Transfusion-transmissible infections in Australia

2017

Surveillance Report

Australian Red Cross BLOOD SERVICE

UNSW SYDNEY

Kirby Institute

This publication is available online at:
http://www.kirby.unsw.edu.au and
http://www.transfusion.com.au

Recommended citation:
Transfusion-transmissible infections in Australia: 2017 Surveillance Report. Kirby Institute, UNSW Sydney, and the Australian Red Cross Blood Service; 2017

Requests for further information should be addressed to:

Dr Skye McGregor
Epidemiologist, Surveillance, Evaluation and Research Program
The Kirby Institute, UNSW Australia
+61 2 9385 0900 I smcgregor@kirby.unsw.edu.au

Or,

Dr Clive Seed
Senior Blood Safety Analyst, Donor and Product Safety (DAPS) Policy Unit
Australian Red Cross Blood Service
+61 8 6213 5913 I cseed@redcrossblood.org.au

ISSN 2203-0751 (Online)

edited by

Clive Seed, Laila Khawar, Veronica Hoad and Rebecca Guy

The Australian Red Cross Blood Service

in collaboration with

The Kirby Institute, UNSW, Sydney

Acknowledgements

The report was prepared by the following investigators of the Australian Red Cross Blood Service[1] and the Kirby Institute.[2]

Edited by Clive Seed,[1] Laila Khawar,[2] Veronica Hoad[1] and Rebecca Guy[2]

Chief investigators Sue Ismay,[1] Rebecca Guy[2]

Associate investigators Skye McGregor,[2] June Lee,[1] Claire Styles[1] and Joanne Pink[1]

The following Australian Red Cross Blood Service staff are acknowledged for their contribution to this report and ongoing surveillance activities:

- Donor Services and Manufacturing staff involved in donor assessment or blood donation testing for transfusion-transmissible infections
- Medical Services staff medical officers undertaking donor counselling and risk factor assessment
- Anthea Cheng, Ashley Henshaw and the Manufacturing Testing teams
- Medical Services Lookback committee
- Performance and Analysis team
- Philip Kiely, Zofia Perkowska-Guse, Denise Herbert and the members of the Donor and Product Safety Policy Unit

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 seventh report that summarises donation testing data, and incidence and prevalence trends for transfusion-transmissible infections (TTIs) among Australian blood donors. While it is an important Blood Service resource, it is also intended to be a reference document for organisations and individuals interested in the occurrence of transfusion-transmissible infections in Australia and the effectiveness of the Blood Service's infectious disease blood safety strategy. The data in the report is current at the time of publication and all efforts have been undertaken to confirm its accuracy, however subsequent data updates may occur and users must consider this.

Ensuring donations do not transmit infectious diseases is a key priority of the Blood Service. Blood donors are required to complete a questionnaire every time they donate to assess their risk of exposure to significant TTIs. The questionnaire for first-time donors includes basic demographic information, as well as questions regarding lifetime exposures to certain risk events. Repeat donors within a two-year time frame are required to complete a shorter questionnaire. The questionnaire is reviewed 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 2016 (n=156). Of these, 87% were either hepatitis B (HBV) or hepatitis C (HCV) virus. Reflecting the effectiveness of donor screening strategies, the prevalence of infection in first-time donors continues to be substantially (15-102 times) lower than the estimated national population prevalence. Only two (1.3%) of all infections in 2016 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). Unlike previous years where there was no significant trend observed for incidence rates of any of the TTIs, this year we note a significant declining trend in the incidence of HCV during the past ten-year period, 2007-2016. While this is encouraging, we cannot exclude that a change to the incident case definition in 2014 contributed to this observation and are planning further analysis for clarity. Notably, no significant decline in the HCV incidence was noted over a nine year study period (2007-2015) among people who inject drugs participating in the Australian Needle and Syringe Program Survey.[1]

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 2016, nearly 19% 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.

Contents

Glossary

Active syphilis
Defined by reactivity on treponemal and nontreponemal syphilis testing, with or without clinically apparent infection (i.e. excluding past treated infections).

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 tested positive to either hepatitis B surface antigen, hepatitis B DNA or 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 tested positive to either antibodies to HCV, HCV RNA or both as defined below:

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

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

Incidence
The rate of newly acquired infection among repeat donors.

Incident donor
A positive repeat donor whose 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 postdonation interview.

Infectious syphilis
Syphilis infection of less than 2-year duration

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.

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 predonation 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 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 using tests that are based on the presence of antibodies.

Summary of the main findings

General characteristics of blood donors in Australia

Over the ten-year period 2007-2016, there were approximately 12.9 million blood donations in Australia with an average of 1.2 million donations per year. Over the past ten years, 2007-2016, there has been no significant change in the total number of donations.* Total blood donations in 2016 increased by nearly 2% (representing 25 131 more donations) compared to 2015.

Of the Australian population aged between 16-80 years, 2.5% donated blood during 2016.

1. First-time and repeat donors comprised 15.7% and 84.3% of all blood donors in Australia over the period 2007-2016, respectively. As in previous years, this ratio remained relatively stable nationally and across all states and territories. Male donors constitute 50% of all donors in 2016, which is almost identical to their proportional representation of 49.6% 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 2016, a total of 156 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 2007-2016 a total of 2 113 TTI-positive donors were detected. In 2016, 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 2016, 87% were positive for either HBV or HCV, a slight decrease from 93% in 2015.
3. Overall HIV was the least common infection among all donors in 2016, with just three donors testing positive. In the ten-year period 2007-2016, HTLV was the least common infection among all donors (42 positive donors); and HIV was the least common infection in the first-time donors (22 positive donors).
4. Although representing only 14.4% of the donor population, first-time blood donors contributed approximately 77% of TTIs in Australia in 2016. This ratio has remained relatively stable since 2007 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 2007-2016. 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 (15 to 102 times) compared with national prevalence estimates for 2016.

* See Methodological Notes for details

HBV infection among Australian blood donors

1. There were 76 HBV infections detected among all donations in 2016 (62 in first-time donors and 14 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 2016 declined by 19% as compared to that observed in 2015, from 80.2 to 64.7 per 100 000 donations (or 0.06% of the total first-time donations); which was 15 times lower than the estimated 1.0% reported in national HBV surveillance data.
4. Among the 76 HBV infections, 16 (5 first-time and 11 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 2016, giving an incidence rate of 0.3 per 100 000 donor-years of observation, identical to that reported in 2015. Overall, there was no temporal trend in HBV donor incidence nationally or in any state/territory during the ten-year study period 2007-2016.
6. In 2016, HBV positive donors were slightly younger as compared to all donors (40 years versus the mean age 41.6 years), were more likely to be male (79% 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, 2012-2016, was ethnicity/country of birth (89%). In Australia over 48% of people living with hepatitis B are born in the Asia Pacific region.[1]
8. Three probable cases of transfusion-transmitted HBV infections were reported in the 2008-2015 period (See *Main Findings* for details).

HCV infection among Australian blood donors

1. There were 60 HCV infections detected among all donors in 2016 (46 in first-time donors and 14 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 2007-2016, there has been a significant decrease in HCV prevalence in first-time donors in Australia, from 0.08% of the total first-time donations in 2007 to 0.04% in 2011 and 0.05% in 2016. This translates into a decrease of 41% from 81.5 per 100 000 first-time donations in 2007 to 48 per 100 000 first-time donations in 2016. The 0.05% first-time donor prevalence in 2016 is 17 times lower than the 0.8% reported for HCV national surveillance data. This decreasing trend is consistent with national HCV new-diagnoses notification rate (from 58 per 100 000 in 2007 to 49.6 per 100 000 in 2016).
4. In 2016, there were 14 repeat donors who tested positive but none met the incidence definition of a previous negative donation within 12 months. Most of these donors were HCV antibody positive without detectable RNA, indicative of 'resolved' infections. Nonetheless, of all TTIs detected, HCV had the highest average incidence rate among previously negative repeat donors during 2007-2016, at 2.2 per 100 000 donor-years of observation.* HCV incidence has shown a significant downward trend in the past ten-year study period, 2007-2016 and the rate has decreased over time from 2.9 in 2007, to 1.7 in 2011 and 0.0 per 100 000 donor-years of observation in 2016. As noted we cannot exclude that a change to the incident case definition in 2014 contributed to this observation and are planning further analysis for clarity.
5. In 2016, the mean age of HCV positive donors was 48 years compared to 41.6 years for all donors. Like HBV, HCV positive donors were more likely to be male as compared to all donors (67% versus 50%) but in contrast to hepatitis B, the majority (67%) were born in Australia.
6. The most common putative risk factor reported by donors with HCV infection during 2012-2016 was a history of tattoo/piercing (26%), followed by injecting drug use (24%). In comparison, injecting drug use (35%) and sexual contact (1.5%) were the two most dominant routes of exposure in cases of newly acquired hepatitis C infection reported in national notification data in 2016.[1]
7. No transfusion-transmitted HCV infections were reported in Australia during 2007-2016.

* See Methodological Notes for details

HIV infection among Australian blood donors

1. There were three HIV infections detected among all donations in 2016 (one first-time and two repeat donors).
2. The prevalence of HIV infection among first-time donors during 2007-2016 remained very low at 1.8 per 100 000 donations (or 0.002% of the total first-time donations) and comparatively much lower than hepatitis B (80.4 per 100 000 donations) and hepatitis C (55.41 per 100 000 donations). However, no significant trend was observed for incidence rates for HIV infection during this time. The 0.002% HIV prevalence in first-time donor is 102 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; 0.6 in 2007, 0.8 in 2011, and 0.3 in 2016.
4. In 2016, the mean age of HIV positive donors was 46 years as compared to 41.6 years for all donors. Like HBV and HCV, HIV positive donors were more likely to be male as compared to all donors (67% vs 50%) but unlike HBV, most (67%) were Australian-born.
5. The two most common reported routes of exposure for donors with HIV infection during 2012-2016 were male-to-male sex (42%), followed by heterosexual sex with partners with known risk factors or known to be HIV positive (21%). This compares to the new HIV diagnoses notification data in Australia where men who have sex with men accounted for 75.3% of new HIV diagnoses in Australia in 2016, followed by heterosexual sex (20.6%).[1]
6. No transfusion-transmitted HIV infections were reported in Australia during 2007-2016.

HTLV infection among Australian blood donors

1. There were five HTLV infections detected among all donations in 2016 (all in first-time donors).
2. The prevalence of HTLV infection among first-time donors during 2007-2016 has remained low at 3.5 per 100 000 donations, and has shown no significant trend. Population prevalence for HTLV is unknown; therefore, comparison of prevalence rates among first-time donors and the general population is not possible.
3. The HTLV incidence among repeat Australian donors in 2016 was zero as it was for the ten-year period 2007-2016.
4. In 2016, the mean age of donors with HTLV infection was 32 years; 60% of the infected donors were male and all were born overseas.
5. The most common putative infective risk factor for donors with HTLV infection during 2012-2016 was ethnicity or country of birth (81%). There are no data to compare risk factors in the general population.
6. No transfusion-transmitted HTLV infections were reported in Australia during 2007-2016.

Active syphilis infection among Australian blood donors

1. There were 12 active syphilis infections (6 first-time and 6 repeat donors) detected in 2016, the highest number recorded in the past ten years, 2007-2016.
2. The prevalence of active syphilis in first-time donors has shown no significant change over time in the past ten years, 2007-2016. In first-time donors the prevalence per 100 000 first-time donations was 0.7 in 2007, 5.1 in 2011 and 6.2 in 2016.
3. The mean age of donors with active syphilis in 2016 was 37 years (compared to 41.6 years for all donors); and donors with active syphilis were more likely to be male as compared to all donors (58% versus 50%).
4. The most common reported route of exposure by donors with active syphilis during 2014-2016 period (risk factor data on donors positive for active syphilis is only available from 2014) was having a partner with an unspecified risk (45%).

Donor Compliance

1. Nearly 19% (162 donors) of the TTI-positive donors in 2012-2016 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, 69% (111 donors) were first-time donors.
2. The non-compliance rate of positive donors has fluctuated in the last five years between 14.8 and 25%. The non-compliance rate among TTI-negative donors is not determined on a regular basis; however, results from a large national survey from 2012-13 showed a comparatively lower rate of non-compliance (in the range of 0.05-0.29%). See *Additional Information* section for more information.

Malaria testing

1. In 2016, a total of 104 687 donations were tested for malaria antibody of which 1 695 (1.6%) were repeatedly reactive for malaria antibodies. None of these repeatedly reactive donors had detectable malaria DNA, suggesting past infection in the donors.
2. There were no reported cases of transfusion-transmitted malaria during 2016, with the last Australian case occurring in 1991.

Bacterial pre-release testing for platelets

1. In 2016, bacterial screening of 120 941 platelets identified 151 as confirmed positive.
2. *Propionibacterium* spp., which are common skin commensals, were by far the most frequently isolated organisms (121). These organisms are rarely, if ever associated with septic transfusion reactions in recipients. Other potential contaminants included Coagulase negative staphylococci (21), *Corynebacterium* sp and unidentified gram positive cocci. A small number of clinically significant organisms including one each of *E.coli, Serratia marcescens, Bacteroides thetaiotaomicron, Streptococcus pneumoniae, Streptococcus gallolyticus* and *Clostridium perfringens* were detected. All contaminated platelets with detected significant organisms were prevented from being transfused.
3. During 2016, two septic transfusion reactions were identified in patients who received apheresis platelets from the same donor contaminated with *Staphylococcus aureus*. Bacterial screening was falsely negative. Such cases are rare, being only the fourth and fifth cases of transfusion-transmitted bacterial infection associated with platelets issued by the Blood Service since the introduction of bacterial screening in 2008.

Emerging infections

1. Along with the ongoing risk from local dengue virus outbreaks and seasonal WNV outbreaks in Europe, outbreaks of Ebola virus and Zika virus have also been closely monitored during 2016-2017.
2. The risk to the blood supply posed by donors returning from Ebola virus and Zika virus outbreak areas has been managed by deferring donors (Ebola) or restricting donations to plasma sent for fractionation for an appropriate period (Zika).

List of figures and tables

List of figures

List of tables

List of Appendices Tables

Abbreviations

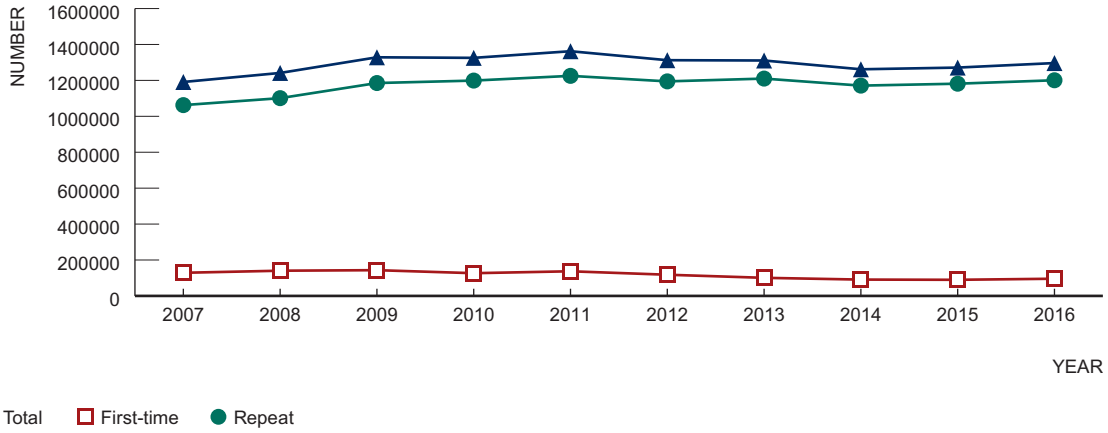
anti-HBc	antibody to hepatitis B core antigen
anti-HBe	antibody to hepatitis B e antigen
anti-HBs	antibody to hepatitis B surface antigen
anti-HeV	antibody to Hendra virus
Blood Service	Australian Red Cross Blood Service
EVD	Ebola virus disease
HBeAg	hepatitis B e antigen
HBsAg	hepatitis B surface antigen
HBV	hepatitis B virus
HCV	hepatitis C virus
HEV	hepatitis E 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
YFV	yellow fever virus
YF	yellow fever
ZIKV	Zika virus

Main Findings

Blood donors in Australia

Over 12.9 million donations were tested for TTIs in Australia during the ten-year period 2007-2016 with an average of 1.2 million donations per year. The number of donations increased from 1.1 in 2007 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 2014 and 2015. In 2016, the number of donations has increased by 2% as compared to 2015 reaching approximately 1.3 million donations. Over the entire ten-year period there was no significant trend in numbers of donations (Figure 1) (See *Methodological Notes* for details). Notably, from September 2016, in accordance with regulatory requirements, plasma donations from repeat donors collected solely for the manufacture of fractionated plasma products were no longer tested for HTLV or syphilis resulting in differing total test numbers. A total of 1.13 million donations were tested for HTLV and syphilis in 2016, as compared to 1.29 million for HBV, HCV and HIV.

