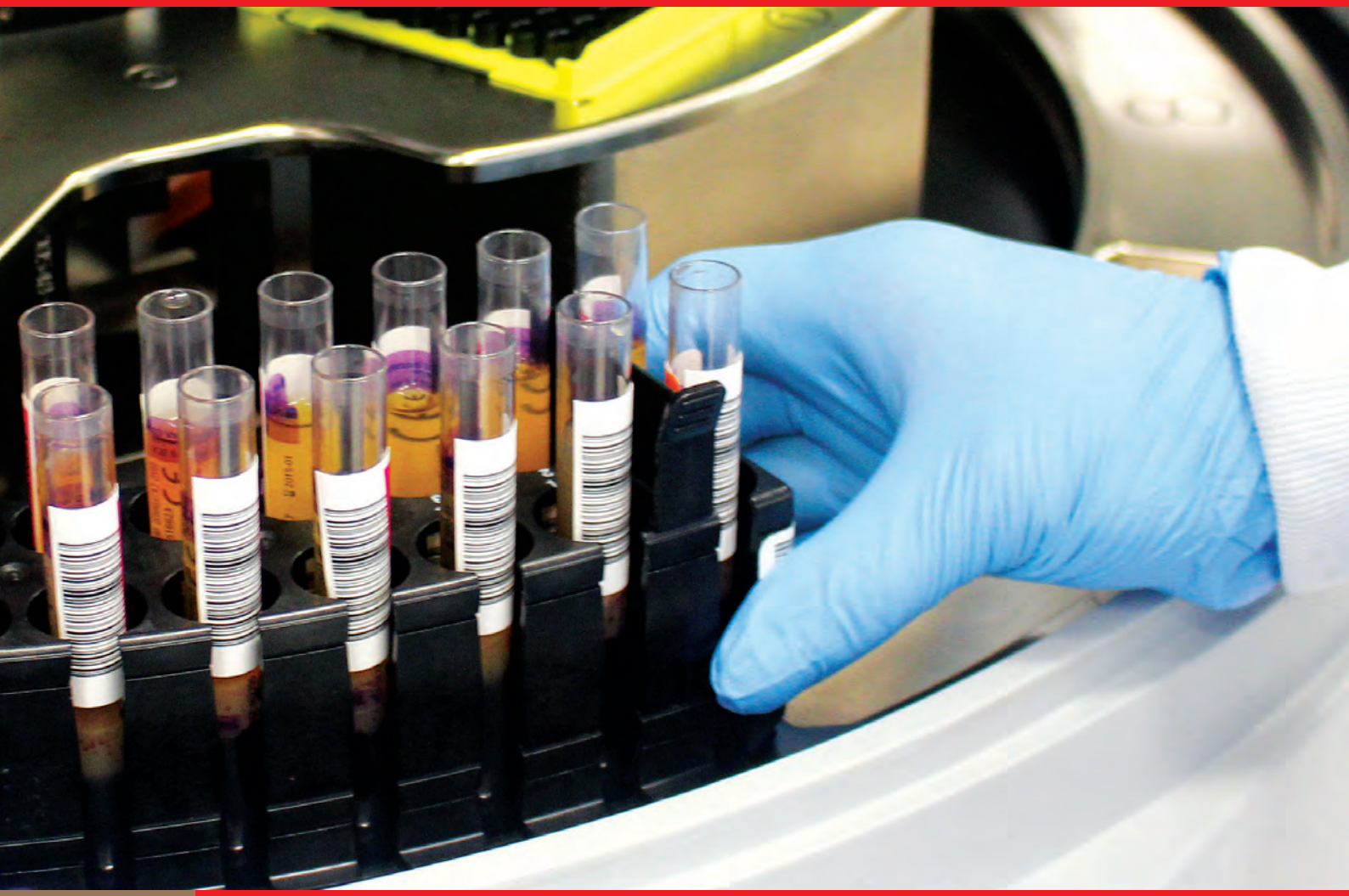

Transfusion-transmissible infections in Australia

2016 Surveillance Report

Australian Red Cross BLOOD SERVICE

UNSW SYDNEY

Kirby Institute

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Australian governments fund the Australian Red Cross Blood Service to provide blood, blood products and services to the Australian community

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 sixth report that summarises donation testing data, and incidence and prevalence trends for transfusion-transmissible infections 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 Services' 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 Australian Red Cross Blood Service. Blood donors are required to complete a questionnaire every time they donate to assess their risk of exposure to significant transfusion-transmissible infections (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 in a private and confidential interview with the donor, 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 Appendix A. 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. Consistent with previous years, the overall number of TTIs detected remained very low in 2015 (n=157, 0.01% of all donations). Of these, 93% were either hepatitis B (HBV) or hepatitis C (HCV). Reflecting the effectiveness of donor screening strategies, the prevalence of infection in first-time donors continues to be substantially (12-95 times) lower than national population prevalence estimates. Only five (3%) of all infections in 2015 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, for the ten-year period 2005-2014 there was no significant trend observed for incidence rates of any of the TTIs with rates remaining stable or declining.

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 2015, 17% had risk factors identified in their post-donation interview which were not disclosed in their initial donation interview (termed 'non-compliance'). While this rate has been fairly stable in the past decade, there has been a fluctuating trend in recent years. As minimising non-compliance is an organisational imperative, the Blood Service continually reviews the donor assessment process for potential improvements.

The structure of 2016 report is different to previous reports: the main findings are now presented under respective sections of the TTIs, namely '*HBV', 'HCV', 'HIV', 'HTLV'* and *'Active Syphilis'*. In addition, information on compliance rates, testing for malaria, bacterial pre-release testing for platelets and surveillance for emerging infections is now presented under a separate section of *'Additional information'*. The 2016 report also presents a five-year trend analysis for the period 2011-2015, reporting on the association of demographic characteristics with the presence of the tested TTIs among blood donors. The supporting information pertaining to blood donors is reported at the end of the report in the '*Supporting information*' section.

Contents

Glossary

Active syphilis
Defined by reactivity on treponemal and non-treponemal syphilis testing and/or clinically apparent infection (i.e. excluding past treated infections).

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

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 OBI, given this is not a new infection (see definition below).

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

Infectious syphilis
Syphilis infection of less than 2 years duration

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

Non-compliance
Disclosure of information post-donation that would have led to deferral from donation had it been disclosed at the pre-donation interview.

Occult HBV infection (OBI)
A form of chronic HBV infection characterized by undetectable HBsAg, usually low/intermittently detectable levels of hepatitis B DNA and 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.

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 screens for, 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.

Summary of the main findings

General characteristics of blood donors in Australia

1. Over the ten-year period 2006-2015, there were approximately 12.7 million blood donations in Australia with an average of 1.2 million donations per year. Over the past ten years, 2006-2015, there has been no significant change in the total number of donations.* Total blood donations in 2015 increased slightly by 0.75% (representing 9 503 more donations) compared to 2014.
2. Of the Australian population aged between 16-80 years, 2.6% donated blood during 2015.
3. First-time and repeat donors comprised 15.9% and 84.1% of all blood donors in Australia over the period 2006-2015, respectively. As in previous years, this ratio remained relatively stable nationally and across all states and territories. Male donors constitute approximately 50% of all donors in 2015, which is almost identical to their proportional representation of 49.8% 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 screens for is discarded and the donor is counselled and referred for medical follow-up.

1. In 2015, a total of 157 blood donors were detected as having a TTI for which screening is in place, namely, hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus (HIV), human T-cell lymphotropic virus (HTLV), or active syphilis. In the ten-year period 2006-2015 a total of 2 172 TTI-positive donors were detected. In 2015, no donor was infected by more than one TTI.
2. The most common TTI was HBV, followed by HCV. Of all the donations positive for a TTI in 2015, 93% were positive for either HBV or HCV.
3. Overall HIV was the least common infection among all donors in 2015, with just two donors testing positive. In the ten year period 2006-2015, HTLV was the least common infection among all donors (40 positive donors); and HIV was the least common infection in the first-time donors (23 positive donors).
4. Although representing only 13.3% of the donor population, first-time blood donors contributed approximately 77% of TTIs in Australia in 2015. This ratio has remained relatively stable since 2008 with an exception of 2014 where the first-time blood donors contributed to a record low of 67% of the total transfusion transmissible infections; 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 2008-2015. Three probable cases of transfusion-transmitted HBV infection were reported in the 2008-2014 period, two in 2009 associated with the same donor and one further case in 2011. All three cases were classified as occult HBV infection (OBI), a form of chronic HBV infection characterized by undetectable HBsAg, usually low/intermittently detectable levels of hepatitis B DNA and detectable anti-HBc in the bloodstream. (see *Main Findings* for details).
6. Consistent with previous years, in 2015, the prevalence of TTIs was substantially lower among first-time blood donors (12 to 95 times) compared with national prevalence estimates for 2015.

*See Methodological notes for details

HBV infection among Australian blood donors

1. There were 84 HBV infections detected among all donations in 2015 (72 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 2015 remained stable at 80.2 per 100 000 donations (or 0.08% of the total first-time donations) which was 12 times lower than the 1.0% reported in national HBV surveillance data.
4. Among the 84 HBV infections, 12 (2 first-time and 10 repeat donors) were classified as occult HBV (OBI) based on the detection of HBV DNA without HBsAg. Consistent with the epidemiology of OBI among blood donors elsewhere, older, male donors, born in Asia were over-represented.
5. Incident HBV donors continue to be rare with only one recorded nationally in 2015, giving an incidence rate of 0.3 per 100 000 donor-years of observation, and 3 cases in 2014, with an incidence of 0.9 per 100 000 donor-years of observation. Overall, there was no temporal trend in HBV donor incidence nationally or in any state/territory during the ten-year study period 2006-2015.
6. In 2015, HBV positive donors were younger as compared to all donors (37 years versus the mean age 41.5 years), were more likely to be male (69% in hepatitis B positive donors versus 50% 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, 2011-2015, was ethnicity/country of birth (87%). In Australia over 38% of people living with hepatitis B are born in the Asia Pacific region.[1]
8. Three probable cases of transfusion-transmitted HBV infection were reported in the 2008-2015 period (See *Main Findings* for details).

HCV infection among Australian blood donors

1. There were 62 HCV infections detected among all donors in 2015 (43 in first-time donors and 19 in repeat donors). The proportion of HCV RNA positive (potentially infectious) donors was 45%, 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 2006-2015, there has been a significant decrease in HCV prevalence in first-time donors in Australia, from 0.08% in 2006 to 0.05% in 2015. This translates into a decrease of 41% from 81.2 per 100 000 first-time donations in 2006 to 48 per 100 000 first-time donations in 2015. The 0.05% first-time donor prevalence in 2015 is 20 times lower than the 0.9% reported for HCV national surveillance data. This decreasing trend is consistent with national HCV new-diagnoses notification data which also shows a decrease in both numbers of notifications (from 12 132 in 2006 to 10 790 in 2015) and rate (from 60 per 100 000 in 2006 to 46 per 100 000 in 2015).
4. Of all TTIs detected, HCV had the highest average incidence rate among previously negative repeat donors during 2006-2015, at 2.4 per 100 000 donor-years of observation.* However, the incidence rate has decreased over time from 4.1 in 2013, to 0.9 in 2014 and 1.2 per 100 000 donor-years of observation in 2015. It is important to note that the fall in 2014 and 2015 is at least in part due to the application of a stricter incidence definition, and should therefore be interpreted with due caution.
5. In 2015, the mean age of HCV positive donors was 44 years compared to 41.5 years for all donors. Like HBV, HCV positive donors were more likely to be male as compared to all donors (63% versus 50%) but in contrast to hepatitis B, the majority (69%) were born in Australia.
6. The most common putative risk factor reported by donors with HCV infection during 2011-2015 was a history of tattoo/piercing (26%), followed by injecting drug use (23%). In comparison, injecting drug use (72%) and sexual contact (4.3%) were the two most dominant routes of exposure in cases of newly acquired hepatitis C infection reported in national notification data in 2015.
7. No transfusion-transmitted HCV infections were reported in Australia during 2006-2015.

*See Methodological notes for details

HIV infection among Australian blood donors

1. There were two HIV infections detected among all donations in 2015 (one first-time and one repeat donor).
2. The prevalence of HIV infection among first-time donors during 2006-2015 remained very low at 1.9 per 100 000 donations (or 0.002% of the total first-time donations) and comparatively much lower than hepatitis B (81.6 per 100 000 donations) and hepatitis C (58.6 per 100 000 donations). The 0.002% HIV prevalence in first-time donors is 56 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; 0.3 in 2006, 1.1 in 2010, 0.9 in 2014 and 0 in 2015.
4. During 2011-2015, the mean age of HIV positive donors (n=23) was 37 years as compared to 41.4 years for all donors during the same time period. Like HBV and HCV, HIV positive donors were more likely to be male as compared to all donors (78% vs 49%) but unlike HCV, less than half (48%) were Australian-born.
5. The two most common reported routes of exposure for donors with HIV infection during 2011-2015 were male-to-male sex (35%), followed by heterosexual sex with partners with known risk factors or known to be HIV positive (30%). This compares to the new HIV diagnoses notification data in Australia where men who have sex with men accounted for 68% of new HIV diagnoses in Australia in 2015, followed by heterosexual sex (20%).[1]
6. No transfusion-transmitted HIV infections were reported in Australia during 2006-2015.

HTLV infection among Australian blood donors

1. There were four HTLV infections detected among all donations in 2015 (3 in first-time and one in repeat donations).
2. The prevalence of HTLV infection among first-time donors during 2006-2015 has shown a slight non-significant increasing trend at 3.2 per 100 000 donations. 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 2015 was zero as it was for the average ten-year period 2006-2015.
4. In 2015, the mean age of donors with HTLV infection was 33 years; 75% of the infected donors were male and most of them (75%) were born overseas.
5. The most common putative infective risk factor for donors with HTLV infection during 2011-2015 was ethnicity or country of birth (79%). There are no data to compare risk factors in the general population.
6. No transfusion-transmitted HTLV infections were reported in Australia during 2006-2015

Active syphilis infection among Australian blood donors

1. There were five active syphilis infections detected among all donations in 2015.
2. The prevalence of active syphilis in first-time donors has shown no significant change over time. In first-time donors the prevalence was 1.6 per 100 000 first-time donations in 2006, 3.9 per 100 000 first-time donations in 2010 and 2.2 per 100 000 first-time donations in 2015.
3. The mean age of active syphilis positive donors in 2014-2015 was 35 years (compared to 41.6 years for all donors for 2014-15). Donors with active syphilis were more likely to be male as compared to all donors (87% versus 50%).
4. The most common reported route of exposure by donors with active syphilis in 2014 and 2015 was having a partner with known risk or known to be positive.

Donor Compliance

1. Over 17% (158 donors) of the TTI-positive donors in 2011-2015 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. Of these, 68% (107 donors) were first-time donors. The non-compliance rate of positive donors has fluctuated in the last four years, from 12.9% in 2011 to 25% in 2014 and 17% in 2015. 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 lower rate of non-compliance (in the range of 0.05-0.29%) See *Additional Information* section for more information.

Malaria testing

1. In 2015, a total 104 808 donations were tested for malaria antibody of which 1 451 (1.4%) were repeatedly reactive. Only one of these repeatedly reactive donors had detectable malaria DNA, indicating current infection.
2. There were no reported cases of transfusion-transmitted malaria during 2015, with the last Australian case occurring in 1991.

Bacterial pre-release testing for platelets

1. In 2015, bacterial screening of 116 748 platelets identified 134 as confirmed positive.
2. *Propionibacterium spp*., which are common skin commensals were by far the most frequently isolated organisms (111). These organisms are rarely, if ever associated with septic transfusion reactions in recipients. Other potential contaminants included *Streptococcus spp., Coagulase negative Staphylococci* and mixed organisms. A small number of clinically significant organisms including *Staphylococcus aureus, Serratia mercescens, Citrobacter braakii, Streptococcus pyogenes, Streptococcus pneumoniae* and *Streptococcus agalactae group* B were also detected. None of the contaminated platelets with significant organisms were transfused.

Emerging infections

1. Along with the ongoing risk from local dengue virus outbreaks and seasonal West Nile Virus (WNV) outbreaks in Europe, large outbreaks of Ebola virus and Zika virus have also been closely monitored during 2015-2016.
2. The risk to the blood supply posed by donors returning from Ebola virus and Zika virus outbreak areas has been managed by deferring or restricting donations to plasma sent for fractionation for an appropriate period.
3. Hepatitis E has been recognised as disease of emerging importance in international blood safety. Hepatitis E virus (HEV) is a known TTI and the prevalence of asymptomatic viraemia in blood donors internationally has been found to be considerably higher than expected. The risk in Australia is lower than other developed nations but the Blood Service is completing a study to determine the risk hepatitis E poses to blood safety in Australia.
4. The first probable case of transfusion-transmitted Ross River virus (RRV) occurred in 2014 and was published in 2015. In 2015 Australia reported its highest number of RRV cases with no transfusion-transmissions reported and given the generally low severity illness the Blood Service managed this risk by strengthening the information given to donors about reporting post-donation illnesses.

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Abbreviations

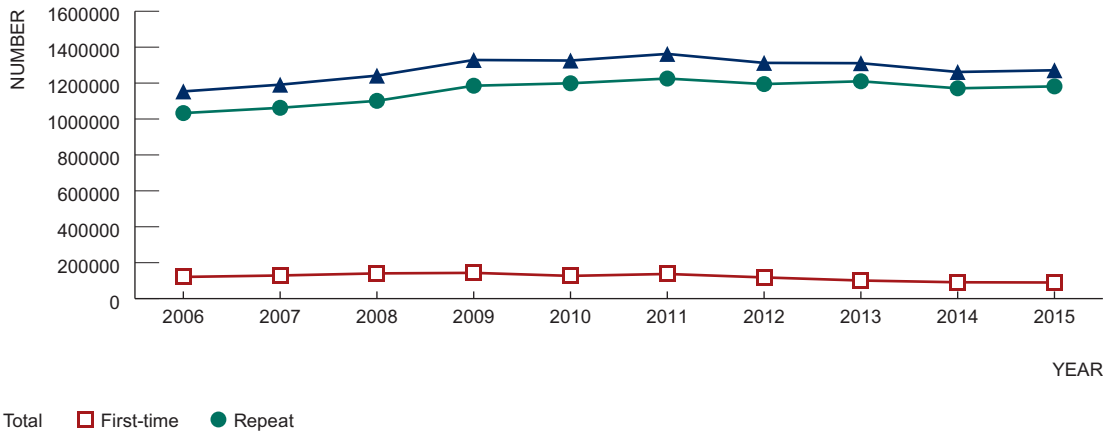
anti-HBc	antibody to hepatitis B core antigen
anti-HBe	antibody to hepatitis B e antigen
anti-HBs	antibody to hepatitis B surface antigen
anti-HeV	antibody to Hendra virus
A(H7N9)	avian influenza H7N9 virus
HBsAg	hepatitis B surface antigen
Blood Service	Australian Red Cross Blood Service
HBeAg	hepatitis 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-cell 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

Main Findings

Blood donors in Australia

Over 12.7 million donations were tested for TTIs in Australia during the ten-year period 2006-2015 with an average of 1.2 million donations per year. The number of donations increased from 1.1 in 2006 to 1.3 million in 2009, and remained steady at around 1.3 million from 2009 to 2013, with a slight decline to around 1.2 million in the past two years. Over the entire ten year period there was no significant trend in numbers of donations (Figure 1) (See *Methodological notes* for details).

Figure 1 Number of blood donations in Australia by year of donation, 2006-2015

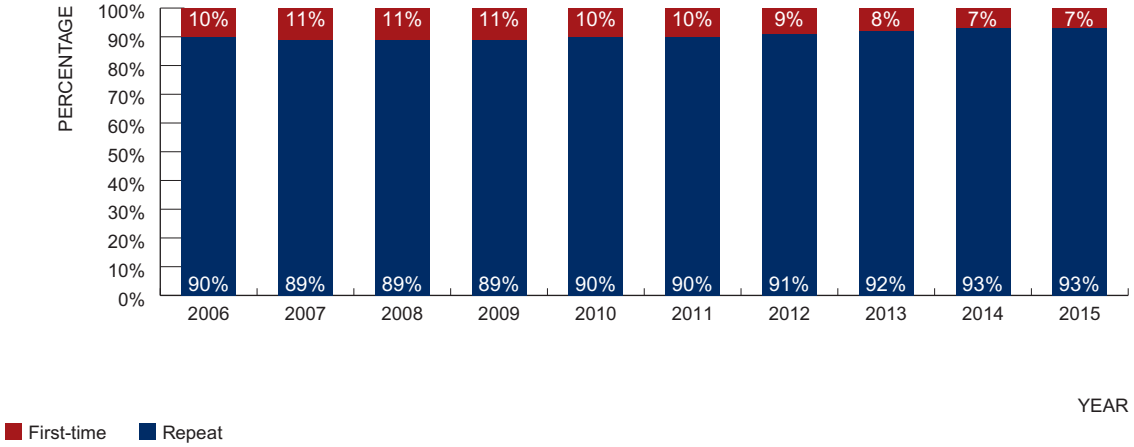


In 2015, 2.6% of the general population who were aged between 16-80 years (age-eligible to donate) donated blood in Australia. Together, New South Wales, Queensland and Victoria accounted for more than 75% of all blood donations. The jurisdictions where the greatest proportion (nearly 4%) of the age-eligible local population donated blood in 2015 were the Australian Capital Territory and Tasmania (Figure 2).

Figure 2 Percentage of age eligible general population who donated blood in 2015, by state/territory

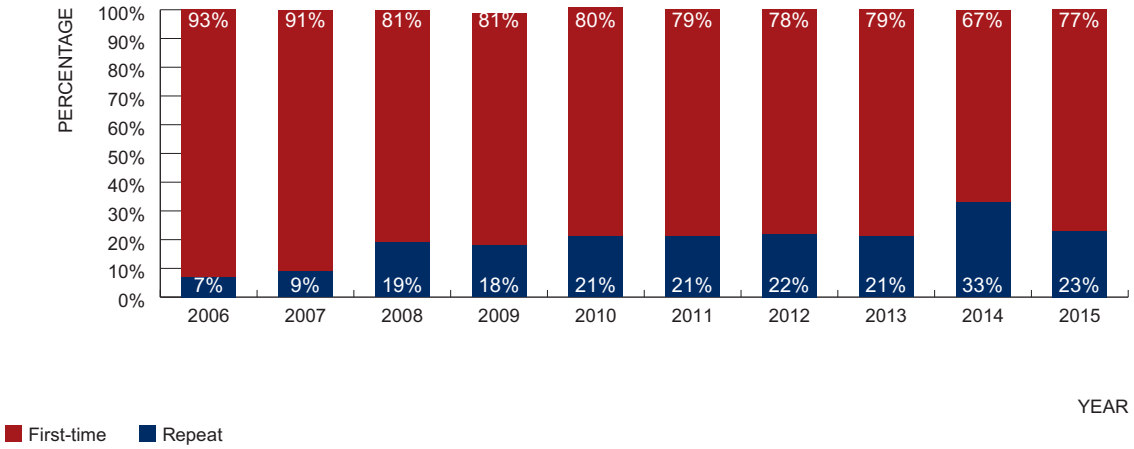
As in previous years, more than 90% of all donations in 2015 were from repeat donors (Figure 3). While first-time blood donors represented only 13.3% of the donor population, and 7% of the total donations, they contributed the majority (77%) of TTIs in Australian blood donors in 2015, reflecting detection 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, 2006-2015



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 7% in 2006 to 21% in 2010 to 23% in 2015 (Figure 4). It is important to note that in 2015 this proportion has dropped by 31%, from a record high of 33% in 2014. 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 it is not reflective of an increase in TTI incidence, which has been stable or declining.

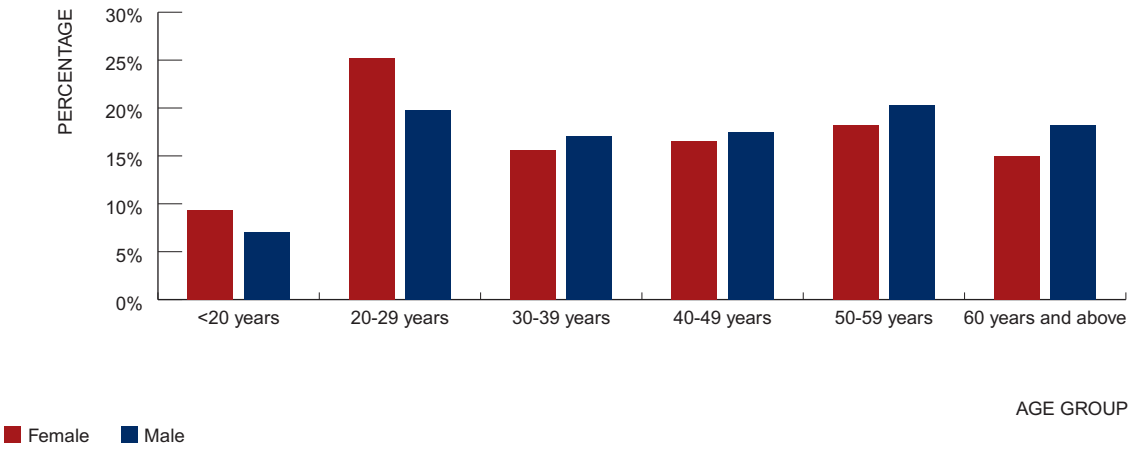
Figure 4 Percentage of first-time and repeat donations among all TTI-positive blood donations in Australia, 2006-2015*



* 2008-2013 data have been updated and may vary from the previous reports

Among all blood donors who donated in 2015, an equal proportion of males and females contributed donations (50% each); however 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). Overall, 35% of donors were from those aged 50 years and above; the median age of male and female donors was 43 and 39 years, respectively.

Figure 5 Distribution of blood donors in Australia by age group and sex, 2015



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 2006-2015 overall in Australia, and trends observed in state/territory jurisdictions. In addition, association of demographic characteristics with presence of TTIs for year 2015 and the five-year period 2011-2015 will be discussed. Also, possible risk factors associated with positive blood donors in Australia are reported for the five-year period, 2011-2015. 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 has been included. This includes a brief description of the number of people living with TTIs in Australia by the end of 2015, 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 2016.[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 2014-15 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 as 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 in infection.

During the past ten years, 2006-2015, a total of 2172 donations (17 per 100 000 donations) (1768 in first-time and 404 in repeat donations) were positive for at least one of the TTI subject to mandatory donation testing (Table 1), of these 93.3% 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 7% in 2006 to 21% in 2010 to 23% in 2015 (Figure 4).

In 2015, a total of 157 donors (12 per 100 000 donations) 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 2015, together contributing to 93% of all infections (Figure 6). HBV and HCV were also the most frequent TTIs in both first-time and repeat donors. TTI-positivity has remained low with a significant* declining

*Throughout the document the term 'significant' is used only where a statistical test has a p value <0.05

trend in overall prevalence during 2006-2015, largely due to declines in HBV and HCV prevalence in donations (Figure 7). During 2006-2015, a total of 121 incident donors were identified. In 2015 a total of five incident infections were detected with one for HBV and four for HCV.

