2] 25%	PRP[2] 20%	PRP[2] 50%	PRP[2] 14%

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

Figure 30 Donors with HTLV infection by sex and donor status, 2013-2017



	2013	2014	2015	2016	2017
Male (first-time)	5	1	3	3	1
Male (repeat)	0	0	0	0	0
Female (first-time)	4	0	0	2	1
Female (repeat)	0	0	1	0	0

No discernible overall trend has been observed for first-time male and female donors and repeat female donors. The number of repeat male donors positive for HTLV has remained zero for the study period 2013-2017 (Figure 30). For more information on the number and percentage of donors with HTLV infection by sex, age group, donor status and country of birth for year 2017 and period 2013-2017, see Supplementary Tables 7-11 and Supplementary Table 13.

HTLV - Comparison of major exposure categories between blood donor 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 was possible. Nonetheless, Aboriginal and Torres Strait Islander populations in inland Australian regions are known to represent a high HTLV-1-prevalence population.[19] 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.[20] This is consistent with the finding that ethnicity or country of birth and a sexual partner with a known risk was the likely infective risk in the two HTLV positive donors in 2017.

Conclusion

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

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Potentially Infectious Syphilis (PIS)

Epidemiology of infectious syphilis in Australia

Population level data are available on notifications of infectious syphilis. PIS is a blood safety definition designed to capture donors that have a theoretical risk of transmitting syphilis by transfusion. To distinguish between PIS and infectious syphilis, the two definitions are presented here: PIS includes repeat donors if they have seroconverted within the last two years (TPHA negative to positive) with a positive confirmatory result, or had a history of syphilis treatment since their last TPHA non-reactive donation, or were previously known to have past treated syphilis and subsequently had possible reinfection (four-fold RPR titre rise). First time donors were included as PIS cases if screening and confirmatory tests for treponemal antibodies were 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 Blood Service surveillance reporting. Active syphilis was defined by reactivity on treponemal and non-treponemal syphilis testing +/- clinically apparent infection (i.e. excluding past treated infections and may also exclude latent syphilis[21]). 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[22]). Although the two definitions are slightly different, this section provides information on the epidemiology of infectious syphilis in Australia to provide a context for the report.

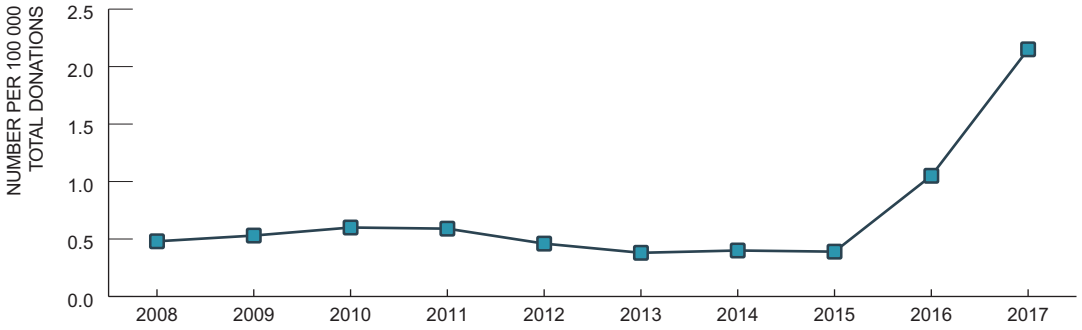
Infectious syphilis in Australia continues to be an infection primarily of men having male to male sex in urban settings, and of heterosexual Aboriginal people in remote and outer regional areas. The number of cases of infectious syphilis (infections of less than 2 years' duration) notified in 2017 was 4 398.[1] The rate of diagnosis of infectious syphilis among men has increased in the past ten years, from 11.0 per 100 000 in 2008 to 31.0 per 100 000 in 2017; similarly the rate among women has increased from 1.4 per 100 000 in 2008 to 5.5 per 100 000 in 2017.[1]

Trends in prevalence

All donations:

Importantly, 2017 is the first full year under the revised testing panel for plasma for fractionation donors (syphilis test not required) resulting in fewer donations screened for syphilis and the impact of this needs due consideration when assessing recent trends. Notwithstanding this, in the past ten years, 2008-2017, a total of 79 donors positive for PIS/active syphilis have been detected (39 first-time donors and 40 repeat donors) (Table 1B). During the period 2008-2017, the overall prevalence of PIS/active syphilis infection among all donations remained very low at 0.6 per 100 000 donations (Table 1B); however, the prevalence in all donations has increased substantially from 0.3 per 100 000 donations in 2015 to 1.0 per 100 000 and 2.1 per 100 000 donations in 2016 and 2017, respectively. As a result, a significant increase in the prevalence of PIS/active syphilis among all donations was observed during 2008-2017 (IRR 1.13; 95% CI: 1.04-1.22) (Figure 31). Although this should be interpreted with caution because of the definition change and impact of the change in syphilis testing profile, there has been a definitive increase in syphilis cases in blood donors. For detail on the number and prevalence rate of potentially infectious syphilis among all donations for the year 2017, see Supplementary Table 3.

Figure 31 Prevalence of PIS/active syphilis in all blood donations in Australia, 2008-2017, by year of donation

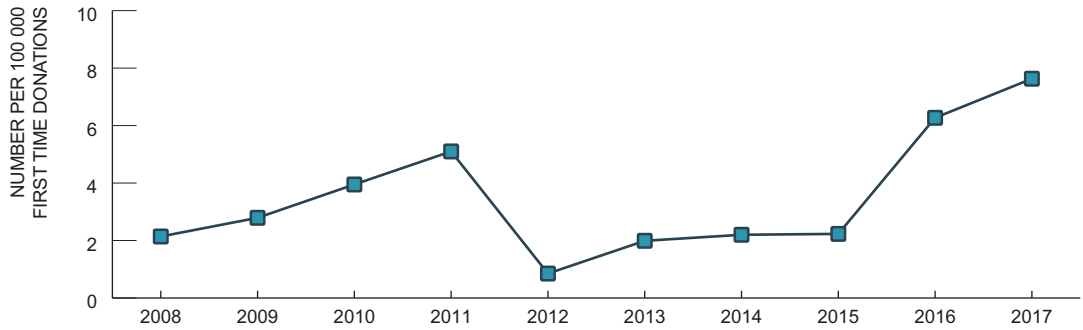


	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Prevalence in all donations	0.48	0.53	0.60	0.59	0.46	0.38	0.40	0.39	1.05	2.15

First-time donors:

In the past ten years, 2008-2017, the prevalence of PIS/active syphilis in first-time donors remained low, at 3.4 per 100 000 donations (Table 1B). Overall, the prevalence of PIS/active syphilis in first-time donors showed no significant trend during 2008-2017 (IRR: 1.09; 95% CI: 0.98-1.22). The prevalence fluctuated from 2.1 per 100 000 donations in 2008, to 5.1 per 100 000 donations in 2011, dropping sharply to 0.8 per 100 000 donations in 2012, and stabilising during 2013-2015 at around 2 per 100 000 donations (Figure 32). However, it increased by nearly 3-fold to 6.2 per 100 000 donations in 2016 as compared to 2.2 per 100 000 donations in 2015, and further increased to 7.6 per 100 000 donations in 2017 (Figure 32). We also analysed the prevalence of PIS/active syphilis in first-time donors for the past five-year period, 2013-2017, which shows a significant upward trend (IRR: 1.49 95% CI: 1.05-2.0). By comparison, the rate of diagnoses of infectious syphilis reported through the Australian National Notifiable Diseases Surveillance System was 12.7 per 100 000 population in 2008; it remained stable for the next 4 years and fluctuated between 11.0 - 12.7 per 100 000 population. The rate showed a steep increase to 19.8 per 100 000 population in 2015, and 26.4 per 100 000 in 2017 corresponding to the highest recorded number of notifications, with 4 399 diagnoses of infectious syphilis.[1] Caution should be taken in interpretation, as the infectious case definition changed in July 2015, to include more cases of likely recent acquisition.[22]

Figure 32 Prevalence of PIS/active syphilis in first-time blood donors in Australia, 2008-2017, by year of donation

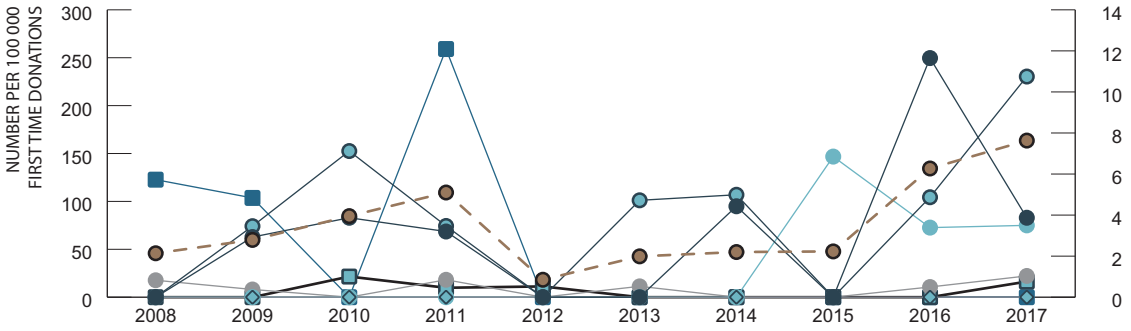


	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Prevalence in first-time donors	2.14	2.79	3.95	5.10	0.85	1.99	2.20	2.23	6.27	7.63

Trends in PIS/active syphilis infection by state/territory

The rate of PIS/active syphilis infection in blood donors increased sharply in 2017 with a record high of 17 donors identified nationally (7 first-time and 10 repeat donors) (Supplementary Table 3). In 2017, PIS syphilis prevalence in first-time donors varied markedly between jurisdictions from zero to 122.2 per 100 000 donations. The highest rate was observed in Western Australia at 22.2 per 100 000 donations (equating to two positive donations in first-time donors), followed by South Australia and Queensland at 16.2 and 10.7 per 100 000 donations, respectively. In New South Wales/Australian Capital Territory, the prevalence decreased from 6.85 per 100 000 donations in 2015 to 3.3 and 3.5 per 100 000 donations in 2016 and 2017, respectively. The prevalence of PIS/active syphilis in first-time donors in Tasmania remained zero over the last ten years. Similarly, in the Northern Territory, the prevalence has remained zero since 2012 after peaking at 259 per 100 000 donations in 2011. There were no discernible trends in most jurisdictions during the ten-year study period, 2008-2017, except for New South Wales/Australian Capital Territory, where a significant upward trend was observed (IRR: 1.8; 95% CI: 1.0-3.4). In comparison, the trend in the general population over the past ten years, 2008-2017, shows an increase in rates of diagnosis of infectious syphilis in all jurisdictions, except Tasmania and Australian Capital Territory.[1]

Figure 33 Prevalence[1] of PIS/active syphilis among first time donors by state/territory and year of donation, 2008-2017



	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
NSW/ACT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	6.85	3.39	3.50
NT	122.70	103.63	0.00	259.07	0.00	0.00	0.00	0.00	0.00	0.00
QLD	0.00	3.46	7.12	3.47	0.00	4.72	4.99	0.00	4.87	10.75
SA	0.00	0.00	21.54	9.84	11.24	0.00	0.00	0.00	0.00	16.29
TAS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
VIC	0.00	2.93	3.87	3.20	0.00	0.00	4.43	0.00	11.65	3.87
WA	17.69	8.07	0.00	18.20	0.00	11.34	0.00	0.00	10.64	22.20
National	2.14	2.79	3.95	5.10	0.85	1.99	2.20	2.23	6.27	7.63

1 Prevalence in QLD, VIC, Tasmania, NSW/ACT and at the National level are provided according to the scale on the secondary axis on the right-hand side

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

As noted above, prevalence of PIS/active syphilis in first-time donors in 2017 and the ten-year study period 2008-2017 was 7.6 and 3.4 per 100 000 donations, respectively (Supplementary Table 3 and Table 1B). However, estimates on population prevalence for infectious syphilis are unknown and information is only available on infectious syphilis notifications,[1] rendering it hard to compare the prevalence of PIS/active syphilis infection among Australian blood donors and the general population as notifications likely represent only a proportion of the total cases (only those cases for which health care was sought, a test conducted and a diagnosis made, followed by a notification to health authorities).