Figure 1 Number of blood donations in Australia by year of donation, 2007-2016

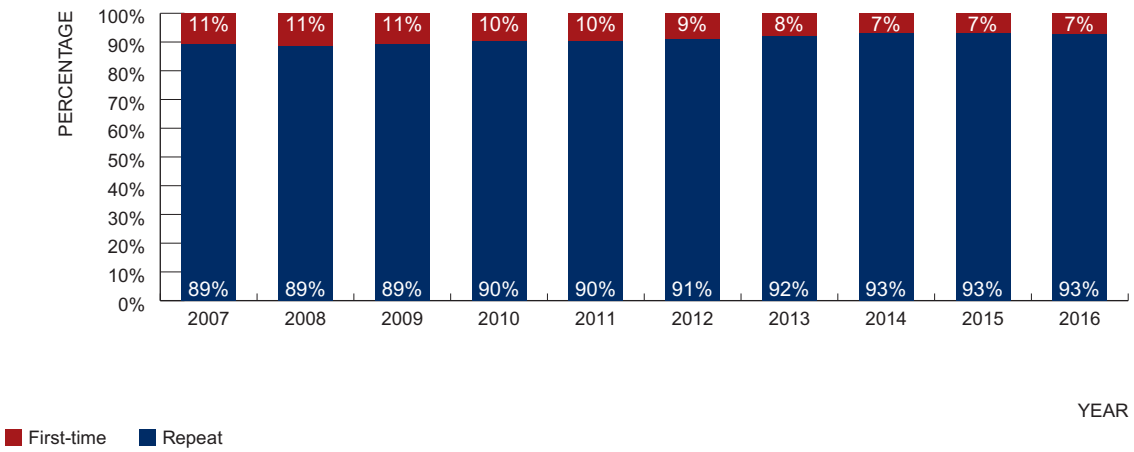


In 2016, 2.5% of the general population who were aged between 16-80 years (age-eligible to donate) donated blood in Australia. Together, New South Wales, Queensland and Victoria accounted for more than 75% of all blood donations. The jurisdictions where the greatest proportion (nearly 4%) of the age-eligible local population donated blood in 2016 were the Australian Capital Territory and Tasmania (Figure 2).

Figure 2 Percentage of age eligible general population who donated blood in 2016, by state/territory

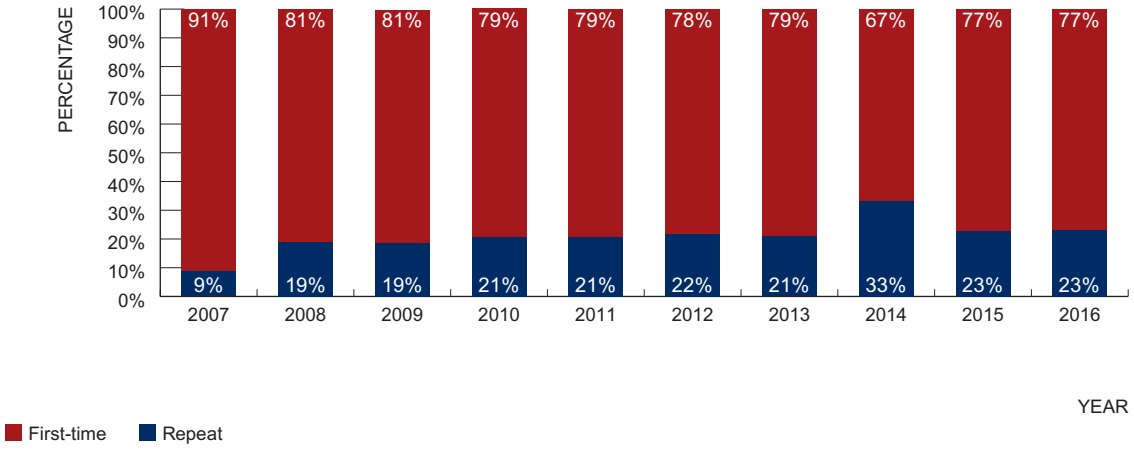
As in previous years, more than 90% of all donations in 2016 were from repeat donors (Figure 3). While first-time blood donors represented only 14.4% of the donor population, and 7% of the total donations, they contributed the majority (77%) of TTIs in Australian blood donors in 2016, reflecting detection 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, 2007-2016



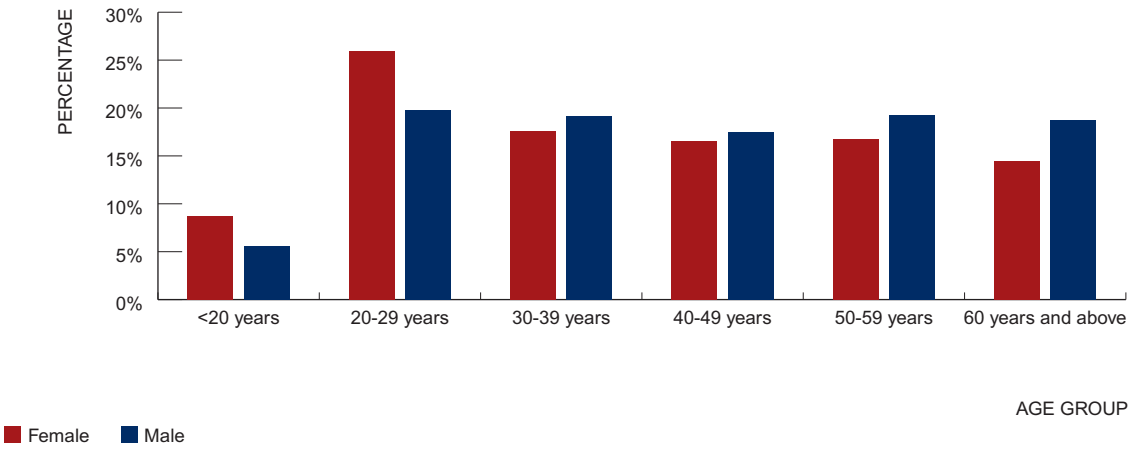
Overall in the past ten years, there has been a steady increase in the proportion of repeat donors among all TTI-positive blood donations in Australia, from 9% in 2007 to 21% in 2010 to 23% in 2016 (Figure 4). It is important to note that since 2015 this proportion has dropped by 31%, from a record high 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, 2007-2016



Among all blood donors who donated in 2016, 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). Nearly 35% of donors were from those aged 50 years and above; the median age of male and female donors was 43 and 40 years, respectively.

Figure 5 Distribution of blood donors in Australia by age group and sex, 2016



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 2007-2016 overall in Australia, and trends observed in state/territory jurisdictions. In addition, association of demographic characteristics with presence of TTIs for year 2016 and the five-year period 2012-2016 will be discussed. Also, possible risk factors associated with positive blood donors in Australia are reported for the five-year period 2012-2016. The findings are presented in respective sections by infection.

Blood donors are a subset of the general population, so to provide a context for the report the epidemiology of each relevant TTI in Australia is also discussed in respective sections. This includes a brief description of the number of people living with TTIs in Australia by the end of 2016, 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 2017.[1]

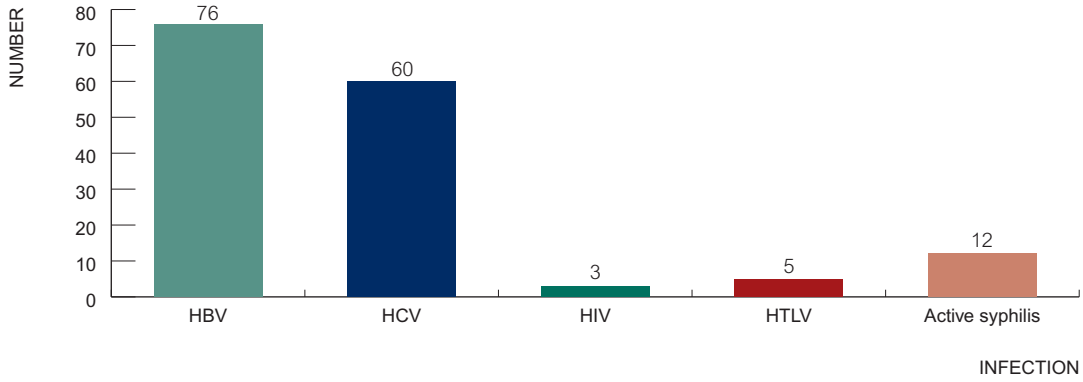
Of note, prevalence is defined as the frequency and proportion of infection among all blood donors, and first-time blood donors, separately; whereas incidence is the rate of newly acquired infection among repeat donors. It is important to note that given the low donor incidence rates nationally and in all jurisdictions, individual year variation should be interpreted with caution. This is particularly relevant to the 2014-16 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 infection.

During the past ten years, 2007-2016, a total of 2 113 donations (1 687 in first-time and 425 in repeat donations) were positive for at least one of the TTIs subject to mandatory donation testing. Of these, 2007 were positive for HBV, HCV and HIV (15.5 per 100 000 donations), and 106 (0.8 per 100 000 donations) were positive for active syphilis and HTLV. As noted above, due to different total number of donations tested for these infections (1.29 million donations for HBV, HCV and HIV, as opposed to 1.13 million donations tested for HTLV and active syphilis), these data are shown separately (Table 1A and 1B). Of the positive donations, 92.5% 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 9% in 2007 to 21% in 2010 to 23% in 2016 (Figure 4).

In 2016, a total of 156 donors were found positive for at least one of the TTIs subject to mandatory donation testing. Overall, HBV and HCV were the two most frequent TTIs identified in Australian blood donors in 2016, together contributing 87.2% of all infections (Figure 6). This proportion has decreased by a relative 6% as compared to 93% in 2015, signifying an overall decreasing trend in the prevalence of HBV and HCV in all donors. HBV and HCV were also the most frequent TTIs in both first-time and repeat donors. During 2007-2016, a total of 114 incident donors were identified. In 2016 a total of two incident infections were detected with one for HBV and one for HIV. For the first time, no HCV incident donor was detected. This finding may be due to chance or because of increased compliance with donor selection criteria. However, as incidence represents new infections, it may be an indicator of a potential decrease in the incidence in the general population as a result of the effectiveness of HCV prevention programs, including new direct acting anti-viral treatment strategies.

Figure 6 Number of blood donors with transfusion-transmissible infections in Australia, in 2016, by infection



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 among Australian blood donors in 2016 and the five-year period 2012-2016 (with the exception of active syphilis) separately. Standardised national data on demographic factors associated with active syphilis-infected donors are available for only 20 donors (3 from 2014, 5 from 2015, and 12 from 2016), therefore analyses are presented for 2016 and the three-year period 2014-2016.

Standardised national data on putative reported risk factors associated with donors infected with HBV, HCV 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 2012 to 2016. A total of 868 positive donors with at least one of the TTIs were observed over the period 2012-2016. Among them, 41 donors were positive for active syphilis, of which only 20 have standardised risk factor data available (3 from 2014, 5 from 2015, and 12 from 2016); therefore, data for the 2014-2016 period only is presented on donors positive for syphilis. The data on the remaining 827 donors who were positive for any of the other TTIs (HBV, HCV, HIV and HTLV) during 2012-2016 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,* 2007-2016

1A: The number and prevalence rate of HBV, HCV and HIV in Australia, nationally, 2007-2016

State/Territory of donation	All accepted donations			HBV			HCV			HIV			Total positive donations		
	First time	Repeat	All	First time	Repeat	All	First time	Repeat	All	First time	Repeat	All	First time	Repeat	All
National	1 171 187	11 730 569	12 901 756	942	131	1 073	649	233	883	22	29	51	1 613	393	2 007
Number (Number per 100 000 donations)				*80.43*	*1.12*	*8.32*	*55.41*	*1.99*	*6.84*	*1.88*	*0.25*	*0.40*	*137.72*	*3.35*	*15.55*

1B: The number and prevalence rate of HTLV and active syphilis in Australia, nationally, 2007-2016

State/Territory of donation	All accepted donations			HTLV			Syphilis			Total positive donations		
	First time	Repeat	All	First time	Repeat	All	First time	Repeat	All	First time	Repeat	All
National	1 171 187	11 573 627	12 744 814	41	1	42	33	31	64	74	32	106
Number (Number per 100 000 donations)				*3.50*	*0.01*	*0.33*	*2.82*	*0.27*	*0.50*	*6.32*	*0.28*	*0.83*

* State/territory breakdown of transfusion-transmissible infections in Australia for the ten-year study period, 2007-2016, are provided in respective infection sections

^ One donor positive for HCV in 2009 has his/her donation status unknown and could not be counted under First-time or Repeat donors; therefore, the total comes up to 883 instead of 882

This page intentionally left blank

Hepatitis B Virus (HBV):

Main findings

1. There were 76 HBV infections detected among all donations in 2016 (62 in first-time donors and 14 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 2016 declined by 19% as compared to that observed in 2015, from 80.2 to 64.7 per 100 000 donations (or 0.06% of the total first-time donations); which was 15 times lower than the 1.0% reported in national HBV surveillance data.

4. Among the 76 HBV infections, 16 (5 first-time and 11 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 2016, giving an incidence rate of 0.3 per 100 000 donor-years of observation, identical to that reported in 2015. Overall, there was no temporal trend in HBV donor incidence nationally or in any state/territory during the ten-year study period 2007-2016.

6. In 2016, HBV positive donors were younger as compared to all donors (40 years versus the mean age 41.6 years), more likely to be male (79% in HBV 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 2012-2016, was ethnicity/country of birth (89%). In Australia over 48% 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 2008-2016 period. Only one case occurred after commencement of universal HBV DNA testing. See *Main Findings* (page 26) for details.

Epidemiology of HBV in Australia

At the end of 2016, an estimated 230 033 people were living with chronic HBV infection in Australia (range 219 465 to 249 457), of whom an estimated 63% were diagnosed with chronic hepatitis B, 48% were born in the Asia-Pacific and 11% were among Aboriginal and Torres Strait Islander peoples. There was a total of 6 557 notifications of newly diagnosed HBV infection in Australia in 2016; of these, over half (54%) were males, and 89% were people aged 25 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 2007-2016, the population rate of diagnosis of HBV infection in Australia has declined in younger age groups: 25 – 29 years (from 84 to 48 per 100 000); 20 – 24 years (from 55 to 27 per 100 000); and 15 – 19 years (from 20 to 12 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 53% from 1.4 per 100 000 in 2007 to 0.6 per 100 000 in 2016. The estimated prevalence of chronic HBV infection among people living in Australia is 1.0%, which is higher than the people living in the United Kingdom (<0.5%) but lower than many other countries in South East Asia and the Pacific.[1]

Trends in prevalence

All donations:

In the past ten years, 2007-2016, a total of 1 073 HBV positive donors have been detected (942 first-time donors & 131 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 44% from 2007 to 2016, from 10.4 to 5.86 per 100 000 total donations (Figure 7).