Figure 6 Number of blood donors with transfusion-transmissible infections in Australia, in 2015, by infection

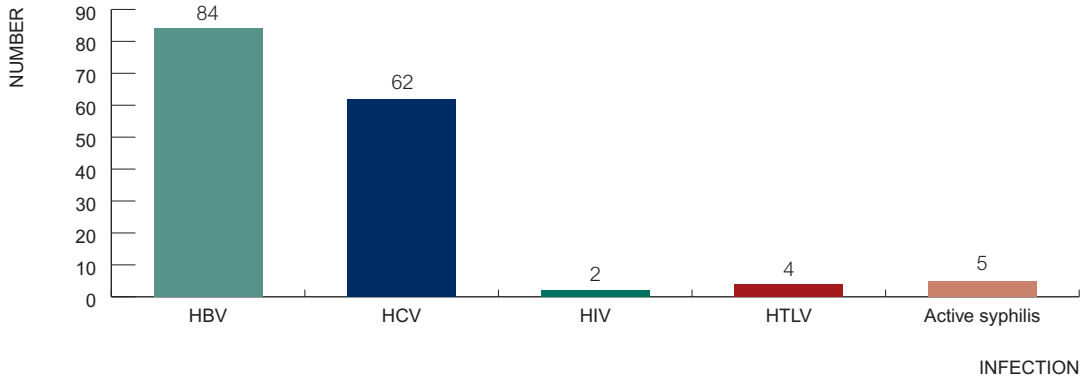
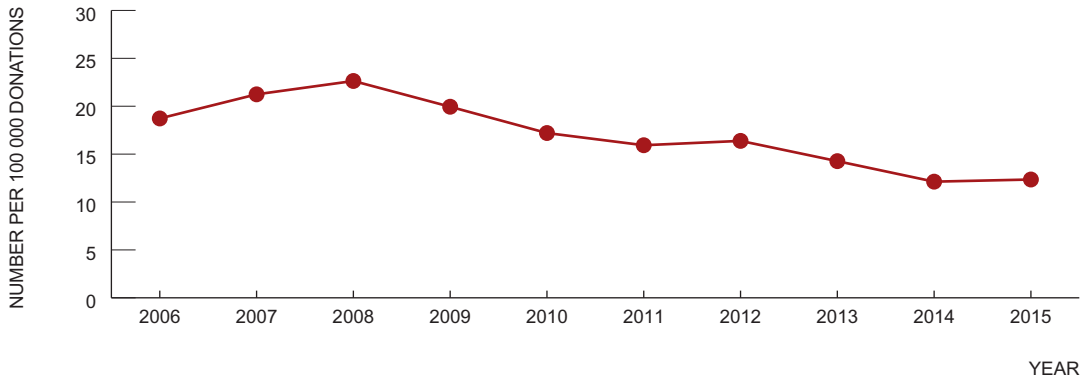


Figure 7 Prevalence* of any transfusion-transmissible infection among all accepted donations, 2006-2015



* 2006-2010, 2013 data have been updated and may vary from the previous reports

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 any TTI (with the exception of active syphilis) among Australian blood donors in 2015, and the five-year period, 2011-2015, separately. Standardised national data on demographic factors associated with active syphilis infected donors are available on only 8 donors (3 from 2014 and 5 from 2015), precluding meaningful temporal trend analyses.

Standardised national data on putative reported risk factors associated with donors infected with HBV, HCV, HTLV and HIV 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.[2]

This report presents risk factor data for the five-year period 2011 to 2015. A total of 929 positive donors with at least one of the TTIs were observed over the period 2011-2015. Among them, 29 donors were positive for active syphilis, of which only eight have standardised risk factor data available (five from 2015 and three from 2014); therefore, grouped data for 2014-2015 is presented on donors positive for syphilis to preserve donors' anonymity. The data on the remaining 900 donors who were positive for any of the other TTIs (HBV, HCV, HIV and HTLV) during 2011-2015 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.

^See Methodological notes for details

Table 1 The number and prevalence rate of transfusion-transmissible Infections in Australia, nationally*, 2006-2015

State/Territory of donation	All accepted donations			HBV			HCV			HIV			HTLV			Syphilis			Total positive donations		
	First time	Repeat	All	First time	Repeat	All	First time	Repeat	All	First time	Repeat	All	First time	Repeat	All	First time	Repeat	All	First time	Repeat	All
National	1 196 138	11 562 808	12 758 946	976	122	1,098	701	228	929	23	28	51	39	1	40	29	25	54	1 768	404	2 172
Number (Number per 100 000 donations)				*81.60*	*1.06*	*8.61*	*58.61*	*1.97*	*7.28*	*1.92*	*0.24*	*0.40*	*3.26*	*0.01*	*0.31*	*2.42*	*0.22*	*0.42*	*147.81*	*3.49*	*17.02*

* State/territory breakdown of transfusion-transmissible infections in Australia for the ten-year study period, 2006-2015, are provided in respective infection sections

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Hepatitis B Virus (HBV):

Main findings

1. There were 84 HBV infections detected among all donations in 2015 (72 in first-time donations and 12 in repeat donations).

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 2015 remained stable at 80.2 per 100 000 donations (or 0.08% of the total first-time donations) which was 12 times lower than the 1.0% reported in national HBV surveillance data.

4. Incident HBV donors continue to be rare with only one recorded nationally in 2015, giving an incidence rate of 0.3 per 100 000 donor-years of observation, and 3 cases in 2014, with an incidence of 0.9 per 100 000 donor-years of observation. Overall, there was no temporal trend in HBV incidence nationally or in any state/territory during the ten-year study period 2006-2015.

5. Among the 84 HBV infections, 12 (2 first-time and 10 repeat donors) were classified as occult HBV (OBI) based on the detection of HBV DNA without HBsAg. Consistent with the epidemiology of OBI among blood donors elsewhere, older, male donors, born in Asia were over-represented.

6. HBV positive donors were younger as compared to all donors (37 years versus 41.5 years), were more likely to be male (69% in hepatitis B positive donors versus 50% 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, 2011-2015, was ethnicity/country of birth (87%). In Australia, over 38% of people living with hepatitis B were born in the Asia Pacific region.[1]

8. Three probable cases of transfusion-transmitted HBV infection were reported in the 2008-2015 period (See *Main Findings* for details).

Epidemiology of HBV in Australia

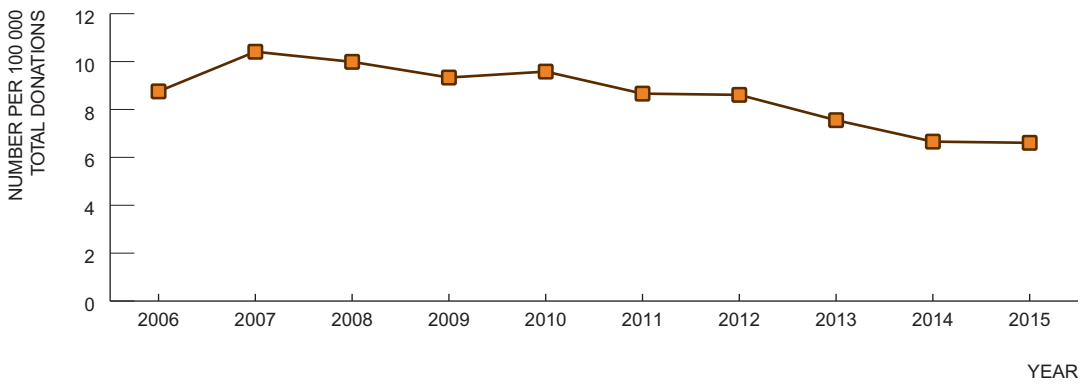
At the end of 2015, an estimated 232 600 people were living with chronic HBV infection in Australia (range 190 738 to 283 781), of whom an estimated 62% were diagnosed with chronic hepatitis B, 38% were born in the Asia-Pacific and 9.3% were among Aboriginal and Torres Strait Islander peoples. There were a total of 6 502 notifications of newly diagnosed HBV infection in Australia in 2015; of these, just over half (53%) were males, and 74% were people aged 30 years and above. Australia has a concentrated hepatitis B epidemic among key populations; migrants from high prevalence countries, particularly South East Asia; men who have sex with men; Aboriginal and Torres Strait Islander peoples; and people who inject drugs. Over the past ten years 2006-2015, the population rate of diagnosis of HBV infection in Australia has declined in younger age groups - 25 – 29 years (from 76 to 58 per 100 000); 20 – 24 year (from 54 to 27 per 100 000); and 15 – 19 years (from 21 to 11 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 39% from 1.4 per 100 000 in 2006 to 0.6 per 100 000 in 2015. The estimated prevalence of chronic HBV infection among people born in Australia is 1.0%, which by country of birth is higher than the people born in the United Kingdom but lower than in people born in many other countries in South East Asia and the Pacific.[1]

Trends in prevalence

All donors:

In the past ten years, 2006-2015, a total of 1 098 HBV positive donors have been detected (976 first-time donors & 122 repeat donors) (Table 2). During this period, the prevalence of HBV infection among all donations has declined significantly (Table 3). There has been an overall reduction of 25% from 2006 to 2015, from 8.7 to 6.6 per 100 000 total donations (Figure 8).

Figure 8 Prevalence* of HBV infection in all blood donations in Australia, 2006-2015



* Data on prevalence rates for HBV in all blood donations for years 2009 and 2010 have been updated and may vary from the previous reports

Table 2 The number and prevalence* rate of HBV infection in Australia by state/territory, 2015 and 2006-2015

State/Territory of donation	All accepted donations 2015			HBV 2015		
	First time	Repeat	All	First time	Repeat	All
NSW/ACT	29 180	347 714	376 894	16	4	20
Number (*Number per 100 000 donations*)				*54.83*	*1.15*	*5.31*
NT	727	9 053	9 780	1	0	1
Number (*Number per 100 000 donations*)				*137.55*	*0.00*	*10.22*
QLD	18 914	242 615	261 529	21	2	23
Number (*Number per 100 000 donations*)				*111.03*	*0.82*	*8.79*
SA	6 202	116 691	122 893	4	1	5
Number (*Number per 100 000 donations*)				*64.50*	*0.86*	*4.07*
TAS	2 807	47 002	49 809	1	0	1
Number (*Number per 100 000 donations*)				*35.63*	*0.00*	*2.01*
VIC	22 966	300 366	323 332	22	4	26
Number (*Number per 100 000 donations*)				*95.79*	*1.33*	*8.04*
WA	8 942	118 145	127 087	7	1	8
Number (*Number per 100 000 donations*)				*78.28*	*0.85*	*6.29*
National	89 738	1 181 586	1 271 324	72	12	84
Number (*Number per 100 000 donations*)				*80.23*	*1.02*	*6.61*

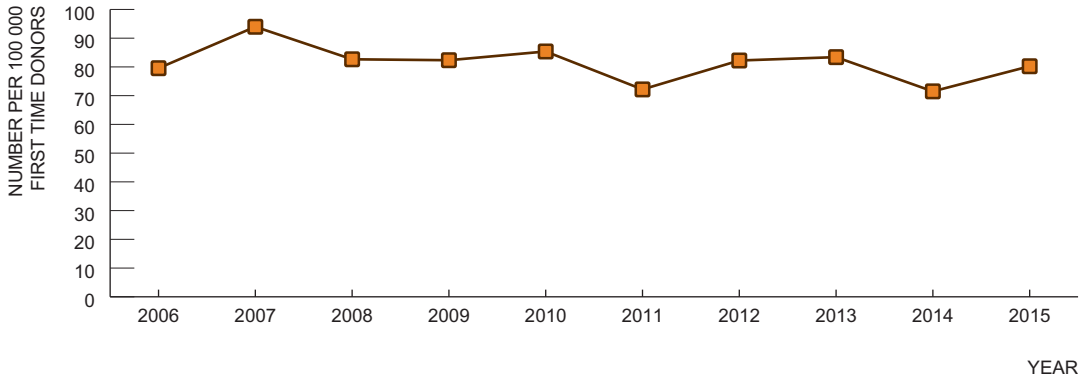
State/Territory of donation	All accepted donations 2006-2015			HBV 2006-2015		
	First time	Repeat	All	First time	Repeat	All
NSW/ACT	432 729	3 605 419	4 038 148	344	40	384
Number (*Number per 100 000 donations*)				*79.50*	*1.11*	*9.51*
NT	8 243	99 419	107 662	12	2	14
Number (*Number per 100 000 donations*)				*145.58*	*2.01*	*13.00*
QLD	256 790	2 347 567	2 604 357	154	18	172
Number (*Number per 100 000 donations*)				*59.97*	*0.77*	*6.60*
SA	96 914	1 189 268	1 286 182	56	10	66
Number (*Number per 100 000 donations*)				*57.78*	*0.84*	*5.13*
TAS	32 256	401 607	433 863	7	2	9
Number (*Number per 100 000 donations*)				*21.70*	*0.50*	*2.07*
VIC	265 309	2 760 238	3 025 547	308	30	338
Number (*Number per 100 000 donations*)				*116.09*	*1.09*	*11.17*
WA	103 897	1 159 290	1 263 187	95	20	115
Number (*Number per 100 000 donations*)				*91.44*	*1.73*	*9.10*
National	1 196 138	11 562 808	12 758 946	976	122	1 098
Number (*Number per 100 000 donations*)				*81.60*	*1.06*	*8.61*

* Some of the data on number/prevalence rates for HBV infection for years 2008-2013 have been updated and may vary from the previous reports

First-time donors:

Over the ten year period 2006-2015, no significant annual trend was observed in the prevalence of HBV infection among first-time donors (Table 3). The rate remained stable at 81.6 per 100 000 first-time donations (0.08% of the total first-time donations) (Figure 9). Likewise, the notification rate of HBV infection in the general population has remained relatively steady in the past ten years, at 31 per 100 000 in 2006 and 2010, and 28 per 100 000 in 2015.

Figure 9 Prevalence* of HBV infection in first-time blood donors in Australia, 2006-2015



* Data on prevalence rates for HBV in first-time blood donors for years 2008, 2009, 2012 and 2013 have been updated and may vary from the previous reports

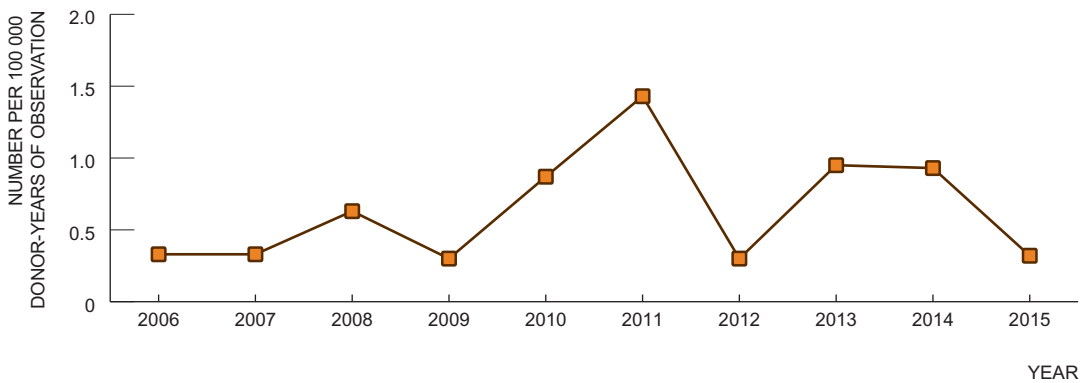
Table 3 Trends in Prevalence and Incidence of HBV Infection in Australia, 2006-2015

Trends in Prevalence and Incidence of HBV Infection in Australia, 2006-2015		
Prevalence	**IRR (95% CI)**	**p-value**
All donors	*0.95 (0.93-0.97)*	*0.00*
First-time donors	*0.98 (0.96-1.01)*	*0.28*
Incidence	**IRR (95% CI)**	**p-value**
Repeat donors	*1.06 (0.91-1.23)*	*0.43*

Trends in incidence

For the ten-year period 2006-2015, there were a total of 21 incident donors detected for HBV infection with no statistically significant trend observed for incidence rates (between 0.3 and 1.4 per 100 000 donor-years of observation) (Table 3 & Figure 10). In 2015, only one incident infection was detected for HBV. The application of the stricter incidence definition from 2014 does not appear to have noticeably impacted the number of incident hepatitis B donors.

Figure 10 Incidence* of HBV in repeat blood donors in Australia, 2006-2015



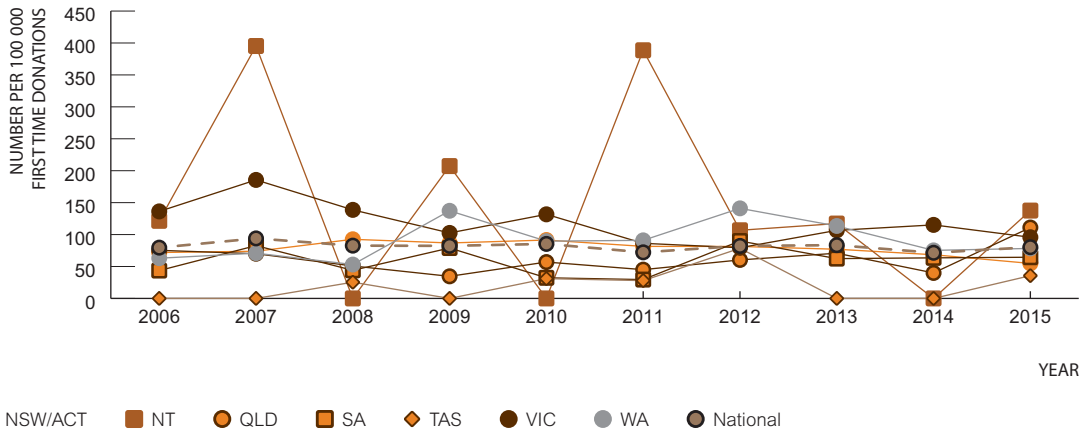
* Data on incidence rate for HBV in repeat blood donors for year 2008 have been updated may vary from the previous reports

No transfusion-transmitted HBV infections were reported in 2015. Three probable cases were reported in the 2008-2014 period, two in 2009 associated with the same donor and one further case in 2011. In the first two cases of HBV transmission in 2009 associated with a common donor, no risk factor for HBV was identified other than the donor's ethnicity. Follow-up testing of the donor suggested occult HBV infection (OBI), a form of chronic HBV infection characterized by undetectable HBsAg, usually low levels of hepatitis B DNA and detectable anti-HBc. At the time these probable cases of transmission were identified, the Blood Service had already commenced planning to implement an upgrade to its existing HIV-HCV nucleic acid testing (NAT) platform that included a 'triplex' NAT assay incorporating hepatitis B DNA detection. The sensitivity of this new test for HBV DNA was 10.4 IU/L (95% detection limit). As the implicated donor had a HBV DNA level < 15 IU/mL, it is unknown if the implicated donation would have been interdicted by the HBV NAT triplex assay had it been implemented at the time. In 2011, after the introduction of hepatitis B NAT, the Blood Service identified another donor with HBV screening results consistent with OBI. The recipient transfused with blood from this donor tested positive for HBV post-transfusion but had tested negative in 2010, pre-transfusion. It was not possible, however, to confirm that the recipient and the donor were infected with the same virus because the donor's viral load was too low to undertake sequence analysis. In this case transmission was considered probable, and the recipient subsequently cleared the virus.

Trends in HBV infection by state/territory

Consistent with previous TTI-surveillance reports, the prevalence of HBV infection among first-time donors varied markedly by jurisdiction in 2015. While the national prevalence was 80.2 per 100 000 donations, this ranged from 35.6 to 137.5 per 100 000 donations across jurisdictions (Table 6 & Figure 11). In 2015, and the ten-year period 2006-2015, the Northern Territory saw the highest prevalence of HBV infection among first-time donors as compared to the other states (137.5 and 145.5 per 100 000 donations, respectively); however, no significant trend was observed in the Northern Territory, and given the small number of positive donors (just one in 2015), this should be interpreted with caution. A significant declining annual prevalence trend was observed in Victoria during 2006-2015 (p-value 0.00) (Table 4); from 136.2 per 100 000 first-time donations in 2006, to 131.6 per 100 000 first-time donations in 2010 and 95.7 per 100 000 first-time donations in 2015 (Table 6). 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 11 Prevalence* of HBV infection among first-time donors by state/territory and year of donation, 2006-2015



* Data on prevalence of HBV infection among first-time donors by state/territory have been updated for years 2008-2013 and may vary from the previous reports

Table 4 Trend in Prevalence of HBV Infection in First-Time Donors, by State and Territory - 2006-2015

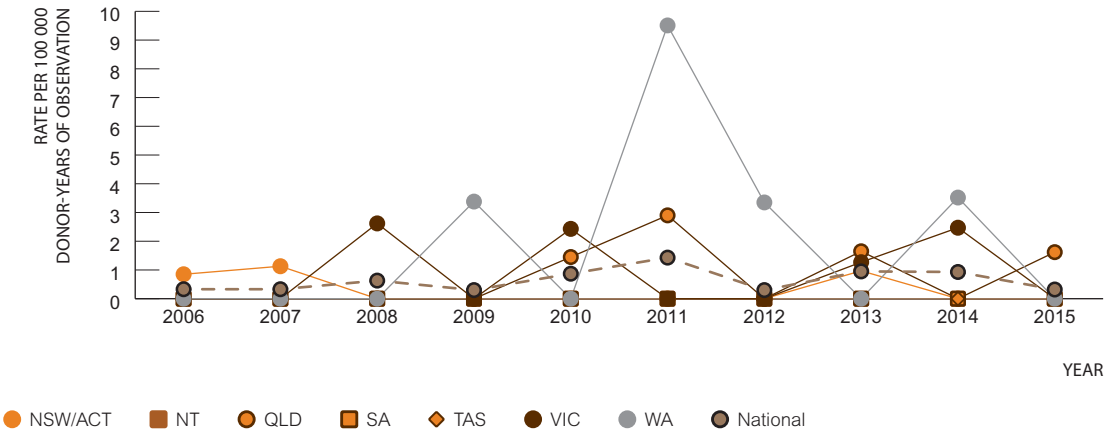
	Prevalence of HBV Infection in First-Time Donors, by State and Territory - 2006-2015	
	IRR (95% CI)	p-value
NSW/ACT	*0.98 (0.94-1.02)*	*0.38*
NT	*0.92 (0.75-1.13)*	*0.43*
QLD	*1.01 (0.96-1.07)*	*0.52*
SA	*1.01 (0.92-1.12)*	*0.70*
TAS	*1.14 (0.86-1.51)*	*0.33*
VIC	*0.94 (0.90-0.98)*	*0.00*
WA	*1.03 (0.96-1.11)*	*0.31*

Incident HBV infection continues to be rare with only one incident donor recorded nationally in 2015. Overall, there was no obvious trend in HBV incidence in any state/territory during the ten-year study period 2006-2015 (Table 5 & Figure 12). Among donors in Northern Territory, South Australia and Tasmania, hepatitis B incidence has been zero since 2006.

Table 5 Incidence of HBV Infection in Repeat Donors, by State and Territory - 2006-2015

	Incidence of HBV Infection in Repeat Donors, by State and Territory - 2006-2015	
	IRR (95% CI)	p-value
NSW/ACT	*0.78 (0.49-1.23)*	*0.29*
NT	…	…
QLD	*1.20 (0.85-1.70)*	*0.28*
SA	…	…
TAS	…	…
VIC	*1.05 (0.81-1.37)*	*0.67*
WA	*1.10 (0.82-1.48)*	*0.50*

Figure 12 Trend in Incidence* of HBV infection among repeat donors by state/territory and year of donation, 2006-2015



*Incidence rates for HBV among repeat blood donors in Victoria have been updated for years 2008 and 2010 and may vary from the previous reports

Table 6 Number and prevalence[1*] of HBV infection among first-time donors, 2006-2015, by state/territory and year of donation

	2006			2007			2008			2009		
State/Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	44 499	32	71.91	51 427	38	73.89	48 607	45	92.58	51 821	45	86.84
NT	823	1	121.51	759	3	395.26	815	0	0.00	965	2	207.25
QLD	27 873	21	75.34	28 575	20	69.99	29 498	15	50.85	28 889	10	34.62
SA	11 457	5	43.64	10 886	9	82.67	15 908	7	44.00	11 400	9	78.95
TAS	2 899	0	0.00	2 650	0	0.00	3 936	1	25.41	3 736	0	0.00
VIC	22 016	30	136.26	23 172	43	185.57	30 286	42	138.68	34 133	35	102.54
WA	11 116	7	62.97	11 292	8	70.85	11 307	6	53.06	12 387	17	137.24
Total	**120 683**	**96**	**79.55**	**128 761**	**121**	**93.97**	**140 357**	**116**	**82.65**	**143 331**	**118**	**82.33**
	2010			**2011**			**2012**			**2013**		
State/Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	48 130	44	91.42	51 528	42	81.51	41 780	34	81.38	35 060	27	77.01
NT	799	0	0.00	772	3	388.60	937	1	106.72	853	1	117.23
QLD	28 097	16	56.95	28 839	13	45.08	24 881	15	60.29	21 181	15	70.82
SA	9 284	3	32.31	10 164	3	29.52	8 900	8	89.89	6 417	4	62.33
TAS	3 222	1	31.04	3 587	1	27.88	3 823	3	78.47	3 058	0	0.00
VIC	25 820	34	131.68	31 286	27	86.30	27 718	22	79.37	25 332	27	106.58
WA	11 149	10	89.69	10 992	10	90.98	9 925	14	141.06	8 815	10	113.44
Total	**126 501**	**108**	**85.37**	**137 168**	**99**	**72.17**	**117 964**	**97**	**82.23**	**100 716**	**84**	**83.40**
	2014			**2015**			**Total 2006-2015**					
State/Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**			
NSW/ACT	30 697	21	68.41	29 180	16	54.83	432 729	344	79. 5			
NT	793	0	0.00	727	1	137.55	8 243	12	145. 58			
QLD	20 043	8	39.91	18 914	21	111.03	256 790	154	59. 97			
SA	6 296	4	63.53	6 202	4	64.50	96 914	56	57. 78			
TAS	2 538	0	0.00	2 807	1	35.63	32 256	7	21. 7			
VIC	22 580	26	115.15	22 966	22	95.79	265 309	308	116. 09			
WA	7 972	6	75.26	8 942	7	78.28	103 897	95	91. 44			
Total	**90 919**	**65**	**71.49**	**89 738**	**72**	**80.23**	**1 196 138**	**976**	**81.60**			

1 Rate per 100 000 first-time donations
*Data on number/prevalence for HBV in first-time blood donors for years 2008, 2009, 2012 and 2013 have been updated and may vary from the previous reports

Table 7 Number and rate[1] of HBV infection among repeat donations, 2006-2015, by state/territory and year of donation

	2006			2007			2008			2009		
State/Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate
NSW/ACT	333 250	5	1.50	338 173	3	0.89	339 062	1	0.29	372 806	0	0.00
NT	8 496	0	0.00	10 214	0	0.00	11 166	0	0.00	11 158	0	0.00
QLD	216 496	0	0.00	209 556	0	0.00	226 726	1	0.44	242 001	2	0.83
SA	107 934	0	0.00	114 618	0	0.00	118 476	1	0.84	126 855	0	0.00
TAS	28 726	0	0.00	28 019	0	0.00	33 321	0	0.00	37 274	0	0.00
VIC	238 684	0	0.00	252 340	0	0.00	259 052	4	1.54	276 835	1	0.36
WA	99 376	0	0.00	109 425	0	0.00	113 274	1	0.88	118 327	3	2.54
Total	1 032 962	5	0.484 045	1 062 345	3	0.28239	1 101 077	8	0.73	1 185 256	6	0.51
	2010[2]			2011			2012			2013		
State/Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate
NSW/ACT	380 014	6	1. 58	390 455	5	1.28	377 220	6	1.59	373 670	5	1.34
NT	10 470	1	9. 55	10 782	0	0.00	9 673	0	0.00	9 493	0	0.00
QLD	243 837	3	1. 23	245 975	3	1.22	237 599	5	2.10	243 042	2	0.82
SA	123 587	4	3. 24	124 199	2	1.61	120 720	0	0.00	119 530	1	0.84
TAS	41 484	0	.	44 661	0	0.00	46 379	0	0.00	48 953	1	2.04
VIC	278 897	4	1. 43	288 085	4	1.39	285 168	2	0.70	292 058	3	1.03
WA	120 646	1	. 83	121 057	5	4.13	117 728	3	2.55	123 298	3	2.43
Total	1 198 935	19	1. 58	1 225 214	19	1.55	1 194 487	16	1.34	1 210 044	15	1.24
	2014			2015			Total 2006-2015					
State/Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate			
NSW/ACT	353 055	5	1. 42	347 714	4	1	3 605 419	40	1.11			
NT	8 914	1	11. 22	9 053	0	0	99 419	2	2.01			
QLD	239 720	0	0.00	242 615	2	1	2 347 567	18	0.77			
SA	116 658	1	0.86	116 691	1	1	1 189 268	10	0.84			
TAS	45 788	1	2. 18	47 002	0	0	401 607	2	0.50			
VIC	288 753	8	2. 77	300 366	4	1	2 760 238	30	1.09			
WA	118 014	3	2. 54	118 145	1	1	1 159 290	20	1.73			
Total	1 170 902	19	1. 62	1 181 586	12	1.02	11 562 808	122	1.06			

1 Rate per 100 000 repeat donations
2 The sustained increase in HBV positive repeat donors since 2010 is attributed to the introduction of HBV NAT which identified additional acute HBsAg negative and chronic occult HBV (OBI) donors

Occult HBV infection

The implementation of HBV DNA testing for all Australian donors from 2010 has facilitated the identification of OBI among the donor population.[3] To the end of 2015, over 110 donors with OBI have been detected, counselled and referred for external clinical assessment reducing the residual risk of HBV infection. Twelve of the 84 HBV positive donors detected in 2015 were classified as OBI. Most (10/12) were repeat donors and the majority (9/12) were older males, predominantly born in Asia, or of Asian parents. This pattern is consistent with previous years' findings and the epidemiology of OBI among blood donors in general.