Demographic factors associated with PIS/active syphilis in blood donors

Standardised national data on demographic factors associated with donors positive with PIS/active syphilis are available on only 37 donors (3 from 2014, 5 from 2015, 12 from 2016, and 17 from 2016). 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 the association between demographic factors and presence of PIS/active syphilis infection among Australian blood donors in 2017, and the four-year period, 2014-2017, separately (Supplementary Tables 4 and 6). Of note, during the four-year period, 2014-2017, there were 39 donors positive for PIS/active syphilis; however, information is available for only three out of five donors positive for active syphilis in 2014. The remaining two positive donors for active syphilis in 2014 are therefore not included in the demographic factors analyses. 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 2017, female donors were significantly less likely (66%) compared to male donors to be positive for PIS (Supplementary Table 4). There was no significant association between donors' age group or location and PIS status. During the four-year period, 2014-2017, female donors were 63% less likely to be to be positive with PIS/active syphilis as compared to male donors. Donors between 40-49 years and 50-years-and-above age groups were 73% and 84% less likely to be positive with PIS/active syphilis, respectively, as compared to the reference group of 20-29 years (Supplementary Table 6). There was no association between state/territory of the donors and PIS/active syphilis infection among Australian blood donors during this period.

Risk factors associated with PIS/active syphilis infected donors

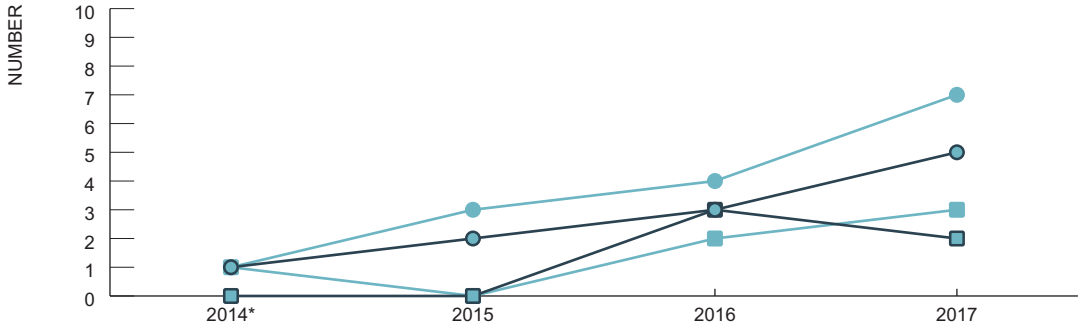
As noted above, this report presents risk factors data for the five-year period, 2013-2017. During this period, a total of 39 donors were positive for PIS/active syphilis, of which 37 have standardised risk factor data available (3 from 2014, 5 from 2015, 12 from 2016, and 17 from 2017), impeding any meaningful analysis for the entire period of 2013-2017; therefore, data for only 2014-2017 period are presented. Of note, in 2014, five donors were positive for active syphilis; of these risk factors data are available for only 3 donors. Of the 37 donors (with known standardised risk factor data) positive for PIS/active syphilis during 2014-17, 43% were first-time donors, 26 of 37 (70%) were male, and 65% were born in Australia (Table 12). The mean age was 33 (range 19-60). Partner with unspecified risk (43%) was the most frequent likely risk factor for PIS/active syphilis positivity. In comparison, in 2017, nationally, 85% of infectious syphilis diagnoses were in males, and 60% were in people aged 20 – 39 years.[1]

Table 12 Characteristics of donors positive for PIS/active syphilis by year of donation, 2014-2017

Characteristics	2014*	2015	2016	2017	2014-2017
Number of positive donors	5	5	12	17	39
Number of positive first-time donors (%)	1 out of 3*	2	6	7 (41%)	16 (43%)^
% male	2 out of 3* (67%)	5 (100%)	7 (58%)	12 (71%)	26 (70%)^
Mean age (range) in years	40 (29-60)	32 (29-60)	37 (24-55)	30 (19-51)	33 (19-60)^
% born in Australia	1 out of 3 (33%)	2 (40%)	9 (75%)	12 (71%)	24 (65%)^
Main reported risk factor	Partner with unspecified risk	Unknown	Partner with unspecified risk Unknown - each	Partner with unspecified risk	Partner with unspecified risk
	100%	60%	42%	47%	43%^
Second reported risk factor	…	MSM contact & PUSR[1] each	PRP[2]	PRP[2]/ Undetermined each	Unknown
		20%	17%	18%	24%^

1 PUSR=Partner with unspecified risk
2 PRP= Partner with known risk/known to be positive
* For 2014 data, information is available for only three out of five donors positive for active syphilis
^ % calculations are based on 37 donors (that have standardised risk data available) as the denominator

Figure 34 Donors with PIS/active syphilis infection by sex and donor status, 2013-2017



	2014*	2015	2016	2017
Male (first-time)	1	2	3	5
Male (repeat)	1	3	4	7
Female (first-time)	0	0	3	2
Female (repeat)	1	0	2	3

* For 2014 data, information is available for only three out of five positive donors

Over the past five years, 2013-2017, there has been an upward trend in the number of PIS/active syphilis positive first-time and repeat male and female donors (Figure 34). For more information on the number and percentage of donors with PIS/active syphilis infection by sex, age group, donor status, country of birth and exposure category for year 2017 and period 2014-2017, see Supplementary Tables 7-13.

Conclusion

- Overall, the prevalence of PIS/active syphilis among all blood donations during 2008-2017 has shown a significant upward trend, although with definition changes this should be interpreted with caution.
- Comparison between prevalence of PIS/active syphilis in blood donors and general population could not be done as estimates on population prevalence for infectious syphilis are unknown and information is only available on infectious syphilis notifications.

Additional information

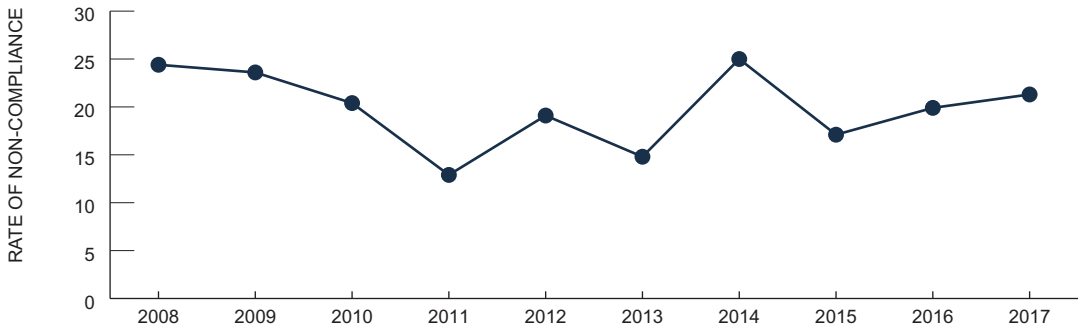
Screening compliance

Every donor is required to self-complete a comprehensive donor questionnaire (Donor Questionnaire –DQ). For whole blood donors, this is a paper document whereas regular plasmapheresis donors at dedicated Blood Service sites whose plasma is exclusively used for the manufacture of plasma-derived blood products complete an electronic version (the Plasma electronic Donor Questionnaire- PeDQ). The PeDQ omits some of the questions asked of whole blood donors because plasma fractionation has dedicated pathogen inactivation steps which substantially reduce the risk of transmission compared to fresh blood components. For example, there is no travel history question as donors exposed to malaria risk are accepted to donate for plasma for fractionation. All donors, with the exception of regular plasmapheresis donors who have answered 'no' to all the questions in the PeDQ undergo a confidential interview with a Blood Service staff where the donor's eligibility to donate is determined. All donors have to sign a legal binding declaration before the donor can donate. The Blood Service is therefore highly reliant on donors truthfully answering all questions (i.e. 'compliance').

Not completing the pre-donation questionnaire truthfully is termed 'non-compliance' with donor selection guidelines and the Blood Service 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). The Blood Service takes measures to minimise this latter risk, including the use of computerised release systems. Non-detection and process failure are both avoidable risks if a positive donor appropriately discloses their risk (i.e. complies - leading to deferral) since no donation will be collected.

Over seventeen percent (153) of infected donors in 2013-2017 disclosed risk factors during their post-donation interview that would have deferred them from donating had they disclosed their risk behaviour at the pre-donation interview (Table 13). Of these, 69% (106 donors) were first-time donors. The rate of non-compliance in TTI positive donors has been relatively stable for the past decade in the range 13-25%. The average rate observed in a previous Blood Service study[5] for 2000-2006 was 22%. There was evidence of a declining trend between 2008 and 2011 with the rate incrementally declining to its lowest ever level of 12.9% in 2011 (Figure 35). However, the rate since has fluctuated between 15 and 25%.

Figure 35 Rate of reported non-compliance in transfusion-transmissible-infection positive donors, 2008-2017



	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Rate of non-compliance	24.4	23.6	20.4	12.9	19.1	14.8	25.0	17.1	19.9	21.3

Table 13 Non-compliance category and rate among donors who were positive for any transfusion-transmissible infection, 2013-2017

Non-compliance by year and reason for deferral	2013	2014	2015*	2016**	2017	2013-2017
Number (%) of non-compliant donors by reasons for deferral						
Intravenous drug use	13 (48.2)	19 (51.3)	14 (52)	15 (48.3)	9 (29.0%)	70 (45.75)
Known status/previous positive ^	11 (40.7)	10 (27)	10 (37)	17 (54.8)	16 (51.6%)	64 (41.83)
Male-to-male-sexual contact	2 (7.4)	2 (5.4)	1 (3.7)	1 (3.2)	2 (6.4%)	8 (5.23)
Partner with known risk or known to be positive	1 (3.7)	4 (10.8)	1 (3.7)	2 (6.4)	4 (12.9%)	12 (7.84)
Others	0 (0)	2 (5.4)	7 (26)	0 (0)	0 (0)	9 (5.88)
Total number (%) of non-compliant donors by year	27 (15)	37 (25)	27 (17)	31 (20)	31 (21)	153 (17)

^ includes people with a history of jaundice
* In 2015, 6 out of 27 non-compliant donors had more than one reason for non-compliance hence the total% is more than 100%
** In 2016, 5 out of 31 non-compliant donors had more than one reason for non-compliance hence the total % is more than 100%

Unlike previous years where the majority of non-compliant positive donors had a history of injecting drug use, in 2016 and 2017 the most common risk behaviour identified was known status of previously being positive for a virus (including history of jaundice) (54.8% and 51.6%, respectively). It is possible that this might reflect an increasing number of returning/prospective donors with past HCV infection who have successfully undergone treatment with direct acting anti-viral medications. While these donors have undetectable RNA and are 'cured', they have detectable HCV antibodies and therefore are not eligible to donate blood. Overall, during the period of 2013-2017, 45.7% of non-compliance was attributed to injecting drug use followed by known status of previously being positive for a virus (41.8%), having a sexual partner with known risk or known to be positive for any transfusion-transmissible infection (7.8%), 'other' (5.8%) and male-to-male sexual contact within the last 12 months (5.27%) (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. Individuals donating in the window period (incident infections) generally pose the majority of the risk in terms of transmission because they may be missed by testing whereas long standing (prevalent) infections are readily detected by modern screening tests. The exception is HBV where chronically infected donors with occult HBV infection (OBI) may contribute a substantial risk. Highlighting this, a model developed by the Blood Service estimated that in 2012/2013 the majority (55%) of the hepatitis B residual risk in Australia resulted from donors with OBI.[23] More recent estimation indicates an increasing proportion of OBI risk, about 75% in the latest estimate (Blood Service, unpublished).

In 2017, the Blood Service changed the method of estimating the window period risk for HIV and HCV, bringing it in line with the method for HBV adopted in 2016. This addresses the current limitation that existing models are overly conservative, estimating the probability of collecting a window period donation, rather than the more appropriate estimate of the risk of infection in a recipient. The adoption of the method of Weusten et al.[24] leads generally to lower estimates and standardises the method with HBV. Using viral testing data including the number of incident donors reported for the 2015 and 2016 calendar year periods and applying these to the Blood Service[25] and Weusten[24] risk models, residual risk estimates (per unit transfused) were derived for the four transfusion-transmissible viral infections subject to mandatory testing (Table 14). Of note, a revised model was applied to HBV which specifically addresses the risk of occult hepatitis B infection (OBI).[26] The risk estimate for active syphilis is not derived by the same method but rather assumed from the lack of reported cases of transfusion-transmission for several decades. The estimates for all fall below the 'negligible' risk threshold of 1 in 1 million used by the Blood Service to contextualise the risks for transfusion recipients. Further information can be obtained from the following website http://www.transfusion.com.au/adverse_events/risks/estimates.