Figure 7 Prevalence of HBV infection in all blood donations in Australia, 2007-2016

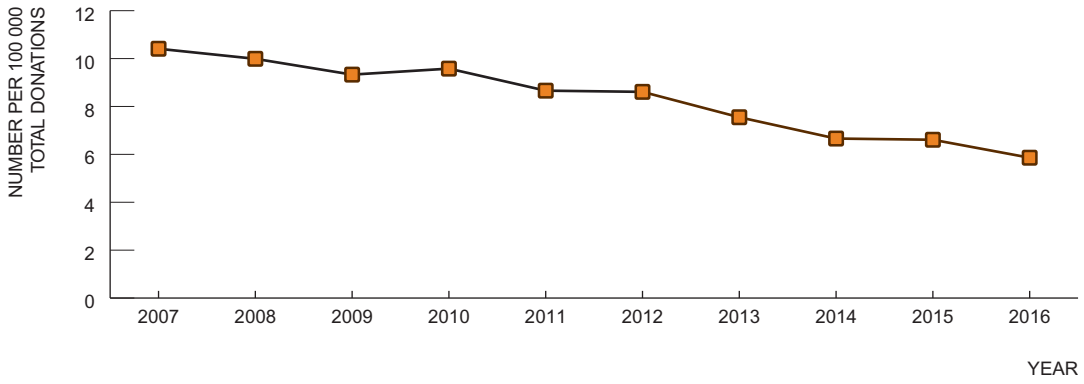


Table 2 The number and prevalence rate of HBV infection in Australia by state/territory, 2016 and 2007-2016 period

State/Territory of donation	All accepted donations 2016			HBV 2016			State/Territory of donation	All accepted donations 2007-2016			HBV 2007-2016		
	First time	Repeat	All	First time	Repeat	All		First time	Repeat	All	First time	Repeat	All
NSW/ACT	29 485	356 162	385 647	19	6	25	NSW/ACT	417 715	3 628 331	4 046 046	331	41	372
Number (*Number per 100 000 donations*)				*64.44*	*1.68*	*6.48*	Number (*Number per 100 000 donations*)				*79.24*	*1.13*	*9.19*
NT	713	8 982	9 695	0	0	0	NT	8 133	99 905	108 038	11	2	13
Number (*Number per 100 000 donations*)				*0.00*	*0.00*	*0.00*	Number (*Number per 100 000 donations*)				*135.25*	*2.00*	*12.03*
QLD	20 513	250 133	270 646	14	1	15	QLD	249 430	2 381 204	2 630 634	147	19	166
Number (*Number per 100 000 donations*)				*68.25*	*0.40*	*5.54*	Number (*Number per 100 000 donations*)				*58.93*	*0.80*	*6.31*
SA	6 824	114 817	121 641	2	0	2	SA	92 281	1 196 151	1 288 432	53	10	63
Number (*Number per 100 000 donations*)				*29.31*	*0.00*	*1.64*	Number (*Number per 100 000 donations*)				*57.43*	*0.84*	*4.89*
TAS	3 037	47 495	50 532	0	0	0	TAS	32 394	420 376	452 770	7	2	9
Number (*Number per 100 000 donations*)				*0.00*	*0.00*	*0.00*	Number (*Number per 100 000 donations*)				*21.61*	*0.48*	*1.99*
VIC	25 762	302 652	328 414	20	5	25	VIC	269 055	2 824 206	3 093 261	298	35	333
Number (*Number per 100 000 donations*)				*77.63*	*1.65*	*7.61*	Number (*Number per 100 000 donations*)				*110.76*	*1.24*	*10.77*
WA	9 398	120 482	129 880	7	2	9	WA	102 179	1 180 396	1 282 575	95	22	117
Number (*Number per 100 000 donations*)				*74.48*	*1.66*	*6.93*	Number (*Number per 100 000 donations*)				*92.97*	*1.86*	*9.12*
National	95 732	1 200 723	1 296 455	62	14	76	National	1 171 187	11 730 569	12 901 756	942	131	1 073
Number (*Number per 100 000 donations*)				*64.76*	*1.17*	*5.86*	Number (*Number per 100 000 donations*)				*80.43*	*1.12*	*8.32*

First-time donors:

Over the ten-year period 2007-2016, a significant downward annual trend was observed in the prevalence of HBV infection among first-time donors (Figure 8 and Table 3). The average rate dropped to 80.4 per 100 000 donations (0.08% of the total first-time donations) for the period 2007-2016, as compared to 82.6 and 81.6 per 100 000 first-time donations for the periods 2005-2014 and 2006-2015, respectively. To a lesser extent this trend is reflected in the Australian general population with the notification rate showing a slight downward trend in the past ten years, at 33 per 100 000 in 2007, 30 per 100 000 in 2010, and 27 per 100 000 in 2016.[1]

Figure 8 Prevalence of HBV infection in first time blood donors in Australia, 2007-2016

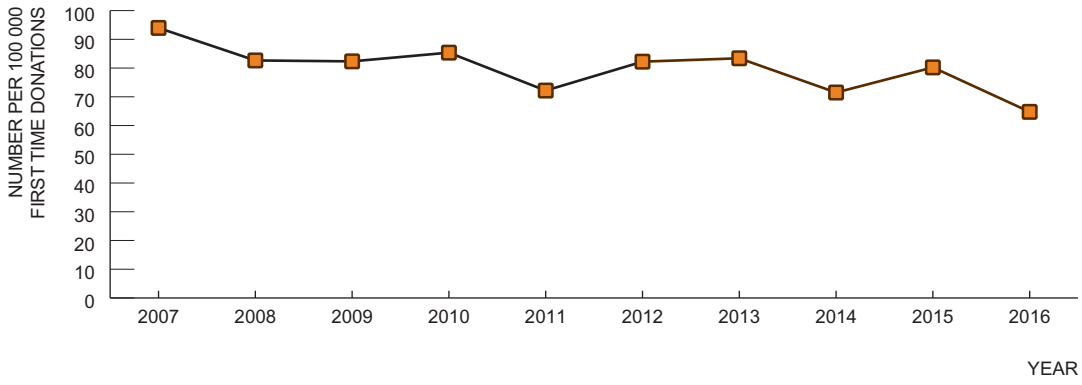


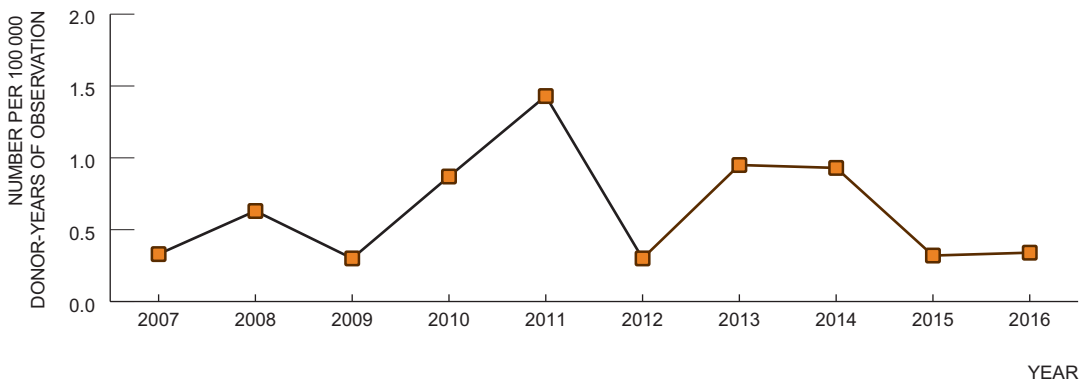
Table 3 Trends in prevalence and incidence of HBV infection in blood donations in Australia, 2007-2016

Trends in prevalence and incidence of HBV infection in blood donations in Australia, 2007-2016		
Prevalence	**IRR (95% CI)**	**p-value**
All donations	*0.94 (0.92-0.96)*	*0*
First-time donors	*0.97 (0.95-0.99)*	*0.03*
Incidence	**IRR (95% CI)**	**p-value**
Repeat donors (donor-years of observation)	*1.00 (0.86-1.16)*	*0.96*

Trends in incidence

For the ten-year period 2007-2016, 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 9). In 2016, only one incident infection was detected for HBV. In contrast to HCV, the application of the stricter incidence definition from 2014 does not appear to have noticeably impacted the number of incident hepatitis B donors.

Figure 9 Incidence of HBV in repeat blood donors in Australia, 2007-2016



No transfusion-transmitted HBV infections were reported in 2016. 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 by jurisdiction in 2016. While the national prevalence was 64.7 per 100 000 donations (an all-time lowest rate), this ranged from 0.0 to 77.6 per 100 000 donations across jurisdictions (Table 6 & Figure 10). In 2016, Victoria recorded the highest prevalence of HBV infection among first-time donors as compared to the other states (77.6 per 100 000 donations). For the ten-year period 2007-2016, the highest average prevalence rate of HBV infection among first-time donors was observed in the Northern Territory at 135.2 per 100 000 donations; however, no significant trend was observed during this period in the Northern Territory, and given the small number of positive donors (ranged between 0-3 per year), this should be interpreted with caution. A significant declining annual prevalence trend was observed in Victoria during 2007-2016 (p-value 0.00) (Table 4); from 185.5 per 100 000 donations in 2007, to 86.3 per 100 000 donations in 2011 and 77.6 per 100 000 donations in 2016 (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 10 Prevalence of HBV infection among first time donors by state/territory and year of donation, 2007-2016

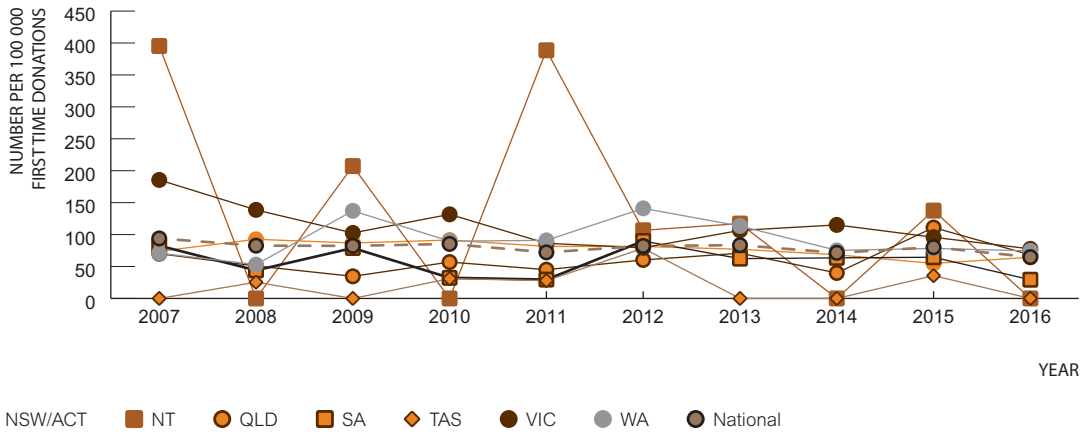


Table 4 Trend in prevalence of HBV infection in first-time donors, by state and territory, 2007-2016

	Prevalence of HBV Infection in First-time Donors, by State and Territory - 2007-2016	
	IRR (95% CI)	p-value
NSW/ACT	*0.96 (0.92-1.00)*	*0.09*
NT	*0.84 (0.67-1.06)*	*0.15*
QLD	*1.04 (0.98-1.10)*	*0.12*
SA	*0.97 (0.88-1.07)*	*0.61*
TAS	*1.01 (0.77-1.31)*	*0.93*
VIC	*0.93 (0.89-0.97)*	*0.00*
WA	*1.00 (0.93-1.07)*	*0.91*

Incident HBV infection continues to be rare with only one incident donor recorded nationally in 2016. Overall, there was no obvious trend in HBV incidence in any state/territory during the ten-year study period 2007-2016 (Table 5 & Figure 11). Among donors in Northern Territory, South Australia and Tasmania, HBV incidence has been zero since 2007.

Table 5 Incidence of HBV infection in repeat donors, by state and territory, 2007-2016

	Incidence of HBV Infection in Repeat Donors, by State and Territory - 2007-2016	
	IRR (95% CI)	p-value
NSW/ACT	*0.81 (0.47-1.41)*	*0.46*
NT	…	…
QLD	*1.07 (0.78-1.46)*	*0.67*
SA	…	…
TAS	…	…
VIC	*1.01 (0.79-1.29)*	*0.89*
WA	*0.98 (0.74-1.31)*	*0.07*

Figure 11 Trend in incidence of HBV infection among repeat donors by state/territory and year of donation, 2007-2016

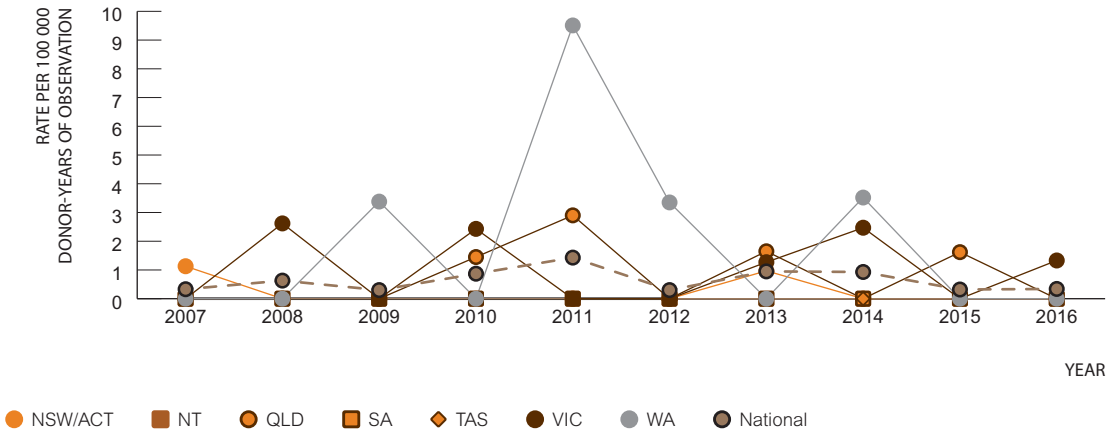


Table 6 Number and prevalence[1] of HBV infection among first-time donors, 2007-2016, by state/territory and year of donation

	2007			2008			2009			2010		
State/Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	51 427	38	73.89	48 607	45	92.58	51 821	45	86.84	48 130	44	91.42
NT	759	3	395.26	815	0	0.00	965	2	207.25	799	0	0.00
QLD	28 575	20	69.99	29 498	15	50.85	28 889	10	34.62	28 097	16	56.95
SA	10 886	9	82.67	15 908	7	44.00	11 400	9	78.95	9 284	3	32.31
TAS	2 650	0	0.00	3 936	1	25.41	3 736	0	0.00	3 222	1	31.04
VIC	23 172	43	185.57	30 286	42	138.68	34 133	35	102.54	25 820	34	131.68
WA	11 292	8	70.85	11 307	6	53.06	12 387	17	137.24	11 149	10	89.69
Total	**128 761**	**121**	**93.97**	**140 357**	**116**	**82.65**	**143 331**	**118**	**82.33**	**126 501**	**108**	**85.37**
	2011			**2012**			**2013**			**2014**		
State/Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	51 528	42	81.51	41 780	34	81.38	35 060	27	77.01	30 697	21	68.41
NT	772	3	388.60	937	1	106.72	853	1	117.23	793	0	0.00
QLD	28 839	13	45.08	24 881	15	60.29	21 181	15	70.82	20 043	8	39.91
SA	10 164	3	29.52	8 900	8	89.89	6 417	4	62.33	6 296	4	63.53
TAS	3 587	1	27.88	3 823	3	78.47	3 058	0	0.00	2 538	0	0.00
VIC	31 286	27	86.30	27 718	22	79.37	25 332	27	106.58	22 580	26	115.15
WA	10 992	10	90.98	9 925	14	141.06	8 815	10	113.44	7 972	6	75.26
Total	**137 168**	**99**	**72.17**	**117 964**	**97**	**82.23**	**100 716**	**84**	**83.40**	**90 919**	**65**	**71.49**
	2015			**2016**			**Total 2007-2016**					
State/Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**			
NSW/ACT	29 180	16	54.83	29 485	19	64.44	417 715	331	79.24			
NT	727	1	137.55	713	0	0.00	8 133	11	135.25			
QLD	18 914	21	111.03	20 513	14	68.25	249 430	147	58.93			
SA	6 202	4	64.50	6 824	2	29.31	92 281	53	57.43			
TAS	2 807	1	35.63	3 037	0	0.00	32 394	7	21.61			
VIC	22 966	22	95.79	25 762	20	77.63	269 055	298	110.76			
WA	8 942	7	78.28	9 398	7	74.48	102 179	95	92.97			
Total	**89 738**	**72**	**80.23**	**95 732**	**62**	**64.76**	**1 171 187**	**942**	**80.43**			

1 Rate per 100 000 First-time donations

Table 7 Number and rate[1] of HBV infection among repeat donations, 2007–2016, by state/territory and year of donation

	2007			2008			2009			2010[2]		
State/Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate
NSW/ACT	338 173	3	0.89	339 062	1	0.29	372 806	0	0.00	380 014	6	1. 58
NT	10 214	0	0.00	11 166	0	0.00	11 158	0	0.00	10 470	1	9. 55
QLD	209 556	0	0.00	226 726	1	0.44	242 001	2	0.83	243 837	3	1. 23
SA	114 618	0	0.00	118 476	1	0.84	126 855	0	0.00	123 587	4	3. 24
TAS	28 019	0	0.00	33 321	0	0.00	37 274	0	0.00	41 484	0	0.00
VIC	252 340	0	0.00	259 052	4	1.54	276 835	1	0.36	278 897	4	1. 43
WA	109 425	0	0.00	113 274	1	0.88	118 327	3	2.54	120 646	1	0.83
Total	1 062 345	3	0.28	1 101 077	8	0.73	1 185 256	6	0.51	1 198 935	19	1. 58

	2011			2012			2013			2014		
State/Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate
NSW/ACT	390 455	5	1.28	377 220	6	1.59	373 670	5	1.34	353 055	5	1. 42
NT	10 782	0	0.00	9 673	0	0.00	9 493	0	0.00	8 914	1	11. 22
QLD	245 975	3	1.22	237 599	5	2.10	243 042	2	0.82	239 720	0	0.00
SA	124 199	2	1.61	120 720	0	0.00	119 530	1	0.84	116 658	1	0.86
TAS	44 661	0	0.00	46 379	0	0.00	48 953	1	2.04	45 788	1	2. 18
VIC	288 085	4	1.39	285 168	2	0.70	292 058	3	1.03	288 753	8	2. 77
WA	121 057	5	4.13	117 728	3	2.55	123 298	3	2.43	118 014	3	2. 54
Total	1 225 214	19	1.55	1 194 487	16	1.34	1 210 044	15	1.24	1 170 902	19	1. 62

	2015			2016			Total 2007-2016		
State/Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate
NSW/ACT	347 714	4	1.15	356 162	6	1.68	3 628 331	41	1.13
NT	9 053	0	0.00	8 982	0	0.00	99 905	2	2.00
QLD	242 615	2	0.82	250 133	1	0.40	2 381 204	19	0.80
SA	116 691	1	0.86	114 817	0	0.00	1 196 151	10	0.84
TAS	47 002	0	0.00	47 495	0	0.00	420 376	2	0.48
VIC	300 366	4	1.33	302 652	5	1.65	2 824 206	35	1.24
WA	118 145	1	0.85	120 482	2	1.66	1 180 396	22	1.86
Total	1 181 586	12	1.02	1 200 723	14	1.17	11 730 569	131	1.12

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 2016, over 120 donors with OBI have been detected, counselled and referred for external clinical assessment reducing the residual risk of HBV infection. Sixteen of the 76 HBV positive donors detected in 2016 were classified as OBI. Most (11/16) were repeat donors and the majority (14/16) were males with an average age of 50 years, 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 2007-2016, and then 2016 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] The prevalence of HBV infection in first-time donors was 11 times lower than in the general population during the period 2007-2016, and 15 times lower for the year 2016. 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, 2007-2016

Infection	Estimated population prevalence* (per 100 000 people)		Prevalence in first time blood donors (per 100 000 donations)		Comparison of HBV prevalence in first time blood donors with population prevalence	
			2007-2016	2016	2007-2016	2016
HBV	908	950	80.43	64.76	11 times lower	15 times lower

* The 2016 HBV prevalence in the general population was calculated by taking the estimated number of people living with chronic HBV[1], and dividing it by the estimated mid-year resident Australian population in 2016 as reported by the Australian Bureau of Statistics. For the period 2007-2016, an average of the ten years' prevalence rates was calculated.