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 2006-2015, and then 2015 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 8), which is consistent with a previous Blood Service study for the period 2000-2006[4] and expected, based on effective donor selection/education. Prevalence of HBV infection is substantially lower in blood donors than in the general population, with an 11 times lower prevalence in first-time donors during the period 2006-2015, and 12 times lower prevalence for the year 2015. Given blood donors are drawn from the general population, the lower prevalence 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 HBV infection in blood donors with population prevalence, 2006-2015

Infection	Population prevalence (per 100 000 people)		Prevalence in first time blood donors (per 100 000 donations)		HBV prevalence in first time blood donors versus the general population	
	2006-2015	2015	2006-2015	2015	2006-2015	2015
HBV	892	978	81.60	80.23	11 times lower	12 times lower

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* to determine the association between demographic factors and presence of HBV infections among Australian blood donors in 2015, and the five-year period, 2011-2015 (Table 9). 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 2015, female donors were approximately half as likely to be HBV positive. Donors from Queensland were approximately twice as likely to be HBV positive. In 2015 there was no significant association between the age group of the donor and HBV infection status.

In the five-year period, 2011-2015, female donors, donors from South Australia & Tasmania, and donors over 40 years of age were significantly less likely to be HBV positive as compared to the reference groups described above. Donors from Western Australia had a significantly (1.39 times) greater rate for HBV positivity. 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 have consistently been highest in the Northern Territory (120 per 100 000 in 2006 to 61 per 100 000 in 2015). In most other jurisdictions the rate of HBV diagnosis has fluctuated over the last ten years, with a small decline observed in New South Wales (37 in 2006 to 31 in 2015) and Victoria in recent years (38 in 2007 to 31 in 2015).[5]

*See Methodological notes for details

Table 9 Association of demographic characteristics with presence of HBV infection among blood donors in Australia, 2015, and 2011-2015

	HBV 2015				HBV 2011-2015			
	Number of donors	Number of positive donors *(Number per 100 000 donors)*	IRR and their 95% CI (Multivariate adjusted)	p-value	Number of donors	Number of positive donors *(Number per 100 000 donors)*	IRR and their 95% CI (Multivariate adjusted)	p-value
Sex								
Male	*233 263*	*58 (24.86)*	*1 (ref)*	*…*	*1 279 978*	*348 (27.19)*	*1 (ref)*	*…*
Female	*230 874*	*26 (11.26)*	*0.44 (0.27-0.70)*	*0.001*	*1 308 894*	*150 (11.46)*	*0.41 (0.33-0.49)*	*0.00*
Age group (years)								
20-29	*37 041*	*8 (21.6)*	*1 (ref)*	*…*	*370 863*	*52 (14.02)*	*1 (ref)*	*…*
Less than 20	*105 449*	*19 (18.02)*	*1.26 (0.55-2.90)*	*0.57*	*430 483*	*128 (29.73)*	*1.01 (0.73-1.40)*	*0.92*
30-39	*79 792*	*26 (32.58)*	*1.70 (0.94-3.07)*	*0.07*	*415 941*	*111 (26.69)*	*1.11 (0.86-1.43)*	*0.41*
40-49	*78 287*	*12 (15.33)*	*0.80 (0.39-1.66)*	*0.56*	*450 532*	*77 (17.09)*	*0.72 (0.54-0.96)*	*0.02*
50 and above	*163 568*	*19 (11.62)*	*0.60 (0.31-1.14)*	*0.12*	*921 053*	*130 (14.11)*	*0.59 (0.46-0.75)*	*0.00*
State/Territory								
NSW	*137 606*	*18 (13.08)*	*1 (ref)*	*…*	*796 480*	*158 (19.84)*	*1 (ref)*	*…*
ACT	*11 793*	*2 (16.96)*	*1.25(0.29-5.41)*	*0.76*	*67 233*	*7 (10.41)*	*0.60 (0.29-1.23)*	*0.16*
NT	*3 442*	*1 (29.05)*	*2.08 (0.27-15.63)*	*0.47*	*20 192*	*7 (34.67)*	*1.75 (0.82-3.74)*	*0.14*
QLD	*92 421*	*23 (24.89)*	*1.94 (1.04-3.60)*	*0.03*	*518 071*	*84 (16.21)*	*0.85 (0.65-1.11)*	*0.24*
SA	*41 670*	*5 (12)*	*0.96 (0.35-2.61)*	*0.95*	*238 108*	*28 (11.76)*	*0.63 (0.42-0.94)*	*0.02*
TAS	*15 355*	*1 (6.51)*	*0.54 (0.07-4.04)*	*0.54*	*82 675*	*7 (8.47)*	*0.46 (0.21-0.99)*	*0.04*
VIC	*119 821*	*26 (21.7)*	*1.65 (0.90-3.02)*	*0.09*	*636 681*	*145 (22.77)*	*1.17 (0.93-1.47)*	*0.16*
WA	*42 029*	*8 (19.03)*	*1.43 (0.62-3.31)*	*0.39*	*229 432*	*62 (27.02)*	*1.39 (1.03-1.86)*	*0.02*
Total	464 137	84 (18.1)			2 588 872	498 (19.24)		

Risk factors associated with HBV infected donors

Of the 498 HBV positive donors during 2011-2015, 84% were first-time donors, 70% were male, and the mean age was 38 years (Table 10). Most (86%) of the HBV positive donors were born overseas, which reflects the epidemiology of hepatitis B in the general population. Ethnicity or country of birth (87%) was the most frequent risk factor for HBV positivity, with nearly 43% born in North & South East Asia in 2015 (Figure 13), followed by having a sexual partner with known risk or known to be positive for any transfusion-transmissible infection (3%). There were only 13 incident hepatitis B blood donors in the last five years, consistent with a low incidence rate.

Table 10 Characteristics of donors positive for HBV infection by year of donation, 2011-2015

Characteristics	2011	2012	2013	2014	2015	2011-2015
Number of positive donors	118	113	99	84	84	498
Number of positive first-time donors (%)	99 (83%)	97 (86%)	85 (86%)	67 (80%)	72 (86%)	420 (84%)
% male	79 (67%)	84 (74%)	72 (73%)	55 (65%)	58 (69%)	348 (70%)
Mean age (range) in years	38 (16 to 77)	37 (16 to 67)	36 (16 to 73)	42 (16-69)	37 (16-67)	38 (16-73)
Number of incident donors	5	1	3	3	1	13
% born in Australia	15 (13%)	19 (17%)	14 (14%)	15 (18%)	8 (10%)	71 (14%)
Main reported risk factor	Ethnicity/COB[1]	Ethnicity/COB[1]	Ethnicity/COB[1]	Ethnicity/COB[1]	Ethnicity/COB[1]	Ethnicity/COB[1]
	85%	89%	90%	77%	93%	87%
Second reported risk factor	TBP[2],PRP[3] each	Partner with known risk or known to be positive	Other	Partner with known risk or known to be positive	PRP[3], Other each	PRP[3]
	3%	4%	2%	8%	2%	3%

1 COB = Country of birth
2 TBP = Tattoo/Body piercing
3 PRP = partner with known risk/known to be positive

Figure 13 Donors with HBV infection by country/region of birth, 2015 (n=84)

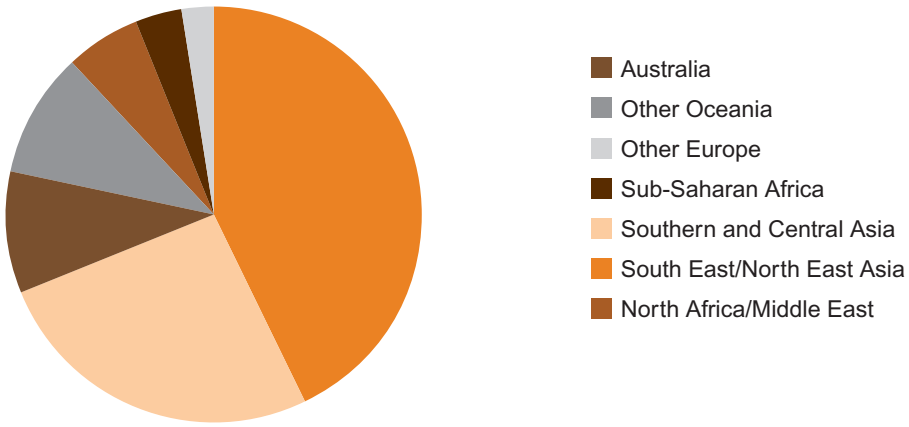
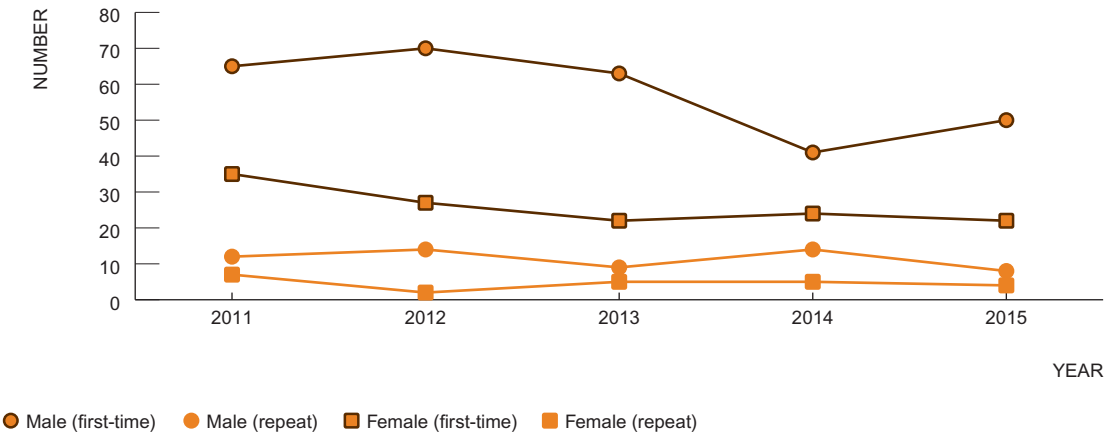


Figure 14 Donors with hepatitis B infection by sex and donor status, 2011-2015



Over the past five years, 2011-2015, there has been a declining trend in the number of HBV positive first-time donors in both genders. In 2015, there have been 23% and 33% reductions in first-time and repeat male donors since 2011, respectively. The number of HBV positive repeat donors on the other hand remained relatively stable in both genders during the same period of time (Figure 14).

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 period 2011-2015, see Appendix B.

Comparison of major exposure categories between blood donor 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 11). 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 92.9% of the HBV positive donors in 2015. Notably, this proportion has increased by 20% from 77.4% observed in 2014. 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, 4.3% had country of birth as a major risk factor; importantly, for 47.5% of the newly acquired HBV infection in general population the risk category was undetermined[1] (Table 11) (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 a vast majority of HBV positive cases in blood donors have chronic HBV infection as opposed to acute infection.

Table 11 Comparison between HBV positive blood donors and general population in Australia by infection and major potential risk categories, 2015

		HBV[1]
Major risk category	**General population (%)**	**Blood donors (%)**
Intravenous drug use	23.7	0.0
Country of birth/Ethnicity	4.3	92.9
Sexual contact[2]	18.0	2.4
Blood or tissue recipient	0.0	0.0
Tattoo or body piercing	2.2	0.0
Exposure in health care setting	1.4	1.2
Household contact	2.9	1.2
Other blood to blood contact	0.0	0.0
Other/undetermined	47.5	2.4
Imprisonment	0.0	0.0
No risk factors identified	0.0	0.0
Not reported	0.0	0.0

1 includes exposure categories for newly acquired HBV;
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:

- Supporting the effectiveness of donor questionnaire, donor education and selection, the prevalence of HBV infection in first-time blood donors has shown a stable or declining trend since 2006 and is substantially lower than in the general population in 2015 (11 times) and for the period 2006-2015 (12 times) .
- The prevalence of HBV infection among first-time-donations was much higher than the prevalence among all donations, highlighting the importance of promoting donor education of potential new donors and ensuring first-time donors read the pre-donation information and understand the importance of 'self-deferral'.
- The incidence of newly acquired HBV infection is also much lower than results 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 (12 of the 84 HBV infections in 2015).
- Infective 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):

Main findings

1. There were 62 HCV infections detected among all donations in 2015 (43 in first donors and 19 in repeat donors).
2. HCV was the second most frequent infection (after HBV) found in first-time blood donors. In 2015, the proportion of HCV RNA positive (potentially infectious) donors was 45%, a figure that has incrementally declined from around 75% when HCV RNA donation testing was introduced in 2000. As the decline was associated predominantly with first-time donors, this may reflect the falling incidence in the general population.
3. During 2006-2015, there has been a significant decrease in HCV prevalence in first-time donors in Australia, from 0.08% in 2006 to 0.05% in 2015. This translates into a decrease of 41% from 81.2 per 100 000 first-time donors in 2006 to 48 per 100 000 first-time donors in 2015. The 0.05% first-time donor prevalence in 2015 is 20 times lower than the 0.9% reported in national HCV surveillance data. This decreasing trend is consistent with national HCV new-diagnoses notification data which also shows a decrease in both numbers of notifications (from 12 132 in 2006 to 10 790 in 2015) and rate (from 60 per 100 000 in 2006 to 46 per 100 000 in 2015).[1]
4. Of all TTIs detected, HCV had the highest incidence rate among previously negative repeat donors during 2006-2015, at 2.4 per 100 000 donor-years of observation. The incidence rate has decreased over time from 4.1 in 2013, to 0.9 in 2014 and 1.2 per 100 000 donor-years of observation in 2015. However, it is important to note that the fall in 2014 and 2015 is at least in part due to the application of a stricter incidence definition, and should therefore be interpreted with due caution.
5. In 2015, the mean age of HCV positive donors was 44 years compared to 41.5 years for all donors. Like HBV, HCV positive donors were more likely to be male as compared to all donors (63% versus 50%) but in contrast to hepatitis B, the majority (69%) were born in Australia.
6. The most common putative reported risk factor for donors with HCV infection during 2011-2015 was a history of tattoo/piercing (26%), followed by injecting drug use (23%). In comparison, injecting drug use (72%) and sexual contact (4.3%) were the two most dominant routes of exposure in cases of newly acquired hepatitis C infection reported in national notification data in 2015.
7. No transfusion-transmitted HCV infections were reported in Australia during 2006-2015.

Epidemiology of HCV in Australia

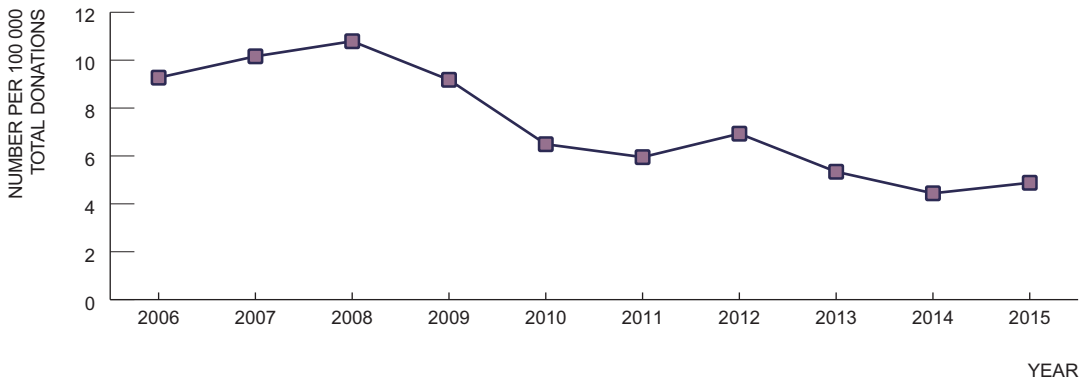
To the end of 2015, an estimated 227 306 (167 623-249 707) people were living with chronic hepatitis C in Australia, of which an estimated 82% or 186 763 (159 578-215 595) were diagnosed with chronic hepatitis C. Australia has a concentrated chronic hepatitis C epidemic among key populations; people 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 2015 was 46 per 100 000 as compared to 60 in 2006. The rate of notification of hepatitis C has remained stable in the past four years, after declines between 2006 and 2011, including in those aged less than 25 years. In contrast, the rate of hepatitis C notification in the Aboriginal and Torres Strait Islander population increased by 43% in the five past years, from 115 per 100 000 in 2011 to 165 per 100 000 in 2015. The 2015 rate is 4 times greater than in the non-Indigenous population (40 per 100 000). Most cases (66%) of newly diagnosed HCV infection were in males and 77% were in people aged 30 years and above.[1]

Trends in prevalence

All donors:

In the past ten years, 2006-2015, a total of 929 HCV positive donors have been detected (701 first-time donors & 228 repeat donors) (Table 12). During the last ten years, the prevalence of HCV infection among all donors has declined significantly (Table 13). There has been an overall reduction of 47% from 2006 to 2015, from 9.2 per 100 000 donations to 4.8 per 100 000 donations (Figure 15).

Figure 15 Prevalence* of HCV infection in all blood donations in Australia, 2006-2015, by year of donation



* Data on prevalence rates for HCV in all blood donors for years 2008 & 2009 have been updated and may vary from the previous reports

Table 12 The number and prevalence rate of HCV infection in Australia by state/territory, 2015 and 2006-2015

State/Territory of donation	All accepted donations 2015			HCV			State/Territory of donation	All accepted donations 2006-2015			HCV		
	First time	Repeat	All	First time	Repeat	All		First time	Repeat	All	First time	Repeat	All
NSW/ACT	29 180	347 714	376 894	13	3	16	**NSW/ACT**	432 729	3 605 419	4 038 148	271	81	352
Number (*Number per 100 000 donations)*				*44.55*	*0.86*	*4.25*	Number (*Number per 100 000 donations)*				*62.63*	*2.25*	*8.72*
NT	727	9 053	9 780	1	2	3	**NT**	8 243	99 419	107 662	8	4	12
Number (*Number per 100 000 donations)*				*137.55*	*22.09*	*30.67*	Number (*Number per 100 000 donations)*				*97.05*	*4.02*	*11.15*
QLD	18 914	242 615	261 529	10	5	15	**QLD**	256 790	2 347 567	2 604 357	151	64	215
Number (*Number per 100 000 donations)*				*52.87*	*2.06*	*5.74*	Number (*Number per 100 000 donations)*				*58.80*	*2.73*	*8.26*
SA	6 202	116 691	122 893	1	3	4	**SA**	96 914	1 189 268	1 286 182	52	18	70
Number (*Number per 100 000 donations)*				*16.12*	*2.57*	*3.25*	Number (*Number per 100 000 donations)*				*53.66*	*1.51*	*5.44*
TAS	2 807	47 002	49 809	3	1	4	**TAS**	32 256	401 607	433 863	15	11	26
Number (*Number per 100 000 donations)*				*106.88*	*2.13*	*8.03*	Number (*Number per 100 000 donations)*				*46.50*	*2.74*	*5.99*
VIC	22 966	300 366	323 332	10	4	14	**VIC**	265 309	2 760 238	3 025 547	157	34	191
Number (*Number per 100 000 donations)*				*43.54*	*1.33*	*4.33*	Number (*Number per 100 000 donations)*				*59.18*	*1.23*	*6.31*
WA	8 942	118 145	127 087	5	1	6	**WA**	103 897	1 159 290	1 263 187	47	16	63
Number (*Number per 100 000 donations)*				*55.92*	*0.85*	*4.72*	Number (*Number per 100 000 donations)*				*45.24*	*1.38*	*4.99*
National	89 738	1181 586	1271 324	43	19	62	**National**	1 196 138	11 562 808	12 758 946	701	228	929
Number (*Number per 100 000 donations)*				*47.92*	*1.61*	*4.88*	Number (*Number per 100 000 donations)*				*58.61*	*1.97*	*7.28*

* Some of the data on number/prevalence rates for HCV infection for years 2008-2013 have been updated and may vary from the previous reports

First-time donors:

During 2006-2015, there has been a significant decrease in HCV prevalence in first-time donors in Australia; from 81.2 per 100 000 donations in 2006, to 52.9 per 100 000 donations in 2010 and 47.9 per 100 000 donations in 2015) (Table 13 & 16). This translates into a decrease from nearly 0.1% of the total first-time donations in 2006 to 0.05% of the total first-time donations in 2015. 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 60 per 100 000 in 2006 to 46 per 100 000 in 2015.[1] In the past five years, 2011-2015, the rate of notification of HCV infection has remained stable, after declining between 2006 and 2011. This suggests that there has been no further reduction in HCV transmission since 2011. In addition, there has also been no change in rates of receptive needle and syringe sharing in the same period, highlighting the importance of sustaining and enhancing harm reduction services.[1]

Figure 16 Prevalence* of HCV infection in first-time blood donors in Australia, 2006-2015, by year of donation

* Data on prevalence rates for HCV in first-time blood donors for years 2008 & 2009 have been updated and may vary from the previous reports

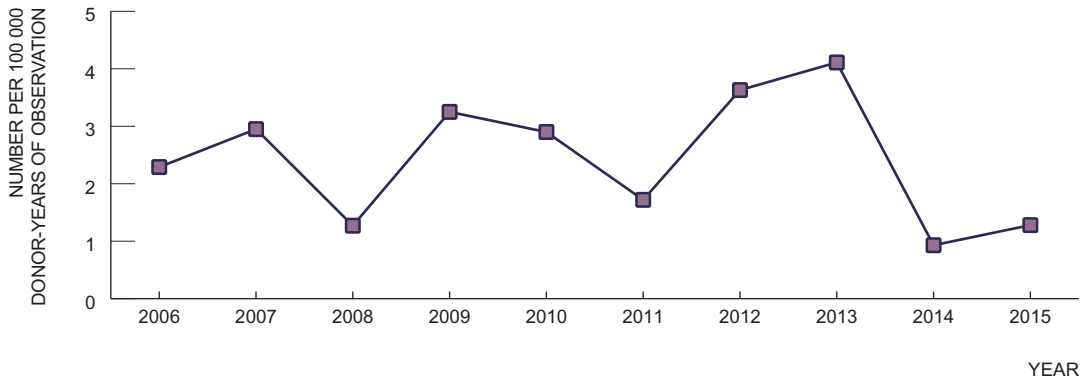
Table 13 Trends in prevalence and Incidence of HCV Infection in Australia, 2006-2015

	Trends in prevalence and Incidence of HCV Infection in Australia, 2006-2015	
Prevalence	**IRR (95% CI)**	**p-value**
All donors	*0.90 (0.88-0.92)*	*0.00*
First-time donors	*0.92 (0.89-0.94)*	*0.00*
Incidence	**IRR (95% CI)**	**p-value**
Repeat donors	*0.97 (0.90-1.05)*	*0.57*

Trends in incidence

Over the period 2006-2015, a total of 79 incident HCV infections in donors were detected. The number of HCV incident donors has considerably decreased in the last two years with only three and four incident infections noted in 2014 and 2015, respectively, compared to 13 during 2013. This decrease at least in part reflects the stricter definition of incident infection from year 2014, requiring the negative donation to have occurred within the past 12 months. With this caveat, there was no significant trend observed for incidence rates for HCV infection during the 2006-2015 period (between 0.9 and 4.1 per 100 000 donor-years of observation) (Table 13 & Figure 17). Similarly, no significant annual trend was observed for incidence of HCV infection over a nine-year study period (2006-2014) among people who inject drugs participating in the Australian Needle and Syringe Program Survey, although following a steady decline in 2006-2009 HCV incidence has remained high in the past five years (between 9.0 and 20.9 per 100 person-years).[1]

Figure 17 Incidence* of HCV in repeat blood donors in Australia, 2006-2015



* Data on incidence rates for HCV in repeat blood donors for years 2008-2010 and 2013 have been updated and may vary from the previous reports

No transfusion-transmitted HCV infections were reported in Australia during 2006-2015.

HCV RNA detection rate in donors

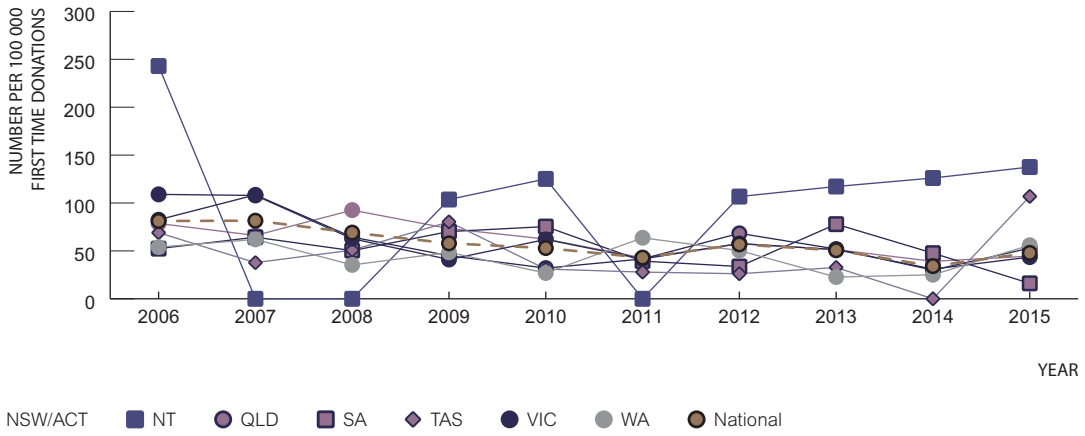
It is generally considered that blood components sourced from HCV antibody positive donors without detectable HCV RNA, pose a negligible risk of transfusion-transmission. These donors are presumed to have past resolved infection, however as they meet the public health HCV notification criteria, the Blood 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 (potentially infectious) donors, which was 45% in 2015 compared to 68% in 2008 and around 75% when HCV RNA donation testing was introduced in 2000.