Table 14 Estimated risk of window period donation/risk of not detecting true infection for HBV, HCV, HIV, HTLV and syphilis in Australian blood donations (2015-2016)

	HBV	HCV	HIV	HTLV	PIS/active syphilis
Estimated number of window period units collected (per annum)	<1	<1	<1	<1	<1
Residual risk to recipient - per unit transfused	Less than 1 in 1 million	Less than 1 in 1 million	Less than 1 in 1 million	Less than 1 in 1 million	Less than 1 in 1 million

Based on the estimates and assuming approximately 1.3 million donations collected per annum, less than one transfusion-transmission for the above mentioned infectious agents (most likely HBV) would be predicted per annum. The lower reported frequency of cases of transfusion-transmission supports that the modelled estimates are conservative with no cases of transfusion-transmitted HCV reported in Australia since 1991, none for HTLV since universal testing commenced in 1993, none for HIV since 1998 and three probable cases of HBV in the 2005-2015 period. It should be noted that no HIV or HCV transfusion-transmissions have been identified since the introduction of NAT testing in 2000.

Testing for malaria

In Australia, donation testing for malaria infection is limited to 'at risk' donors. This includes donors who report at the pre-donation interview travel to or residence in malaria endemic countries, as well as those with a previous history of infection.[27] The availability of malaria antibody testing results in significant recovery of valuable fresh blood components (red blood cells and platelets) as prior to the commencement of testing such donors were restricted to donating plasma for fractionation only, for 1-3 years. Annually, approximately 65 000 red cells and 7 000 platelets are 'recovered' as a result of non-reactive malaria antibody test results. Since malaria antibodies can indicate both recent and past infection, all antibody repeat reactive donors in 2017 were also tested for plasmodial DNA to exclude current infection. Donors with detectable DNA are immediately referred for clinical assessment.

In 2017, 106 863 donations were tested for malaria antibody of which 1 425 (1.3%) were found to be repeat reactive for malaria antibodies. This rate of antibody detection is comparable to the 1.6% rate recorded in 2016. None of the 1 425 donations had detectable malaria DNA suggesting past infection in the donors. No cases of transfusion transmitted malaria were reported in Australia in 2017 with the last recorded Australian case in 1991.[28] The residual risk for transfusion-transmitted malaria is estimated to be substantially less than 1 in 1 million per unit transfused.

Minimising bacterial contamination of blood components

Transfusion with platelets or red cells carries the highest risk of bacterial transmission, with international data indicating that the risk of a clinically-apparent reaction is at least 1 in 75 000 for platelets[29] and 1 in 500 000 for red cells.[30] Contamination may be due to bacteraemia at the time of blood donation (presumably asymptomatic), contamination with commensal skin bacteria during collection or introduction during processing (e.g. when pooling buffy coats). Platelets are stored at room temperature which provides a more favourable growth environment for most pathogenic bacteria than the storage conditions used for red cells (refrigeration) or plasma (freezing). This increases the risk that even small initial numbers of contaminating bacteria in a platelet pack may replicate to levels sufficient to result in a transfusion reaction.[31]

The Blood Service reduces this risk with 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, dermatological lesions.

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

3. **Flow diversion**
   The first 30mL (minimum) of blood collected is diverted away from the collection bag. Introduced in Australia in 2006,[2] this procedure had been previously shown to reduce the bacterial contamination of platelet concentrates by more than 70%.[32]

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 and aseptic collection of donations into sterile, closed collection systems, with appropriate subsequent handling and storage.

5. **Pre-release bacterial contamination screening**
   Since 2008, all platelets produced by the Blood Service have been screened for bacterial contamination using the automated BacT/ALERT 3D system.[33]

6. **Patient Blood Management (PBM)**
   The risk of many adverse transfusion outcomes, including bacterial transmission, is dose-dependent. PBM[34] 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.

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

Bacterial prerelease testing for platelets

Platelet concentrates are manufactured by apheresis or by pooling the buffy coats from four whole blood donations into a single platelet unit. A single apheresis-derived donation may be split into two platelet units. At least 24 hours after collection, a minimum of 15 mL is removed from the platelet pack and used to inoculate a set of specialised anaerobic and aerobic culture bottles. These are incubated and monitored for bacterial growth by the automated BacT/ALERT 3D system.

Due to the short 5-day shelf life of platelet concentrates, platelet packs are released for use immediately after sampling. In 2017 culture bottles were incubated for 7 days in total and if bacterial growth was detected, any unused platelet packs and other components from the associated donation were immediately recalled. If potentially contaminated platelets had already been transfused, the treating clinician was notified and updated regularly as further information became available. Positive culture bottles were investigated at external reference laboratories by Gram staining, subculture to agar media, bacterial identification and antimicrobial susceptibility testing where appropriate.

In 2017 a total of 123 741 platelet units were screened for bacterial contamination.

Of 96 127 pooled platelets, 477 (0.50%) were flagged by the BacT/ALERT as potentially positive. Of the total platelets tested, 117 (0.12%) were designated “confirmed positive”, 107 (0.11%) were “indeterminate” and the remaining 253 (0.26%) were considered to be “false positive”.

Of 27 614 apheresis platelets, 148 (0.54%) were flagged by the BacT/ALERT as potentially positive. Of the total platelets tested, 14 (0.05%) were designated “confirmed positive”, 16 (0.06%) were “indeterminate” and the remaining 118 (0.42%) were considered to be “false positive” (Table 15).

Table 15 Summary of bacterial testing of platelets by BacT/ALERT, 2017

Platelet type	No. components screened	No. initial positive (%) i	No. confirmed positive (%) ii	No. indeterminate (%) iii	No. false positive (%) iv
Pooled platelets	96 127	477 (0.5)	117 (0.12)	107 (0.11)	253 (0.26)
Apheresis platelets	27 614	148 (0.54)	14 (0.05)	16 (0.06)	118 (0.43)
Total	**123 741**	**625 (0.51)**	**131 (0.11)**	**123 (0.1)**	**371 (0.3)**

i One or both culture bottles reported as positive by the BacT/ALERT system
ii Includes the following:
- Platelet pack is available for retesting and the same organism is re-isolated from it
- The same organism is isolated from both the platelets and another associated blood component
- Following a septic transfusion reaction, the same organism is cultured from the patient’s blood and an implicated product

iii An organism is isolated from the original sample; however the follow-up testing is inconclusive because:
- the original platelet pack is not available for resampling AND
- the associated components are either all culture-negative, or some are unavailable for testing (e.g. leaked, discarded or transfused)

iv Includes the following:
- The BacT/ALERT system signals a positive bottle, but no organisms are found by the reference laboratory (negative Gram/other stain and no growth on subcultures)
- An organism identified in the initial sample is not re-isolated when all associated products are tested, including the original platelet pack

Of 131 confirmed positives, the most frequently isolated genus was *Propionibacterium*/*Cutibacterium,** which accounted for 114 (87%) of the total. A further 12 isolates (9.2%) were coagulase-negative staphylococci, which 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 the propionibacteria and coagulase-negative staphylococci were most likely skin contaminants which contaminated the blood at the time of collection (Table 16).

The remaining 5 (3.8%) confirmed positives grew potentially pathogenic species, with one platelet pack growing two different beta-haemolytic streptococci (*Streptococcus dysgalactiae* and *Streptococcus pyogenes*). Other potential pathogens were one isolate each of *Klebsiella pneumoniae*, *Staphylococcus aureus*, *Streptococcus agalactiae* and *Streptococcus pneumoniae* (Table 16). Had they been transfused into a patient, any of these organisms could have caused significant morbidity or death. However, all associated components from these 5 confirmed positive platelet units were recalled prior to clinical use.

* Along with other cutaneous propionibacteria, *P. acnes* was recently moved to the new genus *Cutibacterium*[35]. The new name *C. acnes* has been adopted by several clinical reference laboratories and will thus be used in this and future reports, however it should be noted that the genus *Propionibacterium* still includes many non-cutaneous species and thus the collective term “propionibacteria” (which includes *C. acnes*) has been retained.

Table 16 Summary of organisms detected in confirmed positives, 2017 (n=131)

Confirmed positive organisms	Number
Propionibacterium spp.	114
Coagulase negative staphylococci	12
Staphylococcus aureus	1
*Streptococcus dysgalactiae and Streptococcus pyogenes**	1
Streptococcus agalactiae	1
Streptococcus pneumoniae	1
Klebsiella pneumoniae	1
Total	131

* One platelet pack grew two potentially pathogenic isolates (*Streptococcus dysgalactiae* and *Streptococcus pyogenes*), which are counted here as a single confirmed positive

Investigation of the implicated donors revealed the following:

- *K. pneumoniae*: one donor had experienced sweating and diarrhoea a few days prior to donation but was feeling well on the day he donated. Four months later he was found to have gallstones, raising the possibility that he had transient, asymptomatic bacteraemia during the donation. The other 3 donors were medically cleared.
- *S. dysgalactiae* and *S. pyogenes*: all 4 donors were medically cleared. Although no source could be identified, both organisms may asymptomatically colonise human skin and could have been introduced during phlebotomy.
- *S. aureus*: all 4 donors were well at the time of donation. Only 1 donor submitted evidence of medical clearance in which spontaneous passage of a kidney stone shortly prior to donation was noted, as well as a previously unrecognized cardiac murmur (infective endocarditis was excluded). *S. aureus* is a known but uncommon cause of renal calculus and/or urinary tract infection.
- *S. agalactiae*: all 4 donors were well at the time of donation. One donor had pre-existing vaginal prolapse and although this organism colonizes the genital tract of some women, it is unclear how uncomplicated prolapse could be reasonably linked to bacteraemia.
- *S. pneumoniae*: 2 donors were medically cleared. One donor was well at the time of review but was noted 3 months later to have received a two-week course of antibiotics for a respiratory infection at some point following the implicated donation. Although *S. pneumoniae* is a classic pathogen of community acquired pneumonia, the significance of this later illness is unclear. One donor did not respond to multiple attempts to follow up and could not be assessed.

Septic transfusion reactions are rare. In the 7.7 years following the introduction of universal platelet bacterial contamination screening, the rate of transfusion-transmitted bacterial infection (TTBI) was 0.4 per 100 000 platelet units transfused.[2] This compares favourably with US data indicating a rate of 0.9 per 100 000 platelet units.[36] For red cells, the Australian Red Cross Blood Service rate was similarly low at 0.04 per 100 000 transfused units.[2]

No transfusion-transmitted bacterial infections were recorded in 2017.

Surveillance for emerging infections

The Blood Service maintains surveillance for emerging infections through close liaison with Australian Government communicable disease control units, CSL Behring, membership of international medical/infectious disease groups and active horizon scanning. Potential threats are regularly reviewed by the Blood Service Donor and Product Safety Committee (DAPS Committee) and risk assessment performed in the event that an emerging infection is identified as a clear and present threat to the safety of the blood supply. Where appropriate this will be performed in collaboration with CSL Behring (in their capacity as national plasma fractionator) and the Therapeutic Goods Administration (TGA).

2017-2018 Summary:

Dengue outbreaks in Queensland

Dengue virus transmission by fresh blood components has been demonstrated and thus poses a risk to blood safety.[37] In 2017 there were several small dengue fever outbreaks in Queensland including outbreaks in Cairns, Innisfail and on Boigu and York (Masig) Islands in the Torres Strait. In 2018 to the end of June the only reported outbreak was Mareeba.[38] To mitigate this risk, supplementary donor selection measures and product restrictions were implemented for travel to/residence in affected areas on the Australian mainland. Donations from these areas were restricted to CSL fractionation/processing until the outbreaks were declared over, a strategy that has been shown to effectively eliminate dengue virus.