Demographic factors associated with HBV infections in blood donors

Data on the demographic characteristics (sex, age group, state/territory and year of donation) for all blood donors were analysed** to determine the association between demographic factors and presence of HBV infections among Australian blood donors in 2016, and the five-year period 2012-2016 (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 2016, female donors were 73% less likely to be HBV positive. In 2016 there was no significant association between the age group of the donor & state/territory of donation and HBV infection status.

In the five-year period 2012-2016, female donors 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 (1.43 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 has consistently been highest in the Northern Territory (118 per 100 000 in 2007 to 42 per 100 000 in 2016). In most other jurisdictions the rate of HBV diagnosis has fluctuated over the last ten years, with a small decline observed

** See Methodological Notes for details

in recent years in New South Wales (38 in 2007 to 31 in 2016), Victoria (38 in 2007 to 32 in 2016), and Western Australia (31 in 2007 to 24 in 2016).[1]

Table 9 Association of demographic characteristics with presence of HBV infection among blood donors in Australia, 2016, and 2012-2016

	HBV 2016				HBV 2012-2016			
	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	*229 726*	*60 (26.12)*	*1 (ref)*	*…*	*1 221 021*	*329 (26.94)*	*1 (ref)*	*…*
Female	*228 406*	*16 (7.01)*	*0.27 (0.15-0.47)*	*0*	*1 232 932*	*127 (10.3)*	*0.37 (0.30-0.45)*	*0*
Age group (years)								
20-29	*104 568*	*17 (16.25)*	*1 (ref)*	*…*	*348 855*	*39 (11.18)*	*1 (ref)*	*…*
Less than 20	*32 806*	*3 (9.14)*	*0.60 (0.17-2.06)*	*0.42*	*409 385*	*99 (24.18)*	*0.96 (0.67-1.37)*	*0.85*
30-39	*84 061*	*21 (24.98)*	*1.37 (0.72-2.61)*	*0.32*	*407 699*	*86 (21.09)*	*1.15 (0.88-1.49)*	*0.29*
40-49	*78 090*	*13 (16.64)*	*0.94 (0.45-1.94)*	*0.87*	*422 408*	*55 (13.02)*	*0.71 (0.53-0.96)*	*0.03*
50 and above	*158 607*	*22 (13.87)*	*0.76 (0.40-1.45)*	*0.41*	*865 606*	*101 (11.67)*	*0.62 (0.48-0.80)*	*0*
State/Territory								
NSW	*134 421*	*23 (17.11)*	*1 (ref)*	*…*	*742 406*	*134 (18.05)*	*1 (ref)*	*…*
ACT	*12 030*	*2 (16.63)*	*0.94(0.22-3.99)*	*0.93*	*64 088*	*9 (14.04)*	*0.86 (0.45-1.64)*	*0.66*
NT	*3 260*	*0 (0)*	*…*	*0.99*	*18 831*	*4 (21.24)*	*1.15 (0.42-3.12)*	*0.77*
QLD	*91 333*	*15 (16.63)*	*1.96 (0.50-1.84)*	*0.91*	*489 437*	*83 (16.96)*	*0.98 (0.74-1.29)*	*0.89*
SA	*40 366*	*2 (4.95)*	*0.29 (0.07-1.26)*	*0.1*	*222 369*	*25 (11.24)*	*0.66 (0.43-1.01)*	*0.05*
TAS	*15 371*	*0 (0)*	*…*	*0.99*	*80 354*	*6 (7.47)*	*0.45 (0.19-1.02)*	*0.05*
VIC	*119 434*	*25 (20.93)*	*1.21 (0.68-2.13)*	*0.5*	*617 064*	*139 (22.53)*	*1.27 (1.00-1.61)*	*0.04*
WA	*41 917*	*9 (21.47)*	*1.22 (0.56-2.63)*	*0.61*	*219 404*	*56 (25.52)*	*1.43 (1.04-1.95)*	*0.02*
Total	458 132	76 (16.58)			2 453 953	456 (18.58)		

Risk factors associated with HBV infected donors

Of the 456 HBV positive donors during 2012-2016, 85% were first-time donors, 73% 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 (89%) was the most frequent risk factor for HBV positivity, with nearly 42% born in North & South-East Asia in 2016 (Figure 12), followed by having a sexual partner with known risk or known to be positive for any transfusion-transmissible infection (3%). There were only 9 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, 2012–2016

Characteristics	2012	2013	2014	2015	2016	2012-2016
Number of positive donors	113	99	84	84	76	456
Number of positive First-time donors (%)	97 (86%)	85 (86%)	67 (80%)	72 (86%)	62 (82%)	383 (85%)
% male	84 (74%)	72 (73%)	55 (65%)	58 (69%)	60 (79%)	329 (73%)
Mean age (range) in years	37 (16 to 67)	36 (16 to 73)	42 (16-69)	37 (16-67)	40 (16-68)	38 (16-73)
Number of incident donors	1	3	3	1	1	9
% born in Australia	19 (17%)	14 (14%)	15 (18%)	8 (10%)	5 (7%)	61 (14%)
Main reported risk factor	Ethnicity/COB[1]	Ethnicity/COB[1]	Ethnicity/COB[1]	Ethnicity/COB[1]	Ethnicity/COB[1]	Ethnicity/COB[1]
	89%	89%	77%	93%	97%*	89%
Second reported risk factor	PRP[2]	None reported	PRP[2]	PRP[2], Other each	Other, Unknown each	PRP[2]
	3%	4%	2%	8%	2%	3%

1 COB= Country of birth
2 PRP= partner with known risk/known to be positive
* 4 out of 5 donors born in Australia had Ethnicity as their major risk factor

Figure 12 Donors with HBV infection by country/region of birth, 2016 (n=76)

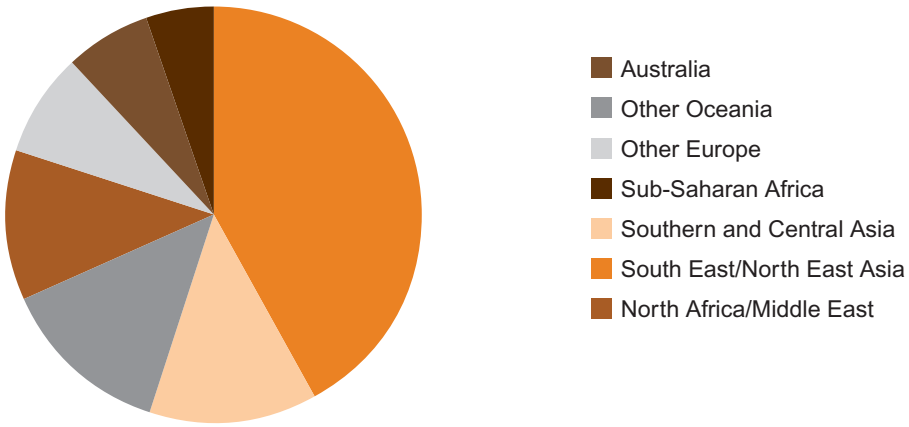
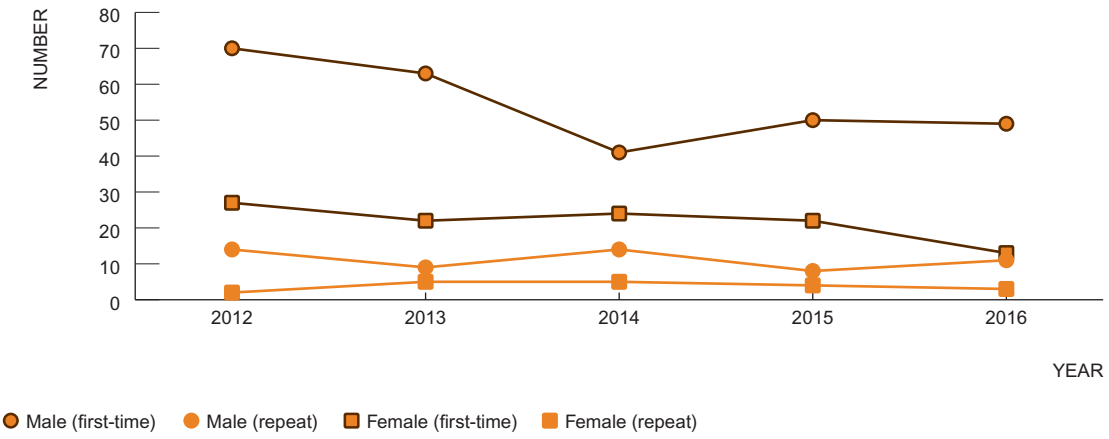


Figure 13 Donors with HBV infection by sex and donor status, 2012-2016



Over the past five years, 2012-2016, there has been a declining trend in the number of HBV positive first-time donors in both genders. Since 2012, there have been 30% and 50% reductions in first-time male and female donors, respectively. On the other hand, the number of HBV positive repeat donors remained relatively stable in both sexes during the same period of time (Figure 13).

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 2012-2016, see Appendix B.

HBV - Comparison of major exposure categories between blood donor and the general population, 2016

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 97.4% of the HBV positive donors in 2016. This proportion has increased by 5% from 92.9% observed in 2015. 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.[5-7]

Nationally, enhanced information on potential risk categories is collected for the newly acquired infections only. For newly acquired HBV infection in the general population, 3.8% had country of birth as a major risk factor; importantly, for 53.5% of the newly acquired HBV infections in the general population the risk category was undetermined[1] (Table 11); the enhanced surveillance procedures related to HBV vary by state/territory with no reported risk factor being grouped with undetermined (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, 2016

		HBV[1]
Major risk category	**General population (%)**	**Blood donors (%)**
Intravenous drug use	21.7	0.0
Country of birth/Ethnicity[2]	3.8	97.4
Sexual contact[3]	10.8	0.0
Blood or tissue recipient	0.0	0.0
Tattoo or body piercing	4.5	0.0
Exposure in health care setting	1.3	0.0
Household contact	1.3	0.0
Other blood to blood contact	2.5	0.0
Other/undetermined/unknown[4]	53.5	2.6
Imprisonment	0.6	0.0
No risk factor identified	0.0	0.0

1 Includes exposure categories for newly acquired HBV infections only in general population
2 Includes 4 out of 5 hepatitis B positive donors born in Australia that had Ethnicity as their major risk factor
3 Includes three sub-groups: Male-to-male sexual contact, Partner with known risk or known to be positive and Engaged in sex work
4 Includes 'no risk factors reported' in general population. Of note, risk factors are not reported for newly acquired HBV cases from QLD and NT

Conclusion:

- The prevalence of HBV infection in first time blood donors has shown a significant declining trend since 2007 and is substantially lower (11 times) than general population estimates for the period 2007-2016.
- The incidence of newly acquired HBV infection is much lower than estimates from specific at-risk populations in Australia. This supports the general effectiveness of the donor questionnaire and specifically that repeat donors understand what constitutes 'risk behaviour' for acquiring transfusion-transmissible infections.
- Screening for HBV DNA continues to identify donors with occult HBV (16 of the 76 HBV infections in 2016).
- 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 60 HCV infections detected among all donors in 2016 (46 in first-time donors and 14 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 2007-2016, there has been a significant decrease in HCV prevalence in first-time donors in Australia, from 0.08% of the total first-time donations in 2007 to 0.04% in 2011 and 0.05% in 2016. This translates into a decrease of 41% from 81.5 per 100 000 first-time donations in 2007 to 48 per 100 000 first-time donations in 2016. The 0.05% first-time donor prevalence in 2016 is 17 times lower than the 0.8% reported for HCV national surveillance data. This decreasing trend is consistent with national HCV new-diagnoses notification rate (from 58 per 100 000 in 2007 to 49.6 per 100 000 in 2016).[1]
4. In 2016, for the first time, there were no incident HCV donors identified. Nonetheless, of all TTIs detected, HCV had the highest average incidence rate among previously negative repeat donors during 2007-2016, at 2.2 per 100 000 donor-years of observation. HCV incidence has shown a significant downward trend in the ten-year study period 2007-2016, and the rate has decreased over time from 2.9 in 2007, to 1.7 in 2011 and 0.0 per 100 000 donor-years of observation in 2016.
5. In 2016, the mean age of HCV positive donors was 48 years compared to 41.6 years for all donors. Like HBV, HCV positive donors were more likely to be male as compared to all donors (67% versus 50%) but in contrast to hepatitis B, the majority (67%) were born in Australia.
6. The most common putative risk factor reported by donors with HCV infection during 2012-2016 was a history of tattoo/piercing (26%), followed by injecting drug use (24%). In comparison, injecting drug use (35%) was the most dominant route of exposure in cases of newly acquired hepatitis C infection reported in national notification data in 2016.
7. No transfusion-transmitted HCV infections were reported in Australia during 2007-2016.

Epidemiology of HCV in Australia

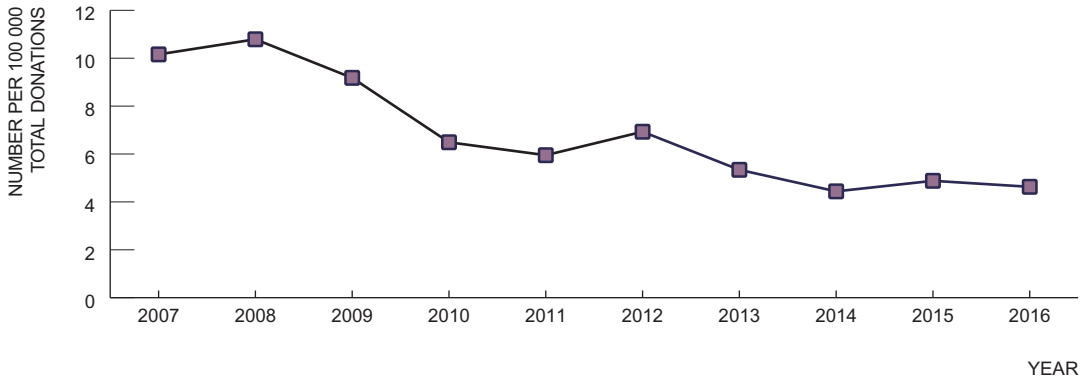
To the end of 2016, an estimated 199 220 (145 759 – 210 200) people were living with chronic hepatitis C in Australia, of which an estimated 81% or 161 509 (130 959 – 191 436) were diagnosed with chronic hepatitis C. Australia has a concentrated chronic hepatitis C epidemic among key populations; people who inject drugs, prisoners, people from high prevalence countries and HIV positive men who have sex with men. The rate of diagnosis of HCV infection in 2016 was 50 per 100 000 which indicates a slight increase after remaining stable in the five-year period 2011-2015, between 44 and 46 per 100 000. This increase in notification rates may reflect a higher number of people coming forward for testing because of the availability of new treatment options. In general, there has been a 15% decline in the rate of notification of hepatitis C over the ten-year period, 2007-2016, from 58 per 100 000 to 50 per 100 000. The rate of diagnosis in those aged less than 25 years has remained stable in the past five years, 2012-2016, after declines between 2007 and 2011. In contrast, the rate of hepatitis C notification in the Aboriginal and Torres Strait Islander population increased by 25.5% in the past five years, from 137 per 100 000 in 2012 to 172 per 100 000 in 2016. The 2016 rate is nearly 4 times greater than in the non-Indigenous population (45 per 100 000). Most cases (64%) of newly diagnosed HCV infection were in males and 54% were in people aged 30 years and above.[1, 8]

Trends in prevalence

All donations:

In the past ten years, 2007-2016, a total of 883* HCV positive donors have been detected (649 first-time donors & 233 repeat donors) (Table 12). During the last ten years, the prevalence of HCV infection among all donations has declined significantly (Table 13). There has been an overall reduction of 54% from 2007 to 2016, from 10.1 per 100 000 donations to 4.6 per 100 000 donations (Figure 14).