Examining 2008 and 2015 data, the decline is significantly associated with a decrease in the proportion of RNA positive only donors among first-time donors (or those not previously RNA tested), from 91.3% in 2008 to 78.6% in 2015. This mirrors the falling HCV incidence (peak seroconversion in 1999)[9] and falling prevalence in the general population. Assuming a continuing incidence decline in the general population, 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

Nationally, the prevalence of HCV infection in first-time donors has shown a significant declining trend throughout the ten-year period 2006-2015 (Table 13). There were some notable jurisdictional decreases in 2006-2015 (Figure 18). A significant decrease was observed in the annual trend in the prevalence of HCV infection among first-time donors in New South Wales/Australian Capital Territory, Queensland and Victoria (Table 14); New South Wales/Australian Capital Territory from 78.6 in 2006, to 62.3 in 2010, and 44.5 in 2015; Queensland from 82.5 in 2006, to 32 in 2010, and 52.8 in 2015; and lastly Victoria from 109 in 2006, to 62 in 2010, and 43.5 in 2015 (Table 16). National notifications data indicate the notification rate of hepatitis C infection in Australia in 2015 was highest in the Northern Territory (80 per 100 000) and Tasmania (57 per 100 000). Between 2006 and 2011, rates declined in all jurisdictions, with stable rates since then. While broadly declining rates have been seen in the Northern Territory and South Australia, these jurisdictions have also experienced some fluctuation in notification rates across the ten-year period.[1] It is interesting to note the prevalence of HCV infection among first-time donors in Western Australia showed a significant decrease during 2005-2014; however during 2006-2015, no statistically significant trend was observed (Table 14). Also worth noting is the fluctuating trend in the prevalence of HCV infection in the first-time donors in the Northern Territory over the past ten years, from 243 in 2006 to 125.1 in 2010 to 137.5 per 100 000 first-time donations in 2015; with an overall increasing trend in the past four years, 2012-2015 (Figure 18). Similar fluctuation in the notification rates were observed in the general population data for the Northern Territory.[1]

Figure 18 Prevalence of HCV infection among first-time donors by state/territory and year of donation, 2006-2015



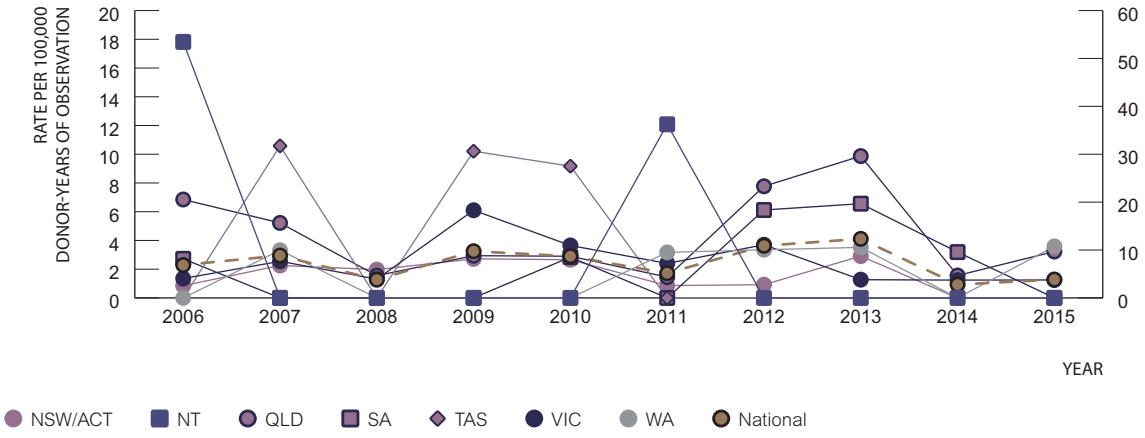
* Some of the data on prevalence rates for HCV in first-time blood donors by state/territory have been updated for years 2008-2013 and may vary from the previous reports

Table 14 Trend in Prevalence of HCV Infection in First-Time Donors, by State and Territory - 2006-2015

	Prevalence of HCV Infections in First-Time Donors, 2006-2015	
	IRR (95% CI)	**p-value**
NSW/ACT	*0.92 (0.88-0.96)*	*0.00*
NT	*1.02 (0.79-1.30)*	*0.87*
QLD	*0.91 (0.85-0.96)*	*0.00*
SA	*0.95 (0.86-1.05)*	*0.38*
TAS	*0.97 (0.80-1.16)*	*0.75*
VIC	*0.89 (0.84-0.94)*	*0.00*
WA	*0.96 (0.87-1.07)*	*0.52*

Generally, the incidence of HCV infection in repeat donors has remained very low across all Australian jurisdictions during the past ten years (Figure 19), and no significant annual trend was observed during the 2006-2015 study period (Table 15). Notably, in Tasmania, HCV incidence has been zero since 2010. Similarly, the rate in the Northern Territory has remained zero in the last four years. The rate in Western Australia has increased to 3.5 per 100 000 donor-years of observation after decreasing to zero in 2014, following a relatively stable rate of around 3 per 100 000 donor-years of observation in 2010-2013 (Figure 19).

Figure 19 Incidence* of HCV infection among repeat donors by state/territory^ and year of donation, 2006-2015



^ HCV incidence in NT provided according to the scale on the secondary axis on the right hand side
* Some of the data on incidence rates for HCV in repeat blood donors have been updated for years 2008-2013 and may vary from the previous reports

Table 15 Incidence of HCV Infection in Repeat Donors, by State and Territory - 2006-2015

	Incidence of HCV Infections in Repeat Donors, 2006-2015	
	IRR (95% CI)	**p-value**
NSW/ACT	*0.90 (0.75-1.08)*	*0.27*
NT	*0.74 (0.40-1.37)*	*0.34*
QLD	*1.00 (0.87-1.15)*	*0.92*
SA	*1.15 (0.88-1.50)*	*0.30*
TAS	*0.76 (0.48-1.20)*	*0.24*
VIC	*0.95 (0.81-1.11)*	*0.53*
WA	*1.14 (0.82-1.59)*	*0.41*

Table 16 Number and prevalence[1*] of HCV infection among first-time donors, 2006-2015, by state/territory and year of donation

	2006			2007			2008			2009		
State/Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	44 499	35	78.65	51 427	34	66.11	48 607	45	92.58	51 821	38	73.33
NT	823	2	243.01	759	0	0.00	815	0	0.00	965	1	103.63
QLD	27 873	23	82.52	28 575	31	108.49	29 498	19	64.41	28 889	13	45.00
SA	11 457	6	52.37	10 886	7	64.30	15 908	8	50.29	11 400	8	70.18
TAS	2 899	2	68.99	2 650	1	37.74	3 936	2	50.81	3 736	3	80.30
VIC	22 016	24	109.01	23 172	25	107.89	30 286	19	62.74	34 133	14	41.02
WA	11 116	6	53.98	11 292	7	61.99	11 307	4	35.38	12 387	6	48.44
Total	**120 683**	**98.00**	**81. 2**	**128 761**	**105**	**81.55**	**140 357**	**97**	**69.11**	**143 331**	**83**	**57.91**

	2010			2011			2012			2013		
State/Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	48 130	30	62.33	51 528	22	42.70	41 780	24	57.44	35 060	18	51.34
NT	799	1	125.16	772	0	0.00	937	1	106.72	853	1	117.23
QLD	28 097	9	32.03	28 839	12	41.61	24 881	17	68.33	21 181	11	51.93
SA	9 284	7	75.40	10 164	4	39.35	8 900	3	33.71	6 417	5	77.92
TAS	3 222	1	31.04	3 587	1	27.88	3 823	1	26.16	3 058	1	32.70
VIC	25 820	16	61.97	31 286	13	41.55	27 718	16	57.72	25 332	13	51.32
WA	11 149	3	26.91	10 992	7	63.68	9 925	5	50.38	8 815	2	22.69
Total	**126 501**	**67**	**52.96**	**137 168**	**59**	**43.01**	**117 964**	**67**	**56.80**	**100 716**	**51**	**50.64**

	2014			2015			Total 2006-2015		
State/Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	30 697	12	39.09	29 180	13	44.55	432 729	271	62.63
NT	793	1	126.10	727	1	137.55	8 243	8	97.05
QLD	20 043	6	29.94	18 914	10	52.87	256 790	151	58.80
SA	6 296	3	47.65	6 202	1	16.12	96 914	52	53.66
TAS	2 538	0	0.00	2 807	3	106.88	32 256	15	46.50
VIC	22 580	7	31.00	22 966	10	43.54	265 309	157	59.18
WA	7 972	2	25.09	8 942	5	55.92	103 897	47	45.24
Total	**90 919**	**31**	**34.10**	**89 738**	**43**	**47.92**	**1 196 138**	**701**	**58.61**

[1] Rate per 100 000 first-time donations

* Some of the data on prevalence rates for HCV in first-time blood donors by state/territory have been updated for years 2008-2013 and may vary from the previous reports

Table 17 Number and rate[1] of HCV infection among repeat donations, 2006-2015, by state/territory and year of donation

	2006			2007			2008			2009		
State/Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate
NSW/ACT	333 250	1	0.30	338 173	7	2.07	339 062	18	5.31	372 806	15	4.02
NT	8 496	1	11.77	10 214	0	0.00	11 166	0	0.00	11 158	0	0.00
QLD	216 496	4	1.85	209 556	3	1.43	226 726	11	4.85	242 001	7	2.89
SA	107 934	2	1.85	114 618	0	0.00	118 476	1	0.84	126 855	3	2.36
TAS	28 726	0	0.00	28 019	1	3.57	33 321	2	6.00	37 274	2	5.37
VIC	238 684	1	0.42	252 340	3	1.19	259 052	3	1.16	276 835	8	2.89
WA	99 376	0	0.00	109 425	2	1.83	113 274	2	1.77	118 327	3	2.54
Total	1 032 962	9	0.87	1 062 345	16	2.00	1 101 077	37	3.36	1 185 256	38	3.21

	2010			2011			2012			2013		
State/Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate
NSW/ACT	380 014	9	2.37	390 455	9	2.31	377 220	8	2.12	373 670	5	1.34
NT	10 470	0	0.00	10 782	1	9.27	9 673	0	0.00	9 493	0	0.00
QLD	243 837	5	2.05	245 975	4	1.63	237 599	8	3.37	243 042	7	2.88
SA	123 587	0	0.00	124 199	1	0.81	120 720	2	1.66	119 530	3	2.51
TAS	41 484	1	2.41	44 661	0	0.00	46 379	1	2.16	48 953	1	2.04
VIC	278 897	3	1.08	288 085	3	1.04	285 168	3	1.05	292 058	2	0.68
WA	120 646	1	0.83	121 057	4	3.30	117 728	2	1.70	123 298	1	0.81
Total	1 198 935	19	1.58	1 225 214	22	1.80	1 194 487	24	2.01	1 210 044	19	1.57

	2014			2015			Total 2006-2015		
State/Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate
NSW/ACT	353 055	6	1.70	347 714	3	0.86	3 605 419	81	2.25
NT	8 914	0	0.00	9 053	2	22.09	99 419	4	4.02
QLD	239 720	10	4.17	242 615	5	2.06	2 347 567	64	2.73
SA	116 658	3	2.57	116 691	3	2.57	1 189 268	18	1.51
TAS	45 788	2	4.37	47 002	1	2.13	401 607	11	2.74
VIC	288 753	4	1.39	300 366	4	1.33	2 760 238	34	1.23
WA	118 014	0	0.00	118 145	1	0.85	1 159 290	16	1.38
Total	1 170 902	25	2.14	1 181 586	19	1.61	11 562 808	228	1.97

[1] Rate per 100 000 repeat donations

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 2006-2015, and then 2015 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.[4] There was a 16 times lower prevalence in first-time donors for the period 2006-2015, and a 20 times lower prevalence in 2015 as compared to the prevalence in general population (Table 18). 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 18 Comparison of prevalence of HCV infection in blood donors with population prevalence by infection, 2006-2015

Infection	Population prevalence (per 100 000 people)		Prevalence in first time blood donors (per 100 000 donations)		HCV prevalence in first time blood donors versus the general population	
	2006-2015	**2015**	**2006-2015**	**2015**	**2006-2015**	**2015**
HCV	1 011	956	63.76	47.92	16 times lower	20 times lower

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* to determine the association between demographic factors and presence of HCV infection among Australian blood donors in 2015, and the five-year period, 2011-2015, separately (Table 19). 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.

Table 19 Association of demographic characteristics with presence of HCV infection among blood donors in Australia, 2015, and 2011-2015

	HCV 2015				HCV 2011-2015			
	Number of donors	Number of positive donors *(Number per 100 000 donors)*	IRR and their 95% CI (Multivariate adjusted)	p-value	Number of donors	Number of positive donors *(Number per 100 000 donors)*	IRR and their 95% CI (Multivariate adjusted)	p-value
Sex								
Male	*233 263*	*39 (16.72)*	*1 (ref)*	*…*	*1 279 978*	*230 (17.97)*	*1 (ref)*	*…*
Female	*230 874*	*23 (9.96)*	*0.62 (0.37-1.04)*	*0.07*	*1 308 894*	*130 (9.93)*	*0.57 (0.46-0.71)*	*0.00*
Age group (years)								
20-29	*37 041*	*4 (10.8)*	*1 (ref)*	*…*	*370 863*	*13 (3.51)*	*1 (ref)*	*…*
Less than 20	*105 449*	*10 (9.48)*	*1.19 (0.37-3.83)*	*0.75*	*430 483*	*51 (11.85)*	*0.61 (0.33-1.13)*	*0.12*
30-39	*79 792*	*7 (8.77)*	*0.89 (0.33-2.34)*	*0.81*	*415 941*	*54 (12.98)*	*1.39 (0.94-2.03)*	*0.09*
40-49	*78 287*	*8 (10.22)*	*1.04 (0.41-2.66)*	*0.91*	*450 532*	*87 (19.31)*	*2.06 (1.46-2.92)*	*0.00*
50 and above	*163 568*	*33 (20.18)*	*2.07 (1.01-4.21)*	*0.04*	*921 053*	*155 (16.83)*	*1.79 (1.30-2.45)*	*0.00*
State/Territory								
NSW	*137 606*	*13 (9.45)*	*1 (ref)*	*…*	*796 480*	*111 (13.94)*	*1 (ref)*	*…*
ACT	*11 793*	*3 (25.44)*	*2.80 (0.79-9.84)*	*0.10*	*67 233*	*9 (13.39)*	*0.94 (0.47-1.85)*	*0.86*
NT	*3 442*	*3 (87.16)*	*9.75 (2.77-34.27)*	*0.00*	*20 192*	*7 (34.67)*	*2.47 (1.15-5.31)*	*0.02*
QLD	*92 421*	*15 (16.23)*	*1.69 (0.80-3.56)*	*0.16*	*518 071*	*90 (17.37)*	*1.22 (0.92-1.61)*	*0.15*
SA	*41 670*	*4 (9.6)*	*0.97 (0.31-2.99)*	*0.96*	*238 108*	*28 (11.76)*	*0.75 (0.48-1.15)*	*0.18*
TAS	*15 355*	*4 (26.05)*	*2.66 (0.86-8.18)*	*0.08*	*82 675*	*11 (13.31)*	*0.92 (0.49-1.71)*	*0.79*
VIC	*119 821*	*14 (11.68)*	*1.25 (0.58-2.66)*	*0.56*	*636 681*	*75 (11.78)*	*0.84 (0.62-1.12)*	*0.24*
WA	*42 029*	*6 (14.28)*	*1.53 (0.58-4.03)*	*0.38*	*229 432*	*29 (12.64)*	*0.87 (0.58-1.31)*	*0.51*
Total	464 137	62 (13.36)			2 588 872	360 (13.91)		

In 2015, unlike HBV, there was no significant association between gender and HCV infection status. Donors over 50 years of age were two times more likely to be HCV positive, and donors from Northern Territory were approximately ten times more likely to be HCV positive as compared to the reference groups mentioned above(Table 19).

During the five-year period, 2011-2015, female donors were significantly less likely to be HCV positive (43%) compared to male donors. There was a significantly greater risk of HCV infection among donors aged 40 years or above, and among donors from Northern Territory as compared to the reference groups mentioned above (Table 19).

*See Methodological notes for details

Risk factors associated with HCV infected donors

Of the 360 HCV positive donors during 2011-2015, 72% were first-time donors and 64% were male. The mean age was 45 years with a wide range (16-78) over the last five years (Table 20). Unlike HBV where birth overseas predominated, the majority (67%) of HCV positive donors were born in Australia during 2011-2015, and over 69% in 2015 (Figure 20). Overall, the main putative reported risk factor for HCV positivity was tattoo or body piercing (26%), followed by intravenous drug use (23%). It should be noted that there is no significant evidence that tattooing and body piercing performed in licensed Australian premises is associated with an increased risk of acquiring HCV. 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 26% of HCV positive donors reporting tattooing or body piercing should be interpreted with caution. A joint Blood Service and Kirby Institute study is planned to further investigate the risk of tattooing in the context of blood donation, noting that blood donors with recent tattoos are currently temporarily deferred from donation. Highlighting the continuing importance of HCV to blood safety, there were 39 incident HCV infections in blood donors in the last five years, the highest among all TTIs.

Table 20 Characteristics of donors positive for HCV infection by year of donation, 2011-2015

Characteristics	2011	2012	2013	2014	2015	2011-2015
Number of positive donors	81	91	70	56	62	360
Number of positive first-time donors (%)	59 (73%)	67 (74%)	52 (74%)	38 (68%)	43 (69%)	259 (72%)
% male	55 (68%)	56 (62%)	43 (61%)	37 (66%)	39 (63%)	230 (64%)
Mean age (range) in years	42 (16 to 78)	44 (16 to 66)	45 (23 to 66)	48 (18 to 71)	44.27 (16-67)	45 (16 to78)
Number of incident donors	6	12	14	3	4	39
% born in Australia	51 (63%)	62 (68%)	41 (59%)	44 (79%)	43 (69%)	241 (67%)
Main reported risk factor	Intravenous drug use 21%	Tattoo/Body piercing 31%	Tattoo/Body piercing 33%	Intravenous drug use 30%	Tattoo/Body piercing 29%	Tattoo/Body piercing 26%
Second reported risk factor	Tattoo/Body piercing 20%	Intravenous drug use 23%	Intravenous drug use 19%	TBP[1], BTR[2] each 13%	Intravenous drug use 23%	Intravenous drug use 23%

1 TBP = Tattoo/Body Piercing
2 BTR = Blood /Tissue recipient

Figure 20 Donors with HCV infection by country/region of birth, 2015 (n=62)

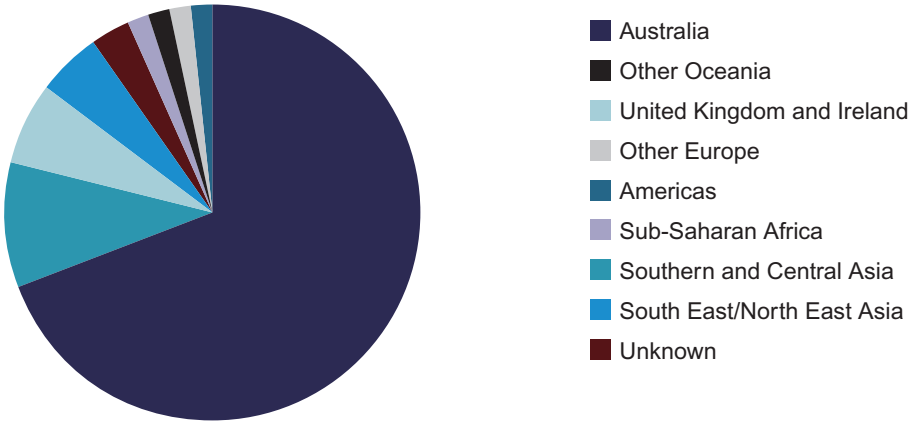
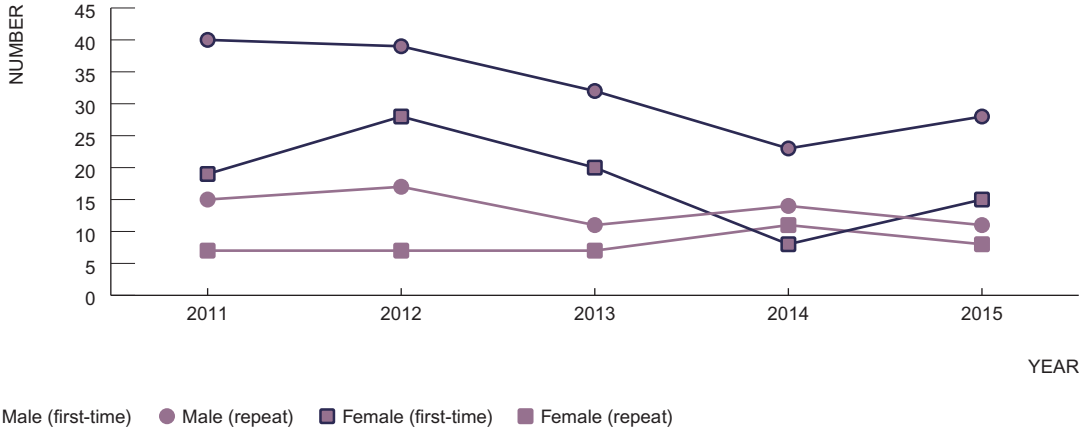


Figure 21 Donors with HCV infection by sex and donor status, 2011-2015



Over the past five years, 2011-2015, there has been a downward trend in the number of HCV positive first-time and repeat male donors, and first-time female donors (Figure 21); however, female repeat donors show a 14% increase in 2015 as compared to 2011. 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 period 2011-2015, see Appendix C.

HCV - Comparison of major exposure categories between blood donors and the general population, 2015

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 21). 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. In addition 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, making the utility of the comparison limited.

The most frequent risk factor for HCV infection in blood donors in 2015 was tattoo or body piercing (29%), followed by intravenous drug use (IDU) (22.6%). As discussed, the figure for tattooing and body piercing overestimates the importance of this as a risk factor for HCV and it is likely that IDU is in fact the predominant

HCV risk factor in blood donors. This correlates with the general population where intravenous drug use was the most common risk factor for newly acquired HCV infection in the general population in 2014.[1] Notably, for around 19% of the newly acquired HCV infection in the general population the risk category was undetermined (newly acquired HCV is defined as newly diagnosed hepatitis C infection with evidence of acquisition in the 24 months prior to diagnosis - laboratory or clinical evidence).

Of note, the enhanced surveillance procedures related to HCV vary by state/territory with no reported risk factor being grouped with undetermined. Nonetheless, the proportion of individuals reporting intravenous drug use among newly acquired HCV infections in the general population[1] (72%) was comparatively higher than in the donor population (22.6%) in 2015. This difference reflects the positive contribution of the Blood Services' permanent deferral for intravenous drug use but in part could also reflect HCV positive donors' failure to disclose risk factors both on the Donor Questionnaire and post-donation interview after testing positive.

Table 21 Comparison between HCV positive blood donors and general population in Australia by major potential risk categories, 2015

		HCV[1]
Major risk category	**General population (%)**	**Blood donors (%)**
Intravenous drug use	72.1	22.6
Country of birth/Ethnicity	0.0	0.0
Sexual contact[2]	4.3	4.8
Blood or tissue recipient	0.0	4.8
Tattoo or body piercing	0.2	29.0*
Exposure in health care setting	0.5	4.8
Household contact	0.9	6.5
Other blood to blood contact	0.0	0.0
Other/undetermined	18.6	8.1
Imprisonment	3.4	6.5
No risk factors identified	0.0	12.9
Not reported	0.0	0.0

1 Includes exposure categories for newly acquired HCV infections only
2 Includes three sub-groups: Male-to-male sexual contact, Partner with known risk or known to be positive and engaged in sex work
* This is a likely overestimate of the importance of tattooing and body piercing as a risk factor for HCV as there is no evidence that tattooing and body piercing performed in licensed Australian premises is associated with an increased risk of acquiring HCV.

Conclusion:

- Supporting the effectiveness of donor questionnaire, donor education and selection, the prevalence of HCV infection shows a declining trend since 2006 and was substantially lower among first-time blood donors than in the general population in 2015 (20 times) and for the period 2006-2015 (16 times).
- The incidence rate of HCV infection is the highest among all TTIs detected during the past ten years, 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 with detectable RNA and this reflects declining incidence in the general population.
- Infective risk factors identified in blood donors with HCV infection in 2015 likely parallels those for the general population with no 'unique' risk factors identified to date among blood donors.

Human Immunodeficiency Virus (HIV)

Main findings:

1. There were two HIV infections detected in 2015 (one in first-time and one in repeat donors).

2. The prevalence of HIV infection among first-time donors during 2006-2015 remained very low at 1.9 per 100 000 donations (or 0.002% of the total first-time donations) and comparatively much lower than hepatitis B (81.6 per 100 000 donations) and hepatitis C (58.6 per 100 000 donations). The 0.002% HIV prevalence in first-time donors is 56 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; 0.3 in 2006, 1.1 in 2010, 0.9 in 2014 and 0 in 2015.

4. Of the 23 donors who tested HIV positive during 2011-2015, 78% were males, and 48% were Australian-born with an average age of 37 years as compared to 41.5 years for all donors.

5. The two most frequent putative reported routes of exposure for donors with HIV infection during 2011-2015 were male-to-male sex (35%), followed by heterosexual sex with partners with known risk factors or known to be HIV positive (30%). This compares to the new HIV diagnoses notification data in Australia where men who have sex with men accounted for 68% of new HIV diagnoses in Australia in 2015, followed by heterosexual sex (20%).[1]

6. No transfusion-transmitted HIV infections were reported in Australia during 2006-2015.

Epidemiology of HIV in Australia

During 2015, an estimated 25 313 (22 513 – 28 281) people were living with HIV (about a tenth of infections compared to HBV and HCV), and an estimated majority (89%) or 22 695 were diagnosed (22,246 – 23,357). Transmission of HIV in Australia continues to occur primarily through sexual contact between men, with 88% of newly acquired cases of HIV infection in Australia in the period 2006 to 2015 involving men who reported sexual contact with men. The annual number of new HIV diagnoses has gradually increased by 13% over the past 10 years, from 987 diagnoses in 2006 to 1 065 in 2012 and stabilised since then with 1 025 cases of HIV infection newly diagnosed in Australia in 2015. Of these newly diagnosed HIV infections in 2015, 89% were in males, 68% occurred among men who have sex with men, 5% due to male-to-male sex and injecting drug use, 20% 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 donors:

In the past ten years, 2006-2015, a total of 51 HIV positive donors have been detected (23 first-time donors & 28 repeat donors) (Table 22). During this period, the prevalence of HIV infection among all donors has shown no statistically significant trend (Table 23 & Figure 22). The prevalence rate among all donors has fluctuated over time from 0.2 per 100 000 donations in 2006 to 0.5 in 2010 and was 0.1 per 100 000 donations in 2015 (Figure 22).