West Nile virus (WNV)

Outbreaks in Europe and Blood Service risk assessment

Transmission of West Nile virus (WNV) by blood, tissue and organ transplantation has been documented.[39] A virulent strain of WNV is endemic in North America and therefore donors visiting USA (including Hawaii) and Canada are restricted to donating plasma for fractionation for 28 days after their return. During the 2017 transmission season (May to November) in the EU and neighbouring countries there were outbreaks of West Nile fever (WNF) in Austria (5 confirmed/probable cases), Bulgaria (1), Croatia (5), France (1), Greece (48), Hungary (21), Italy (57), Romania (66), Israel (28), Serbia (49) and Turkey (7). The total number of reported confirmed/probable WNF cases in 2017 was 288. This compares with 491 in 2016 and 315 in 2015. The 2018 transmission season was notable due to the earlier than usual start and an increase in reported WNF cases compared to recent years. By 6 September, approximately 1 112 cases had been reported in the EU and neighbouring countries with outbreaks reported in Italy (327 confirmed/probable cases), Serbia (262), Greece (168), Romania (117), Hungary (134), Israel (49), Croatia (25), France (16), Austria (10), Kosovo (3) and Slovenia (1). The Blood Service monitored these outbreaks based on regular updates of WNV cases provided by the European Centre for Disease Prevention and Control (ECDC). The Blood Service performed weekly risk modelling to estimate the risk of a donor returning from these countries and donating while infectious (i.e. viraemic). This modelling indicated that the additional level of risk to the Australian blood supply associated with donors returning from these countries during the 2017 and 2018 to date WNV transmission seasons did not exceed the threshold (established for local dengue outbreaks) that requires cessation of fresh blood component manufacture.[40]

Hendra virus

Human Hendra virus (HeV) infection is an emerging Australian zoonotic disease associated with high mortality.[41] Since 1994 there have been 4 human deaths from HeV infection from a total of 7 confirmed human infections, the last case reported in 2008. To date all seven recorded cases of HeV transmission to humans have been due to contact with horses infected by *Pteropus* bats (flying foxes). There was 1 reported case of equine HeV infection in (late) 2016 (NSW), 3 in 2017 (2 in NSW and 1 in QLD) and 1 reported case in 2018 (to mid-September). On 1 November 2012, the world's first commercially available HeV vaccine for horses, Equivac(R) HeV, was launched in Australia. The Equivac(R) HeV vaccine is seen as an important step towards breaking the transmission cycle of HeV and reducing its impact on the horse-owning community. The Australian Veterinarian Association (AVA) encourages all horse owners to consider using this vaccine, but use is not mandatory. It would be predicted that the risk of human infection would progressively decline as the number of susceptible horses diminishes as a consequence of vaccination. However, the continued reporting of equine cases indicates a need for wider uptake of the vaccine. The primary mode of human exposure to HeV is thought to be from the respiratory secretions and/or blood of infected horses. HeV has been isolated from the nasopharyngeal secretions, saliva, urine, foetal material and organs of horses.[41] Transfusion-transmission has not been reported but is theoretically possible and as a precautionary measure the Blood Service permanently excludes donors with HeV infection. In addition, contacts of infected horses are notified that they should not donate blood for a period of at least 6 weeks and thereafter are required to provide documented evidence of lack of anti-HeV seroconversion before being accepted to donate.

Middle East respiratory syndrome coronavirus (MERS-CoV)

Human cases of infection with Middle East respiratory syndrome coronavirus (MERS-CoV) were first reported by WHO in September 2012 and the first known cases were retrospectively recognised as occurring in March of that year. MERS-CoV has been classified as a member of the *Betacoronavirus* genus that also includes the severe acute respiratory syndrome-related coronavirus (SARS-CoV), which raised initial concerns that the new virus may result in a pandemic similar to that of SARS in 2003-04. The clinical presentation of MERS-CoV infection ranges from asymptomatic to very severe pneumonia with acute respiratory distress syndrome (ARDS), septic shock and multi-organ failure resulting in death. The origin of human MERS-CoV has not yet been established. However, current evidence suggests a bat origin by which the virus was introduced to dromedary camels with subsequent overflow from camels to humans. Although it is likely that zoonotic transmission is the starting point of most clusters, human-to-human transmission is the most common mode of transmission for MERS-CoV.[42] While human-to-human transmission has been observed to a limited extent in households, the majority of human cases reported to date have resulted from human-to-human transmission in health care settings. Sustained transmission within communities has not been observed. By the end of 2012 there had only been 9 reported human cases of MERS-CoV, 5 of which were in Saudi Arabia, 2 cases in Qatar and 2 in Jordan. Subsequently, reported human cases substantially increased to approximately 169 in 2013, 638 in 2014, 680 in 2015, 250 in 2016, 248 in 2017 and 111 in 2018 to mid-September. Approximately 84% of human MERS-CoV cases have been reported in Saudi Arabia and only a small number of cases have been reported outside the Middle East. In its August 2018 Global Summary and Risk Assessment the WHO maintained its assessment that given the lack of evidence of sustained human-to-human transmission in the community, it does not advise special screening at points of entry with regard to this event nor does it currently recommend the application of any travel or trade restrictions.[43] In its most recent risk assessment (August 2018), the European Centre for Disease Prevention and Control (ECDC) concurred with the WHO assessment and noted that the risk of sustained human-to-human transmission in Europe remains very low and there is only a very low risk of a MERS-CoV outbreak in the EU.[44] Transfusion transmission of MERS-CoV has not been reported. However, given that infection includes a viraemic phase, the possibility of asymptomatic viraemia and potential transfusion transmission cannot be excluded. The current risk posed by MERS-CoV to blood safety in Australia is considered to be very low. The Blood Service is managing the potential risk from MERS-CoV by ongoing monitoring of reports of laboratory-confirmed cases, the geographical location of case clusters and local human-to-human transmission.

Ebola viruses

There are 5 known species of the *Ebolavirus* genus which belongs to the *Filoviridae* family and are referred to collectively as ebolaviruses. Ebola virus infection causes severe disease in humans, including internal and external haemorrhaging, with a case fatality rate of about 50%. The first reported outbreak of Ebola virus disease (EVD) was reported in 1976 in Sudan and the Democratic Republic of the Congo. Between 1976 and 2013 there were 20 reported EVD outbreaks, all in equatorial African countries. In March 2014, the largest known EVD outbreak was reported in West Africa. The worst affected countries, which accounted for >99.9% reported cases of EVD were Guinea, Liberia and Sierra Leone. The outbreak continued for 2 years, and by June 10, 2016, a total of 28 616 confirmed, probable and suspected cases were reported, with 11 310 deaths.[45] On 8 May 2018 the government of the Democratic Republic of the Congo (DRC) officially declared a new outbreak of Ebola virus disease (EVD) following laboratory confirmation of 2 cases in Equateur Province. The outbreak was declared over in late July by which time a total of 54 EVD cases (38 confirmed and 16 probable) had been reported, including 33 deaths. A second EVD outbreak was declared on 1 August 2018 with the epicentre North Kivu Province, in the east of the country. By 10 September a total of 132 cases (131 confirmed and 31 probable) had been reported with 61 deaths. Although transfusion-transmission of EBOV has not been reported, it cannot be excluded as ebolaviruses are typically detectable in the blood for about 1-2 weeks during acute infection. However, the risk of transfusion-transmitted ebolavirus infection may be mitigated by the observation that ebolavirus DNA is usually not detectable until symptoms appear, by which time the infected individual would be unlikely to attempt to donate blood. The Blood Service manages the potential risk from EBOV by ongoing monitoring of reports of laboratory-confirmed cases, the geographical location of case clusters and local human-to-human transmission. Donors reporting a current or past ebolavirus infection are permanently deferred. Additionally, donors who have travelled to countries defined as risk areas for ebolavirus, or have had contact with someone who has a current infection or had a past infection, are deferred from donating for 8 weeks after leaving the risk area. In summary, the current risk posed by EBOV to Australia's blood safety is very low.

Zika virus (ZIKV)

ZIKV is a mosquito-borne virus (arbovirus) classified as a member of the *Flaviviridae* family and *Flavivirus* genus. ZIKV was first isolated in 1947 from the blood of a sentinel Rhesus monkey in the Zika forest, near Lake Victoria in Uganda. The first reported case of ZIKV isolated from a human was in Nigeria in 1954. Phylogenetic analyses have indicated that ZIKV emerged in Uganda between 1892 and 1943, most probably around 1920. There are 2 main ZIKV lineages—an Asian and African lineage which has 2 genotypes.[46] Until a ZIKV outbreak on Yap Island in 2007, no major outbreaks and only 14 cases of human ZIKV-associated illness had been reported. However, since 2007 there have been 3 major ZIKV outbreaks: Yap island in 2007, Western Pacific region in 2013-15 and an outbreak in the Americas is the largest ever reported ZIKV outbreak.[47] By 18 August 2016 a total of 406 496 suspected ZIKV cases and 107 888 confirmed cases were reported by countries and territories in the Americas. Countries with the highest number of reported suspected/confirmed cases were Brazil (174 003/78 421), Colombia (92 842/8 826), Venezuela (54 551/1 632), Martinique (34 310/12), Honduras (29 896/191) and Guadeloupe (26 520/379).[48]

The annual numbers of confirmed ZIKV cases reported in Australia for the period 2012 to 2015 were 1, 1, 13 and 9, respectively. In 2016 the number of reported cases increased to 102. Country of origin was reported for 101 of these cases–54 (53.4%) were acquired in the Asia/Pacific region and 47 (46.6%) in the Americas. The number of reported cases declined to 9 in 2017 and 2 in 2018 to 25 August. All reported confirmed cases of ZIKV in Australia have been imported cases.[49] Approximately 80% of ZIKV infections are asymptomatic and most symptomatic infections are accompanied by mild symptoms including rash and fever.[46, 50] However, there is now a general consensus that ZIKV is a causative agent of neurological disease in some infected individuals. In particular, ZIKV infection is associated with microcephaly in newborns and Guillain-Barre syndrome (GBS).[51] ZIKV is considered to be transfusion-transmissible as infection includes an asymptomatic viraemic phase and at least three cases of probable transfusion-transmitted ZIKV infection were reported during the outbreak in the Americas.[52, 53]

In response to the potential risk of ZIKV to blood safety in Australia, the Blood Service has implemented a number of donor deferrals. All countries that reported autochthonous cases of ZIKV transmission in the recent outbreaks in the Western Pacific and Americas were already subject to donor travel deferrals related to either malaria (120 days), DENV or CHIKV (4 weeks). The Blood Service has also implemented a 4-month deferral from date of recovery for donors with a current ZIKV infection and a four-week deferral from date of last contact for donors who have had sexual contact with someone infected with ZIKV. With the geographical spread of ZIKV it is possible that local transmission may be reported in countries without current donor travel deferrals. Therefore, the Blood Service has also implemented a 4-week deferral for donors who may have travelled to countries where ZIKV transmission has been reported but do not have travel deferrals relating to other EIDs. Given these donor deferrals, the low number of imported ZIKV infections reported in Australia, the absence of reported local transmission, the limited distribution of mosquito vectors and rarity of reported transfusion-transmission cases worldwide,[54, 55] ZIKV represents a low risk to blood safety in Australia.

Listeria monocytogenes

Listeria monocytogenes is a gram-positive bacterium that causes listeriosis. Although *L. monocytogenes* is found widely in nature including in soil, decaying vegetation, water and faeces of many mammals, it is an uncommon cause of human illness. The primary route of transmission to humans is believed to be through the consumption of contaminated food. In early 2017 the largest ever reported outbreak of listeriosis began in South Africa and was not brought under control until March 2018. Genome sequencing of isolates indicated that most belonged to the same strain which was identified in a widely consumed ready-to-eat processed meat product. Between 1 Jan 2017 through to 24 Apr 2018, 1024 laboratory-confirmed listeriosis cases were reported. The outcome of illness is known for 700 patients, of whom 200 (28.6 percent) died; this case fatality rate is comparable to other recorded listeriosis outbreaks worldwide. Most of the cases are persons who have higher risks for a severe disease outcome, such as neonates, pregnant women, the elderly and immunocompromised persons. In this outbreak, 42 percent of the cases are neonates who were infected during pregnancy or delivery.[56]

Only a single case of transfusion transmission of *Listeria monocytogenes* has been reported worldwide and typically <100 cases of listeriosis are reported annually in Australia. In 2018, there have been two Australian food-based recalls associated with *Listeria monocytogenes* contamination risk. The first[57] involved contaminated rock melons from a single NSW producer and the second[58] potentially contaminated imported frozen vegetables distributed nationally. The Blood Service undertook individual risk assessments at the time of reporting of these recalls, and concluded that, in both cases the risk to the blood supply was extremely low and did not justify any additional risk mitigation strategies over and above routine practice. The latter includes; health screening questions in the donor questionnaire which would exclude symptomatic individuals presenting to donate and bacterial screening of all platelets and a proportion of red blood cells, which would detect *Listeria monocytogenes*.