Figure 14 Prevalence of HCV infection in all blood donations in Australia, 2007-2016, by year of donation



* One donor positive for HCV in 2009 has his/her donation status unknown and could not be counted under First-time or Repeat donors; therefore, the total comes up to 883 instead of 882

Table 12 The number and prevalence rate of HCV infection in Australia by state/territory, 2016 and 2007-2016

State/Territory of donation	All accepted donations 2016			HCV			State/Territory of donation	All accepted donations 2007-2016			HCV		
	First time	Repeat	All	First time	Repeat	All		First time	Repeat	All	First time	Repeat	All
NSW/ACT	29 485	356 162	385 647	16	3	19	**NSW/ACT**	417 715	3 628 331	4 046 046	252	83	335
Number (*Number per 100 000 donations)*				*54.26*	*0.84*	*4.93*	Number (*Number per 100 000 donations)*				*60.33*	*2.29*	*8.28*
NT	713	8 982	9 695	1	1	2	**NT**	8 133	99 905	108 038	7	4	11
Number (*Number per 100 000 donations)*				*140.25*	*11.13*	*20.63*	Number (*Number per 100 000 donations)*				*86.07*	*4.00*	*10.18*
QLD	20 513	250 133	270 646	9	4	13	**QLD**	249 430	2 381 204	2 630 634	137	64	201
Number (*Number per 100 000 donations)*				*43.87*	*1.60*	*4.80*	Number (*Number per 100 000 donations)*				*54.93*	*2.69*	*7.64*
SA	6 824	114 817	121 641	4	1	5	**SA***	92 281	1 196 151	1 288 432	50	17	68
Number (*Number per 100 000 donations)*				*58.62*	*0.87*	*4.11*	Number (*Number per 100 000 donations)*				*54.18*	*1.42*	*5.28*
TAS	3 037	47 495	50 532	2	0	2	**TAS**	32 394	420 376	452 770	15	11	26
Number (*Number per 100 000 donations)*				*65.85*	*0.00*	*3.96*	Number (*Number per 100 000 donations)*				*46.30*	*2.62*	*5.74*
VIC	25 762	302 652	328 414	14	4	18	**VIC**	269 055	2 824 206	3 093 261	147	37	184
Number (*Number per 100 000 donations)*				*54.34*	*1.32*	*5.48*	Number (*Number per 100 000 donations)*				*54.64*	*1.31*	*5.95*
WA	9 398	120 482	129 880	0	1	1	**WA**	102 179	1 180 396	1 282 575	41	17	58
Number (*Number per 100 000 donations)*				*0.00*	*0.83*	*0.77*	Number (*Number per 100 000 donations)*				*40.13*	*1.44*	*4.52*
National	95 732	1 200 723	1 296 455	46	14	60	**National**	1 171 187	11 730 569	12 901 756	649	233	883
Number (*Number per 100 000 donations)*				*48.05*	*1.17*	*4.63*	Number (*Number per 100 000 donations)*				*55.41*	*1.99*	*6.84*

* One donor positive for HCV from SA in 2009 has his/her donation status unknown and could not be counted under First-time or Repeat donors; therefore, the total comes up to 68 instead of 67

First-time donors:

During 2007-2016, there has been a significant decrease in HCV prevalence in first-time donors in Australia; from 81.5 per 100 000 donations in 2007, to 43.0 per 100 000 donations in 2011 and 48.0 per 100 000 donations in 2016 (Table 13 & 16 and Figure 15). This translates into a decrease from 0.06% of the total first-time donations in 2007 to 0.05% of the total first-time donations in 2016. 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 58 per 100 000 in 2007 to 50 per 100 000 in 2016.[1] .In addition, there has also been a decrease in prevalence of hepatitis C among people seen at needle and syringe programs from 62% in 2007 to 51% in 2016, whilst the rates of receptive needle and syringe sharing in the same period remained stable at an average of 16%, highlighting the importance of sustaining and enhancing harm reduction services.[1]

Figure 15 Prevalence of HCV infection in first time blood donors in Australia, 2007-2016, by year of donation

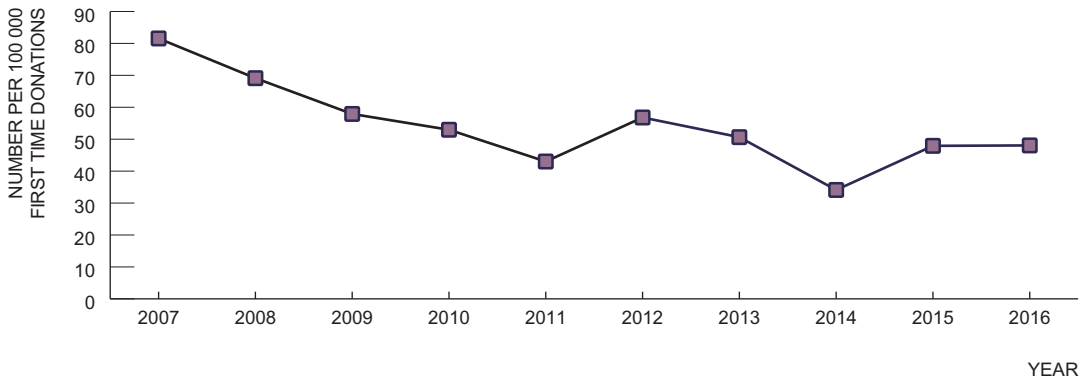


Table 13 Trends in prevalence and incidence of HCV infection in blood donations in Australia, 2007-2016

	Trends in prevalence and Incidence of HCV Infection in blood donations in Australia, 2007-2016	
Prevalence	**IRR (95% CI)**	**p-value**
All donations	*0.90 (0.87-0.92)*	*0.00*
First-time donors	*0.93 (0.91-0.96)*	*0.00*
Incidence	**IRR (95% CI)**	**p-value**
Repeat donors (donor-years of observation)	*0.91 (0.84-0.99)*	*0.03*

Trends in incidence

Over the period 2007-2016, a total of 72 incident HCV infections in donors were detected. For the first time, no HCV incident donor was identified in 2016. The number of HCV incident donors has considerably decreased in the last three 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. This is underscored by the 2016 data in which there were 14 repeat HCV infected donors, but none had their prior negative result in the previous 12 months and thus did not qualify as incident infections. Also, for the first time, a significant downward trend was observed for incidence rates for HCV infection during the 2007-2016 period at 2.23 per 100 000 donor-years of observation (p-value 0.03) (Table 13 & Figure 16). Again, we cannot exclude that the stricter incident case definition contributed to this trend. In contrast, no significant annual trend was observed for incidence of HCV infection over a nine year study period (2007-2015) among people who inject drugs participating in the Australian Needle and Syringe Program Survey, although following a steady decline in 2007-2009 HCV incidence has remained high in the past six years (between 8.0 and 20 per 100 person-years).[1]

Figure 16 Incidence of HCV in repeat blood donors in Australia, 2007-2016

No transfusion-transmitted HCV infections were reported in Australia during 2007-2016.

HCV RNA detection rate in donors

It is generally considered that blood components sourced from HCV antibody positive donors without detectable HCV RNA pose a negligible risk of transfusion-transmission. These donors are presumed to have past resolved infection, however as they meet the public health HCV notification criteria, the Blood Service continues to counsel and refer them for medical follow-up. Notably there has been a steady decline in the proportion of HCV RNA positive (infectious) donors, which was 45% in 2016 (similar to that observed in 2015), 68% in 2008 and around 75% when HCV RNA donation testing was introduced in 2000.

Examining 2008 and 2016 data, the decline is significantly associated with a decrease in the rate of RNA positive donors among first-time donors (or those not previously RNA tested), from 60 per 100 000 in 2008 to 25 per 100 000 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 2007-2016 (Table 13). There were some notable jurisdictional decreases in 2007-2016 (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 66.1 in 2007, to 42.7 in 2011, and 54.26 in 2016; Queensland from 108.4 in 2007, to 41.6 in 2011, and 43.8 in 2016; and lastly Victoria from 107.8 in 2007, to 41.5 in 2011, and 54.3 in 2016 (Table 16). National notifications data indicate the notification rate of hepatitis C infection in Australia in 2015 was highest in the Northern Territory (76 per 100 000) and Queensland (59 per 100 000).[1] 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 0.0 in 2007 and 2011 to 140.2 per 100 000 first-time donations in 2016; with an overall increasing trend in the past five years, 2012-2016 (Figure 17). Similar fluctuation in the notification rates were observed in the general population data for the Northern Territory.[1]

Figure 17 Prevalence of HCV infection among first time donors by state/territory and year of donation, 2007-2016

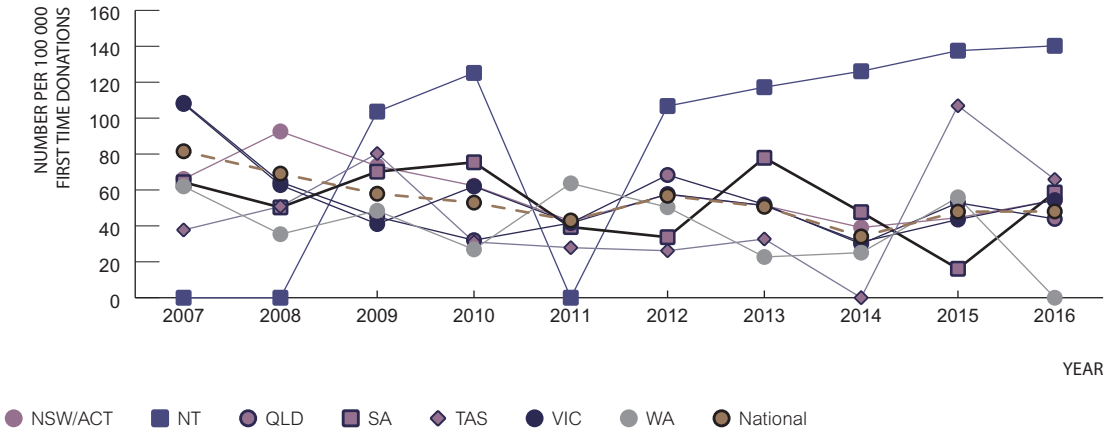
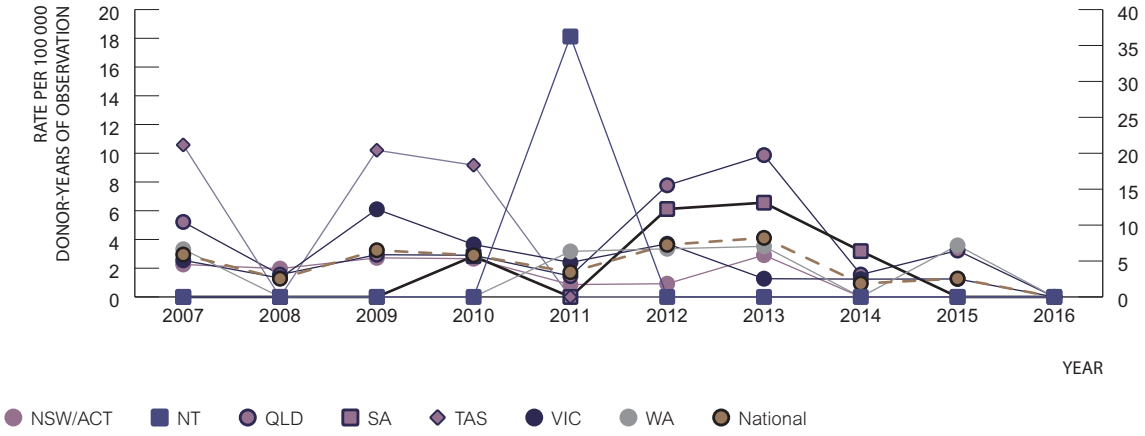


Table 14 Trend in prevalence of HCV infection in first-time donors, by state and territory, 2007-2016

	Prevalence of HCV Infections in First-time Donors, 2007-2016	
	IRR (95% CI)	**p-value**
NSW/ACT	*0.93 (0.89-0.97)*	*0.00*
NT	*1.18 (0.89-1.57)*	*0.22*
QLD	*0.92 (0.86-0.98)*	*0.01*
SA	*0.95 (0.86-1.06)*	*0.41*
TAS	*1.02 (0.85-1.22)*	*0.78*
VIC	*0.93 (0.88-0.99)*	*0.02*
WA	*0.93 (0.83-1.04)*	*0.21*

For the first time, a significant downward annual trend was observed for the HCV incidence in repeat donors nationally during the 2007-2016 study period (Table 15). Generally, the incidence of HCV infection in repeat donors has remained very low across all Australian jurisdictions during the past ten years (Figure 18), with a significant decrease observed for New South Wales/ Australian Capital Territory (p-value 0.03). Notably, in Tasmania and Northern Territory, HCV incidence has remained zero since 2011 and 2012, respectively. The rate in Western Australia has fluctuated in the last three years, 2014-2016, between 0.0 and 3.5 per 100 000 donor-years of observation, following a relatively stable rate of around 3 per 100 000 donor-years of observation in 2010-2013 (Figure 18).

Figure 18 Incidence of HCV infection among repeat donors by state/territory^ and year of donation, 2007-2016



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

Table 15 Incidence of HCV infection in repeat donors, by state and territory, 2007-2016

	Incidence of HCV Infections in Repeat Donors, 2007-2016	
	IRR (95% CI)	**p-value**
NSW/ACT	*0.80 (0.65-0.98)*	*0.03*
NT	*0.97 (0.48-1.95)*	*0.94*
QLD	*0.98 (0.84-1.13)*	*0.78*
SA	*1.14 (0.85-1.52)*	*0.36*
TAS	*0.62 (0.34-1.11)*	*0.11*
VIC	*0.86 (0.73-1.02)*	*0.09*
WA	*1.02 (0.75-1.39)*	*0.88*

Table 16 Number and prevalence[1] of HCV infection among first-time donors, 2007-2016, by state/territory and year of donation

	2007			2008			2009			2010		
State/Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate
NSW/ACT	51 427	34	66.11	48 607	45	92.58	51 821	38	73.33	48 130	30	62.33
NT	759	0	0.00	815	0	0.00	965	1	103.63	799	1	125.16
QLD	28 575	31	108.49	29 498	19	64.41	28 889	13	45.00	28 097	9	32.03
SA	10 886	7	64.30	15 908	8	50.29	11 400	8	70.18	9 284	7	75.40
TAS	2 650	1	37.74	3 936	2	50.81	3 736	3	80.30	3 222	1	31.04
VIC	23 172	25	107.89	30 286	19	62.74	34 133	14	41.02	25 820	16	61.97
WA	11 292	7	61.99	11 307	4	35.38	12 387	6	48.44	11 149	3	26.91
Total	128 761	105	81.55	140 357	97	69.11	143 331	83	57.91	126 501	67	52.96

	2011			2012			2013			2014		
State/Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate
NSW/ACT	51 528	22	42.70	41 780	24	57.44	35 060	18	51.34	30 697	12	39.09
NT	772	0	0.00	937	1	106.72	853	1	117.23	793	1	126.10
QLD	28 839	12	41.61	24 881	17	68.33	21 181	11	51.93	20 043	6	29.94
SA	10 164	4	39.35	8 900	3	33.71	6 417	5	77.92	6 296	3	47.65
TAS	3 587	1	27.88	3 823	1	26.16	3 058	1	32.70	2 538	0	0.00
VIC	31 286	13	41.55	27 718	16	57.72	25 332	13	51.32	22 580	7	31.00
WA	10 992	7	63.68	9 925	5	50.38	8 815	2	22.69	7 972	2	25.09
Total	137 168	59	43.01	117 964	67	56.80	100 716	51	50.64	90 919	31	34.10

	2015			2016			Total 2007-2016		
State/Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate
NSW/ACT	29 180	13	44.55	29 485	16	54.26	417 715	252	60.33
NT	727	1	137.55	713	1	140.25	8 133	7	86.07
QLD	18 914	10	52.87	20 513	9	43.87	249 430	137	54.93
SA	6 202	1	16.12	6 824	4	58.62	92 281	50	54.18
TAS	2 807	3	106.88	3 037	2	65.85	32 394	15	46.30
VIC	22 966	10	43.54	25 762	14	54.34	269 055	147	54.64
WA	8 942	5	55.92	9 398	0	0.00	102 179	41	40.13
Total	89 738	43	47.92	95 732	46	48.05	1 171 187	649	55.41