Figure 22 Prevalence of HIV infection in all blood donations in Australia, 2006-2015, by year of donation

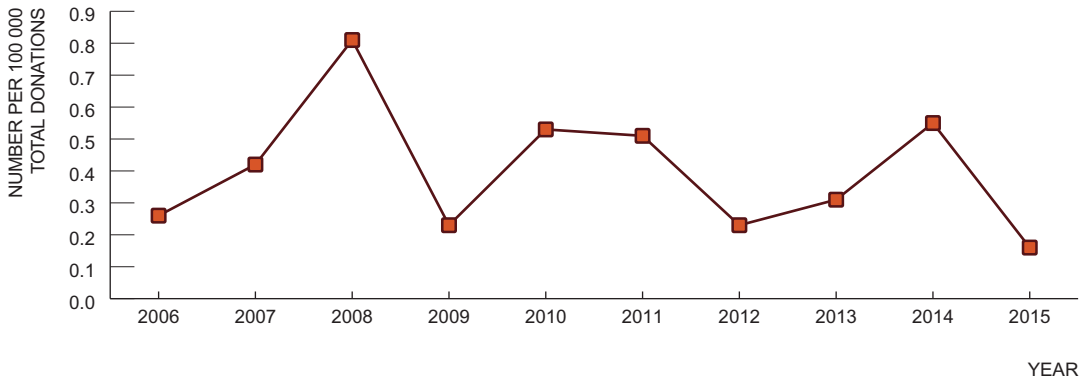


Table 22 The number and prevalence* rate of HIV infection in Australia by state/territory, 2015 and 2006-2015

State/Territory of donation	All accepted donations 2015			HIV			State/Territory of donation	All accepted donations 2006-2015			HIV		
	First time	Repeat	All	First time	Repeat	All		First time	Repeat	All	First time	Repeat	All
NSW/ACT	29 180	347 714	376 894	1	0	1	**NSW/ACT**	432 729	3 605 419	4 038 148	9	5	14
Number (*Number per 100 000 donations)*				*3.43*	*0.00*	*0.27*	Number (*Number per 100 000 donations)*				*2.08*	*0.14*	*0.35*
NT	727	9 053	9 780	0	0	0	**NT**	8 243	99 419	107 662	0	1	1
Number (*Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*	Number (*Number per 100 000 donations)*				*0.00*	*1.01*	*0.93*
QLD	18 914	242 615	261 529	0	0	0	**QLD**	256 790	2 347 567	2 604 357	7	10	17
Number (*Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*	Number (*Number per 100 000 donations)*				*2.73*	*0.43*	*0.65*
SA	6 202	116 691	122 893	0	0	0	**SA**	96 914	1 189 268	1 286 182	0	3	3
Number (*Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*	Number (*Number per 100 000 donations)*				*0.00*	*0.25*	*0.23*
TAS	2 807	47 002	49 809	0	0	0	**TAS**	32 256	401 607	433 863	0	0	0
Number (*Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*	Number (*Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*
VIC	22 966	300 366	323 332	0	1	1	**VIC**	265 309	2 760 238	3 025 547	5	8	13
Number (*Number per 100 000 donations)*				*0.00*	*0.33*	*0.31*	Number (*Number per 100 000 donations)*				*1.88*	*0.29*	*0.43*
WA	8 942	118 145	127 087	0	0	0	**WA**	103 897	1 159 290	1 263 187	2	1	3
Number (*Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*	Number (*Number per 100 000 donations)*				*1.92*	*0.09*	*0.24*
National	89 738	1 181 586	1 271 324	1	1	2	**National**	1 196 138	11 562 808	12 758 946	23	28	51
Number (*Number per 100 000 donations)*				*1.11*	*0.08*	*0.16*	Number (*Number per 100 000 donations)*				*1.92*	*0.24*	*0.40*

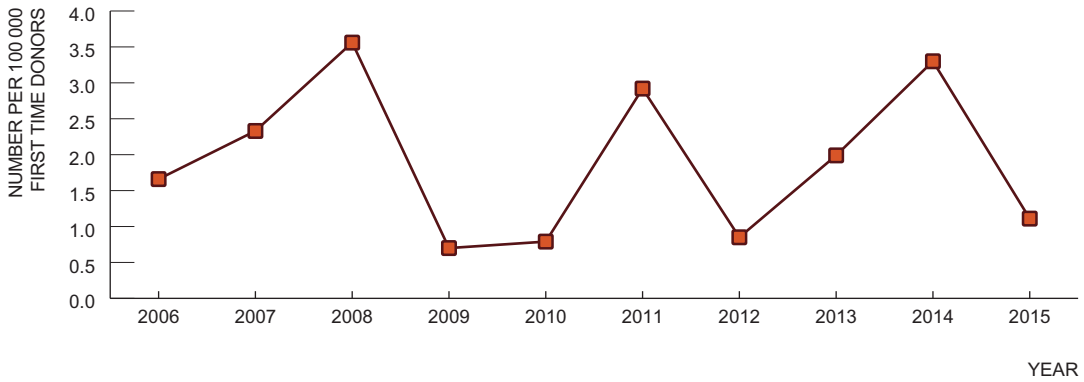
* Some of the data on number/prevalence rates for HIV infection for years 2010 & 2012 have been updated and may vary from the previous reports

First-time donors:

HIV prevalence in first-time donors remained very low at 1.9 per 100 000 over the ten-year period 2006-2015 (Table 26); it peaked in 2008 at 3.6 per 100 000 donations followed by a sharp fall in 2009-10 to 0.7 per 100 000 donations. However, it increased from 2.0 per 100 000 donations in 2013 to 3.3 per 100 000 donations in 2014, and dropped again to 1.1 per 100 000 donations in 2015 (Figure 23). Overall, no significant trends were observed in the prevalence of HIV infection among first-time donors in the past ten years (Table 23).

The very low prevalence (0.002%) of HIV infection among first-time donors during 2006-2015 is encouraging given that the number of newly diagnosed HIV infections in the general Australian population increased steadily in the past decade by 4%, from 987 diagnoses in 2006 to 1 025 cases of newly diagnosed HIV infection in Australia in 2015.[1]

Figure 23 Prevalence* of HIV infection in first-time blood donors in Australia, 2006-2015, by year of donation



* Data on prevalence rates for HIV infection among first-time blood donors for years 2010 & 2012 have been updated and may vary from the previous reports

Table 23 Trends in prevalence and Incidence of HIV Infection in Australia, 2006-2015

	Trends in prevalence and Incidence of HIV Infection in Australia, 2006-2015	
Prevalence	**IRR (95% CI)**	**p-value**
All donors	*0.96 (0.87-1.05)*	*0.42*
First-time donors	*0.98 (0.84-1.14)*	*0.83*
Incidence	**IRR (95% CI)**	**p-value**
Repeat donors	*0.96 (0.82-1.12)*	*0.64*

Trends in incidence

In 2015 no incident infections were detected for HIV. For the ten-year period 2006-2015, there were a total of 21 incident donors identified for HIV, however no significant trend was observed for incidence rates for HIV infection during this time (ranged between 0.0 and 1.1 per 100 000 donor-years of observation) (Table 23 & Figure 24). Likewise, no significant trend was observed for the incidence of HIV in a five-year study period among gay and bisexual men attending sexual health services, with the highest incidence recorded in 2011 at 1.32, declining to 0.89 in 2015.[1]

Figure 24 Incidence* of HIV in repeat blood donors in Australia, 2006-2015, by year of donation

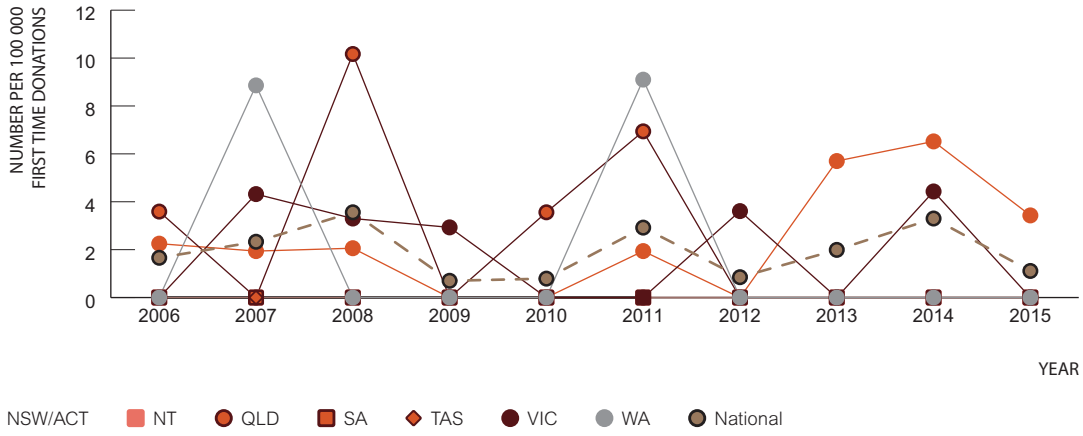
* Data on incidence rates for HIV infection in repeat donors have been updated for year 2008 and may vary from the previous reports

No transfusion-transmitted HIV infections were reported in Australia during 2005-2014.

Trends in HIV infection by state/territory

The prevalence of HIV infection in first-time donors remained substantially lower than hepatitis B and hepatitis C throughout the 2006-2015 period, with a national prevalence of 1.9 per 100 000 donations (Table 26). No significant annual trend was observed during the 2006-2015 period in any jurisdiction (Table 24 & Figure 25). In 2015, HIV prevalence in the first-time donors was zero in all jurisdictions except New South Wales/Australian Capital Territory where the rate was 3.4 per 100 000 donations (Table 26). During 2006-2015, HIV prevalence in the first-time donors was zero in the Northern Territory, South Australia and Tasmania (Table 26).

Figure 25 Prevalence* of HIV infection among first-time donors by state/territory and year of donation, 2006-2015



* Some of the data on prevalence rates for HIV infection among first-time donors by state/territory for years 2010 & 2012 have been updated and may vary from the previous reports

Table 24 Trend in Prevalence of HIV Infection in First-Time Donors, by State and Territory - 2006-2015

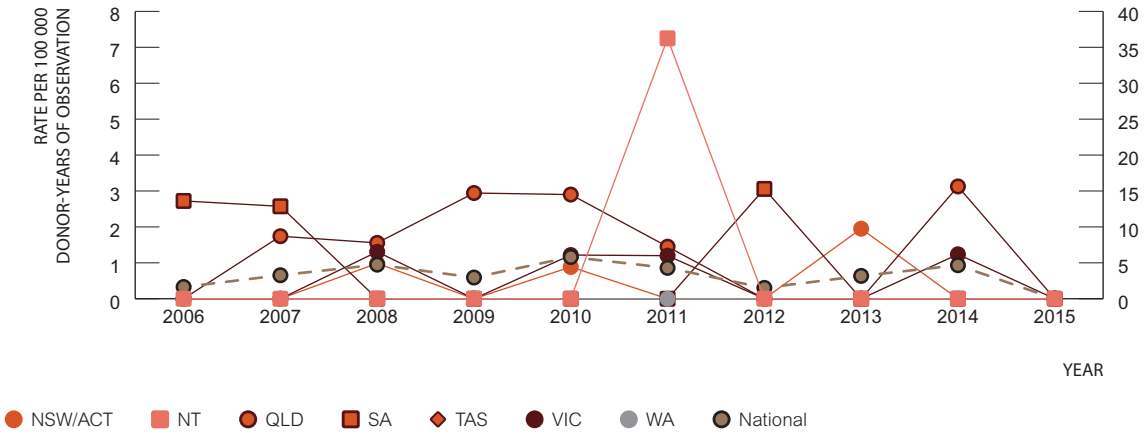
	Trends in prevalence and Incidence of HIV Infection in Australia, 2006-2015	
	IRR (95% CI)	p-value
NSW/ACT	*1.16 (0.91-1.49)*	*0.20*
NT	…	…
QLD	*0.83 (0.61-1.12)*	*0.23*
SA	…	…
TAS	…	…
VIC	*0.94 (0.68-1.30)*	*0.72*
WA	*0.84 (0.49-1.45)*	*0.55*

Incident HIV infections in blood donors continue to be a rare occurrence with no incident donor identified in 2015. No incident HIV donors were recorded in Tasmania or in Western Australia in the past ten years, 2006-2015. No significant annual trend was observed in any jurisdiction during 2005-2014 (Table 25). The incidence rate has fluctuated in Queensland, it steadily declined by approximately 50% from 2.9 per 100 000 donor-years of observation in 2010 to 1.4 per 100 000 donor-years of observation in 2011, and was zero in both 2012 and 2013 before increasing to 3.1 in 2014 and returning to zero per 100 000 donor-years of observation in 2015 (Figure 26). However, given this rise in 2014 equates to only two incident infections, caution should be taken in interpretation.

Table 25 Incidence of HIV Infection in Repeat Donors, by State and Territory - 2006-2015

	Incidence of HIV Infections in Repeat Donors, 2006-2015	
	IRR (95% CI)	p-value
NSW/ACT	*1.06 (0.75-1.51)*	*0.70*
NT	*1.07 (0.52-2.20)*	*0.83*
QLD	*0.94 (0.74-1.20)*	*0.64*
SA	*0.75 (0.46-1.22)*	*0.25*
TAS	…	…
VIC	*1.02 (0.72-1.44)*	*0.88*
WA	…	…

Figure 26 Incidence* of HIV infection among repeat donors by state/territory^ and year of donation, 2006-2015



* Some of the data on incidence prevalence rates for HIV infection among repeat donors by state/territory for year 2008 have been updated and may vary from the previous reports

^ HIV incidence in NT provided according to the scale on the secondary axis on the right hand side.

Table 26 Number and prevalence[1*] of HIV infection among first-time donors, 2006-2015, by state/territory and year of donation

	2006			2007			2008			2009		
State/Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	44 499	1	2.25	51 427	1	1.94	48 607	1	2.06	51 821	0	0.00
NT	823	0	0.00	759	0	0.00	815	0	0.00	965	0	0.00
QLD	27 873	1	3.59	28 575	0	0.00	29 498	3	10.17	28 889	0	0.00
SA	11 457	0	0.00	10 886	0	0.00	15 908	0	0.00	11 400	0	0.00
TAS	2 899	0	0.00	2 650	0	0.00	3 936	0	0.00	3 736	0	0.00
VIC	22 016	0	0.00	23 172	1	4.32	30 286	1	3.30	34 133	1	2.93
WA	11 116	0	0.00	11 292	1	8.86	11 307	0	0.00	12 387	0	0.00
Total	**120 683**	**2**	**1.66**	**128 761**	**3**	**2.33**	**140 357**	**5**	**3.56**	**143 331**	**1**	**0.70**

	2010			2011			2012			2013		
State/Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	48 130	0	0.00	51 528	1	1.94	41 780	0	0.00	35 060	2	5.70
NT	799	0	0.00	772	0	0.00	937	0	0.00	853	0	0.00
QLD	28 097	1	3.56	28 839	2	6.94	24 881	0	0.00	21 181	0	0.00
SA	9 284	0	0.00	10 164	0	0.00	8 900	0	0.00	6 417	0	0.00
TAS	3 222	0	0.00	3 587	0	0.00	3 823	0	0.00	3 058	0	0.00
VIC	25 820	0	0.00	31 286	0	0.00	27 718	1	3.61	25 332	0	0.00
WA	11 149	0	0.00	10 992	1	9.10	9 925	0	0.00	8 815	0	0.00
Total	**126 501**	**1**	**0.79**	**137 168**	**4**	**2.92**	**117 964**	**1**	**0.85**	**100 716**	**2**	**1.99**

	2014			2015			Total 2006-2015		
State/Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	30 697	2	6.52	29 180	1	3.43	432 729	9	2.08
NT	793	0	0.00	727	0	0.00	8 243	0	0.00
QLD	20 043	0	0.00	18 914	0	0.00	256 790	7	2.73
SA	6 296	0	0.00	6 202	0	0.00	96 914	0	0.00
TAS	2 538	0	0.00	2 807	0	0.00	32 256	0	0.00
VIC	22 580	1	4.43	22 966	0	0.00	265 309	5	1.88
WA	7 972	0	0.00	8 942	0	0.00	103 897	2	1.92
Total	**90 919**	**3**	**3.30**	**89 738**	**1**	**1.11**	**1 196 138**	**23**	**1.92**

[1] Rate per 100 000 first-time donations

* Some of the data on number/prevalence rates for HIV infection among first-time donors by state/territory for years 2010 & 2012 have been updated and may vary from the previous reports

Table 27 Number and rate[1] of HIV infection among repeat donations, 2006-2015, by state/territory and year of donation

	2006			2007			2008			2009		
State/Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	333 250	0	0.00	338 173	0	0.00	339 062	1	0.29	372 806	0	0.00
NT	8 496	0	0.00	10 214	0	0.00	11 166	0	0.00	11 158	0	0.00
QLD	216 496	0	0.00	209 556	1	0.48	226 726	1	0.44	242 001	2	0.83
SA	107 934	1	0.93	114 618	1	0.87	118 476	0	0.00	126 855	0	0.00
TAS	28 726	0	0.00	28 019	0	0.00	33 321	0	0.00	37 274	0	0.00
VIC	238 684	0	0.00	252 340	0	0.00	259 052	3	1.16	276 835	0	0.00
WA	99 376	0	0.00	109 425	0	0.00	113 274	0	0.00	118 327	0	0.00
Total	**1 032 962**	**1**	**0.10**	**1 062 345**	**2**	**0.19**	**1 101 077**	**5**	**0.45**	**1 185 256**	**2**	**0.17**

	2010			2011			2012			2013		
State/Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	380 014	2	0.53	390 455	0	0.00	377 220	0	0.00	373 670	2	0.54
NT	10 470	0	0.00	10 782	1	9.27	9 673	0	0.00	9 493	0	0.00
QLD	243 837	3	1.23	245 975	1	0.41	237 599	0	0.00	243 042	0	0.00
SA	123 587	0	0.00	124 199	0	0.00	120 720	1	0.83	119 530	0	0.00
TAS	41 484	0	0.00	44 661	0	0.00	46 379	0	0.00	48 953	0	0.00
VIC	278 897	1	0.36	288 085	1	0.35	285 168	1	0.35	292 058	0	0.00
WA	120 646	0	0.00	121 057	0	0.00	117 728	0	0.00	123 298	0	0.00
Total	**1 198 935**	**6**	**0.50**	**1 225 214**	**3**	**0.24**	**1 194 487**	**2**	**0.17**	**1 210 044**	**2**	**0.17**

	2014			2015			Total 2006-2015		
State/Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	353 055	0	0.00	347 714	0	0.00	3 605 419	5	0.14
NT	8 914	0	0.00	9 053	0	0.00	99 419	1	1.01
QLD	239 720	2	0.83	18 914	0	0.00	2 123 866	10	0.47
SA	116 658	0	0.00	116 691	0	0.00	1 189 268	3	0.25
TAS	45 788	0	0.00	47 002	0	0.00	401 607	0	0.00
VIC	288 753	1	0.35	300 366	1	0.33	2 760 238	8	0.29
WA	118 014	1	0.85	118 145	0	0.00	1 159 290	1	0.09
Total	**1 170 902**	**4**	**0.34**	**957 885**	**1**	**0.10**	**11 339 107**	**28**	**0.25**

[1] Rate per 100 000 repeat donations

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 2006-2015, and then 2015 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.[4] There was a 56 times lower prevalence in first-time donors for the period 2006-2015, and a 95 times lower prevalence in 2015 as compared to the general population (Table 28). 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 28 Comparison of prevalence of HIV infection in blood donors with population prevalence by infection, 2006-2015

Infection	Population prevalence (per 100 000 people)		Prevalence in first time blood donors (per 100 000 donations)		HIV prevalence in first time blood donors versus the general population	
	2006-2015	**2015**	**2006-2015**	**2015**	**2006-2015**	**2015**
HIV	107	106	1.92	1.11	56 times lower	95 times lower

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* to determine the association between demographic factors and presence of HIV infection among Australian blood donors in 2015, and the five-year period, 2011-2015, separately (Table 29). 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.

*See Methodological notes for details

Table 29 Association of demographic characteristics with presence of HIV infection among blood donors in Australia, 2015 and 2011-2015

	HIV 2015				HIV 2011-2015			
	Number of donors	Number of positive donors *(Number per 100 000 donors)*	IRR and their 95% CI (Multivariate adjusted)	p-value	Number of donors	Number of positive donors *(Number per 100 000 donors)*	IRR and their 95% CI (Multivariate adjusted)	p-value
Sex								
Male	*233 263*	*1 (0.43)*	*1 (ref)*	*…*	*1 279 978*	*18 (1.41)*	*1 (ref)*	*…*
Female	*230 874*	*1 (0.43)*	*0.94 (0.05-15.22)*	*0.96*	*1 308 894*	*5 (0.38)*	*0.25 (0.09-0.69)*	*0.00*
Age group (years)								
20-29	*37 041*	*0 (0)*	*1 (ref)*	*…*	*370 863*	*1 (0.27)*	*1 (ref)*	*…*
Less than 20	*105 449*	*1 (0.95)*	*..*	*0.99*	*430 483*	*9 (2.09)*	*0.28 (0.03-2.28)*	*0.23*
30-39	*79 792*	*1 (1.25)*	*1.31 (0.08-21.31)*	*0.84*	*415 941*	*4 (0.96)*	*0.55 (0.17-1.80)*	
40-49	*78 287*	*0 (0)*	*..*	*0.99*	*450 532*	*4 (0.89)*	*0.52 (0.16-1.70)*	*0.28*
50 and above	*163 568*	*0 (0)*	*..*	*0.99*	*921 053*	*5 (0.54)*	*0.32 (0.10-0.96)*	*0.04*
State/Territory								
NSW	*137 606*	*1 (0.73)*	*1 (ref)*	*…*	*796 480*	*6 (0.75)*	*1 (ref)*	*…*
ACT	*11 793*	*0 (0)*	*..*	*0.08*	*67 233*	*2 (2.97)*	*3.77 (0.76-18.7)*	*0.10*
NT	*3 442*	*0 (0)*	*..*	*0.99*	*20 192*	*1 (4.95)*	*6.01 (0.72-50.05)*	*0.09*
QLD	*92 421*	*0 (0)*	*..*	*0.99*	*518 071*	*5 (0.97)*	*1.27 (0.38-4.19)*	*0.68*
SA	*41 670*	*0 (0)*	*..*	*0.99*	*238 108*	*1 (0.42)*	*0.58 (0.07-4.87)*	*0.62*
TAS	*15 355*	*0 (0)*	*..*	*0.99*	*82 675*	*0 (0)*	*…*	*0.98*
VIC	*119 821*	*1 (0.83)*	*1.05 (0.06-16.84)*	*0.97*	*636 681*	*6 (0.94)*	*1.22 (0.39-3.79)*	*0.73*
WA	*42 029*	*0 (0)*	*..*	*0.99*	*229 432*	*2 (0.87)*	*1.11 (0.22-5.53)*	*0.89*
Total	464 137	2 (0.43)			2 588 872	23 (0.89)		

In 2015, unlike HBV, there was no significant association between gender and HIV infection status. Given the small number of donors with HIV in 2015, no meaningful analysis was possible for association between HIV positivity and donors' age group or location (Table 30).

During the five-year period, 2011-2015, female donors were significantly less likely (75%) compared to male donors to be HIV positive. Also, there was a significantly lesser risk of HIV infection among donors aged 50 years or above as compared to the reference group of 20-29 years. There was no association with state/territory of the donors and HIV infection among Australian blood donors during this period (Table 29).

Risk factors associated with HIV infected donors

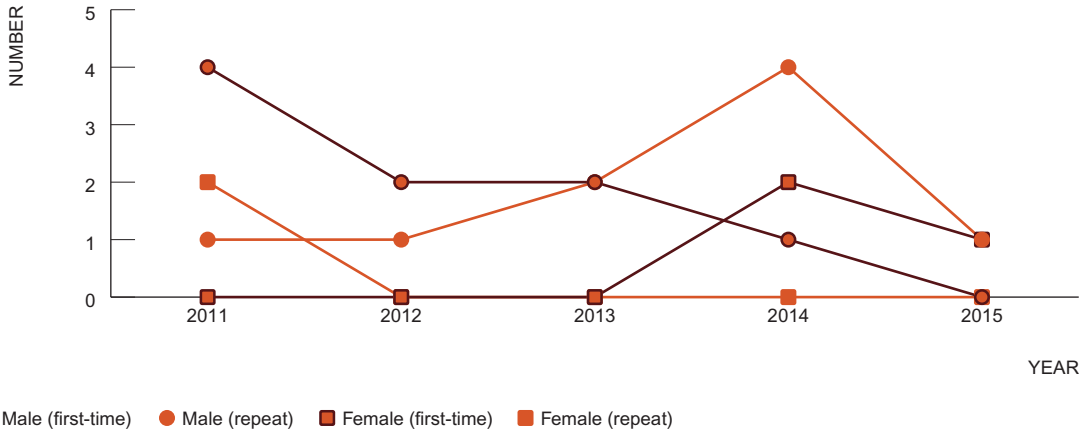
In contrast to HBV and HCV infected donors, the majority of HIV infected donors during 2011-2015 were repeat donors (57%) (Table 30). Most were male (78%) with a mean age of 37 years. Male-to-male sexual contact (35%) and having a sexual partner with known risk or known to be positive for any TTI (30%) were the two most common reported risk factors for HIV positivity in blood donors during 2011-2015. Similarly, male-to-male sexual contact and heterosexual contact accounted for 68% and 20% of the new HIV diagnoses in the general population in 2015, respectively.[1] Of 23 HIV positive donors in the five-year period 2011-2015, nine were incident HIV infections.

Table 30 Characteristics of donors positive for HIV infection by year of donation, 2011-2015

Characteristics	2011	2012	2013	2014	2015	2011-2015
Number of positive donors	7	3	4	7	2	23
Number of positive first-time donors (%)	4 (57%)	1 (33%)	2 (50%)	2 (29%)	1 (50%)	10 (43%)
% male	5 (71%)	3 (100%)	4 (100%)	5 (71%)	1 (50%)	18 (78)
Mean age (range) in years	36 (22 to 62)	36 (19 to 56)	47 (28 to 65)	36 (26 to 56)	30 (26-33)	37 (19 to 65)
Number of incident donors	3	1	2	3	0	9
% born in Australia	2 (29%)	2 (67%)	3 (75%)	3 (43%)	1 (50%)	11 (48%)
Main reported risk factor	Partner with known risk or known to be positive	Partner with known risk or known to be positive	Male-to-male sexual contact	Male-to-male sexual contact	Other, Unknown each	Male-to-male sexual contact
	57%	100%	75%	43%	50%	35%
Second reported risk factor	Male-to-male sexual contact	...	Ethnicity/COB[1]	COB[1], PRP[2], each	...	Partner with known risk or known to be positive
	14%		25%	14%		30%

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

Figure 27 Donors with HIV infection by sex and donor status, 2011-2015



Over the past five years, 2011-2015, there has been a downward trend in the number of HIV positive first-time male donors; there has been no discernible overall trend in repeat male, and first-time and repeat female donors (Figure 27); 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 2011-2015, see Appendix D.

HIV - Comparison of major exposure categories between blood donors and the general population, 2015

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 31). 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%).[10] In contrast, no major exposure category was identified among blood donors due to small number of donors with HIV infection (only two).

Table 31 Comparison between HIV positive blood donors and general population in Australia by major potential risk categories, 2015

		HIV[1]
Major risk category	**General population (%)**	**Blood donors (%)**
Intravenous drug use	2.9	0.0
Country of birth/Ethnicity	0.0	0.0
Sexual contact[2]	93.0	0.0
Blood or tissue recipient	0.8	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	2.9	50.0
Imprisonment		
No risk factors identified	0.0	50.0
Not reported	0.0	0.0

1 Includes exposure categories for new HIV diagnoses
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 substantially lower among first-time blood donors than in the general population, 95 times lower in 2015 and 56 times lower for the period 2006-2015.
- 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 infective risk factor identified in blood donors with HIV infection in 2015.