Japanese encephalitis virus (JEV)

JEV is a mosquito-borne flavivirus. Similar to WNF, most cases of JEV are asymptomatic with <1% of infections resulting in a severe encephalitis. In July 2017 the Hong Kong Centre for Health Protection reported the first cases of transfusion-transmission, subsequently published in January 2018, where an asymptomatic viraemic donor transmitted JEV to 2 immunocompromised recipients.[59] In Australia, the risk JEV poses to blood safety is extremely low. There has not been a reported locally acquired case of JEV in Australia since 1998 (Torres Strait).[60] Overseas-acquired cases of JEV reported are rare and countries where the vast majority of cases of JE occur are covered by existing malarial or dengue restrictions that prevent a donation that is destined for fresh component manufacture. Although Hong Kong is not subject to donor travel restrictions, reported cases of JE in Hong Kong are rare and risk modelling has demonstrated that the risk to blood safety is negligible.

Conclusion

- The non-compliance rate during the ten-year study period has fluctuated between 13%-25%. The rate highlights the importance of promoting donor education to ensure that the potential donors understand the importance of 'self-deferral' to reduce the risk of collecting blood from a potentially infected donor whose infection may not be detected by testing.
- While non-compliance among positive donors has been routinely monitored since 2000, the rate among TTI test-negative donors is more difficult to track. Results from a large national survey conducted in 2012-2013 showed a comparatively low rate of non-compliance (in the range 0.05 to 0.29%) among TTI test-negative donors for several sexual activity-based donor deferrals.
- The estimated residual risk of transmission for HIV, HCV, HBV, HTLV and syphilis are all less than 1 in 1 million per unit transfused, which is considered a 'negligible' risk.
- In 2017, 131 (0.11%) of a total 123 741 screened platelet units had confirmed bacterial contamination. The majority of organisms identified were slow-growing anaerobic skin flora not usually associated with post-transfusion septic reactions. However, a minority of platelets grew clinically-significant organisms which were likely to have been due to transient or occult bacteraemia in the donor and could have led to potentially serious septic transfusion reactions in the recipient. During 2017 no septic transfusion reactions were identified.
- In addition to established transfusion-transmissible infections, emerging infectious diseases continue to demand vigilant surveillance and risk assessment. Along with the ongoing risk from local dengue outbreaks and seasonal WNV outbreaks in Europe, large outbreaks of Ebola virus and Zika virus have also been closely monitored during 2017-2018. The risk to the blood supply posed by donors returning from Ebola virus and Zika virus outbreak areas has been managed by deferring donation (or restricting to plasma for fractionation) for an appropriate period.

Supplementary Tables

Supplementary Table 1 Screening tests for transfusion transmissible infections

Transfusion-transmissible infection	Mandatory screening tests	Test target	Year of introduction	Median window period estimate	Estimated risk of window period donation (per million transfusion)
Syphilis	*Treponema pallidum* Haemagglutination Assay (TPHA)	Antibodies to *Treponema pallidum*	~1949	30 days	---
	HBsAg[1]	Hepatitis B surface antigen (HBsAg)	1970	38 days	---
HBV	Nucleic Acid Test for HBV	HBV DNA	2010	15 days	<1 in 1 million
	anti-HIV 1[1] anti-HIV 2[1]	Antibody to both HIV 1 and HIV 2 (anti-HIV-1/2)	1985 (HIV-1) 1993 (HIV-1/HIV-2)	22 days	---
HIV	Nucleic Acid Test for HIV 1[2]	HIV 1 RNA	2000	5.9 days	<1 in 1 million
	anti-HCV	Antibody to HCV	1990	66 days	---
HCV	Nucleic Acid Test for HCV[2]	HCV RNA	2000	2.6 days	<1 in 1 million
HTLV	anti-HTLV 1[1] anti-HTLV 2[1]	Antibody to both HTLV 1 and HTLV 2	1993	51 days	<1 in 1 million

1 Currently Abbott PRISM (Abbott Diagnostics, Wiesbaden-Delkenheim, Germany) Chemiluminescent Immunoassay system
2 Chiron Procleix HIV-1/HCV (Multiplex) Assay, and the HIV-1 and HCV Discriminatory Assays (Chiron Blood Testing, Emeryville, California) from June 2000 until July 2010. Subsequently replaced in 2010 by Novartis HIV-1/HCV/HBV Procleix Ultrio assay using a fully automated testing system (Procleix Tigris). Ultrio assay replaced by Grifols/Hologic HIV-1/HCV/HBV Procleix Ultrio plus assay in August 2013

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Supplementary Table 2 The number and prevalence rate of transfusion transmissible infections (HBV, HCV and HIV) in Australia, by state/territory, 2017

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	28 587	367 090	395 677	18	1	19	9	5	14	1	0	1	28	6	34
Number *(Number per 100 000 donations)*				*62.97*	*0.27*	*4.80*	*31.48*	*1.36*	*3.54*	*3.50*	*0.00*	*0.25*	*97.95*	*1.63*	*8.59*
NT	681	9 200	9 881	1	0	0	0	0	0	0	0	0	1	0	0
Number *(Number per 100 000 donations)*				*146.84*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*146.84*	*0.00*	*0.00*
QLD	18 602	251 476	270 078	7	3	15	13	1	14	1	0	1	21	4	30
Number *(Number per 100 000 donations)*				*37.63*	*1.19*	*5.55*	*69.88*	*0.40*	*5.18*	*5.38*	*0.00*	*0.37*	*112.89*	*1.59*	*11.11*
SA	6 140	115 450	121 590	4	1	2	2	1	3	0	0	0	6	2	5
Number *(Number per 100 000 donations)*				*65.15*	*0.87*	*1.64*	*32.57*	*0.87*	*2.47*	*0.00*	*0.00*	*0.00*	*97.72*	*1.73*	*4.11*
TAS	2 874	49 835	52 709	1	0	0	3	0	3	0	0	0	4	0	3
Number *(Number per 100 000 donations)*				*34.79*	*0.00*	*0.00*	*104.38*	*0.00*	*5.69*	*0.00*	*0.00*	*0.00*	*139.18*	*0.00*	*5.69*
VIC	25 851	314 544	340 395	29	6	25	6	3	9	0	1	1	35	10	35
Number *(Number per 100 000 donations)*				*112.18*	*1.91*	*7.34*	*23.21*	*0.95*	*2.64*	*0.00*	*0.32*	*0.29*	*135.39*	*3.18*	*10.28*
WA	9 007	124 942	133 949	3	1	9	5	0	5	0	0	0	8	1	14
Number *(Number per 100 000 donations)*				*33.31*	*0.80*	*6.72*	*55.51*	*0.00*	*3.73*	*0.00*	*0.00*	*0.00*	*88.82*	*0.80*	*10.45*
National	91 742	1 232 537	1 324 279	63	12	75	38	10	48	2	1	3	103	23	126
Number *(Number per 100 000 donations)*				*68.67*	*0.97*	*5.66*	*41.42*	*0.81*	*3.62*	*2.18*	*0.08*	*0.23*	*112.27*	*1.87*	*9.51*

Supplementary Table 3 The number and prevalence rate of transfusion transmissible infections (HTLV and potentially infectious syphilis) in Australia, by state/territory, 2017

State/Territory of donation	All accepted donations			HTLV			Potentially infectious syphilis			Total positive donations		
	First time	Repeat	All	First time	Repeat	All	First time	Repeat	All	First time	Repeat	All
NSW/ACT	28 587	228 201	256 788	1	0	1	1	6	7	2	6	8
Number *(Number per 100 000 donations)*				*3.50*	*0.00*	*0.25*	*3.50*	*1.63*	*1.77*	*7.00*	*2.63*	*3.12*
NT	681	3 458	4 139	0	0	0	0	1	1	0	1	1
Number *(Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*	*0.00*	*10.87*	*10.12*	*0.00*	*28.92*	*24.16*
QLD	18 602	143 844	162 446	0	0	0	2	0	2	2	0	2
Number *(Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*	*10.75*	*0.00*	*0.74*	*10.75*	*0.00*	*1.23*
SA	6 140	57 483	63 623	0	0	0	1	0	1	1	0	1
Number *(Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*	*16.29*	*0.00*	*0.82*	*16.29*	*0.00*	*1.57*
TAS	2 874	24 541	27 415	1	0	1	0	0	0	1	0	1
Number *(Number per 100 000 donations)*				*34.79*	*0.00*	*1.90*	*0.00*	*0.00*	*0.00*	*34.79*	*0.00*	*3.65*
VIC	25 851	181 530	207 381	0	0	0	1	3	4	1	3	4
Number *(Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*	*3.87*	*0.95*	*1.18*	*3.87*	*1.65*	*1.93*
WA	9 007	59 574	68 581	0	0	0	2	0	2	2	0	2
Number *(Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*	*22.2*	*0.00*	*1.49*	*22.2*	*0.00*	*2.92*
National	91 742	698 631	790 373	2	0	2	7	10	17	9	10	19
Number *(Number per 100 000 donations)*				*2.18*	*0.00*	*0.15*	*7.63*	*0.81*	*1.28*	*9.81*	*1.43*	*2.40*

Supplementary Table 4 Association of demographic characteristics with presence of transfusion-transmissible infections among blood donors in Australia, 2017

		HBV			HCV		
	Number of donors	Number of positive donors *(Number per 100 000 donors)*	IRR and their 95% CI (Multivariate adjusted)	p-value	Number of positive donors *(Number per 100 000 donors)*	IRR and their 95% CI (Multivariate adjusted)	p-value
Sex							
Male	*233 784*	*47 (20.1)*	*1 (ref)*	*…*	*35 (14.97)*	*1 (ref)*	*…*
Female	*226 875*	*28 (12.34)*	*0.58 (0.36-0.93)*	*0.02*	*13 (5.73)*	*0.39 (0.20-0.74)*	*0.00*
Age group (years)							
20-29	*110 645*	*16 (14.46)*	*1 (ref)*	*…*	*6 (5.42)*	*1 (ref)*	*…*
Less than 20	*27 537*	*3 (10.89)*	*0.81 (0.23-2.81)*	*0.75*	*0 (0)*	*2.05 (0.37-11.22)*	*0.40*
30-39	*89 905*	*20 (22.25)*	*1.47 (0.76-2.81)*	*0.25*	*7 (7.79)*	*2.00 (0.58-6.83)*	*0.26*
40-49	*79 119*	*14 (17.69)*	*1.20 (0.58-2.46)*	*0.61*	*11 (13.9)*	*3.51 (1.11-11.04)*	*0.03*
50 and above	*153 453*	*22 (14.34)*	*0.96 (0.50-1.83)*	*0.90*	*24 (15.64)*	*3.82 (1.32-11.05)*	*0.01*
State/Territory							
NSW	*133 308*	*17 (12.75)*	*1 (ref)*	*…*	*12 (9)*	*1 (ref)*	*…*
ACT	*12 433*	*2 (16.09)*	*1.23(0.28-5.34)*	*0.77*	*2 (16.09)*	*1.83 (0.41-8.19)*	*0.42*
NT	*3 182*	*1 (31.43)*	*2.43 (0.32-18.29)*	*0.38*	*0 (0)*	*…*	*0.99*
QLD	*90 816*	*10 (11.01)*	*0.86 (0.39-1.89)*	*0.71*	*14 (15.42)*	*1.69 (0.78-3.65)*	*0.18*
SA	*39 304*	*5 (12.72)*	*1.01 (0.37-2.74)*	*0.98*	*3 (7.63)*	*0.81 (0.22-2.88)*	*0.75*
TAS	*15 572*	*1 (6.42)*	*0.51 (0.06-3.90)*	*0.52*	*3 (19.27)*	*2.08 (0.58-7.38)*	*0.25*
VIC	*123 250*	*35 (28.4)*	*2.21 (1.24-3.95)*	*0.01*	*9 (7.3)*	*0.83 (0.35-1.97*	*0.67*
WA	*42 793*	*4 (9.35)*	*0.72 (0.24-2.15)*	*0.56*	*5 (11.68)*	*1.32 (0.46-3.75)*	*0.60*
Total	460 659	75 (16.28)			48 (10.42)		