1 Rate per 100 000 First-time donations

Table 17 Number and rate[1] of HCV infection among repeat donations, 2007-2016, by state/territory and year of donation

	2007			2008			2009			2010		
State/Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate
NSW/ACT	338 173	7	2.07	339 062	18	5.31	372 806	15	4.02	380 014	9	2.37
NT	10 214	0	0.00	11 166	0	0.00	11 158	0	0.00	10 470	0	0.00
QLD	209 556	3	1.43	226 726	11	4.85	242 001	7	2.89	243 837	5	2.05
SA	114 618	0	0.00	118 476	1	0.84	126 855	3	2.36	123 587	0	0.00
TAS	28 019	1	3.57	33 321	2	6.00	37 274	2	5.37	41 484	1	2.41
VIC	252 340	3	1.19	259 052	3	1.16	276 835	8	2.89	278 897	3	1.08
WA	109 425	2	1.83	113 274	2	1.77	118 327	3	2.54	120 646	1	0.83
Total	1 062 345.00	16	2	1 101 077	37	3.36	1 185 256	38	3.21	1 198 935	19	1.58

	2010			2011			2012			2013		
State/Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate
NSW/ACT	390 455	9	2.31	377 220	8	2.12	373 670	5	1.34	353 055	6	1.70
NT	10 782	1	9.27	9 673	0	0.00	9 493	0	0.00	8 914	0	0.00
QLD	245 975	4	1.63	237 599	8	3.37	243 042	7	2.88	239 720	10	4.17
SA	124 199	1	0.81	120 720	2	1.66	119 530	3	2.51	116 658	3	2.57
TAS	44 661	0	0.00	46 379	1	2.16	48 953	1	2.04	45 788	2	4.37
VIC	288 085	3	1.04	285 168	3	1.05	292 058	2	0.68	288 753	4	1.39
WA	121 057	4	3.30	117 728	2	1.70	123 298	1	0.81	118 014	0	0.00
Total	1 225 214	22	1.80	1 194 487	24	2.01	1 210 044	19	1.57	1 170 902	25	2.14

	2014			2015			Total 2006-2015		
State/Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate
NSW/ACT	347 714	3	0.86	356 162	3	0.84	3 628 331	83	2.29
NT	9 053	2	22.09	8 982	1	11.13	99 905	4	4.00
QLD	242 615	5	2.06	250 133	4	1.59	2 381 204	64	2.69
SA	116 691	3	2.57	114 817	1	0.87	1 196 151	17	1.42
TAS	47 002	1	2.13	47 495	0	0.00	420 376	11	2.62
VIC	300 366	4	1.33	302 652	4	1.32	2 824 206	37	1.31
WA	118 145	1	0.85	120 482	1	0.82	1 180 396	17	1.44
Total	1 181 586	19	1.61	1 200 723	14	1.16	11 730 569	233	1.99

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 HCV prevalence among first-time blood donors and the general population for a combined period of 2007-2016, and then 2016 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 17 times lower prevalence in first-time donors for the period 2007-2016 and for the year 2016 as compared to the prevalence in the 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, 2007-2016

Infection	Estimated population prevalence* (per 100 000 people)		Prevalence in first time blood donors (per 100 000 donations)		Comparison of HCV prevalence in first time blood donors with population prevalence	
	2007-2016	**2016**	**2007-2016**	**2016**	**2007-2016**	**2016**
HCV	962	823	55.41	48.05	17 times lower	17 times lower

* The 2016 HCV prevalence in the general population was calculated by taking the estimated number of people living with chronic HCV[1], and dividing it by the estimated mid-year resident Australian population in 2016 reported by the Australian Bureau of Statistics. For the period 2007-2016, an average of the ten years' prevalence rates was calculated.

Demographic factors associated with HCV infections in blood donors

Data on the demographic characteristics (sex, age group, state/territory and year of donation) for all blood donors were analysed** to determine the association between demographic factors and presence of HCV infection among Australian blood donors in 2016 and the five-year period 2012-2016 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, 2016, and 2012-2016

	HCV 2016				HCV 2012-2016			
	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	*229 726*	*40 (17.41)*	*1 (ref)*	*…*	*1 221 021*	*215 (17.61)*	*1 (ref)*	*…*
Female	*228 406*	*20 (8.76)*	*0.56 (0.32-0.96)*	*0.03*	*1 232 932*	*124 (10.06)*	*0.60 (0.48-0.75)*	*0.00*
Age group (years)								
20-29	*104 568*	*5 (4.78)*	*1 (ref)*	*…*	*348 855*	*10 (2.87)*	*1 (ref)*	*…*
Less than 20	*32 806*	*0 (0)*	*…*	*0.99*	*409 385*	*41 (10.02)*	*0.62 (0.31-1.25)*	*0.18*
30-39	*84 061*	*11 (13.09)*	*2.64 (0.91-7.61)*	*0.07*	*407 699*	*52 (12.75)*	*1.64 (1.09-2.48)*	*0.01*
40-49	*78 090*	*11 (14.09)*	*2.85 (0.98-8.21)*	*0.05*	*422 408*	*75 (17.76)*	*2.28 (1.55-3.34)*	*0.00*
50 and above	*158 607*	*33 (20.81)*	*4.15 (1.61-10.66)*	*0.00*	*865 606*	*161 (18.6)*	*2.37 (1.68-3.35)*	*0.00*
State/Territory								
NSW	*134 421*	*17 (12.65)*	*1 (ref)*	*…*	*742 406*	*98 (13.2)*	*1 (ref)*	*…*
ACT	*12 030*	*2 (16.63)*	*1.34 (0.31-5.81)*	*0.69*	*64 088*	*10 (15.6)*	*1.17 (0.61-2.25)*	*0.62*
NT	*3 260*	*2 (61.35)*	*5.13 (1.18-22.26)*	*0.02*	*18 831*	*8 (42.48)*	*3.28 (1.59-6.74)*	*0.00*
QLD	*91 333*	*13 (14.23)*	*1.11 (0.54-2.29)*	*0.77*	*489 437*	*87 (17.78)*	*1.32 (0.99-1.77)*	*0.05*
SA	*40 366*	*5 (12.39)*	*0.92 (0.33-2.49)*	*0.87*	*222 369*	*28 (12.59)*	*0.83 (0.54-1.29)*	*0.42*
TAS	*15 371*	*2 (13.01)*	*0.97 (0.22-4.23)*	*0.97*	*80 354*	*12 (14.93)*	*1.08 (0.59-1.97)*	*0.79*
VIC	*119 434*	*18 (15.07)*	*1.18 (0.61-2.30)*	*0.61*	*617 064*	*77 (12.48)*	*0.94 (0.70-1.27)*	*0.7*
WA	*41 917*	*1 (2.39)*	*0.18 (0.02-1.40)*	*0.1*	*219 404*	*19 (8.66)*	*0.63 (0.39-1.04)*	*0.07*
Total	458 132	60 (13.09)			2 453 953	339 (13.81)		

In 2016, like HBV, female donors were 44% less likely to be HCV positive. Donors over 50 years of age were four times more likely to be HCV positive, and donors from Northern Territory were five 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 (40%) 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 339 HCV positive donors during 2012-2016, 73% were first-time donors and 63% were male. The mean age was 46 years with a wide range (16-71) over the last five years (Table 20). Unlike HBV where birth overseas predominated, the majority (68%) of HCV positive donors were born in Australia during 2012-2016, and 67% in 2016 (Figure 19). Overall, the main putative reported risk factor for HCV positivity during 2012-2016 was tattoo or body piercing (26%), followed by intravenous drug use (24%). 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 and this may reflect association rather than causation and non-disclosure of another risk factor. 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 32 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, 2012–2016

Characteristics	2012	2013	2014	2015	2016	2012-2016
Number of positive donors	91	70	56	62	60	339
Number of positive First-time donors (%)	67 (74%)	52 (74%)	38 (68%)	43 (69%)	46 (77%)	246 (73%)
% male	56 (62%)	43 (61%)	37 (66%)	39 (63%)	40 (67%)	215 (63%)
Mean age (range) in years	44 (16 to 66)	45 (23 to 66)	48 (18 to 71)	44.27 (16-67)	48 (22-67)	46 (16 to71)
Number of incident donors	12	13	3	4	0	32
% born in Australia	62 (68%)	41 (59%)	44 (79%)	43 (69%)	40 (67%)	230 (68%)
Main reported risk factor	Tattoo/Body piercing 31%	Tattoo/Body piercing 34%	Intravenous drug use 30%	Tattoo/Body piercing 29%	Intravenous drug use 27%	Tattoo/Body piercing 26%
Second reported risk factor	Intravenous drug use 23%	Intravenous drug use 19%	TBP[1], BTR[2] each 13%	Intravenous drug use 23%	Tattoo/Body piercing 20%	Intravenous drug use 24%

1 TBP= Tattoo/Body piercing
2 BTR= Blood/tissue recipient

Figure 19 Donors with HCV infection by country/region of birth, 2016 (n=60)

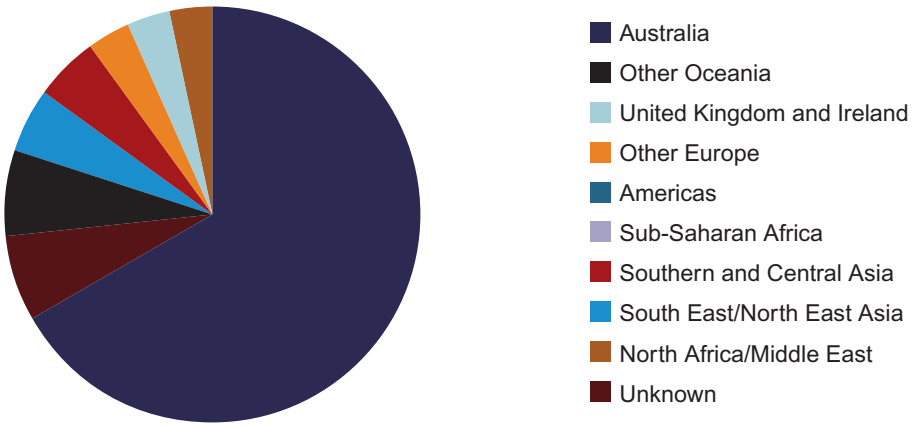
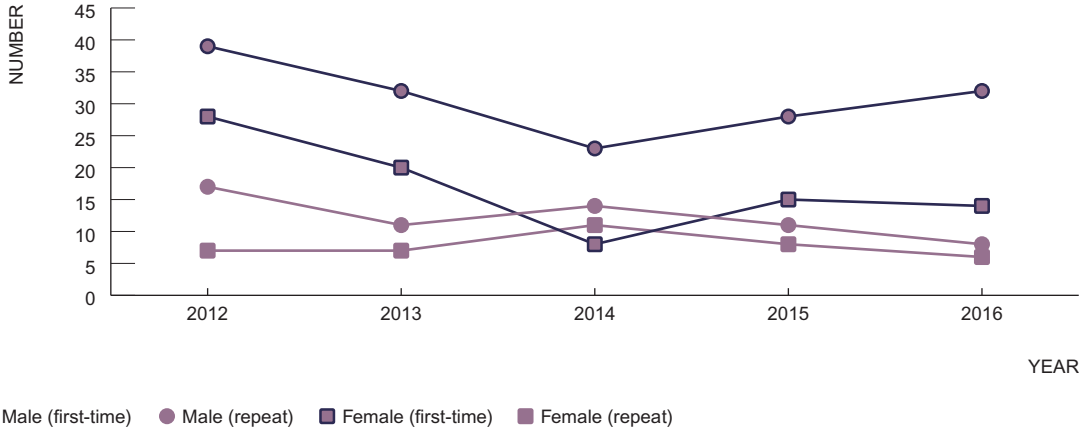


Figure 20 Donors with HCV infection by sex and donor status, 2012-2016



Over the past five years, 2012-2016, there has been a downward trend in the number of HCV positive first-time and repeat male donors, and first-time female donors (Figure 20); the number of HCV positive repeat female donors on the other hand remained relatively stable during the same period of time. For more information on the number and percentage of donors with HCV infection by sex, age group, donor status, country of birth and exposure category for period 2012-2016, see Appendix C.

HCV - Comparison of major exposure categories between blood donors and the general population, 2016

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 2016 was intravenous drug use (26.7%), followed by tattoo or body piercing (20%). 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 60% of the newly acquired HCV infections 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] (nearly 35%) was slightly higher than in the donor population (26.7%) in 2016. 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 postdonation interview after testing positive.

Table 21 Comparison between HCV positive blood donors and general population in Australia by major potential risk categories, 2016

		HCV[1]
Major risk category	**General population (%)**	**Blood donors (%)**
Intravenous drug use	34.6	26.7
Country of birth/Ethnicity	0.6	8.3
Sexual contact[2]	1.5	5
Blood or tissue recipient	0.0	10
Tattoo or body piercing	0.6	20
Exposure in health care setting	0.4	11.7
Household contact	0.7	1.7
Other blood to blood contact	0.4	1.7
Other/undetermined/unknown[3]	60	13.3
Imprisonment	2.6	1.7
No risk factor Identified	0.3	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
3 Includes 'no risk factors reported' in general population. Of note, risk factors are not reported for newly acquired HCV cases from QLD and NT

Conclusion:

- Supporting the effectiveness of the donor questionnaire, donor education and selection, the prevalence of HCV infection among first-time donors has shown a significant declining trend since 2007 and was 17 times lower among first-time blood donors than the general population estimate in 2016, and for the period 2007-2016.
- For the first time, the incidence of HCV has shown a significant declining trend in the ten-year study period 2007-2016, although this might be confounded by a change in the incident case definition in 2014. The incidence rate of HCV infection remains 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 (or previously untested) with detectable RNA and this reflects declining incidence in the general population.
- Infective risk factors identified in blood donors with HCV infection in 2016 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 three HIV infections detected among all donations in 2016 (one first-time and two repeat donors).

2. The prevalence of HIV infection among first-time donors during 2007-2016 remained very low at 1.8 per 100 000 donations (or 0.002% of the total first-time donations) and comparatively much lower than hepatitis B (80.4 per 100 000 donations) and hepatitis C (55.41 per 100 000 donations). However, no significant trend was observed for prevalence rates for HIV infection during this time. The 0.002% HIV prevalence in first-time donors during 2007-2016 is 102 times lower than the 0.1% prevalence reported for HIV national surveillance data.

3. During 2007-2016, the incidence of HIV infection per 100 000 donor-years of observation among previously negative repeat donors remained low over time; 0.6 in 2007, 0.8 in 2011, and 0.3 in 2016.

4. In 2016, the mean age of HIV positive donors was 46 years as compared to 41.6 years for all donors in 2016. Like HBV and HCV, HIV positive donors were more likely to be male as compared to all donors (67% vs 50%) but unlike HBV, most (67%) were Australian-born.

5. The two most common reported routes of exposure for donors with HIV infection during 2012-2016 were male-to-male sex (42%), followed by heterosexual sex with partners with known risk factors or known to be HIV positive (21%). This compares to the new HIV diagnoses notification data in Australia where men who have sex with men accounted for 75.3% of new HIV diagnoses in Australia in 2016, followed by heterosexual sex (20.6%).[1]

6. No transfusion-transmitted HIV infections were reported in Australia during 2007-2016.

Epidemiology of HIV in Australia

During 2016, an estimated 25 820 (22 820 – 28 970) people were living with HIV and an estimated majority (90%) or 23 650 were diagnosed (21 030 – 26 290). Transmission of HIV in Australia continues to occur primarily through sexual contact between men, with 84% of newly acquired cases of HIV infection in Australia in the period 2007 to 2016 involving men who reported sexual contact with men. The annual number of new HIV diagnoses has gradually increased by 7% over the past 10 years, from 947 diagnoses in 2007 to 1 013 in 2016. Of these newly diagnosed HIV infections in 2016, 91% were in males, 70% occurred among men who have sex with men, 5% due to male-to-male sex and injecting drug use, 21% were attributed to heterosexual sex, and 1% 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 other countries in the region.[1]

Trends in prevalence

All donations:

In the past ten years, 2007-2016, a total of 51 HIV positive donors have been detected (22 first-time donors & 29 repeat donors) (Table 22). During this period, the prevalence of HIV infection among all donations has shown no statistically significant trend (Table 23 & Figure 22). The prevalence rate among all donors has fluctuated over time from 0.4 per 100 000 donations in 2007 to 0.5 in 2011 and was 0.2 per 100 000 donations in 2016 (Figure 21).