Human T-Lymphotropic Virus (HTLV)

Main findings

1. There were four HTLV infections detected among all donations in 2015 (3 in first-time and one in repeat donations).

2. The prevalence of HTLV infection among first-time donors during 2006-2015 has shown a slight non-significant increasing trend at 3.2 per 100 000 donations. 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 2015 was zero, as it was for the average ten-year period 2006-2015.

4. In 2015, the mean age of donors with HTLV infection was 33 years; 75% of the infected donors were male and most of them (75%) were born overseas.

5. The most common putative infective risk factor for donors with HTLV infection during 2011-2015 was ethnicity or country of birth (79%). There are no data to compare risk factors in the general population.

6. No transfusion-transmitted HTLV infections were reported in Australia during 2006-2015

Epidemiology of HTLV in Australia

HTLV is not a notifiable infection in Australia, and very few studies have examined the epidemiology in Australia. There has been a focus on HTLV-1, due to disease outcomes, including HTLV-1-associated myelopathy and adult T-cell leukemia/lymphoma.[11, 12] The HTLV-1 prevalence reported in published studies varies considerably, from 1.7% among Aboriginal and Torres Strait Islander adults in the Northern Territory to 51.7% among adults in the Anangu Pitjantjatjara Lands of South Australia.[13-15] 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 with 30 of 74 (40.5%) of adults and 1 of 23 (4.3%) of children <15 years.[16]

Trends in prevalence

All donors:

In the past ten years, 2006-2015, a total of 40 HTLV positive donors have been detected (39 first-time donors & one repeat donor) (Table 32). During the period 2006-2015, the overall prevalence of HTLV infection among all donors was 0.3 per 100 000 donations (Table 32) and has shown no statistically significant trend (Table 33) (Figure 28).

Figure 28 Prevalence of HTLV infection in all blood donations in Australia, 2006-2015, by year of donation

Table 32 The number and prevalence rate of HTLV infection in Australia by state/territory, 2015 and 2006-2015

State/Territory of donation	All accepted donations 2015			HTLV			State/Territory of donation	All accepted donations 2006-2015			HTLV		
	First time	Repeat	All	First time	Repeat	All		First time	Repeat	All	First time	Repeat	All
NSW/ACT	29 180	347 714	376 894	1	1	2	**NSW/ACT**	432 729	3 605 419	4 038 148	9	1	10
Number (*Number per 100 000 donations)*				*3.43*	*0.29*	*0.53*	Number (*Number per 100 000 donations)*				*2.08*	*0.03*	*0.25*
NT	727	9 053	9 780	0	0	0	**NT**	8 243	99 419	107 662	0	0	0
Number (*Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*	Number (*Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*
QLD	18 914	242 615	261 529	0	0	0	**QLD**	256 790	2 347 567	2 604 357	5	0	5
Number (*Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*	Number (*Number per 100 000 donations)*				*1.95*	*0.00*	*0.19*
SA	6 202	116 691	122 893	0	0	0	**SA**	96 914	1 189 268	1 286 182	3	0	3
Number (*Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*	Number (*Number per 100 000 donations)*				*3.10*	*0.00*	*0.23*
TAS	2 807	47 002	49 809	0	0	0	**TAS**	32 256	401 607	433 863	0	0	0
Number (*Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*	Number (*Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*
VIC	22 966	300 366	323 332	2	0	2	**VIC**	265 309	2 760 238	3 025 547	17	0	17
Number (*Number per 100 000 donations)*				*8.71*	*0.00*	*0.62*	Number (*Number per 100 000 donations)*				*6.41*	*0.00*	*0.56*
WA	8 942	118 145	127 087	0	0	0	**WA**	103 897	1 159 290	1 263 187	5	0	5
Number (*Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*	Number (*Number per 100 000 donations)*				*4.81*	*0.00*	*0.40*
National	89 738	1 181 586	1 271 324	3	1	4	**National**	1 196 138	11 562 808	12 758 946	39	1	40
Number (*Number per 100 000 donations)*				*3.34*	*0.08*	*0.31*	Number (*Number per 100 000 donations)*				*3.26*	*0.01*	*0.31*

First-time donors:

The prevalence of HTLV infection in first-time donors remained very low over the past ten years, 2006-2015, and has shown no significant trend (Table 33); from 2.4 per 100 000 donations in 2006, to 0.8 per 100 000 donations in 2010, and 3.3 per 100 000 donations in 2015 (Figure 29). There has been a more than three-fold increase in the prevalence of HTLV infection in the first-time donors in 2015 (3.3 per 100 000 donations) as compared to 2014 (1.1 per 100 000 donations), which is not unexpected given the low numbers can cause baseline fluctuation (Figure 29).

Table 33 Trends in prevalence of HTLV infection in All Donors and First-Time Donors, 2006-2015

	Trends in prevalence of HTLV Infection in Australia, 2006-2015	
Prevalence	**IRR (95% CI)**	**p-value**
All donors	*0.99 (0.88-1.10)*	*0.86*
First-time donors	*1.02 (0.91-1.15)*	*0.61*

Figure 29 Prevalence of HTLV infection in first time blood donors in Australia, 2006-2015, by year of donation

Trends in incidence

The HTLV incidence infection among repeat Australian donors in 2015 was zero, as it was for the averaged ten-year period 2006-2015. Of note, one lapsed donor from 2007 seroconverted in 2015; however this case does 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 2006-2015.

Trends in HTLV infection by state/territory

In 2015, HTLV infection prevalence in first-time donors was zero in all jurisdictions except New South Wales/ Australian Capital Territory and Victoria where the prevalence was 3.43 and 8.71 per 100 000 donations, respectively (Figure 30). No significant trend was observed for prevalence in the first-time donors during period 2006-2015 (Table 34). The prevalence of HTLV infection in the first-time donors has remained zero in Northern Territory and Tasmania during the ten year study period, 2006-2015 (Figure 30 and Table 35).

No incident HTLV infected donors where reported during 2015, and HTLV incidence has remained zero in the ten-year period 2006-2015 with the last incident donor identified in 2004.

Figure 30 Prevalence of HTLV infection among first-time donors by state/territory and year of donation, 2006-2015

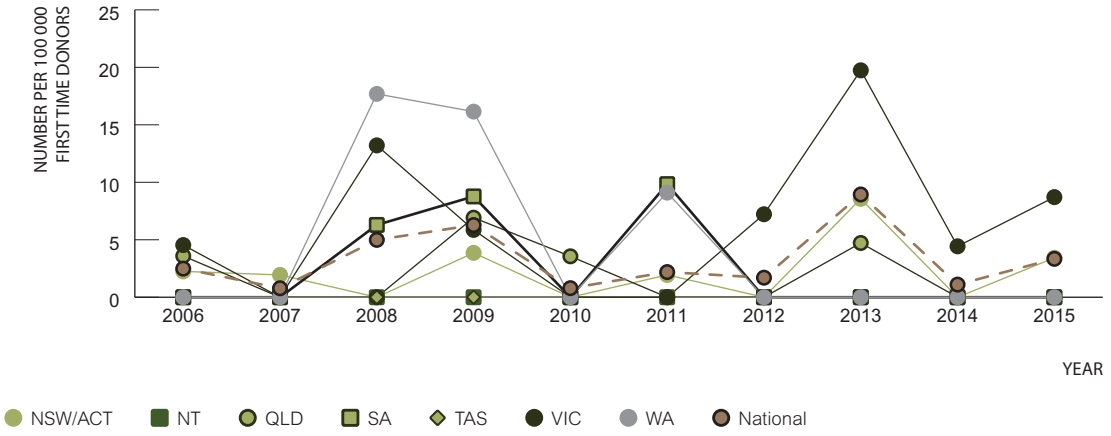


Table 34 Trend in Prevalence of HTLV Infection in First-Time Donors, by State and Territory - 2006-2015

	Prevalence of HTLV Infections in First-Time Donors, 2006-2015	
	IRR (95% CI)	**p-value**
NSW/ACT	*1.08 (0.85-1.37)*	*0.50*
NT	…	…
QLD	*0.90 (0.65-1.26)*	*0.56*
SA	*0.93 (0.60-1.44)*	*0.76*
TAS	…	…
VIC	*1.09 (0.91-1.30)*	*0.30*
WA	*0.84 (0.60-1.19)*	*0.34*

Table 35 Number and prevalence[1] of HTLV infection among first-time donors, 2006-2015, by state/territory and year of donation

	2006			2007			2008			2009		
State/Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate
NSW/ACT	44 499	1	2.25	51 427	1	1.94	48 607	0	0.00	51 821	2	3.86
NT	823	0	0.00	759	0	0.00	815	0	0.00	965	0	0.00
QLD	27 873	1	3.59	28 575	0	0.00	29 498	0	0.00	28 889	2	6.92
SA	11 457	0	0.00	10 886	0	0.00	15 908	1	6.29	11 400	1	8.77
TAS	2 899	0	0.00	2 650	0	0.00	3 936	0	0.00	3 736	0	0.00
VIC	22 016	1	4.54	23 172	0	0.00	30 286	4	13.21	34 133	2	5.86
WA	11 116	0	0.00	11 292	0	0.00	11 307	2	17.69	12 387	2	16.15
Total	**120 683.00**	**3**	**2.49**	**128 761**	**1**	**0.78**	**140 357**	**7**	**4.99**	**143 331**	**9**	**6.28**

	2010			2011			2012			2013		
State/Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate
NSW/ACT	48 130	0	0.00	51 528	1	1.94	41 780	0	0.00	35 060	3	8.56
NT	799	0	0.00	772	0	0.00	937	0	0.00	853	0	0.00
QLD	28 097	1	3.56	28 839	0	0.00	24 881	0	0.00	21 181	1	4.72
SA	9 284	0	0.00	10 164	1	9.84	8 900	0	0.00	6 417	0	0.00
TAS	3 222	0	0.00	3 587	0	0.00	3 823	0	0.00	3 058	0	0.00
VIC	25 820	0	0.00	31 286	0	0.00	27 718	2	7.22	25 332	5	19.74
WA	11 149	0	0.00	10 992	1	9.10	9 925	0	0.00	8 815	0	0.00
Total	**126 501**	**1**	**0.79**	**137 168**	**3**	**2.19**	**117 964**	**2**	**1.70**	**100 716**	**9**	**8.94**

	2014			2015			Total 2006-2015		
State/Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate
NSW/ACT	30 697	0	0.00	29 180.00	1.00	3.43	432 729	9	2.08
NT	793	0	0.00	727.00	0.00	0.00	8 243	0	0.00
QLD	20 043	0	0.00	18 914.00	0.00	0.00	256 790	5	1.95
SA	6 296	0	0.00	6 202.00	0.00	0.00	96 914	3	3.10
TAS	2 538	0	0.00	2 807.00	0.00	0.00	32 256	0	0.00
VIC	22 580	1	4.43	22 966.00	2.00	8.71	265 309	17	6.41
WA	7 972	0	0.00	8 942.00	0.00	0.00	103 897	5	4.81
Total	**90 919**	**1**	**1.10**	**89 738.00**	**3.00**	**3.34**	**1 196 138**	**39**	**3.26**

[1] Rate per 100 000 first-time donations

* During period 2006-2015, there is only one repeat donor identified as positive for HTLV infection (in 2015). Therefore, the table for number/rate of HTLV infection among repeat donor is not shown separately

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 2015, and the ten-year study period 2006-2015 was 3.3 and 3.2 per 100 000 donations, respectively (Table 35). However, population prevalence for HTLV infection is unknown; 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 2015, and the five-year period, 2011-2015, separately (Table 36). 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.

Table 36 Association of demographic characteristics with presence of HTLV infection among blood donors in Australia, 2015

	HTLV 2015				HTLV 2011-2015			
	Number of donors	Number of positive donors *(Number per 100 000 donors)*	IRR and their 95% CI (Multivariate adjusted)	p-value	Number of donors	Number of positive donors *(Number per 100 000 donors)*	IRR and their 95% CI (Multivariate adjusted)	p-value
Sex								
Male	*233 263*	*3 (1.29)*	*1 (ref)*	*…*	*1 279 978*	*12 (0.94)*	*1 (ref)*	*…*
Female	*230 874*	*1 (0.43)*	*0.37(0.03-3.58)*	*0.39*	*1 308 894*	*7 (0.53)*	*0.60 (0.23-1.54)*	*0.63*
Age group (years)								
20-29	*37 041*	*0 (0)*	*1 (ref)*	*…*	*370 863*	*0 (0)*	*1 (ref)*	*…*
Less than 20	*105 449*	*0 (0)*	*..*	*1*	*430 483*	*2 (0.46)*	*…*	*0.99*
30-39	*79 792*	*3 (3.76)*	*..*	*0.99*	*415 941*	*6 (1.44)*	*3.94 (0.79-19.57)*	*0.09*
40-49	*78 287*	*1 (1.28)*	*..*	*0.99*	*450 532*	*7 (1.55)*	*4.43 (0.91-21.38)*	*0.06*
50 and above	*163 568*	*0 (0)*	*..*	*1*	*921 053*	*4 (0.43)*	*1.23 (0.22-6.78)*	*0.8*
State/Territory								
NSW	*137 606*	*2 (1.45)*	*1 (ref)*	*…*	*796 480*	*3 (0.38)*	*1 (ref)*	*…*
ACT	*11 793*	*0 (0)*	*..*	*0.99*	*67 233*	*3 (4.46)*	*…*	*0.99*
NT	*3 442*	*0 (0)*	*..*	*0.99*	*20 192*	*0 (0)*	*…*	*0.99*
QLD	*92 421*	*0 (0)*	*..*	*0.99*	*518 071*	*1 (0.19)*	*0.24 (0.02-2.06)*	*0.19*
SA	*41 670*	*0 (0)*	*..*	*0.99*	*238 108*	*1 (0.42)*	*0.55 (0.06-4.58)*	*0.58*
TAS	*15 355*	*0 (0)*	*..*	*0.99*	*82 675*	*0 (0)*	*…*	*0.99*
VIC	*119 821*	*2 (1.67)*	*1.08(0.15-7.71)*	*0.93*	*636 681*	*10 (1.57)*	*1.98 (0.72-5.45)*	*0.18*
WA	*42 029*	*0 (0)*	*..*	*0.99*	*229 432*	*1 (0.44)*	*0.54 (0.06-4.50)*	*0.57*
Total	464 137	4 (0.86)			2 588 872	19 (0.73)		

In 2015, there was no significant association between gender and HTLV infection status. Given the small number of donors with HTLV infection in 2015, no meaningful analysis was possible for association between HTLV positivity and donors' age group or location (Table 36).

During the five-year period, 2011-2015, there was no significant association between gender, age & donor location and HTLV infection status (Table 36).

Risk factors associated with HTLV infected donors

Only 19 donors were positive for HTLV infection during the 2011-2015 period; 18 were first-time donors, the only repeat positive donor was identified in 2015; 63% were male, and the mean age was 43 years (Table 37). The majority of the HTLV positive donors (84%) were born overseas. Ethnicity or country of birth (79%) 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 (16%). 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 2011-2015.

Table 37 Characteristics of donors positive for HTLV infection by year of donation, 2011-2015

Characteristics	2011	2012	2013	2014	2015	2011-2015
Number of positive donors	3	2	9	1	4	19
Number of positive first-time donors (%)	3 (100%)	2 (100%)	9 (100%)	1 (100%)	3 (75%)	18 (95%)
% male	1 (33%)	2 (100%)	5 (56%)	1 (100%)	3 (75%)	12 (63%)
Mean age (range) in years	38 (23 to 46)	32 (27 to 37)	45 (30 to 58)	68	33(30-40)	43 (23 to 68)
Number of incident donors	0	0	0	0	0	0
% born in Australia	0 (0%)	0 (0%)	2 (22%)	0 (0%)	1(25%)	3 (16%)
Main reported risk factor	Ethnicity/COB[1]	Ethnicity/COB[1]	Ethnicity/COB[1]	Ethnicity/COB[1]	Ethnicity/COB[1]	Ethnicity/COB[1]
	66%	100%	78%	100%	75%	79%
Second reported risk factor	Tattoo/Body piercing	...	Partner with known risk or known to be positive		Partner with known risk or known to be positive	Partner with known risk or known to be positive
	33%		22%		25%	16%

1 COB = Country of Birth

Figure 31 Donors with HTLV infection by sex and donor status, 2011-2015

For more information on the number and percentage of donors with HTLV infection by sex, age group, donor status and country of birth for period 2011-2015, see Figure 31 and Appendix E.

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, evidence suggests that Aboriginal and Torres Strait Islander populations in inland Australian regions represent a high HTLV-1 endemic population.[17] 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.[18] This is consistent with the finding that ethnicity or country of birth was the likely infective risk in three of four HTLV positive donors in 2015.

Conclusion

- The prevalence of HTLV among first-time donors remained very low; however there are no data to compare prevalence rates in the general population.
- Infective 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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Active Syphilis

Main findings

1. There were five active syphilis infections detected among all donations in 2015.

2. The prevalence of active syphilis in first-time donors has shown no significant temporal change. In first-time donors the prevalence was 1.6 per 100 000 first-time donations in 2006, 3.9 per 100 000 first-time donations in 2010 and 2.2 per 100 000 first-time donations in 2015.

3. The mean age of active syphilis positive donors in 2014-2015 was 35 years (compared to 41.5 years for all donors). Donors with active syphilis were more likely to be male as compared to all donors (87% versus 50%).

4. The most common likely route of exposure for donors with active syphilis in 2014 and 2015 was having a partner with known risk, or known to be positive.

Epidemiology of Infectious Syphilis in Australia

Population level data is available on notifications of infectious syphilis. To distinguish between active and infectious syphilis, the two definitions are presented here: Active syphilis is defined by reactivity on treponemal and non-treponemal syphilis testing and/or clinically apparent infection (i.e. excluding past treated infections or latent syphilis).[19] Infectious syphilis, on the other hand, is defined as syphilis infection of less than two years duration (including primary, secondary and early latent stages).[20] Although the two definitions are slightly different - where active syphilis diagnoses might not include cases that are in the (early) latent stage, 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 2015 was 2 736.[1] An expanded national infectious syphilis case definition was implemented in July 2015[20] which includes a new subcategory of 'probable' infectious syphilis. The probable category was developed to capture infectious syphilis cases in people without a prior testing history. Of the 2 736 cases of infectious syphilis notified in 2015, 233 cases were categorised as probable, accounting for 12% of the 36% increase in notifications between 2014 and 2015. The rate of diagnosis of infectious syphilis among men has increased in the past ten years, from 6.5 per 100 000 in 2006 to 21.0 per 100 000 in 2015 whereas the rate among women has fluctuated and remained low (2.5 per 100 000 in 2014).[1]

Trends in prevalence

All donors:

In the past ten years, 2006-2015, a total of 54 donors positive for active syphilis have been detected (29 first-time donors & 25 repeat donors) (Table 38). During the period 2006-2015, the overall prevalence of active syphilis infection among all donors remained very low at 0.4 per 100 000 donations (Table 38). Of note, the prevalence of active syphilis infection among all donors showed a slight but significant increase during 2005-2014; however during 2006-2015, no statistically significant trend was observed (Table 39) (Figure 32).

Figure 32 Prevalence of Active Syphilis in all blood donations in Australia, 2006-2015, by year of donation

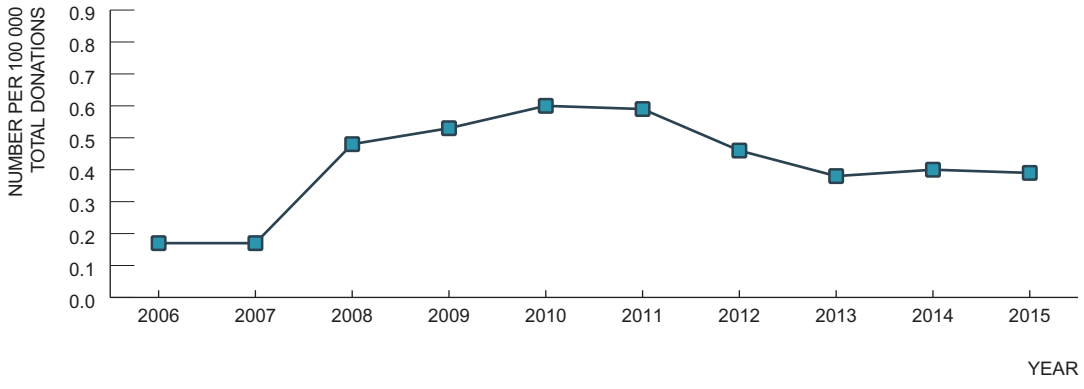


Table 38 The number and prevalence rate of Syphilis infection in Australia by state/territory, 2015 and 2006-2015

State/Territory of donation	All accepted donations 2015			Syphilis			State/Territory of donation	All accepted donations 2006-2015			Syphilis		
	First time	Repeat	All	First time	Repeat	All		First time	Repeat	All	First time	Repeat	All
NSW/ACT	29180	347 714	376 894	2	2	4	**NSW/ACT**	432 729	3 605 419	4 038 148	2	9	11
Number (*Number per 100 000 donations)*				*6.85*	*0.58*	*1.06*	Number (*Number per 100 000 donations)*				*0.46*	*0.25*	*0.27*
NT	727	9 053	9 780	0	0	0	**NT**	8 243	99 419	107 662	4	2	6
Number (*Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*	Number (*Number per 100 000 donations)*				*48.53*	*2.01*	*5.57*
QLD	18 914	242 615	261 529	0	0	0	**QLD**	256 790	2 347 567	2 604 357	8	4	12
Number (*Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*	Number (*Number per 100 000 donations)*				*3.12*	*0.17*	*0.46*
SA	6 202	116 691	122 893	0	0	0	**SA**	96 914	1 189 268	1 286 182	5	0	5
Number (*Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*	Number (*Number per 100 000 donations)*				*5.16*	*0.00*	*0.39*
TAS	2 807	47 002	49 809	0	0	0	**TAS**	32 256	401 607	433 863	0	1	1
Number (*Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*	Number (*Number per 100 000 donations)*				*0.00*	*0.25*	*0.23*
VIC	22 966	300 366	323 332	0	1	1	**VIC**	265 309	2 760 238	3 025 547	4	5	9
Number (*Number per 100 000 donations)*				*0.00*	*0.33*	*0.31*	Number (*Number per 100 000 donations)*				*1.51*	*0.18*	*0.30*
WA	8 942	118 145	127 087	0	0	0	**WA**	103 897	1 159 290	1 263 187	6	4	10
Number (*Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*	Number (*Number per 100 000 donations)*				*5.77*	*0.35*	*0.79*
National	89 738	1 181 586	1 271 324	2	3	5	**National**	1 196 138	11 562 808	12 758 946	29	25	54
Number (*Number per 100 000 donations)*				*2.23*	*0.25*	*0.39*	Number (*Number per 100 000 donations)*				*2.42*	*0.22*	*0.42*

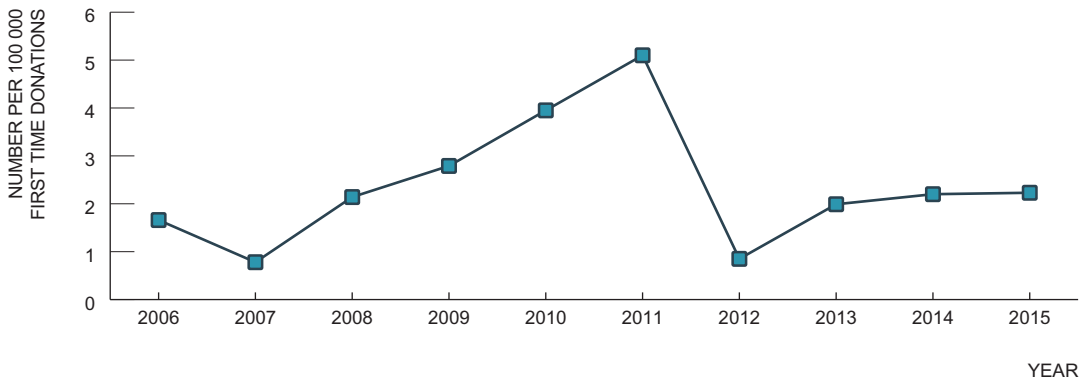
First-time donors:

In the past ten years, 2006-2015, the prevalence of active syphilis in first-time donors remained very low, at 2.4 per 100 000 donations (Table 38). Overall, the prevalence of active syphilis in first-time donors showed no significant trend during 2006-2015 (Table 39). The prevalence increased steadily from 0.7 per 100 000 first-time donations in 2007, and peaked at 5.1 per 100 000 first-time donations in 2011, and falling sharply in 2012 to 0.8 per 100 000 donations (Table 41). The prevalence has stabilised in the past three years, 2013-2015, at around 2 per 100 000 donations (Table 41 & Figure 33). By comparison, the rate of diagnoses of infectious syphilis reported through the Australian National Notifiable Diseases Surveillance System was 4.2 per 100 000 population in 2006, gradually declining in 2007-2010 before a steady increase from 5.1 per 100 000 population in 2010 to 8.7 per 100 000 population in 2014. The rate reached 11.8 per 100 000 population in 2015, corresponding to the highest recorded number of notifications, with 2 736 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.[20]

Table 39 Trends in prevalence of Active Syphilis in All Donors and First-Time Donors, 2006-2015

	Trends in prevalence of Active Syphilis Infection in Australia, 2006-2015	
Prevalence	**IRR (95% CI)**	**p-value**
All donors	*1.03 (0.94-1.14)*	*0.44*
First-time donors	*1.03 (0.90-1.17)*	*0.62*

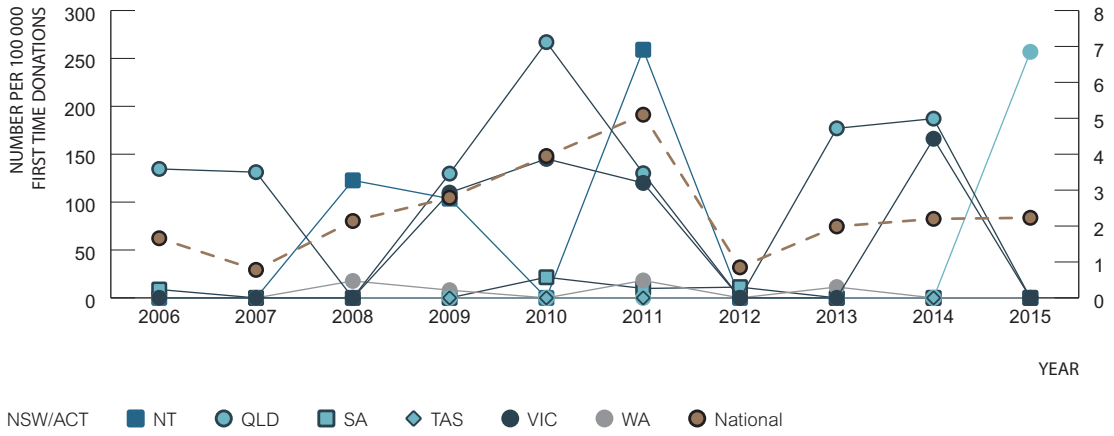
Figure 33 Prevalence of Active Syphilis in first time blood donors in Australia, 2006-2015, by year of donation