		HIV			HTLV		
	Number of donors	Number of positive donors *(Number per 100 000 donors)*	IRR and their 95% CI (Multivariate adjusted)	p-value	Number of positive donors *(Number per 100 000 donors)*	IRR and their 95% CI (Multivariate adjusted)	p-value
Sex							
Male	*233 784*	*2 (0.86)*	*1 (ref)*	*…*	*1 (0.43)*	*1 (ref)*	*…*
Female	*226 875*	*1 (0.44)*	*0.42 (0.03-4.78)*	*0.49*	*1 (0.44)*	*1.03 90.064-16.71)*	*0.97*
Age group (years)							
20-29	*110 645*	*2 (1.81)*	*1 (ref)*	*…*	*0 (0)*	*1 (ref)*	*…*
Less than 20	*27 537*	*0 (0)*	*…*	*0.99*	*0 (0)*	*…*	*1.00*
30-39	*89 905*	*0 (0)*	*..*	*0.99*	*0 (0)*	*…*	*1.00*
40-49	*79 119*	*0 (0)*	*..*	*1.00*	*1 (1.26)*	*…*	*0.99*
50 and above	*153 453*	*1 (0.65)*	*0.33 (0.029-3.73)*	*0.37*	*1 (0.65)*	*…*	*0.99*
State/Territory							
NSW	*133 308*	*1 (0.75)*	*1 (ref)*	*…*	*1 (0.75)*	*1 (ref)*	*…*
ACT	*12 433*	*0 (0)*	*..*	*0.99*	*0 (0)*	*…*	*0.99*
NT	*3 182*	*0 (0)*	*..*	*0.99*	*0 (0)*	*…*	*0.99*
QLD	*90 816*	*1 (1.1)*	*1.4 (0.08-22.94)*	*0.79*	*0 (0)*	*…*	*0.99*
SA	*39 304*	*0 (0)*	*..*	*0.99*	*0 (0)*	*…*	*0.99*
TAS	*15 572*	*0 (0)*	*..*	*0.99*	*1 (6.42)*	*7.6 (0.47-122.47)*	*0.15*
VIC	*123 250*	*1 (0.81)*	*1.03 (0.06-16.63)*	*0.97*	*0 (0)*	*…*	*0.99*
WA	*42 793*	*0 (0)*	*..*	*0.99*	*0 (0)*	*...*	*0.99*
Total	460 659	3 (0.65)			2 (0.43)		

	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	*233 784*	*12 (5.13)*	*1 (ref)*	*…*
Female	*226 875*	*5 (2.2)*	*0.34 (0.11-0.97)*	*0.04*
Age group (years)				
20-29	*110 645*	*10 (9.04)*	*1 (ref)*	*…*
Less than 20	*27 537*	*1 (3.63)*	*0.42 (0.05-3.31)*	*0.41*
30-39	*89 905*	*4 (4.45)*	*0.44 (0.13-1.42)*	*0.17*
40-49	*79 119*	*1 (1.26)*	*0.13 (0.01-1.01)*	*0.05*
50 and above	*153 453*	*1 (0.65)*	*0.06 (0.00-0.50)*	*0.00*
State/Territory				
NSW	*133 308*	*7 (5.25)*	*1 (ref)*	*…*
ACT	*12 433*	*0 (0)*	*…*	*0.99*
NT	*3 182*	*1 (31.43)*	*5.56 (0.68-45.33)*	*0.11*
QLD	*90 816*	*2 (2.2)*	*0.42 (0.08-2.04)*	*0.28*
SA	*39 304*	*1 (2.54)*	*0.54 (0.06-4.43)*	*0.57*
TAS	*15 572*	*0 (0)*	*…*	*0.99*
VIC	*123 250*	*4 (3.25)*	*0.59 (0.17-2.02)*	*0.40*
WA	*42 793*	*2 (4.67)*	*0.85 (0.17-4.12)*	*0.84*
Total	460 659	17 (3.69)		

Supplementary Table 5 Association of demographic characteristics with presence of transfusion-transmissible infections (HBV, HCV, HIV & HTLV) among blood donors in Australia, 2013-2017

		HBV			HCV		
	Number of donors	Number of positive donors *(Number per 100 000 donors)*	IRR and their 95% CI (Multivariate adjusted)	p-value	Number of positive donors *(Number per 100 000 donors)*	IRR and their 95% CI (Multivariate adjusted)	p-value
Sex							
Male	*1 185 221*	*292 (24.64)*	*1 (ref)*	*…*	*194 (16.37)*	*1 (ref)*	*…*
Female	*1 180 821*	*126 (10.67)*	*0.42 (0.34-0.52)*	*0.00*	*102 (8.64)*	*0.55 (0.43-0.70)*	*0.00*
Age group (years)							
20-29	*539 874*	*64 (11.85)*	*1 (ref)*	*…*	*36 (6.67)*	*1 (ref)*	*…*
Less than 20	*179 368*	*30 (16.73)*	*1.17 (0.79-1.72)*	*0.41*	*7 (3.9)*	*0.80 (0.38-1.68)*	*0.56*
30-39	*412 183*	*60 (14.56)*	*1.27 (0.96-1.68)*	*0.85*	*42 (10.19)*	*1.55 (0.98-2.44)*	*0.05*
40-49	*403 204*	*39 (9.67)*	*0.86 (0.63-1.18)*	*0.38*	*62 (15.38)*	*2.33 (1.53-3.54)*	*0.00*
50 and above	*831 413*	*74 (8.9)*	*0.74 (0.56-0.97)*	*0.03*	*149 (17.92)*	*2.68 (1.84-3.89)*	*0.00*
State/Territory							
NSW	*705 462*	*91 (12.9)*	*1 (ref)*	*…*	*78 (11.06)*	*1 (ref)*	*…*
ACT	*62 018*	*6 (9.67)*	*0.90 (0.45-1.78)*	*0.76*	*12 (19.35)*	*1.77 (0.96-3.25)*	*0.06*
NT	*17 530*	*4 (22.82)*	*1.40 (0.51-3.80)*	*0.50*	*7 (39.93)*	*3.75 (1.73-8.13)*	*0.00*
QLD	*470 457*	*58 (12.33)*	*1.00 (0.74-1.34)*	*0.97*	*76 (16.15)*	*1.45 (1.05-1.98)*	*0.02*
SA	*210 008*	*20 (9.52)*	*0.68 (0.43-1.08)*	*0.10*	*26 (12.38)*	*0.98 (0.62-1.54)*	*0.93*
TAS	*78 410*	*4 (5.1)*	*0.34 (0.12-0.92)*	*0.03*	*13 (16.58)*	*1.43 (0.79-2.58)*	*0.22*
VIC	*608 476*	*125 (20.54)*	*1.56 (1.22-2.00)*	*0.00*	*67 (11.01)*	*1.01 (0.73-1.40)*	*0.94*
WA	*213 680*	*34 (15.91)*	*1.26 (0.89-1.80)*	*0.18*	*17 (7.96)*	*0.71 (0.42-1.20)*	*0.20*
Total	2 366 042	342 (14.45)			296 (12.51)		

		HIV			HTLV		
	Number of donors	Number of positive donors *(Number per 100 000 donors)*	IRR and their 95% CI (Multivariate adjusted)	p-value	Number of positive donors *(Number per 100 000 donors)*	IRR and their 95% CI (Multivariate adjusted)	p-value
Sex							
Male	*1 185 221*	*14 (1.18)*	*1 (ref)*	*…*	*13 (1.1)*	*1 (ref)*	*…*
Female	*1 180 821*	*5 (0.42)*	*0.34 (0.12-0.96)*	*0.04*	*8 (0.68)*	*0.64 (0.26-1.56)*	*0.33*
Age group (years)							
20-29	*539 874*	*7 (1.3)*	*1 (ref)*	*…*	*2 (0.37)*	*1 (ref)*	*…*
Less than 20	*179 368*	*0 (0)*	*…*	*0.99*	*0 (0)*	*…*	*0.99*
30-39	*412 183*	*4 (0.97)*	*0.69 (0.20-2.37)*	*0.56*	*7 (1.7)*	*4.49 (0.93-21.68)*	*0.06*
40-49	*403 204*	*2 (0.5)*	*0.35 (0.07-1.72)*	*0.20*	*7 (1.74)*	*4.56 (0.94-22.03)*	*0.05*
50 and above	*831 413*	*6 (0.72)*	*0.52 (0.17-1.56)*	*0.24*	*5 (0.6)*	*1.58 (0.30-8.21)*	*0.58*
State/Territory							
NSW	*705 462*	*7 (0.99)*	*1 (ref)*	*…*	*4 (0.57)*	*1 (ref)*	*…*
ACT	*62 018*	*2 (3.22)*	*3.09 (0.64-14.9)*	*0.15*	*4 (6.45)*	*1.51 (0.18-12.35)*	*0.69*
NT	*17 530*	*0 (0)*	*…*	*0.99*	*0 (0)*	*…*	*0.99*
QLD	*470 457*	*3 (0.64)*	*0.63 (0.16-2.44)*	*0.50*	*2 (0.43)*	*0.42 (0.08-2.04)*	*0.28*
SA	*210 008*	*0 (0)*	*…*	*0.99*	*0 (0)*	*…*	*0.99*
TAS	*78 410*	*0 (0)*	*…*	*0.99*	*1 (1.28)*	*1.29 (0.15-10.52)*	*0.81*
VIC	*608 476*	*6 (0.99)*	*0.96 (0.32-2.86)*	*0.94*	*10 (1.64)*	*1.62 (0.61-4.27)*	*0.32*
WA	*213 680*	*1 (0.47)*	*0.44 (0.05-3.63)*	*0.45*	*0 (0)*	*…*	*0.99*
Total	2 366 042	19 (0.8)			21 (0.89)		

Supplementary Table 6 Association of demographic characteristics with presence of transfusion-transmissible infections (potentially infectious/active syphilis) among blood donors in Australia, 2014-2017

		Potentially infectious syphilis		
	Number of donors	Number of positive donors *(Number per 100 000 donors)*	IRR and their 95% CI (Multivariate adjusted)	p-value
Sex				
Male	*933 925*	*26 (2.78)*	*1 (ref)*	*…*
Female	*923 678*	*11 (1.19)*	*0.37 (0.18-0.76)*	*0.01*
Age group (years)				
20-29	*427 497*	*19 (4.44)*	*1 (ref)*	*…*
Less than 20	*136 344*	*1 (0.73)*	*0.18 (0.02-1.40)*	*0.10*
30-39	*331 313*	*8 (2.41)*	*0.49 (0.21-1.12)*	*0.09*
40-49	*316 358*	*4 (1.26)*	*0.27 (0.09-0.80)*	*0.01*
50 and above	*646 091*	*5 (0.77)*	*0.16 (0.06-0.45)*	*0.00*
State/Territory				
NSW	*549 602*	*13 (2.37)*	*1 (ref)*	*…*
ACT	*47 887*	*1 (2.09)*	*0.79 (0.10-6.09)*	*0.82*
NT	*13 425*	*1 (7.45)*	*2.74 (0.35-21.01)*	*0.33*
QLD	*369 619*	*7 (1.89)*	*0.79 (0.31-1.99)*	*0.62*
SA	*164 513*	*1 (0.61)*	*0.27 (0.03-2.12)*	*0.21*
TAS	*61 641*	*0 (0)*	*…*	*0.99*
VIC	*482 432*	*11 (2.28)*	*0.90 (0.40-2.02)*	*0.80*
WA	*168 483*	*3 (1.78)*	*0.70 (0.20-2.47)*	*0.58*
Total	1 857 603	37 (1.99)		

Supplementary Table 7 Number and percentage of donors positive with transfusion-transmissible infections, by sex and age group, 2017