Figure 21 Prevalence of HIV infection in all blood donations in Australia, 2007-2016, by year of donation

Table 22 The number and prevalence rate of HIV infection in Australia by state/territory, 2016 and 2007-2016

State/Territory of donation	All accepted donations 2016			HIV			State/Territory of donation	All accepted donations 2007-2016			HIV		
	First time	Repeat	All	First time	Repeat	All		First time	Repeat	All	First time	Repeat	All
NSW/ACT	29 485	356 162	385 647	0	1	1	**NSW/ACT**	417 715	3 628 331	4 046 046	8	6	14
Number (*Number per 100 000 donations)*				*0.00*	*0.28*	*0.26*	Number (*Number per 100 000 donations)*				*1.92*	*0.17*	*0.35*
NT	713	8 982	9 695	0	0	0	**NT**	8 133	99 905	108 038	0	1	1
Number (*Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*	Number (*Number per 100 000 donations)*				*0.00*	*1.00*	*0.93*
QLD	20 513	250 133	270 646	0	0	0	**QLD**	249 430	2 381 204	2 630 634	6	10	16
Number (*Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*	Number (*Number per 100 000 donations)*				*2.41*	*0.42*	*0.61*
SA	6 824	114 817	121 641	0	0	0	**SA**	92 281	1 196 151	1 288 432	0	2	2
Number (*Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*	Number (*Number per 100 000 donations)*				*0.00*	*0.17*	*0.16*
TAS	3 037	47 495	50 532	0	0	0	**TAS**	32 394	420 376	452 770	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	25 762	302 652	328 414	1	1	2	**VIC**	269 055	2 824 206	3 093 261	6	9	15
Number (*Number per 100 000 donations)*				*3.88*	*0.33*	*0.61*	Number (*Number per 100 000 donations)*				*2.23*	*0.32*	*0.48*
WA	9 398	120 482	129 880	0	0	0	**WA**	102 179	1 180 396	1 282 575	2	1	3
Number (*Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*	Number (*Number per 100 000 donations)*				*1.96*	*0.08*	*0.23*
National	95 732	1 200 723	1 296 455	1	2	3	**National**	1 171 187	11 730 569	12 901 756	22	29	51
Number (*Number per 100 000 donations)*				*1.04*	*0.17*	*0.23*	Number (*Number per 100 000 donations)*				*1.88*	*0.25*	*0.40*

First-time donors:

The overall HIV prevalence in first-time donors remained very low at 1.8 per 100 000 over the ten-year period 2007-2016 (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. Since 2011, it fluctuated between 3.3 and 0.8 per 100 000 donations, and was 1.0 per 100 000 donations in 2016 (Figure 22). 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 2007-2016 is encouraging given that the number of newly diagnosed HIV infections in the general Australian population increased steadily in the past decade by 7%, from 947 diagnoses in 2007 to 1 013 cases of newly diagnosed HIV infection in Australia in 2016.[1]

Figure 22 Prevalence of HIV infection in first-time blood donors in Australia, 2007-2016, by year of donation

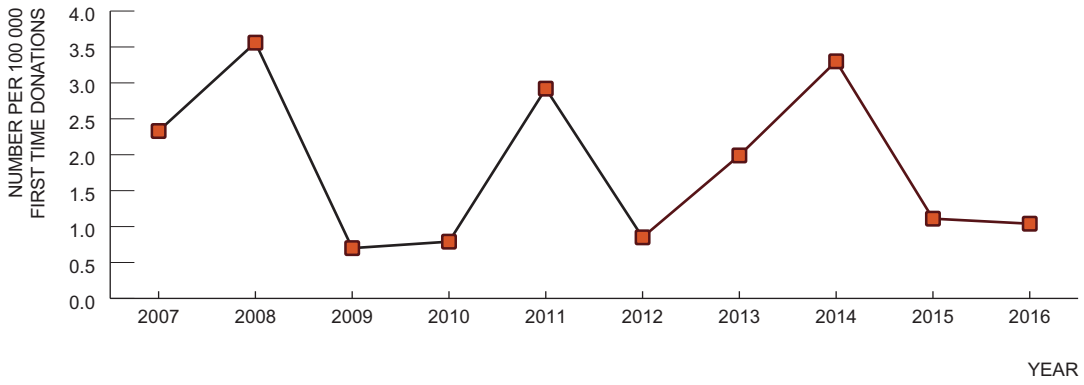


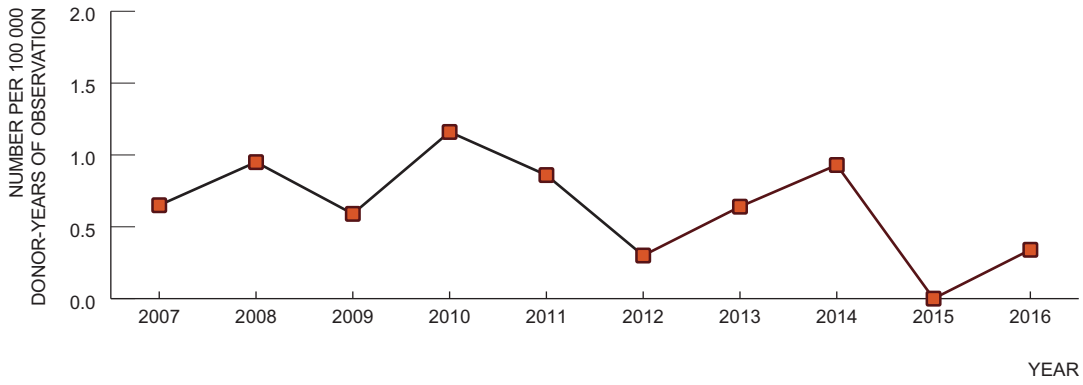
Table 23 Trends in prevalence and incidence of HIV infection in blood donations in Australia, 2007-2016

Trends in prevalence and Incidence of HIV Infection in blood donations in Australia, 2007-2016		
Prevalence	**IRR (95% CI)**	**p-value**
All donations	*0.91 (0.83-1.01)*	*0.08*
First-time donors	*0.95 (0.81-1.10)*	*0.51*
Incidence	**IRR (95% CI)**	**p-value**
Repeat donors (donor-years of observation)	*0.90 (0.77-1.06)*	*0.23*

Trends in incidence

In 2016 one incident infection was detected for HIV. For the ten-year period 2007-2016, 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 23). Likewise, no significant trend was observed for the incidence of HIV in a five-year study period (2012-2016) among gay and bisexual men attending sexual health services; the incidence remained less than 0.1 per 100 person years (fluctuating between 0.58 per 100 person years to 0.85 per 100 person years).[1]

Figure 23 Incidence of HIV in repeat blood donors in Australia, 2007-2016, by year of donation



No transfusion-transmitted HIV infections were reported in Australia during 2007-2016.

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 2007-2016 period, with an average national prevalence of 1.8 per 100 000 donations (Table 26). No significant annual trend was observed during the 2007-2016 period in any jurisdiction (Table 24 & Figure 24). In 2016, HIV prevalence in the first-time donors was zero in all jurisdictions except Victoria where the rate was 3.8 per 100 000 donations (Table 26). During 2007-2016, HIV prevalence in first-time donors was zero in the Northern Territory, South Australia and Tasmania (Table 26).

Figure 24 Prevalence of HIV infection among first time donors by state/territory and year of donation, 2007-2016

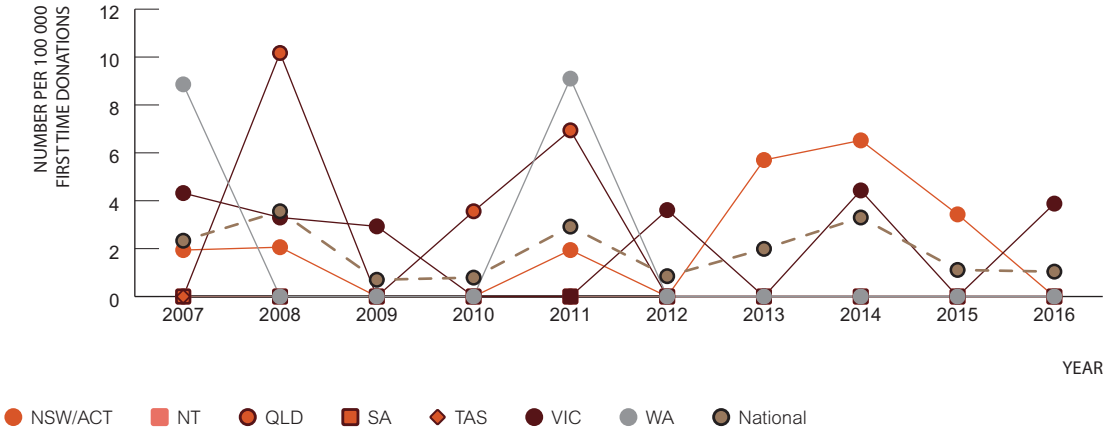


Table 24 Trend in prevalence of HIV infection in first-time donors, by state and territory, 2007-2016

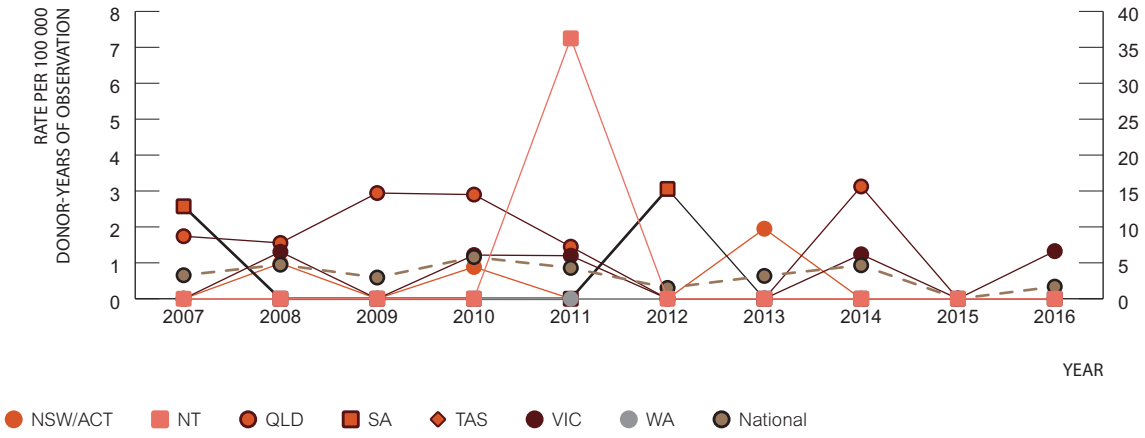
	Prevalence of HIV Infections in First-time Donors, 2007-2016	
	IRR (95% CI)	p-value
NSW/ACT	*1.13 (0.88-1.44)*	*0.33*
NT	…	…
QLD	*0.77 (0.54-1.09)*	*0.14*
SA	…	…
TAS	…	…
VIC	*0.95 (0.71-1.27)*	*0.77*
WA	*0.71 (0.37-1.37)*	*0.31*

Incident HIV infections in blood donors continue to be a rare occurrence with only one incident donor identified in 2016. No incident HIV donors were recorded in Tasmania or in Western Australia in the past ten years, 2007-2016. No significant annual trend was observed in any jurisdiction during 2007-2016 (Table 25). The incidence rate has fluctuated in Queensland during the past ten years; it steadily declined from 2.9 per 100 000 donor-years of observation in 2010 to 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 and 2016 (Figure 26). However, given this rise in 2014 equates to only two incident infections, caution should be taken in interpretation. Similarly, the incidence rate of 36.2 per 100 000 donor-years of observation noted in the Northern territory in 2011 should be interpreted with caution as this is associated with only one incident donor (Figure 25).

Table 25 Incidence of HIV infection in repeat donors, by state and territory, 2007-2016

	Incidence of HIV Infections in Repeat Donors, 2007-2016	
	IRR (95% CI)	p-value
NSW/ACT	*0.93 (0.65-1.34)*	*0.73*
NT	*0.97 (0.48-1.95)*	*0.94*
QLD	*0.84 (0.66-1.08)*	*0.19*
SA	*0.78 (0.44-1.38)*	*0.4*
TAS	…	…
VIC	*1.03 (0.76-1.41)*	*0.8*
WA	…	…

Figure 25 Incidence of HIV infection among repeat donors by state/territory^ and year of donation, 2007-2016



^ 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, 2007-2016, by state/territory and year of donation

	2007			2008			2009			2010		
State/Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate
NSW/ACT	51 427	1	1.94	48 607	1	2.06	51 821	0	0.00	48 130	0	0.00
NT	759	0	0.00	815	0	0.00	965	0	0.00	799	0	0.00
QLD	28 575	0	0.00	29 498	3	10.17	28 889	0	0.00	28 097	1	3.56
SA	10 886	0	0.00	15 908	0	0.00	11 400	0	0.00	9 284	0	0.00
TAS	2 650	0	0.00	3 936	0	0.00	3 736	0	0.00	3 222	0	0.00
VIC	23 172	1	4.32	30 286	1	3.30	34 133	1	2.93	25 820	0	0.00
WA	11 292	1	8.86	11 307	0	0.00	12 387	0	0.00	11 149	0	0.00
Total	128 761	3	2.33	140 357	5	3.56	143 331	1	0.70	126 501	1	0.79

	2011			2012			2013			2014		
State/Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate
NSW/ACT	51 528	1	1.94	41 780	0	0.00	35 060	2	5.70	30 697	2	6.52
NT	772	0	0.00	937	0	0.00	853	0	0.00	793	0	0.00
QLD	28 839	2	6.94	24 881	0	0.00	21 181	0	0.00	20 043	0	0.00
SA	10 164	0	0.00	8 900	0	0.00	6 417	0	0.00	6 296	0	0.00
TAS	3 587	0	0.00	3 823	0	0.00	3 058	0	0.00	2 538	0	0.00
VIC	31 286	0	0.00	27 718	1	3.61	25 332	0	0.00	22 580	1	4.43
WA	10 992	1	9.10	9 925	0	0.00	8 815	0	0.00	7 972	0	0.00
Total	137 168	4	2.92	117 964	1	0.85	100 716	2	1.99	90 919	3	3.30

	2015			2016			Total 2007-2016		
State/Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate
NSW/ACT	29 180	1	3.43	29 485	0	0.00	417 715	8	1.92
NT	727	0	0.00	713	0	0.00	8 133	0	0.00
QLD	18 914	0	0.00	20 513	0	0.00	249 430	6	2.41
SA	6 202	0	0.00	6 824	0	0.00	92 281	0	0.00
TAS	2 807	0	0.00	3 037	0	0.00	32 394	0	0.00
VIC	22 966	0	0.00	25 762	1	3.88	269 055	6	2.23
WA	8 942	0	0.00	9 398	0	0.00	102 179	2	1.96
Total	89 738	1	1.11	95 732	1	1.04	1 171 187	22	1.88

[1] Rate per 100 000 First-time donations

Table 27 Number and rate[1] of HIV infection among repeat donations, 2007-2016, by state/territory and year of donation

	2007			2008			2009			2010		
State/Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate
NSW/ACT	338 173	0	0.00	339 062	1	0.29	372 806	0	0.00	380 014	2	0.53
NT	10 214	0	0.00	11 166	0	0.00	11 158	0	0.00	10 470	0	0.00
QLD	209 556	1	0.48	226 726	1	0.44	242 001	2	0.83	243 837	3	1.23
SA	114 618	1	0.87	118 476	0	0.00	126 855	0	0.00	123 587	0	0.00
TAS	28 019	0	0.00	33 321	0	0.00	37 274	0	0.00	41 484	0	0.00
VIC	252 340	0	0.00	259 052	3	1.16	276 835	0	0.00	278 897	1	0.36
WA	109 425	0	0.00	113 274	0	0.00	118 327	0	0.00	120 646	0	0.00
Total	1 062 345	2	0.19	1 101 077	5	0.45	1 185 256	2	0.17	1 198 935	6	0.50

	2011			2012			2013			2014		
State/Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate
NSW/ACT	390 455	0	0.00	377 220	0	0.00	373 670	2	0.54	353 055	0	0.00
NT	10 782	1	9.27	9 673	0	0.00	9 493	0	0.00	8 914	0	0.00
QLD	245 975	1	0.41	237 599	0	0.00	243 042	0	0.00	239 720	2	0.83
SA	124 199	0	0.00	120 720	1	0.83	119 530	0	0.00	116 658	0	0.00
TAS	44 661	0	0.00	46 379	0	0.00	48 953	0	0.00	45 788	0	0.00
VIC	288 085	1	0.35	285 168	1	0.35	292 058	0	0.00	288 753	1	0.35
WA	121 057	0	0.00	117 728	0	0.00	123 298	0	0.00	118 014	1	0.85
Total	1 225 214	3	0.24	1 194 487	2	0.17	1 210 044	2	0.17	1 170 902	4	0.34