Trends in Active Syphilis infection by state/territory

The rate of active syphilis infection in blood donors remained low in 2015 with only five donors identified nationally (2 first-time and 3 repeat donors) (Table 41 & Table 42). In 2015, active syphilis prevalence in first-time donors was zero in all jurisdictions except New South Wales/ Australian Capital Territory, where the prevalence was 6.8 per 100 000 donations - remarkably, after remaining zero during the nine-year period, 2006-2014 (Figure 34). The prevalence of active syphilis in first-time donors in Tasmania remained zero over the last ten years. There were no discernible trends in the jurisdictional data during the ten-year study period, 2006-2015 (Table 40). In comparison, the trend in the general population over the past ten years, 2006-2015, shows an increase in rates of diagnosis of infectious syphilis in all jurisdictions; however, it is unclear as to what proportion is real increase versus increase due to change in case definition.[1]

Figure 34 Prevalence[1] of Active Syphilis among first-time donors by state/territory and year of donation, 2006-2015



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

Table 40 Trend in Prevalence of Active Syphilis in First-Time Donors, by State and Territory - 2006-2015

	Prevalence of HTLV Infections in First-Time Donors, 2006-2015	
	IRR (95% CI)	p-value
NSW/ACT*	…	…
NT	*0.91 (0.64-1.30)*	*0.61*
QLD	*0.98 (0.76-1.26)*	*0.89*
SA	*0.99 (0.72-1.37)*	*0.99*
TAS	…	…
VIC	*1.07 (0.75-1.54)*	*0.68*
WA	*0.97 (0.73-1.30)*	*0.86*

* Given the small number of first-time donors with active syphilis infection in period 2006-15 no meaningful analysis was possible for NSW/ACT

Table 41 Number and prevalence[1] of Active Syphilis among first-time donors, 2006-2015, by state/territory and year of donation

	2006			2007			2008			2009		
State/Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate
NSW/ACT	44 499	0	0.00	51 427	0	0.00	48 607	0	0.00	51 821	0	0.00
NT	823	0	0.00	759	0	0.00	815	1	122.70	965	1	103.63
QLD	27 873	1	3.59	28 575	1	3.50	29 498	0	0.00	28 889	1	3.46
SA	11 457	1	8.73	10 886	0	0.00	15 908	0	0.00	11 400	0	0.00
TAS	2 899	0	0.00	2 650	0	0.00	3 936	0	0.00	3 736	0	0.00
VIC	22 016	0	0.00	23 172	0	0.00	30 286	0	0.00	34 133	1	2.93
WA	11 116	0	0.00	11 292	0	0.00	11 307	2	17.69	12 387	1	8.07
Total	120 683.00	2	1.66	128 761	1	0.78	140 357	3	2.14	143 331	4	2.79

	2010			2011			2012			2013		
State/Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate
NSW/ACT	48 130	0	0.00	51 528	0	0.00	41 780	0	0.00	35 060	0	0.00
NT	799	0	0.00	772	2	259.07	937	0	0.00	853	0	0.00
QLD	28 097	2	7.12	28 839	1	3.47	24 881	0	0.00	21 181	1	4.72
SA	9 284	2	21.54	10 164	1	9.84	8 900	1	11.24	6 417	0	0.00
TAS	3 222	0	0.00	3 587	0	0.00	3 823	0	0.00	3 058	0	0.00
VIC	25 820	1	3.87	31 286	1	3.20	27 718	0	0.00	25 332	0	0.00
WA	11 149	0	0.00	10 992	2	18.20	9 925	0	0.00	8 815	1	11.34
Total	126 501	5	3.95	137 168	7	5.10	117 964	1	0.85	100 716	2	1.99

	2014			2015			Total 2006-2015		
State/Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate
NSW/ACT	30 697	0	0.00	29 180	2	6.85	432 729	2	0.46
NT	793	0	0.00	727	0	0.00	8 243	4	48.53
QLD	20 043	1	4.99	18 914	0	0.00	256 790	8	3.12
SA	6 296	0	0.00	6 202	0	0.00	96 914	5	5.16
TAS	2 538	0	0.00	2 807	0	0.00	32 256	0	0.00
VIC	22 580	1	4.43	22 966	0	0.00	265 309	4	1.51
WA	7 972	0	0.00	8 942	0	0.00	103 897	6	5.77
Total	90 919	2	2.20	89 738	2	2.23	1 196 138	29	2.42

1 Rate per 100 000 first-time donations

Table 42 Number and rate[1] of Active Syphilis among repeat donors, 2006–2015, by state/territory and year of donation

	2006			2007			2008			2009		
State/Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate
NSW/ACT	333 250	0	0.00	338 173	0	0.00	339 062	1	0.29	372 806	0	0.00
NT	8 496	0	0.00	10 214	0	0.00	11 166	0	0.00	11 158	1	8.96
QLD	216 496	0	0.00	209 556	0	0.00	226 726	0	0.00	242 001	1	0.41
SA	107 934	0	0.00	114 618	0	0.00	118 476	0	0.00	126 855	0	0.00
TAS	28 726	0	0.00	28 019	0	0.00	33 321	1	3.00	37 274	0	0.00
VIC	238 684	0	0.00	252 340	1	0.40	259 052	0	0.00	276 835	0	0.00
WA	99 376	0	0.00	109 425	0	0.00	113 274	1	0.88	118 327	1	0.85
Total	1 032 962	0	0.00	1 062 345	1	0.09	1 101 077	3	0.27	1 185 256	3	0.25

	2010			2011			2012			2013		
State/Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate
NSW/ACT	380 014	1	0.26	390 455	1	0.26	377 220	2	0.53	373 670	2	0.54
NT	10 470	1	9.55	10 782	0	0.00	9 673	0	0.00	9 493	0	0.00
QLD	243 837	1	0.41	245 975	0	0.00	237 599	0	0.00	243 042	1	0.41
SA	123 587	0	0.00	124 199	0	0.00	120 720	0	0.00	119 530	0	0.00
TAS	41 484	0	0.00	44 661	0	0.00	46 379	0	0.00	48 953	0	0.00
VIC	278 897	0	0.00	288 085	0	0.00	285 168	1	0.35	292 058	0	0.00
WA	120 646	0	0.00	121 057	0	0.00	117 728	2	1.70	123 298	0	0.00
Total	1 198 935	3	0.25	1 225 214	1	0.08	1 194 487	5	0.42	1 210 044	3	0.25

	2014			2015			Total 2006-2015		
State/Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate
NSW/ACT	353 055	0	0.00	347 714.00	2.00	0.58	3 605 419	9	0.25
NT	8 914	0	0.00	9 053.00	0.00	0.00	99 419	2	2.01
QLD	239 720	1	0.42	242 615.00	0.00	0.00	2 347 567	4	0.17
SA	116 658	0	0.00	116 691.00	0.00	0.00	1 189 268	0	0.00
TAS	45 788	0	0.00	47 002.00	0.00	0.00	401 607	1	0.25
VIC	288 753	2	0.69	300 366.00	1.00	0.33	2 760 238	5	0.18
WA	118 014	0	0.00	118 145.00	0.00	0.00	1 159 290	4	0.35
Total	1 170 902	3	0.26	1 181 586.00	3.00	0.25	11 562 808	25	0.22

1 Rate per 100 000 repeat donations

Comparison of prevalence of Active Syphilis infection among blood donors and the general population

As noted above, prevalence of active syphilis in the first-time donors in 2015, and the ten-year study period 2006-2015 was 2.2 and 2.4 per 100 000 donations, respectively (Table 41). 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 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 Active Syphilis in blood donors

Standardised national data on demographic factors associated with active syphilis infected donors are available on only 8 donors (3 from 2014 and 5 from 2015), precluding meaningful analysis.

Risk factors associated with Active Syphilis infected donors

As noted above, this report presents risk factors data for the five-year period - 2011 to 2015. During this period, a total of 29 donors were positive for active syphilis, of which only 8 have standardised risk factor data available (3 from 2014 and 5 from 2015), impeding any meaningful analysis for the entire period of 2011-2015. Grouped data for 2014-2015 is presented to preserve donors' privacy. Of note, in 2014, five donors were positive for active syphilis; of these risk factors data are available for only 3 donors. Of the 10 donors positive for active syphilis during 2014-15, 40% were first-time donors, 7 out of 8 (87%) were male (Table 43). The mean age was 35 (range 27-60). Partner with known risk, known to be positive (50%) was the most frequent likely risk factor for active syphilis positivity. In comparison, in 2015, nationally, 89.4% of infectious syphilis diagnoses were in males, 58% were in people aged 20-39 years.[1]

Table 43 Characteristics of donors positive for Active Syphilis by year of donation, 2014 and 2015

Characteristics	2014-2015
Number of positive donors	10
Number of positive first-time donors (%)*	3 (37.5%)
%* male	7 (87.5%)
Mean age (range) in years	35.12
Number of incident donors	N/A
%* born in Australia	4 (50%)
Main reported risk factor	Sexual partner with known risks/known to be positive 50%*
Second reported risk factor	Unknown 37%*

* % calculations are based on 8 donors (that have standardised risk data available) as the denominator.

Conclusion

- Overall, the prevalence of active syphilis among all blood donations during 2006-2015 has remained very low and no statistically significant trend was observed.
- Comparison between prevalence of 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.

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Additional information

Main findings

1. Over 17% of donors who were detected as infected with HIV, HCV, HBV, HTLV or active syphilis in 2011-2015 were confirmed 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. The non-compliance rate among TTI-positive donors has fluctuated in the last four years, from 12.9% in 2011 to 25% in 2014 and 17% in 2015. These findings highlight the importance of ongoing 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.

2. In 2015, a total 104 808 donations were tested for malaria antibody of which 1 451 (1.4%) were repeatedly reactive. Only one of these repeatedly reactive donors had detectable malaria DNA, suggesting current infection.

3. There were no reported cases of transfusion-transmitted malaria during 2015, with the last Australian case occurring in 1991.

4. 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.

5. Bacterial testing of 116 748 platelets identified 134 as confirmed positive.

6. Propionibacterium spp., which are common skin commensals were by far the most frequently isolated organisms (111). These organisms are rarely, if ever associated with septic transfusion reactions in recipients. Other potential contaminants included Streptococcus spp., Coagulase negative staphylococci and mixed organisms. A small number of clinically significant organisms including *Staphylococcus aureus, Serratia mercescens, Citrobacter braakii, Streptococcus pyogenes, Streptococcus pneumoniae* and *Streptococcus agalactae* group B were also detected. None of the contaminated platelets with significant organisms were transfused.

7. 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 West Nile Virus (WNV) outbreaks in Europe, large outbreaks of Ebola virus and Zika virus have also been closely monitored during 2015-2016. The risk to the blood supply posed by donors returning from Ebola virus and Zika virus outbreak areas has been managed by deferring or restricting donation to plasma sent for fractionation for an appropriate period.

Screening compliance

Every donor is required to self-complete a comprehensive donor questionnaire every time they donate, followed by a brief interview with Blood Service staff. The questionnaire asks about various medical conditions, travel history and activities related to increased risk of a blood-borne infection. The Blood Service is therefore highly reliant on donors truthfully answering all questions (i.e. 'compliance'). All donors undergo a confidential interview with a Blood Service staff during which the donor's eligibility to donate is determined and a legal binding declaration is signed by the donor before the donor can donate.

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.

Just over 17% (158 donors) of infected donors in 2011-2015 had risk factors identified during their post-donation interview that would have deferred them from donating had they disclosed their risk behaviour at the pre-donation interview (Table 44). Of these, 68% (107 donors) were first-time donors. The rate of non-compliance in TTI-positive donors appears to have been relatively stable for the past decade in the range 20-25%. The average rate observed in a previous Blood Service study[4] 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, 2008-2015

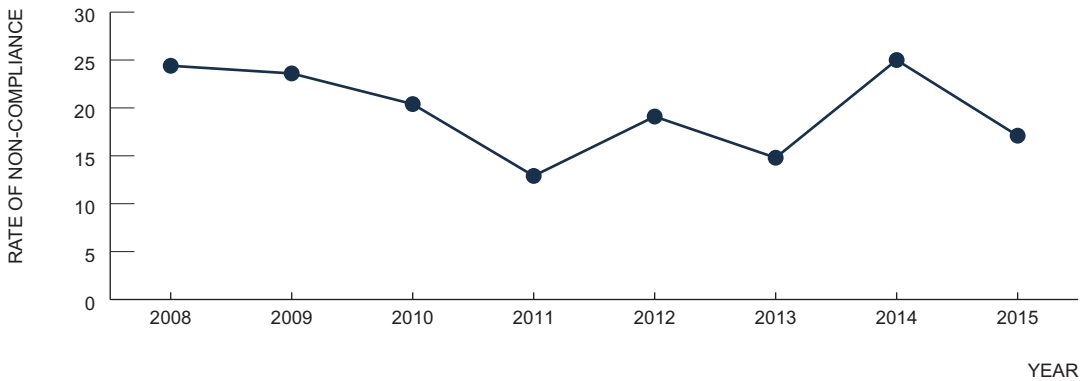

Table 44 Non-compliance category and rate among donors who were positive for HBV, HCV, HIV and HTLV, 2011-2015

Non-compliance by year and reason for deferral	2011	2012	2013	2014	2015	2011-2015
Number (%) of non-compliant donors by deferral category						
Intravenous drug user	15 (55.6)	21 (52.5)	13 (48.2)	19 (51.3)	14 (52)	82 (51.9)
Known status/previous positive	8 (29.6)	13 (32.5)	11 (40.7)	10 (27)	10 (37)	52 (32.9)
Male-to-male-sexual contact	0 (0)	0	2 (7.4)	2 (5.4)	1 (3.7)	5 (3.2)
Partner with known risk or known to be positive	3 (11.1)	4 (10)	1 (3.7)	4 (10.8)	1 (3.7)	13 (8.2)
Others	1 (3.7)	2 (5)	0 (0)	2 (5.4)	7 (26)	12 (7.6)
Total number (per 100 positive donors) of non-compliant donors by year	27 (12.9)	40 (19.1)	27 (14.8)	37 (25)	27* (17)	158 (17)

* In 2015, 6 out of 27 non-compliant donors had more than one reason for non-compliance hence the total% is more than 100%

Consistent with previous years, the majority of non-compliant positive donors in 2015 had a history of injecting drug use (52%); however, this proportion has been gradually declining over the past five years (from 77% in 2009 to 52% in 2015). Notably, this is a permanent donor deferral criterion in Australia irrespective of time since last episode of injection. Overall, during the period of 2011-2015, 51.9% of non-compliance was attributed to injecting drug use followed by known status of previously being positive for a virus (32.9%), having a sexual partner with known risk or known to be positive for any transfusion-transmissible infection (8.2%) and male-to-male sexual contact within the last 12 months (3.2%) (Table 44).

In the 2014 report, we presented results from a large national survey conducted among our donors in 2012-2013 which 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.[21, 22] Non-compliance with the 12-month deferral for male-to-male sex was 0.23%. This is generally lower than published overseas studies which range from 0.3-2.3%. The estimated prevalence of overall non-compliance (i.e. to at least one screening question related to the deferrals for injecting drug use, sex with an injecting drug user, male-to-male sex, sex worker activity/contact and sex with a partner from a high HIV prevalence country) was 1.65%. While these estimates are minimum estimates because non-compliant donors might have chosen not to take the survey or been non-compliant if they did, overall these findings are reassuring and support the effectiveness of the current screening questions.

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 the majority (55%) of the hepatitis B residual risk in Australia results from donors with OBI.[23]

Using viral testing data including the number of incident donors reported for the 2013 and 2014 calendar year periods and applying these to four published risk models, residual risk estimates[24] (per unit transfused) were derived for the four transfusion-transmissible viral infections subject to mandatory testing (Table 45). Of note, a revised model was applied to HBV which specifically addresses the risk of occult hepatitis B infection (OBI).[25] 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 45 Estimated risk of window period donation/risk of not detecting true infection for HBV, HCV, HIV, HTLV and syphilis in Australian blood donations (2013-2014)

	HBV	HCV	HIV	HTLV	Active syphilis
Estimated rate of collecting infectious unit (per million donations)	<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, at most one transfusion-transmission (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.[26] 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 are also tested for *Plasmodial* DNA to exclude current infection. Donors with detectable DNA are immediately referred for clinical assessment.

In 2015, 104 808 donations were tested for malaria antibody of which 1 451 (1.4%) were found to be repeat reactive for malaria antibodies. This rate of antibody detection is identical to the rate recorded in 2014. Only one of these 1 451 donations had detectable malaria DNA indicating current infection, while the remainder likely had past infection. Detecting malaria DNA among screened donations is rare, with only three occurrences since malaria testing commenced at the Blood Service in 2005. Like the donor detected in 2015 (who was born in Ghana), all three prior donors with detectable DNA were also born in malaria endemic countries and had very low parasite loads consistent with 'semi-immunity', a clinical state in which malaria parasites persist at low levels without symptoms of infection.

Minimising bacterial contamination of blood components

The risk of bacterial transmission following transfusion of platelets and red cells is the most common infectious risk of transfusion. International data indicates the risk of clinically apparent reactions to be at least 1:75 000[27] for platelets and 1:500 000[28] for red cells. Platelet transfusion is associated with the majority of the risk as unlike red cells and plasma which are stored refrigerated and frozen respectively, platelets are stored at room temperature providing an environment favourable for bacterial growth. This increases the risk that bacteria present in the donor's bloodstream, at the site of needle insertion or contaminating the blood bag can grow to levels that can cause 'septic' transfusion reactions in blood recipients.[29] Between 1:1 000 and 1:3 000 platelet units are bacterially contaminated at the time of transfusion which in the absence of screening is estimated to cause life-threatening sepsis in between 10-40% of recipients.

To minimise this risk the Blood Service employs a number of complementary strategies as follows:

1. **Pre-donation health screening**
   Using specific questions on the donor questionnaire donors are selected to exclude those having identified risks for bacterial contamination of blood components including recent dental procedures, gastrointestinal symptoms and skin lesions.

2. **Donor skin disinfection**
   Careful cleansing and validated disinfection of the site of needle insertion by the Blood Service phlebotomist effectively reduces the bacterial load and thus the likelihood of contamination of blood components.

3. **Flow diversion techniques**
   The Blood Service diverts the initial 30mL of blood away from the collection bag which has been shown to reduce the bacterial load in blood components by up to 70%.[30]

4. **Process control**
   The Blood Service operates within the principles of Good Manufacturing Practice (GMP) designed to ensure optimal process control. Key principles include the use of competent, trained staff adhering to documented standard operating procedures for donor assessment, aseptic collection of donations into sterile blood collection systems, processing via closed systems, storage and handling.

5. **Bacterial pre-release testing**
   Since 2008 the Blood Service has used an automated bacterial testing system (BacT/ALERT 3D) to test all platelets for bacterial contamination - prior to issue.[31]

Combined, these strategies substantially reduce but do not eliminate the residual risk of transfusion-transmissible bacterial infection.

Bacterial pre-release testing for platelets

Platelets are manufactured either from 'apheresis' collections or 'pooling' buffy coats from four whole blood collections. An apheresis donation can result in up to two platelet units whilst pooling results in a single platelet pack. Using a closed system 15-20 mL is removed from platelet packs no earlier than 24 hours after collection and samples are inoculated into aerobic and anaerobic culture bottles and incubated on the BacT/ALERT 3D system.

Platelets can be issued immediately after inoculation and the culture maintained for 7 days. Samples flagging as 'reactive' after platelet issue lead to immediate recall and clinician notification in the event they have already been transfused. All initially reactive samples are subject to further investigation and follow-up testing.

Table 46 Summary of bacterial testing of platelets by BacT/ALERT, 2015

Platelet type	No. components Screened	No. Initial positive[1] (%)	No. confirmed positive[2] (%)	No. indeterminate[3] (%)	No. false positive[4] (%)
Pooled platelets	87 870	411 (0.47)	125 (0.14)	98 (0.11)	188 (0.21)
Apheresis platelets	28 878	109 (0.38)	9 (0.03)	28 (0.1)	72 (0.25)
Total	116 748	520 (0.44)	134 (0.11)	126 (0.11)	260 (0.22)

1 A sample culture bottle which has flagged as initially positive by the BacT/ALERT screening system
2 One of the following occurs after identification of an organism in the original sample:
- A platelet component is available for retest and the same organism is identified
- Any other associated blood component has the same organism identified
- A recipient has a septic reaction following transfusion and the same organism is identified in both the patient's blood and a Blood Service component

3 An organism is identified in the original sample, however follow-up testing is inconclusive due to:
- The platelet component being unavailable for retest and other components from the same donation either screening as negative or being unavailable

4 Any of the following:
- The BacT/ALERT system flags a positive but no organisms are identified by confirmatory testing (gram stain, subculture and microbial identification by external Pathology provider) or;
- An organism is identified in the initial sample, but subsequent follow up testing of all associated platelet product(s) did not confirm the initial result

During 2015, 116 748 platelet units were screened for bacterial contamination (Table 46). Of the 28 878 apheresis units tested 109(0.38%) were flagged as initially positive however only 9(0.03%) were determined as 'confirmed positive' with an additional 28(0.1%) classified as 'indeterminate'. The remaining 72(0.61%) were classified as 'false positive' predominantly associated with anaerobic culture bottles. There were 87 870 pooled platelet units tested of which 411(0.47%) flagged as initially positive with 125(0.14%) determined as 'confirmed positive'. A further 98(0.11%) were classified as 'indeterminate' and the remaining 188 (0.21%) were classified as 'false positive'.

Propionibacterium spp., which are common skin commensals were by far the most frequently isolated organisms but are rarely, if ever associated with septic transfusion reactions in recipients. The propensity for Propionibacterium spp. to be contaminants likely relates to their colonisation of hair follicles and deep skin layers which are not reached by skin cleansing agents. The next most frequently isolated organisms, collectively termed coagulase-negative Staphylococci (CNS) are also common skin commensals, and often not clinically significant. However, these organisms can lead to intravascular grafts or catheter-associated bacteraemias or prosthetic devices infections particularly in immunocompromised patients.

A minority of platelets grew clinically-significant organisms (Table 47) 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. These included *Serratia marcescens Citrobacter braakii and Staphylococcus aureus*, as well as three Streptococci species : *Streptococcus pyogenes , Streptococcus pneumoniae and Streptococcus agalactiae* group B which are clinically significant. In all cases where an organism was detected, associated blood components were recalled and discarded prior to transfusion, thus preventing potential septic transfusion reactions. All our donors were clinically well during their donation. On donor follow up, one of the donors contributing to *Serratia marcescens* contaminated pooled platelets had a past history of urinary tract infection. One of the donors of *Streptococcus pneumoniae* contaminated platelets developed respiratory illness post donation and one of the donors of *Citrobacter braakii* contaminated platelets developed a febrile episode shortly after donation. Therefore microbial detection likely represents transient bacteraemia from a bowel, urinary tract, throat source or contaminated skin.

During 2015, no cases of septic transfusion reactions were identified in patients who received platelets.

Table 47 Summary of organisms detected in confirmed positives, 2015 (n=134)

Confirmed positive organisms	Number
Propionibacterium spp.	111
Coagulase Negative Staphylococci	10
Staphylococcus aureus	2
Streptococcus spp.	3
Serratia marcescens	1
Mixed - including *Citrobacter braakii*	7
Total	134

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 Advisory Committee (DAPS Advisory Committee) and risk assessment performed in the event that a threat 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).

2015-16 Summary:

Dengue

Dengue virus transmission by fresh blood components has been demonstrated and thus poses a risk to transfusion safety.[32] In January 2015, there were dengue fever outbreaks in the Cairns suburbs of Edmonton (carried over from 2014), Trinity Beach, Mooroobool, Tully/El Arish and Brinsmead. Subsequently, there were outbreaks in Innisfail (May) and Townsville (June). In 2016, to 11 August, there were dengue fever outbreaks in Townsville in February (closed in May), Charters Towers in March, three outbreaks in Cairns in March (closed June), May and July, and an outbreak in Cranbrook in May 2016.[33] To mitigate this risk, supplementary donor selection measures and product restrictions were implemented for travel to/residence in affected. Donations from these areas were restricted to plasma only which were subject 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)

Transmission of West Nile virus (WNV) by blood, tissue and organ transplantation has been documented.[34] 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 2015 transmission season (May to November) in the EU and neighbouring countries there were outbreaks of West Nile fever (WNF) in Austria (7 confirmed/probable cases), France (1), Hungary (18), Italy (61), Portugal (1), Romania (32), Israel (125), Palestine (1), Russian Federation (39) and , Serbia (28). The total number of reported confirmed/probable WNF Nile fever cases in 2015 was 315. This compares with 210, 785 and 937 cases in 2014, 2013 and 2012, respectively. For the 2016 transmission season to 3 Novemeber, the number of reported confirmed/probable cases of WNF in the EU and neighbouring countries was 467 and countries reporting the highest number of cases were Russia (135 cases), Romania (93), Israel (66), Italy (62), Serbia (41) and Hungary (39). Only a single case of WNF was reported in the week ending 3 November indicating the 2016 transmission season was coming to an end. The Blood Service monitors these outbreaks based on regular updates of WNV cases provided by the European Centre for Disease Prevention and Control (ECDC). During the transmission season, the Blood Service performs weekly risk modelling to estimate the risk of a donor returning from these countries reporting outbreaks 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 2015 and 2016 (to date) WNV transmission season did not exceed the threshold (established for local dengue outbreaks) that requires cessation of fresh blood component manufacture.[35, 36]

Hendra virus

Human Hendra virus (HeV) infection is an emerging Australian zoonotic disease associated with high mortality (4/7 infections fatal).[37] To date all seven recorded cases of HeV transmission to humans have occurred from *Pteropus* bats (flying foxes) via horses. While no cases of human HeV infection were recorded in 2015 or 2016 to date, there were 2 reported equine cases in 2015, 1 in Queensland and 1 in New South Wales. There have been no reported cases of equine HeV cases in 2016 to date (12 October).[38, 39] Since 1994 there have been 94 reported equine cases in Australia of which 84 were fatal.[40] 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. It is predicted that the risk of human infection would progressively decline as the

number of susceptible horses diminishes due to the impact of vaccination. However, the reporting of occasional 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.[37] 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 from 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 MERS_CoV clusters, subsequent human-to-human transmission is the most common mode of ongoing transmission.[41] 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, approximately 310 cases were reported in 2013, 638 in 2014, 680 in 2015 and 200 in 2016 (to 31 October).As at October 2016, approximately 81% of human MERS-CoV cases had been reported in Saudi Arabia. The largest outbreak of MERS-CoV outside the Middle East occurred in South Korea between May and July 2015 with 186 confirmed locally acquired cases. The Korean outbreak was due to an imported case followed by nosocomial transmission. In its most recent update (25 July 2016) WHO maintained it assessment that given the lack of evidence of sustained human-to-human transmission in the community, it does not recommend travel or trade restrictions with regard to MERS-CoV. In its most recent risk assessment (August 2015), the ECDC concurred with the WHO assessment and noted that the risk of widespread transmission of MERS-CoV in the community after sporadic importation into the EU/EEA remains low. 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.[42-44]

Ebola viruses

There are 5 known species of the *Ebola virus* genus which belongs to the *Filoviridae* family and are referred to collectively as ebolaviruses. The first reported outbreak of ebolavirus disease (EVD) was reported in 1976 in Sudan and Democratic Republic of the Congo. Between 1976 and 2013 there were 20 reported EVD outbreaks, all in equatorial African countries. Ebola virus infection causes severe disease in humans, including internal and external haemorrhaging, with a case fatality rate of about 50%. In March 2014, an EVD outbreak was reported in West Africa and quickly became the largest known outbreak. The virus species was identified as Zaire ebolavirus, also referred to as Ebola virus (EBOV). The worst affected countries, which accounted for most (>99.9%) reported cases of EVD were Guinea, Liberia and Sierra Leone. The outbreak continued for 2 years until March 29, 2016, when WHO announced that the outbreak of EVD in the countries of West Africa was no longer a Public Health Emergency of International Concern (PHEIC). As at 10 June 2016, a total of 28 616 confirmed, probable and suspected cases have been reported in Guinea, Liberia and Sierra Leone, with 11 310 deaths. The current risk posed by EBOV to Australia's blood safety is considered to be very low. 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 is managing 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, respectively. Additionally, donors who have travelled to countries defined as risk areas for ebolavirus are deferred from donating for 8 weeks after leaving the risk area.[45, 46]

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 3 main ZIKV lineages, one from Asia and two from Africa.[47] 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 which was first report in early 2015, remains ongoing and is the largest ever reported ZIKV outbreak.[48] By 3 November, 2016 a total of 515, 348 suspected ZIKV cases and 168,258 confirmed cases had been reported by countries and territories in the Americas. Countries with the highest number of reported suspected/confirmed cases were Brazil (200,465/109,596), Colombia (95,929/8,826), Venezuela (58,758/2,244), Martinique (36,590/12), Honduras (31,719/285) and Guadeloupe (30,755/379)[49] In July 2016, local transmission of ZIKV was first reported on the US mainland when cases were reported in Florida. As at the 2 November, 139 cases of locally transmitted ZIKV had been reported, all in Florida.[50]

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 has increased with 53 cases reported as at 4 November, 2016. All of these 53 cases were imported with 30 (56.6%) acquired in the Pacific region and 23 (43.4%) in the Americas. The highest number of cases in 2016 to date have been reported in Queensland with 47.2% (25/53) of all Australian cases. Approximately 80% of ZIKV infections are asymptomatic and most symptomatic infections are accompanied by mild symptoms including rash and fever.[47, 51] However, there is now a general consensus, based on an increasing body of evidence, 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).[52, 53] ZIKV is considered to be transfusion-transmissible as infection includes an asymptomatic vireamic phase and 4 cases of transfusion-transmitted ZIKV infection have been reported.[54-57]

In response to the potential risk of ZIKV to blood safety in Australia, the Blood Service has implemented a number of donor deferrals. To date (9 November, 2016), all countries that have reported autochthonous cases of ZIKV transmission in the recent outbreaks in the Western Pacific and Americas are 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 6-month 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 infectious diseases. 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,[58, 59] at present ZIKV is considered to represent a low risk to blood safety in Australia.