	HBV (2017)				HCV (2017)				HIV (2017)				HTLV (2017)				Potentially infectious syphilis (2017)			
Donor status	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%
First time donors																				
<20 years	0	3	3	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
20-29 years	10	6	16	21	5	1	6	13	1	0	1	33	0	0	0	0	4	1	5	29
30-39 years	14	3	17	23	3	2	5	10	0	0	0	0	0	0	0	0	1	1	2	12
40-49 years	9	5	14	19	5	2	7	15	0	0	0	0	1	0	1	50	0	0	0	0
50-59 years	3	3	6	8	8	7	15	31	1	0	1	33	0	0	0	0	0	0	0	0
60 years and above	3	4	7	9	5	0	5	10	0	0	0	0	0	1	1	50	0	0	0	0
Repeat donors																				
<20 years	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	6
20-29 years	0	0	0	0	0	0	0	0	0	1	1	33	0	0	0	0	2	3	5	29
30-39 years	3	0	3	4	1	1	2	4	0	0	0	0	0	0	0	0	2	0	2	12
40-49 years	0	0	0	0	4	0	4	8	0	0	0	0	0	0	0	0	1	0	1	6
50-59 years	4	0	4	5	3	0	3	6	0	0	0	0	0	0	0	0	1	0	1	6
60 years and above	1	4	5	7	1	0	1	2	0	0	0	0	0	0	0	0	0	0	0	0
Total	47	28	75	100	35	13	48	100	2	1	3	100	1	1	2	100	12	5	17	100

Supplementary Table 8 Number and percentage of donors positive with transfusion-transmissible infections, by sex and age group, 2013-2017

	HBV (2013-2017)				HCV (2013-2017)				HIV (2013-2017)				HTLV (2013-2017)				PIS/active syphilis (2014-2017)*			
Donor status	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%
First time donors																				
<20 years	20	15	35	8	3	4	7	2	0	0	0	0	0	0	0	0	0	0	0	0
20-29 years	61	31	92	22	17	10	27	9	3	1	4	21	2	0	2	10	8	4	12	32
30-39 years	74	18	92	22	26	7	33	11	0	1	1	5	4	2	6	29	1	1	2	5
40-49 years	38	19	57	14	24	16	40	14	0	1	1	5	5	2	7	33	2	0	2	5
50-59 years	31	13	44	11	49	27	76	26	2	1	3	16	1	2	3	14	0	0	0	0
60 years and above	18	9	27	6	22	5	27	9	0	0	0	0	1	1	2	10	0	0	0	0
Repeat donors																				
<20 years	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	3
20-29 years	2	3	5	1	5	4	9	3	2	1	3	16	0	0	0	0	3	4	7	19
30-39 years	8	1	9	2	4	5	9	3	3	0	3	16	0	1	1	5	5	1	6	16
40-49 years	7	2	9	2	12	10	22	7	1	0	1	5	0	0	0	0	1	1	2	5
50-59 years	20	5	25	6	22	10	32	11	2	0	2	11	0	0	0	0	4	0	4	11
60 years and above	13	9	22	5	10	4	14	5	1	0	1	5	0	0	0	0	1	0	1	3
Total	292	126	418	100	194	102	296	100	14	5	19	100	13	8	21	100	26	11	37	100

* For PIS/active syphilis, data are presented for the 2014-2017 period as standardised national data on demographic factors associated with PIS/active syphilis infected donors are available from 2014 onward. Of note, during the four-year period, 2014-2017, there were 39 donors positive for PIS/active syphilis; however, information is available for only three out of five donors positive for active syphilis in 2014, therefore the total comes to 37

Supplementary Table 9 Number and percentage of donors with transfusion-transmissible infections, by country/region of birth^, 2013-2017

	HBV (2013-2017)		HCV (2013-2017)		HIV (2013-2017)		HTLV (2013-2017)		PIS/active syphilis (2014-2017)*	
Region of birth	Number	%	Number	%	Number	%	Number	%	Number	%
Australia	56	13	205	69	11	58	4	19	25	68
Overseas born										
Other Oceania	49	12	13	4	2	11	0	0	2	5
United Kingdom and Ireland	2	0	16	5	0	0	0	0	0	0
Other Europe	41	10	12	4	2	11	0	0	1	3
Middle East/North Africa	18	4	3	1	0	0	9	43	0	0
Sub-Saharan Africa	14	3	3	1	1	5	0	0	1	3
South & North East Asia	161	39	13	4	2	11	3	14	2	5
Southern and Central Asia	75	18	19	6	0	0	5	24	1	3
North America	0	0	2	1	0	0	0	0	0	0
South/Central America and the Caribbean	0	0	0	0	1	5	0	0	0	0
Total with a reported country of birth	416	100	286	97	19	100	21	100	32	86
Not reported	2	0	10	3	0	0	0	0	5	14
Total	418	100	296	100	19	100	21	100	37	100

^ Region of birth from the Australian Bureau of Statistics

* For PIS/active syphilis, data are presented for the 2014-2017 period as standardised national data on demographic factors associated with PIS/active syphilis infected donors are available from 2014 onward. Of note, during the four-year period, 2014-2017, there were 39 donors positive for PIS/active syphilis; however, information is available for only three out of five donors positive for active syphilis in 2014, therefore the total comes to 37

Supplementary Table 10 Number and percentage of transfusion-transmissible infections among first time donors, by potential reported exposure category and sex, 2017

	HBV (2017)				HCV (2017)				HIV (2017)				HTLV (2017)				Potentially infectious syphilis (2017)			
Exposure categories	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%
Ethnicity/Country of birth	37	21	58	92	0	0	0	0	1	0	1	50	1	0	1	50	0	0	0	0
Intravenous drug user	0	0	0	0	6	1	7	18	0	0	0	0	0	0	0	0	0	0	0	0
Tattoo/Piercing	0	0	0	0	5	5	10	26	0	0	0	0	0	0	0	0	0	0	0	0
Partners with any risks or known to be positive	0	1	1	2	2	1	3	8	0	1	1	50	0	1	1	50	0	0	0	0
Partner with unspecified risks	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3	2	5	71
Male-to-male sexual contact	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	2	29
Exposure in health care setting	0	1	1	2	2	1	3	8	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
Blood or tissue recipient	0	0	0	0	1	2	3	8	0	0	0	0	0	0	0	0	0	0	0	0
Household contact	2	0	2	3	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
Other	0	0	0	0	7	1	8	21	0	0	0	0	0	0	0	0	0	0	0	0
No risk factors identified/Unknown	0	1	1	2	3	1	4	11	0	0	0	0	0	0	0	0	0	0	0	0
Not reported	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Total	39	24	63	100	26	12	38	100	1	1	2	100	1	1	2	100	5	2	7	100

Supplementary Table 11 Number and percentage of transfusion-transmissible infections among first time donors, by potential reported exposure category and sex, 2013-2017

	HBV (2013-2017)				HCV (2013-2017)				HIV (2013-2017)				HTLV (2013-2017)				PIS/active syphilis (2014-2017)*			
Exposure categories	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%
Ethnicity/Country of birth	227	94	321	93	9	3	12	6	1	1	2	22	13	3	16	80	0	0	0	0
Intravenous drug user	0	0	0	0	38	8	46	22	0	0	0	0	0	0	0	0	0	0	0	0
Tattoo/Piercing	1	2	3	1	33	23	56	27	0	0	0	0	0	0	0	0	0	0	0	0
Partners with any risks or known to be positive	4	2	6	2	3	9	12	6	2	1	3	33	0	4	4	20	0	1	1	6.25
Partners with unspecified risks	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	5	4	9	56.3
Male-to-male sexual contact	0	0	0	0	0	0	0	0	2	0	2	22	0	0	0	0	3	0	3	18.8
Exposure in health care setting	1	2	3	1	11	6	17	8	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
Blood or tissue recipient	0	0	0	0	6	8	14	7	0	0	0	0	0	0	0	0	0	0	0	0
Household contact	4	3	7	2	6	3	9	4	0	0	0	0	0	0	0	0	0	0	0	0
Other blood to blood contact	0	0	0	0	2	0	2	1	0	0	0	0	0	0	0	0	0	0	0	0
Other	2	1	3	1	16	5	21	10	0	1	1	11	0	0	0	0	0	0	0	0
No risk factors identified/Unknown	1	1	2	1	13	4	17	8	0	0	0	0	0	0	0	0	3	0	3	18.8
Not reported	1	0	1	0	3	0	3	1	0	1	1	11	0	0	0	0	0	0	0	0
Total	241	105	346	100	140	69	209	100	5	4	9	100	13	7	20	100	11	5	16	100

* For PIS/active syphilis, data are presented for the 2014-2017 period as standardised national data on demographic factors associated with PIS/active syphilis infected donors are available from 2014 onward. Of note, during the four-year period, 2014-2017, there were 17 first-time donors positive for PIS/active syphilis; however, information is available for only one out of two first-time donors positive for active syphilis in 2014, therefore the total comes to 16

Supplementary Table 12 Number and percentage of transfusion-transmissible infections among repeat donors, by potential reported exposure category and sex, 2017

	HBV (2017)				HCV (2017)				HIV (2017)				Potentially infectious syphilis (2017)			
Exposure categories	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%
Ethnicity/Country of birth	5	2	7	58	0	0	0	0	0	0	0	0	0	0	0	0
Intravenous drug user	0	0	0	0	4	0	4	40	0	0	0	0	0	0	0	0
Tattoo/Piercing	1	0	1	8	1	0	1	10	0	0	0	0	0	0	0	0
Partners with any risks or known to be positive	1	0	1	8	0	1	1	10	0	1	1	100	2	1	3	30
Partner with unspecified risks	0	0	0	0	0	0	0	0	0	0	0	0	2	1	3	30
Male-to-male sexual contact	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Exposure in health care setting	1	0	1	8	1	0	1	10	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
Blood or tissue recipient	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Household contact	0	0	0	0	1	0	1	10	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
Other	0	2	2	17	1	0	1	10	0	0	0	0	0	0	0	0
No risk factors identified/Unknown	0	0	0	0	1	0	1	10	0	0	0	0	3	1	4	40
Not reported	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Total	8	4	12	100	9	1	10	100	0	1	1	100	7	3	10	100

Supplementary Table 13 Number and percentage of transfusion-transmissible infections among repeat donors, by potential reported exposure category and sex, 2013-2017

	HBV (2013-2017)				HCV (2013-2017)				HIV (2013-2017)				HTLV (2013-2017)				PIS/active syphilis (2014-2017)*			
Exposure categories	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%
Ethnicity/Country of birth	37	13	50	69	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Intravenous drug user	1	1	2	3	21	3	24	28	0	0	0	0	0	0	0	0	0	0	0	0
Tattoo/Piercing	2	0	2	3	9	9	18	21	0	0	0	0	0	0	0	0	0	0	0	0
Partners with any risks or known to be positive	6	0	6	8	2	5	7	8	1	1	2	20	0	1	1	100	3	2	5	24
Partners with unspecified risks	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4	3	7	33
Male-to-male sexual contact	0	0	0	0	0	0	0	0	5	0	5	50	0	0	0	0	0	0	0	0
Exposure in health care setting	2	3	5	7	4	4	8	9	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
Blood or tissue recipient	0	0	0	0	4	3	7	8	0	0	0	0	0	0	0	0	0	0	0	0
Household contact	0	0	0	0	4	1	5	6	0	0	0	0	0	0	0	0	0	0	0	0
Other blood to blood contact	0	0	0	0	1	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0
Other	1	2	3	4	5	2	7	8	0	0	0	0	0	0	0	0	0	0	0	0
No risk factors identified/Unknown	2	2	4	6	3	6	9	10	3	0	3	30	0	0	0	0	8	1	9	43
Not reported	0	0	0	0	1	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0
Total	51	21	72	100	54	33	87	100	9	1	10	100	0	1	1	100	15	6	21	100

* For PIS/active syphilis, data are presented for the 2014-2017 period as standardised national data on demographic factors associated with PIS/active syphilis infected donors are available from 2014 onward. Of note, during the four-year period, 2014-2017, there were 22 repeat donors positive for PIS/active syphilis; however, information is available for only two out of three repeat donors positive for active syphilis in 2014, therefore the total comes to 21.