Hepatitis E (HEV)

HEV has been recognised as disease of emerging importance in international blood safety. Hepatitis E is a known TTI and the prevalence of the virus in asymptomatic blood donors internationally has been found to be considerably higher than expected.[60, 61] However, HEV is a rarely notified disease in Australia[62] and the risk to Blood Safety in Australia is lower than other developed nations. However, given the prevalence of HEV in Australian blood donors is uncertain, the Blood Service is completing a study to determine the risk HEV poses to blood safety in Australia.

Ross River virus (RRV)

The first probable case of transfusion-transmitted Ross River virus (RRV) in Australia occurred in 2014.[63] In 2015 Australia reported its largest ever RRV outbreak with approximately twice the usual number of RRV notifications.[64] No transfusion-transmissions were reported during this large outbreak. The risk of a severe adverse transfusion outcome is low and given the generally low severity of the illness, the Blood Service managed this risk by strengthening the information given to donors about reporting post-donation illnesses.[65]

Conclusion

- The non-compliance rate has decreased to 17% as compared to the record high of 25% in 2014; although this drop in the non-compliance rate is encouraging, it stills 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.
- Bacterial screening of 116 748 platelets identified 134 (0.1%) as confirmed positive. 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 2015, no septic transfusion reactions were identified in patients who received platelets.
- 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 2015-2016. The risk to the blood supply posed by donors returning from ebolavirus and Zika virus outbreak areas has been managed by deferring or restricting donation to plasma sent for fractionation for an appropriate period.

Appendices

Appendix A

Table A 1 Screening tests for transfusion transmissible infections

Transfusion-Transmissible infection	Mandatory screening tests	Test Target	Year of introduction	Median window period estimate	Residual risk of transmission (per unit transfused)
Syphilis	*Treponema pallidum* Haemagglutination Assay (TPHA)	Antibodies to *Treponema pallidum*	~1949	45 days	---
HBV	HBsAg[1]	Hepatitis B surface antigen (HBsAg)	1970	38 days	–
	Nucleic Acid Test for HBV	HBV DNA	2010	15 days	<1 in 1 million
HIV	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	–
	Nucleic Acid Test for HIV 1[2]	HIV 1 RNA	2000	5.9 days	<1 in 1 million
HCV	anti-HCV*	Antibody to HCV	1990	66 days	---
	Nucleic Acid Test for HCV[2]	hepatitis C 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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Appendices

Appendix B

Table B 1 Number and percentage of donors with HBV infection, 2011-2015, by year of donation, sex and age group

	Year of donation													
	2011		2012		2013		2014		2015		2011-2015			
Donor status	M	F	M	F	M	F	M	F	M	F	M	F	Total	%
First-time donors														
<20 years	6	7	3	6	9	7	3	2	6	2	27	24	51	10.2
20-29 years	17	12	28	7	18	7	9	6	14	5	86	37	123	24.7
30-39 years	17	5	18	6	16	4	9	3	18	6	78	24	102	20.5
40-49 years	16	4	10	5	9	0	7	7	6	5	48	21	69	13.9
50-59 years	5	5	11	2	8	3	9	3	5	3	38	16	54	10.8
60 years and above	4	1	0	1	3	1	4	3	1	1	12	7	19	3.8
Repeat donors														
<20 years	0	0	0	0	0	0	0	1	0	0	0	1	1	0.2
20-29 years	0	0	0	0	0	2	2	1	0	0	2	3	5	1.0
30-39 years	3	0	2	0	1	1	0	0	2	0	8	1	9	1.8
40-49 years	2	0	1	0	0	0	3	1	1	0	7	1	8	1.6
50-59 years	6	2	7	0	4	0	4	2	3	1	24	5	29	5.8
60 years and above	3	3	4	2	4	2	5	0	2	3	18	10	28	5.6
Total	79	39	84	29	72	27	55	29	58	26	348	150	498	100

Table B 2 Number and percentage of donors with HBV infection, 2011-2015, by year of donation and country/region of birth*

	2011		2012		2013		2014		2015		2011-2015	
Region of birth	Number	%	Number	%	Number	%	Number	%	Number	%	Number	%
Australia	15	13	19	17	14	14	15	18	8	10	71	14
Overseas born												
Other Oceania	15	13	10	9	14	14	10	12	8	10	57	11
United Kingdom and Ireland	2	2	1	1	1	1	1	1	0	0	5	1
Other Europe	5	4	9	8	10	10	16	19	2	2	42	8
Middle East/North Africa	10	8	4	4	2	2	1	1	5	6	22	4
Sub-Saharan Africa	4	3	4	4	3	3	3	4	3	4	17	3
South & North East Asia	45	38	51	45	43	43	26	31	36	43	201	40
Southern and Central Asia	14	12	14	12	10	10	12	14	22	26	72	14
North America	0	0	0	0	0	0	0	0	0	0	0	0
South/Central America and the Caribbean	0	0	1	1	0	0	0	0	0	0	1	0
Total with a reported country of birth	110	93	113	100	97	98	84	100	84	100	488	98
Not reported	8	7	0	0	2	2	0	0	0	0	10	2
Total	118	100	113	100	99	100	84	100	84	100	498	100

* Region of birth from the Australian Bureau of Statistics

Table B 3 Number and percentage of hepatitis B infection among first-time donors, 2011-2015, by potential reported exposure category and sex

	2011		2012		2013v		2014		2015		Total (2011-2015)			
Exposure categories	M	F	M	F	M	F	M	F	M	F	M	F	Total	%
Ethnicity/Country of birth	56	32	66	24	59	22	35	19	50	19	266	116	382	91.4
Intravenous drug user	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Tattoo/Piercing	1	1	0	2	0	0	1	2	0	0	2	5	7	1.7
Partners with any risks or known to be positive	1	0	1	1	0	0	4	0	0	1	6	2	8	1.9
Male-to-male sexual contact	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Exposure in health care setting	0	0	0	0	0	0	1	1	0	0	1	1	2	0.5
Engaged in sex work	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
Household contact	0	0	3	0	1	0	0	2	0	1	4	3	7	1.7
Other blood to blood contact	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Other	1	0	0	0	2	0	0	0	0	1	3	1	4	1.0
											0	0		
No risk factors identified	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Not reported	6	1	0	0	1	0	0	0	0	0	7	1	8	1.9
Total	65	34	70	27	63	22	41	24	50	22	289	129	418	100

Table B 4 Number and percentage of hepatitis B infection among repeat donors, 2011-2015 by potential reported exposure category and sex

	2011		2012		2013		2014		2015		Total (2011-2015)			
Exposure categories	M	F	M	F	M	F	M	F	M	F	M	F	Total	%
Ethnicity/Country of birth	10	2	8	2	6	2	8	3	6	3	38	12	50	62.5
Intravenous drug user	0	0	0	0	0	1	1	0	0	0	1	1	2	2.5
Tattoo/Piercing	0	1	1	0	1	0	0	0	0	0	2	1	3	3.8
Partners with any risks or known to be positive	1	1	2	0	1	0	3	0	1	0	8	1	9	11.3
Male-to-male sexual contact	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Exposure in health care setting	1	0	2	0	0	1	1	1	0	1	4	3	7	8.8
Engaged in sex work	0	0	1	0	0	0	0	0	0	0	1	0	1	1.3
Blood or tissue recipient	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Household contact	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
Other	2	0	0	0	0	0	0	0	1	0	3	0	3	3.8
No risk factors identified	0	1	0	0	1	1	1	1	0	0	2	3	5	6.3
Not reported	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Total	14	5	14	2	9	5	14	5	8	4	59	21	80	100

Appendices

Appendix C

Table C 1 Number and percentage of donors with HCV infection, 2011-2015, by year of donation, sex and age group

	Year of donation													
	2011		2012		2013		2014		2015		2011-2015			
Donor status	M	F	M	F	M	F	M	F	M	F	M	F	Total	%
First-time donors														
<20 years	2	1	1	2	0	0	0	3	3	1	6	7	13	3.6
20-29 years	8	6	7	4	5	2	2	0	3	5	25	17	42	11.7
30-39 years	11	2	9	6	9	2	3	0	3	2	35	12	47	13.1
40-49 years	12	4	9	4	7	6	4	3	4	2	36	19	55	15.3
50-59 years	6	5	12	11	10	7	10	1	12	4	50	28	78	21.7
60 years and above	1	1	1	1	1	3	4	1	3	1	10	7	17	4.7
Repeat donors														
<20 years	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
20-29 years	1	0	0	0	2	0	1	3	1	1	5	4	9	2.5
30-39 years	0	0	2	0	1	1	0	1	1	1	4	3	7	1.9
40-49 years	5	2	8	3	4	4	2	2	0	2	19	13	32	8.9
50-59 years	8	5	4	3	3	2	6	3	8	4	29	17	46	12.8
60 years and above	1	0	3	1	1	0	5	2	1	0	11	3	14	3.9
Total	55	26	56	35	43	27	37	19	39	23	230	130	360	100

Table C 2 Number and percentage of donors with HCV infection, 2011-2015, by year of donation and country/region of birth*

	2011		2012		2013		2014		2015		2011-2015	
Region of birth	Number	%	Number	%	Number	%	Number	%	Number	%	Number	%
Australia	51	63	62	68	41	59	44	79	43	69	241	67
Overseas born												
Other Oceania	4	5	6	7	4	6	3	5	1	2	18	5
United Kingdom and Ireland	3	4	6	7	6	9	2	4	4	6	21	6
Other Europe	2	2	3	3	7	10	1	2	1	2	14	4
Middle East/North Africa	0	0	1	1	0	0	0	0	0	0	1	0
Sub-Saharan Africa	0	0	1	1	1	1	1	2	1	2	4	1
South & North East Asia	11	14	4	4	4	6	2	4	3	5	24	7
Southern and Central Asia	3	4	2	2	4	6	2	4	6	10	17	5
North America	1	1	3	3	1	1	0	0	1	2	6	2
South/Central America and the Caribbean	0	0	0	0	0	0	0	0			0	0
Total with a reported country of birth	75	93	88	97	68	97	55	98	60	97	346	96
Not reported	6	7	3	3	2	3	1	2	2	3	14	4
Total	81	100	91	100	70	100	56	100	62	100	360	100

* Region of birth from the Australian Bureau of Statistics

Table C 3 Number and percentage of HCV infection among first-time donors, 2011-2015, by potential reported exposure category and sex

	2011		2012		2013		2014		2015		Total (2011-2015)			
Exposure categories	M	F	M	F	M	F	M	F	M	F	M	F	Total	%
Ethnicity/Country of birth	10	1	3	2	3	2	1	0	0	0	17	5	22	10.1
Intravenous drug user	7	2	10	4	9	2	10	1	5	1	41	10	51	23.5
Tattoo/Piercing*	8	3	0	0	10	6	5	0	10*	8	33	17	50	23.0
Partners with any risks or known to be positive	1	1	0	0	1	6	0	1	0	1	2	9	11	5.1
Male-to-male sexual contact	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Exposure in health care setting	0	2	2	0	4	1	0	0	3	0	9	3	12	5.5
Engaged in sex work	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Blood or tissue recipient	5	2	4	1	0	1	0	2	1	2	10	8	18	8.3
Household contact	1	4	2	2	0	1	0	2	4	0	7	9	16	7.4
Other blood to blood contact	3	2	0	0	1	0	1	0			5	2	7	3.2
Other	0	0	1	0	0	1	1	1	1	1	3	3	6	2.8
No risk factors identified	2	0	0	1	1	0	2	1	4	2	9	4	13	6.0
Not reported	3	2	0	0	3	0	3	0	0	0	9	2	11	5.1
Total	40	19	22	10	32	20	23	8	28	15	145	72	217	100

* Four out of 10 first time male donors positive for HCV in 2015 also had imprisonment as a risk factor alongside tattoo/piercing

Table C 4 Number and percentage of HCV infection among repeat donors, 2011-2015, by potential reported exposure category and sex

	2011		2012		2013		2014		2015		Total (2011-2015)			
Exposure categories	M	F	M	F	M	F	M	F	M	F	M	F	Total	%
Ethnicity/Country of birth	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Intravenous drug user	7	1	0	1	2	0	4	2	8	0	21	4	25	24.5
Tattoo/Piercing*	3	2	5	3	3	4	1	1	1	3	13	13	26	25.5
Partners with any risks or known to be positive	0	0	1	0	2	0	0	1	0	2	3	3	6	5.9
Male-to-male sexual contact	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Exposure in health care setting	0	2	2	1	1	2	2	1	0	0	5	6	11	10.8
Engaged in sex work	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Blood or tissue recipient	0	2	0	0	1	0	2	3	0	0	3	5	8	7.8
Household contact	2	0	0	1	0	0	2	1	0	0	4	2	6	5.9
Other blood to blood contact	0	0	1	0	1	0	1	0	0	0	3	0	3	2.9
Other	0	0	0	0	1	0	0	1	2	1	3	2	5	4.9
No risk factors identified	0	0	0	1	0	1	1	1	0	2	1	5	6	5.9
Not reported	3	0	2	0	0	0	1	0	0	0	6	0	6	5.9
Total	15	7	11	7	11	7	14	11	11	8	62	40	102	100

Appendices

Appendix D

Table D 1 Number and percentage of donors with HIV infection, 2011-2015, by year of donation, sex and age group

	Year of donation													
	2011		2012		2013		2014		2015		2011-2015			
Donor status	M	F	M	F	M	F	M	F	M	F	M	F	Total	%
First-time donors														
<20 years	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
20-29 years	3	0	0	0	1	0	1	0	0	1	5	1	6	26.1
30-39 years	0	0	1	0	0	0	0	1	0	0	1	1	2	8.7
40-49 years	1	0	0	0	0	0	0	1	0	0	1	1	2	8.7
50-59 years	0	0	1	0	1	0	0	0	0	0	2	0	2	8.7
60 years and above	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Repeat donors														
<20 years	0	0	1	0	0	0	0	0	0	0	1	0	1	4.3
20-29 years	0	1	0	0	0	0	2	0	0	0	2	1	3	13.0
30-39 years	0	0	0	0	1	0	0	0	1	0	2	0	2	8.7
40-49 years	0	1	0	0	0	0	1	0	0	0	1	1	2	8.7
50-59 years	0	0	0	0	0	0	1	0	0	0	1	0	1	4.3
60 years and above	1	0	0	0	1	0	0	0	0	0	2	0	2	8.7
Total	5	2	3	0	4	0	5	2	1	1	18	5	23	100

Table D 2 Number and percentage of donors with HIV infection, 2011-2015, by year of donation and country/region of birth*

	2011		2012		2013		2014		2015		2011-2015	
Region of birth	Number	%	Number	%	Number	%	Number	%	Number	%	Number	%
Australia	2	29	2	67	3	75	3	43	1	50	11	48
Overseas born												
Other Oceania	0	0	0	0	0	0	2	29	0	0	2	9
United Kingdom and Ireland	1	14	0	0	0	0	0	0	0	0	1	4
Other Europe	1	14	0	0	0	0	1	14	0	0	2	9
Middle East/North Africa	0	0	0	0	0	0	0	0	0	0	0	0
Sub-Saharan Africa	0	0	0	0	0	0	1	14	0	0	1	4
South & North East Asia	1	14	0	0	1	25	0	0	1	50	3	13
Southern and Central Asia	0	0	1	33	0	0	0	0	0	0	1	4
North America	0	0	0	0	0	0	0	0	0	0	0	0
South/Central America and the Caribbean	1	14	0	0	0	0	0	0	0	0	1	4
Total with a reported country of birth	6	86	3	100	4	100	7	100	2	100	22	96
Not reported	1	14	0	0	0	0	0	0	0	0	1	4
Total	7	100	3	100	4	100	7	100	2	100	23	100

* Region of birth from the Australian Bureau of Statistics

Table D 3 Number and percentage of HIV infection among first-time donors, 2011-2015, by potential reported exposure category and sex

	2011		2012		2013		2014		2015		Total (2011-2015)			
Exposure categories	M	F	M	F	M	F	M	F	M	F	M	F	Total	%
Ethnicity/Country of birth	0	0	0	0	1	0	0	1	0	0	1	1	2	16.7
Intravenous drug user	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Tattoo/Piercing	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Partners with any risks or known to be positive	3	0	1	0	0	0	0	0	0	0	4	0	4	33.3
Male-to-male sexual contact	1	0	1	0	1	0	1	0	0	0	4	0	4	33.3
Exposure in health care setting	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Engaged in sex work	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Blood or tissue recipient	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Household contact	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
Other	0	0	0	0	0	0	0	0	0	1	0	1	1	8.3
No risk factors identified	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Not reported	0	0	0	0	0	0	0	1	0	0	0	1	1	8.3
Total	4	0	2	0	2	0	1	2	0	1	9	3	12	100

Table D 4 Number and percentage of HIV infection among repeat donors, 2011-2015, by potential reported exposure category and sex

	2011		2012		2013		2014		2015		Total (2011-2015)			
Exposure categories	M	F	M	F	M	F	M	F	M	F	M	F	Total	%
Ethnicity/Country of birth	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Intravenous drug user	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Tattoo/Piercing	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Partners with any risks or known to be positive	0	1	1	0	0	0	1	0	0	0	2	1	3	27.3
Male-to-male sexual contact	0	0	0	0	2	0	2	0	0	0	4	0	4	36.4
Exposure in health care setting	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Engaged in sex work	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Blood or tissue recipient	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Household contact	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Other blood to blood contact	1	0	0	0	0	0	0	0	0	0	1	0	1	9.1
Other	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
No risk factors identified	0	0	0	0	0	0	1	0	1	0	2	0	2	18.2
Not reported	0	1	0	0	0	0	0	0	0	0	0	1	1	9.1
Total	1	2	1	0	2	0	4	0	1	0	9	2	11	100

Appendices

Appendix E

Table E 1 Number and percentage of donors with HTLV infection, 2011-2015, by year of donation, sex and age group

	Year of donation													
	2011		2012		2013		2014		2015		2011-2015			
Donor status	M	F	M	F	M	F	M	F	M	F	M	F	Total	%
First-time donors														
<20 years	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
20-29 years	0	1	1	0	0	0	0	0	0	0	1	1	2	10.5
30-39 years	0	0	1	0	1	1	0	0	2	0	4	1	5	26.3
40-49 years	1	1	0	0	3	1	0	0	1	0	5	2	7	36.8
50-59 years	0	0	0	0	1	2	0	0	0	0	1	2	3	15.8
60 years and above	0	0	0	0	0	0	1	0	0	0	1	0	1	5.3
Repeat donors														
<20 years	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
20-29 years	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
30-39 years	0	0	0	0	0	0	0	0	0	1	0	1	1	5.3
40-49 years	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
50-59 years	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
60 years and above	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Total	1	2	2	0	5	4	1	0	3	1	12	7	19	100

Table E 2 Number and percentage of donors with HTLV infection, 2011-2015, by year of donation and country/region of birth*

	2011		2012		2013		2014		2015		2011-2015	
Region of birth	Number	%	Number	%	Number	%	Number	%	Number	%	Number	%
Australia	0	0	0	0	2	22	0	0	1	25	3	16
Overseas born												
Other Oceania	0	0	0	0	0	0	0	0	0	0	0	0
United Kingdom and Ireland	0	0	0	0	0	0	0	0	0	0	0	0
Other Europe	0	0	0	0	0	0	0	0	0	0	0	0
Middle East/North Africa	1	33	0	0	5	56	1	100	1	25	8	42
Sub-Saharan Africa	0	0	0	0	0	0	0	0	0	0	0	0
South East Asia	0	0	0	0	1	11	0	0	0	0	1	5
Southern and Central Asia	0	0	2	100	1	11	0	0	2	50	5	26
North America	0	0	0	0	0	0	0	0	0	0	0	0
South/Central America and the Caribbean	0	0	0	0	0	0	0	0	0	0	0	0
Total with a reported country of birth	1	33	2	100	9	100	1	100	4	100	17	89
Not reported	2	67	0	0	0	0	0	0	0	0	2	11
Total	3	100	2	100	9	100	1	100	4	100	19	100

* Region of birth from the Australian Bureau of Statistics

Table E 3 Number and percentage of HTLV infection among first-time donors, 2011-2015, by potential reported exposure category and sex

	2011		2012		2013		2014		2015		Total (2011-2015)			
Exposure categories	M	F	M	F	M	F	M	F	M	F	M	F	Total	%
Ethnicity/Country of birth	1	1	2	0	5	2	1	0	3	0	12	3	15	83.3
Intravenous drug user	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Tattoo/Piercing	0	1	0	0	0	0	0	0	0	0	0	1	1	5.6
Partners with any risks or known to be positive	0	0	0	0	0	2	0	0	0	0	0	2	2	11.1
Male-to-male sexual contact	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Exposure in health care setting	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Engaged in sex work	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
Household contact	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
Other	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
No risk factors identified	0	0	0	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
Total	1	2	2	0	5	4	1	0	3	0	12	6	18	100

Supporting information

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 Services' 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 questionnaire is reviewed at a private and confidential interview with the donor and a legally binding Declaration Form is signed in the presence of the interviewer 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 donation is processed and undergoes mandatory tests for specific transfusion-transmissible infections (TTIs) including HIV, HBV, HCV, HTLV and syphilis. 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 reduction technologies or PRT). Presently PRT are used for manufactured plasma products but are not routinely available in Australia for fresh blood components.

Each donation is tested for hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus (HIV), human T- lymphotropic virus (HTLV) and *T. pallidum* (syphilis). Testing of selected donors at risk for malaria (e.g. travelers 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.[66] During 2010, the Blood Service implemented NAT for HBV DNA as a mandatory screen for all blood donations in addition to existing HBV test (HBsAg), which reduced the HBV window period from approximately 38 to 24 days.[67] 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 non-zero risk of transmission from donors with very recently acquired infection, who may test negative if they donate during the window period.

Using donation testing results, 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 2005-2010 and demonstrated an overall reduction in prevalence of TTIs by almost 30% over the six years. Subsequently five 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 2015, with a steady or declining trend for all infections. Infected first-time donors in 2015 mostly had undiagnosed prevalent infections but we continued to identify a small number of recently acquired (incident) infections among repeat donors.

This is the sixth 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 2006-2015 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 2006 to 2015. Anonymous donor data for all donors who donated blood between January 2006 and December 2015 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 2006-2015. Demographic factors associated with TTIs in blood donors were analysed for donations made in 2015 and were compared with the findings from 2011-2015. Likely routes of exposure (termed 'infective risk factors') for each TTI in blood donors were also identified and analysed. Data from the 2013 and 2014 calendar years was 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 January 2014 to April 2015.

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 2014-2015 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 ten year period, 2006-2015, was calculated as follows:

$$\text{Incidence per 100 000 donor-years of observation} = \left(\frac{\text{Total number of incident donors in 2006-2015}}{\text{Average of 2006-2015 total donor-years of observation}} \right) \times 100\,000$$

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

Estimates were derived based on minor refinement to the method described in earlier studies.[24, 68] An additional refinement since 2015 is a revised model applied to HBV which specifically addresses the risk of occult hepatitis B infection (OBI).[25] These estimates are updated annually using blood donation viral screening tests results for a 'rolling' two year period, or in the case of the OBI model, the most recent 12 months' data. It should be noted that, as the order of magnitude of these risks is very small, the calculated median risk estimate may fluctuate from year to year.

Furthermore the estimates are conservative since they are based on the 'worst case' assumption that an infectious donation is always issued for transfusion and, that if transfused will always lead to infection in the recipient (i.e., infectivity is 100%). There are other mitigating factors which may affect transmission including the volume of plasma in the component transfused, the number of viral particles per unit volume and the immune status of the recipient.

Three of the four models derive point estimates determining the probability of an undetected 'window period' (WP) donation in a given time period. WP is defined as the interval between infection and first positive test marker in the bloodstream. These WP-based models assess the rate of incident donors (i.e., positive donors who have previously tested negative at the Blood Service for the same viral marker) in the repeat donor (RD) population as a measure of viral incidence (i.e. the rate of newly acquired infection).

In order to incorporate the incidence in first-time donors (who have no previous testing at the Blood Service), one of the three WP-based models uses a separate calculation whereas the other two use a correction factor for the RD incidence based on the proportion of NAT positive/antibody negative (i.e. NAT 'yield') donors in the FTD and RD populations, respectively.

Two of the WP-based models also incorporate the average inter-donation interval for all incident donors (in days) between the positive result and previous negative result. The longer this interval for an individual donor, the lower the probability that the donor was in the WP at the time of donation. In other words, the inter-donation interval is inversely proportional to the risk.

The fourth model, applied only to HBV, estimates the risk specifically for OBI. The method is based on assessing the probability of 'non-detection' by HBV NAT and the average probability of HBV transmission from NAT non-reactive donations. NAT non detection is derived by examining HBV NAT data and assessing the frequency of prior NAT non-detectable donations from donors identified as OBI by NAT. The transmission function is based on investigation of the outcome of transfusions from blood components (termed lookback) sourced from donors with OBI. The HBV residual risk is the sum of the risk estimated from the WP-based and OBI models. 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, 2006-2015. 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 2006-2015 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 2015, and ten year period, 2006-2015. The association between demographic factors and presence of any transfusion-transmissible infections (hepatitis B, hepatitis B, HIV and HTLV) 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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