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Supporting information for transfusion-transmissible infections surveillance report

Blood donation: from volunteer to recipient

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

Australian volunteer blood donors may be aged 16 to 80 years of age. Each donor is required to self-complete a comprehensive donor questionnaire every time they donate. The process is different for whole blood donors and regular plasmapheresis donors (see Additional Information for more detail) The questionnaire is reviewed to determine eligibility and a legally binding Declaration Form is signed in the presence of a Blood Service staff prior to donation. There are penalties including fines and imprisonment for anyone providing false or misleading information. The questionnaire asks about various medical conditions, travel history and behaviours related to increased risk of a blood-borne infection. The Blood Service is highly reliant on the donor's complete and truthful answers to all interview questions (i.e. 'compliance'). This is particularly important for questions relating to risk behaviour for transfusion-transmissible infection given the existence of the testing window period (see below). Should a donor in the window period fail to truthfully answer a question that would normally result in their deferral from donation, they will place recipients at risk because a potentially infectious unit of blood will be collected that testing will not identify.

Subsequent to satisfactorily completing the above assessment process the donor proceeds to donate. Every first-time donation is processed and undergoes mandatory tests for specific transfusion-transmissible infections (TTIs) including HIV, HBV, HCV, HTLV and syphilis. From September 2016, repeat donors donating plasma for fractionation only no longer require testing for syphilis and HTLV resulting in a different test denominator for these TTIs. Additional testing for other transfusion-transmissible infections (e.g. malaria) as well as testing for bacteria is performed on selected donations. Donations positive for mandatory screening tests are quarantined and subsequently discarded. Confirmatory testing is conducted to determine the infectious status of the donor and if positive, they are recalled for follow-up testing and counselling.

An overview of current donor selection criteria can be accessed from the Blood Service website www.donateblood.com.au.

The 'tiered' safety approach

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

1. Through pre-donation public education using the www.donateblood.com.au website, Blood Service Community Relations staff, the media and the Blood Service National Contact Centre as well as brochures and handouts in collection facilities, donors are informed of eligibility criteria for blood donation and the reasons for deferral from donation.

2. Individuals whose behaviours or actions result in them having an increased risk of transmitting blood-borne infection are excluded by specific responses to questions asked prior to donation.

3. State-of-the-art tests are undertaken on donated blood to identify prospective donors with pre-existing infection and newly acquired infections in repeat donors.

4. Where available, physical and/or chemical measures are applied to inactivate viruses and other infectious agents (pathogen inactivation or PI). Presently PI is used for manufactured plasma products but is not routinely available in Australia for fresh blood components.

Each donation used for the manufacture of fresh blood components is tested for hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus (HIV), human T- lymphotropic virus (HTLV) and *Treponema pallidum* (syphilis). Testing of selected donors at risk for malaria (e.g. travellers to/residents of endemic countries) has also been performed since 2005. Despite incremental improvements, testing is not 100% effective in identifying infected donors. The primary limitation relates to the existence of a 'window period' (WP), defined as the period immediately after infection but before the agent is first detectable in the bloodstream. The window period varies in duration from several days (for HIV) to several weeks (for HBV) depending on the transfusion-transmissible infectious agent and the specific test used.

The addition of nucleic acid tests (NAT) to existing serological assays for HIV and HCV in June 2000 substantially reduced the WP from approximately 22 days and 66 days to approximately 9 days for HIV-1 and 5 days for HCV.[61] During 2010, the Blood Service implemented NAT for HBV DNA as a mandatory screen for all blood donations in addition to the existing HBV test (HBsAg), which reduced the HBV window period from approximately 38 to 24 days.[62] An updated NAT triplex (HIV-1/HCV/HBV) test was implemented during 2013 reducing the HBV window period to approximately 15 days. These advances incrementally lower risk of not detecting a recently infected donor but importantly the WP is not eliminated. Thus, despite state-of-the-art donation testing there remains a small but nonzero risk of transmission from donors with very recently acquired infection, who may test negative if they donate during the window period.

Using donation testing results, the Blood Service monitors for trends in both prevalence (i.e. the frequency of infection in first-time donors) and incidence (i.e. the rate of newly acquired infection in repeat donors). In addition, all viral positive donors are invited to participate in confidential interviews to establish likely routes of infection. The Blood Service also estimates the risk of transmission (termed 'residual risk') per unit transfused for each TTI and publishes annual updates.

The Blood Service has collected and periodically presented data about detected infections in Australian blood donors since its establishment in 1996. In 2011, a review of available data pertaining to TTIs in Australia was jointly produced by the Australian Red Cross Blood Service and the Surveillance and Evaluation Program for Public Health at the Kirby Institute. This was the first, of what have now been established as annual reports that summarise data and trends for detected infections among Australian blood donors. The 2011 report included data for the period of 20052010 and demonstrated an overall reduction in prevalence of TTIs by almost 30% over the six years. Subsequently seven annual surveillance reports have now been published. While these focus on data from the current year they also assess for trends against the previously published data. Data on malaria testing and surveillance activity for emerging infections were also included from the 2011 report. Consistent with previous years, both the prevalence and incidence of TTIs in Australian blood donors generally remained low in 2017, with a steady or declining trend for all infections. Infected first-time donors in 2017 mostly had undiagnosed prevalent infections but a small number of recently acquired (incident) infections among repeat donors continued to be identified.

This is the eighth annual surveillance report that analyses data from the national surveillance system for blood donors maintained electronically by the Blood Service. The analysis of the previous report is extended to accommodate the most recent available data pertaining to the presence of TTIs among Australian blood donors. The report aims to inform further revision and evaluation of donor education/selection guidelines and donation testing algorithms in Australia. Finally, the residual risk estimates provide an important tool particularly for clinical stakeholders involved in patient consent for transfusion.

Objective

The main objectives of the report are to:

1. Monitor trends over time in the incidence and prevalence of TTIs in blood donors in Australia, in particular, for HCV, HBV, HIV, HTLV and syphilis, and to compare the findings from the most recent analysis with that reported for the 2008-2017 period.
2. Compare the level of TTIs in first-time and in previously negative repeat blood donors with the general population.
3. Identify and analyse the risk factors that are associated with TTIs in blood donors and compare them to the risk factors in the general population.
4. Provide estimates of the residual risk of infection in the blood supply for HCV, HBV, HIV and HTLV.
5. Summarise the data from bacterial testing of platelets and assess the risk of transfusion-associated sepsis.
6. Estimate the rate of 'non-compliance' with TTI specific deferral questions.
7. Summarise major surveillance activity for emerging infectious disease and the Blood Service response.

Data

This report incorporates national donation testing data on Australian blood donors for the period 2008 to 2017. Anonymous donor data for all donors who donated blood between January 2008 and December 2017 were extracted from the Blood Service national donor database. Trends in TTIs among first-time and previously negative repeat donors were analysed for donations in the years from 2008-2017. Demographic factors associated with TTIs in blood donors were analysed for donations made in 2017 and were compared with the findings from 2013-2017. Likely routes of exposure (termed 'putative risk factors') for each TTI in blood donors were also identified and analysed. Data from the 2015 and 2016 calendar years were combined and risk modelling conducted to derive estimates of the risk of transmission for HIV, HCV, HBV and HTLV in Australia. Additional modelling was performed to account for the risk associated with blood components from donors with occult HBV infection (OBI). This modelling used data from July 2016 to June 2017.

Methodological notes

Age-specific rate

Age-specific rate is defined as the proportion of blood donors in a particular age group who have the infection, usually expressed per 100 000 donors in the specified age group. Age-specific rate was calculated as follows:

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

Donor-years of observation

Data on interval between each donation by all donors who donated at least twice in 2017 were available from the Blood Service database. For all donors with negative tests for transfusion-transmissible viral infections, donor-years of observation were calculated as the sum of all inter-donation intervals. For positive donors, donor-years of observation were calculated as the sum of all inter-donation intervals between the first negative and the positive donation.

Exposure categories

A single most important risk factor for each positive donor was identified using the primary risk factor data from the Blood Service risk factor database. The key exposure categories for positive donors were classified as follows:

1. Intravenous drug use (IDU)
2. Country of birth (COB)/Ethnicity
3. Partners with any risks or known to be positive
4. Engaged in sex work
5. Male-to-male sexual contact
6. Blood or tissue recipient
7. Tattoo or body piercing
8. Exposure in health care setting (both occupational and non-occupational)
9. Household contact
10. Other blood to blood contact
11. Others
12. No risk factors identified
13. Not reported

For a consistent comparison of the prevalence of major exposure categories between blood donors and the general population, *Partners with any risks or known to be positive*, *Engaged in sex work* and *Male-to-male sexual contact* were combined to create a broader risk category named *Sexual contact*. Thus, from the above thirteen key categories, the following exposure groups were established to match the main exposure groups in general population for each of the transfusion-transmissible infections.

The key exposure categories modified for comparison with general population were as follows:

1. Intravenous drug use (IDU)
2. Country of birth (COB)/Ethnicity
3. Sexual contact
    a. Partners with any risks or known to be positive
    b. Engaged in sex work
    c. Male-to-male sexual contact
4. Blood or tissue recipient
5. Tattoo or body piercing
6. Exposure in health care setting
7. Household contact
8. Other blood to blood contact
9. Others
10. No risk factors identified
11. Not reported

Incidence

Incidence of TTI is defined as a rate per 100 000 donor-years of observation. It was calculated as follows:

$$\text{Incidence per 100 000 donor-years of observation} = \left(\frac{\text{Number of incident donors}}{\text{Total donor-years of observation}} \right) \times 100\,000$$

Incidence rate of any TTI over the five-year period, 2013-2017, was calculated as follows:

$$\text{Incidence per 100 000 donor-years of observation} = \left(\frac{\text{Total number of incident donors in 2013-2017}}{\text{Average of 2013-2017 total donor-years of observation}} \right) \times 100\,000$$

Of note, the methodology for calculating incidence has been modified in this year's report due to a change in methodology to calculate the Donor-years of observation (DYO) and includes the inter-donation intervals from 2017 only. Previous reports used two years of inter-donation interval data. For this reason, updated data were used for a five-year period, 2013-2017, and retrospectively applied the updated DYO calculation method, that is, changing the inter-donation intervals from two years to one year for each year.

Newly acquired infection

Newly acquired infection was defined as newly diagnosed infection with evidence of a previous negative or indeterminate test result.

Newly diagnosed infection

Newly diagnosed infection was defined as the first occasion of diagnosis in Australia.

Prevalence

Prevalence is defined as the number of positive donations per 100 000 donations. It was calculated as follows:

$$\text{Prevalence in first-time donors} = \left(\frac{\text{Number of positive first time donations}}{\text{Total number of first-time donations}} \right) \times 100\,000$$

$$\text{Prevalence in all donors} = \left(\frac{\text{Number of donations (both first time and repeat) positive for a TTI marker}}{\text{Total number of accepted donations (both first time and repeat)}} \right) \times 100\,000$$

Residual risk estimates

The Blood Service routinely applies published models to derive risk estimates based on viral testing data from rolling two calendar year periods. In 2017, the Blood Service 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 addresses the current limitation that existing models are 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[24] leads generally to lower estimates and standardises the method with HBV. For HBV, there is a separate estimation of the risk associated with chronic OBI, defined as HBcAb negative or positive, HBsAg negative and HBV DNA positive outside the acute phase of infection. This risk is summed with the HBsAg WP risk to derive an overall HBV residual risk. The method is based on assessing the probability of 'non-detection' by HBV NAT and the average probability of HBV transmission from NAT non-reactive donations. NAT non detection is derived by examining HBV NAT data and assessing the frequency of prior NAT non-detectable donations from donors identified as OBI by NAT. The transmission function is based on investigation of the outcome of transfusions from blood components (termed lookback) sourced from donors with OBI.

For HTLV, there were no incident infections for the period which necessitated estimation based on the Model C method for first time donors based on the method from Seed et al.[25]

Further information is available at http://www.transfusion.com.au/adverse_events/risks/estimates.

Statistical tests to analyse trends in transfusion-transmissible infections

Trends in prevalence and incidence of transfusion-transmissible infections were examined for the ten-year period, 2008-2017, and the five-year period, 2013-2017, 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 2008-2017 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 2017, and five-year period, 2013-2017 (for HBV, HCV, HIV and HTLV), and for four-year period, 2014-2017 (for PIS/active syphilis). The association between demographic factors and presence of any transfusion-transmissible infections (HBV, HCV, HIV, HTLV and PIS/active syphilis) among Australian blood donors were assessed using multivariate Poisson regression model for each infection separately. The predictor variables were analysed simultaneously thus adjusting for all variables in the model. A p-value of less than 0.05 was considered as statistically significant.

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