	2015			2016			Total 2007-2016		
State/Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate
NSW/ACT	347 714	0	0.00	356 162	1	0.28	3 628 331	6	0.17
NT	9 053	0	0.00	8 982	0	0.00	99 905	1	1.00
QLD	242 615	0	0.00	250 133	0	0.00	2 381 204	10	0.42
SA	116 691	0	0.00	114 817	0	0.00	1 196 151	2	0.17
TAS	47 002	0	0.00	47 495	0	0.00	420 376	0	0.00
VIC	300 366	1	0.33	302 652	1	0.33	2 824 206	9	0.32
WA	118 145	0	0.00	120 482	0	0.00	1 180 396	1	0.08
Total	1 181 586	1	0.08	1 200 723	2	0.17	11 730 569	29	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 2007-2016, and then 2016 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 58 times lower prevalence in first-time donors for the period 2007-2016, and a 102 times lower prevalence in 2016 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, 2007-2016

Infection	Estimated population prevalence (per 100 000 people)		Prevalence in first time blood donors (per 100 000 donations)		Comparison of HIV prevalence in first time blood donors with population prevalence	
	2007-2016	**2016**	**2007-2016**	**2016**	**2007-2016**	**2016**
HIV	108	107	1.88	1.04	58 times lower	102 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 2016 and the five-year period 2012-2016 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, 2016, and 2012-2016

	HIV 2016				HIV 2012-2016			
	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	*229 726*	*2 (0.87)*	*1 (ref)*	*…*	*1 221 021*	*15 (1.23)*	*1 (ref)*	*…*
Female	*228 406*	*1 (0.44)*	*0.58 (0.05-6.49)*	*0.66*	*1 232 932*	*4 (0.32)*	*0.26 (0.08-0.79)*	*0.01*
Age group (years)								
20-29	*104 568*	*0 (0)*	*1 (ref)*	*…*	*348 855*	*1 (0.29)*	*1 (ref)*	*…*
Less than 20	*32 806*	*0 (0)*	*..*	*1*	*409 385*	*5 (1.22)*	*0.53 (0.06-4.60)*	*0.56*
30-39	*84 061*	*1 (1.19)*	*..*	*0.99*	*407 699*	*5 (1.23)*	*1.20 (0.34-4.18)*	*0.76*
40-49	*78 090*	*0 (0)*	*..*	*1*	*422 408*	*2 (0.47)*	*0.48 (0.09-2.48)*	*0.38*
50 and above	*158 607*	*2 (1.26)*	*..*	*0.99*	*865 606*	*6 (0.69)*	*0.70 (0.21-2.32)*	*0.56*
State/Territory								
NSW	*134 421*	*1 (0.74)*	*1 (ref)*	*…*	*742 406*	*6 (0.81)*	*1 (ref)*	*…*
ACT	*12 030*	*0 (0)*	*..*	*1*	*64 088*	*2 (3.12)*	*3.75 (0.75-18.6)*	*0.1*
NT	*3 260*	*0 (0)*	*..*	*1*	*18 831*	*0 (0)*	*…*	*0.99*
QLD	*91 333*	*0 (0)*	*..*	*1*	*489 437*	*2 (0.41)*	*0.50 (0.10-2.50)*	*0.4*
SA	*40 366*	*0 (0)*	*..*	*1*	*222 369*	*1 (0.45)*	*0.57 (0.06-4.74)*	*0.6*
TAS	*15 371*	*0 (0)*	*..*	*1*	*80 354*	*0 (0)*	*…*	*0.99*
VIC	*119 434*	*2 (1.67)*	*2.23 (0.20-24.70)*	*0.51*	*617 064*	*7 (1.13)*	*1.38 (0.46-4.12)*	*0.56*
WA	*41 917*	*0 (0)*	*..*	*0.99*	*219 404*	*1 (0.46)*	*0.54 (0.06-4.53)*	*0.57*
Total	458 132	3 (0.65)			2 453 953	19 (0.77)		

In 2016, unlike HBV, there was no significant association between gender and HIV infection status. Given the small number of donors with HIV in 2016, no meaningful analysis was possible for association between HIV positivity and donors' age group or location (Table 30).

During the five-year period, 2012-2016, female donors were significantly less likely (74%) compared to male donors to be HIV positive. Unlike last year where 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 between HIV positivity and donor's age group for the period 2012-2016. Similarly, 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

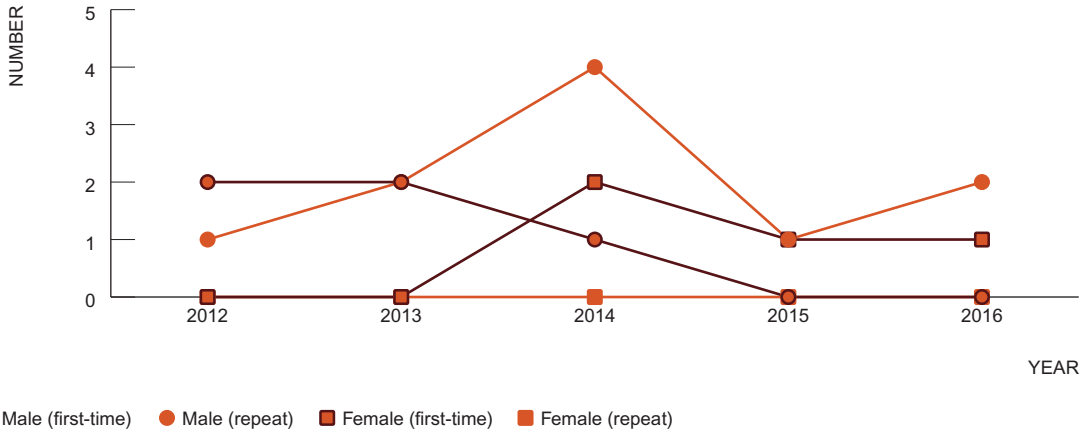
In contrast to HBV and HCV infected donors, the majority of HIV infected donors during 2012-2016 were repeat donors (63%) (Table 30). Most were male (79%) with a mean age of 39 years. Male-to-male sexual contact (42%) and having a sexual partner with known risk or known to be positive for any TTI (21%) were the two most common reported risk factors for HIV positivity in blood donors during 2012-2016. Similarly, male-to-male sexual contact and heterosexual contact accounted for 70% and 21% of the new HIV diagnoses in the general population in 2016, respectively.[1] Of 19 HIV positive donors in the five-year period 2012-2016, seven were incident HIV infections.

Table 30 Characteristics of donors positive for HIV infection by year of donation, 2012–2016

Characteristics	2012	2013	2014	2015	2016	2012-2016
Number of positive donors	3	4	7	2	3	19
Number of positive First-time donors (%)	1 (33%)	2 (50%)	2 (29%)	1 (50%)	1 (33%)	7 (37%)
% male	3 (100%)	4 (100%)	5 (71%)	1 (50%)	2 (67%)	15 (79)
Mean age (range) in years	36 (19 to 56)	47 (28 to 65)	36 (26 to 56)	30 (26-33)	46 (30-56)	39 (19 to 65)
Number of incident donors	1	2	3	0	1	7
% born in Australia	2 (67%)	3 (75%)	3 (43%)	1 (50%)	2 (67%)	11 (58%)
Main reported risk factor	PRP[2]	MSM[1] contact	MSM[1] contact	Other, Unknown each	PRP[2], MSM[1] contact, Unknown each	MSM[1] contact
	100%	75%	43%	50%	33%	42%
Second reported risk factor	MSM[1] contact	Ethnicity/COB	PRP[2], BTR[3], Unknown each	…	…	PRP[2]
	33%*	25%	14%			21%

1 MSM= Male to male contact
2 PRP= Partner with known risk/known to be positive
3 BTR= Blood/tissue recipient
* 1 out of 3 positive donors in 2012 who reported partner with known risks/known to be positive also reported a MSM contact

Figure 26 Donors with HIV infection by sex and donor status, 2012-2016



Over the past five years, 2012-2016, 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 female donors. There has been no repeat female donor positive for HIV during this time (Figure 26); For more information on the number and percentage of donors with HIV infection by sex, age group, donor status, country of birth and exposure category for the period 2012-2016, see Appendix D.

HIV - Comparison of major exposure categories between blood donors and the general population, 2016

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 infections in the general population were attributed to sexual contact (96%).[1] This was consistent with the findings among blood donors, where sexual contact was identified as the primary risk factor for 2 out of 3 positive donors (66.7%).

Table 31 Comparison between HIV positive blood donors and general population in Australia by major potential risk categories, 2016

		HIV[1]
Major risk category	**General population (%)**	**Blood donors (%)**
Intravenous drug use	1.4	0.0
Country of birth/Ethnicity	0.0	0.0
Sexual contact[2]	95.9	66.7
Blood or tissue recipient[3]	0.1	0.0
Tattoo or body piercing	0.0	0.0
Exposure in health care setting	0.0	0.0
Household contact	0.0	0.0
Other blood to blood contact	0.0	0.0
Other/undetermined/unknown	2.6	33.3
Imprisonment	0.0	0.0
No risk factor identified	0.0	0.0

1 Includes exposure categories for new HIV diagnoses only in general population
2 Includes three sub-groups: Male-to-male sexual contact, Partner with known risk or known to be positive and Engaged in sex work
3 Includes receipt of blood/tissue overseas, so does not indicate transmission through blood products in Australia

Conclusion

- The prevalence of HIV infection is 102 times lower among first-time blood donors than in the general population in 2016, and 58 times lower for the period 2007-2016.
- 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 2016.

Human T-Lymphotropic Virus (HTLV):

Main findings

1. There were five HTLV infections detected among all donations in 2016 (all in first-time donors).

2. The prevalence of HTLV infection among first-time donors during 2007-2016 has remained low at 3.5 per 100 000 donations, and has shown no significant trend. Population prevalence for HTLV is unknown; therefore, comparison of prevalence rates among first-time donors and the general population is not possible.

3. The HTLV incidence among repeat Australian donors in 2016 was zero as it was for the ten-year period 2007-2016.

4. In 2016, the mean age of donors with HTLV infection was 32 years; 60% of the infected donors were male and all of them were born overseas.

5. The most common putative infective risk factor for donors with HTLV infection during 2012-2016 was ethnicity or country of birth (81%). There are no data to compare risk factors in the general population.

6. No transfusion-transmitted HTLV infections were reported in Australia during 2007-2016.

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 leukaemia/lymphoma.[10, 11] 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.[12-14] 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.[15]

Trends in prevalence

All donations:

In the past ten years, 2007-2016, a total of 42 HTLV positive donors have been detected (41 first-time donors & one repeat donor) (Table 32). During the period 2007-2016, the overall prevalence of HTLV infection among all donations was 0.4 per 100 000 donations (Table 32) and has shown no statistically significant trend (Table 33) (Figure 27).

Figure 27 Prevalence of HTLV infection in all blood donations in Australia, 2007-2016, by year of donation

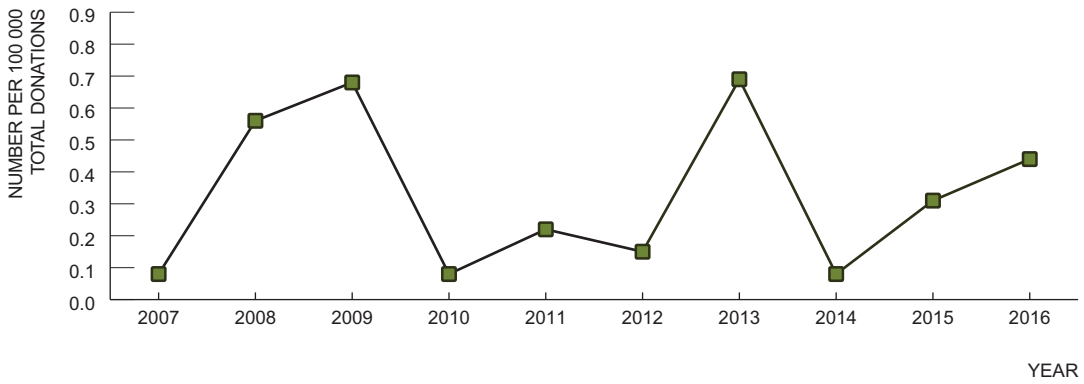


Table 32 The number and prevalence rate of HTLV infection in Australia by state/territory, 2016 and 2007-2016

State/Territory of donation	All accepted donations 2016			HTLV			State/Territory of donation	All accepted donations 2007-2016			HTLV		
	First time	Repeat	All	First time	Repeat	All		First time	Repeat	All	First time	Repeat	All
NSW/ACT	29 485	314 802	344 287	2	0	2	**NSW/ACT**	417 715	3 586 971	4 004 686	10	1	11
Number (*Number per 100 000 donations)*				*6.78*	*0.00*	*0.58*	Number (*Number per 100 000 donations)*				*2.39*	*0.03*	*0.27*
NT	713	7 333	8 046	0	0	0	**NT**	8 133	98 256	106 389	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	20 513	217 741	238 254	1	0	1	**QLD**	249 430	2 348 812	2 598 242	5	0	5
Number (*Number per 100 000 donations)*				*4.87*	*0.00*	*0.42*	Number (*Number per 100 000 donations)*				*2.00*	*0.00*	*0.19*
SA	6 824	97 701	104 525	0	0	0	**SA**	92 281	1 179 035	1 271 316	3	0	3
Number (*Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*	Number (*Number per 100 000 donations)*				*3.25*	*0.00*	*0.24*
TAS	3 037	40 343	43 380	0	0	0	**TAS**	32 394	413 224	445 618	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	25 762	264 472	290 234	2	0	2	**VIC**	269 055	2 786 026	3 055 081	18	0	18
Number (*Number per 100 000 donations)*				*7.76*	*0.00*	*0.69*	Number (*Number per 100 000 donations)*				*6.69*	*0.00*	*0.59*
WA	9 398	101 389	110 787	0	0	0	**WA**	102 179	1 161 303	1 263 482	5	0	5
Number (*Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*	Number (*Number per 100 000 donations)*				*4.89*	*0.00*	*0.40*
National	95 732	1 043 781	1 139 513	5	0	5	**National**	1 171 187	11 573 627	12 744 814	41	1	42
Number (*Number per 100 000 donations)*				*5.22*	*0.00*	*0.44*	Number (*Number per 100 000 donations)*				*3.50*	*0.01*	*0.33*

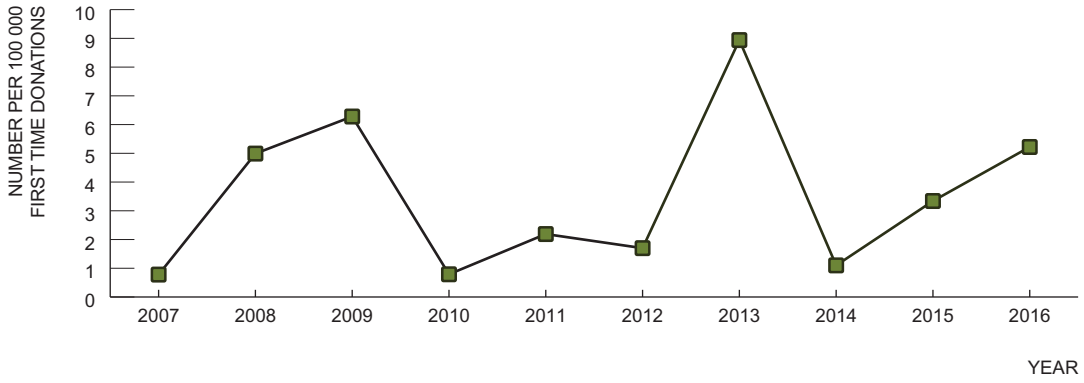
First-time donors:

The prevalence of HTLV infection in first-time donors remained very low over the past ten years, 2007-2016 with an overall rate of 3.5 per 100 000 donations, and has shown no significant trend (Table 33). The prevalence rate fluctuated between 0.7 and 8.9 per 100 000 donations during this period (Figure 29). Although, the prevalence of HTLV infection in the first-time donors in 2016 increased by over 50% (5.2 per 100 000 donations) as compared to 2015 (3.3 per 100 000 donations), it is not unexpected given the low numbers can cause baseline fluctuation (Figure 28).

Table 33 Trends in prevalence of HTLV infection in all donations and first-time donors in Australia, 2007-2016

Trends in prevalence of HTLV Infection in all donations and First-time donors in Australia, 2007-2016		
Prevalence	**IRR (95% CI)**	**p-value**
All Donations	*0.99 (0.89-1.10)*	*0.99*
First time Donors	*1.04 (0.93-1.16)*	*0.73*

Figure 28 Prevalence of HTLV infection in first time blood donors in Australia, 2007-2016, by year of donation



Trends in incidence

The HTLV infection incidence among repeat Australian donors in 2016 was zero, as it was for the averaged ten-year period 2007-2016. Of note, one lapsed donor from 2007 seroconverted in 2015; however, this case did not meet the definition for an incident donor which is a positive repeat donor whose last donation was within the last 12 months and tested negative for the same TTI. No transfusion-transmitted HTLV infections were reported in Australia during 2007-2016.

Trends in HTLV infection by state/territory

In 2016, HTLV infection prevalence in first-time donors was zero in most jurisdictions except New South Wales/ Australian Capital Territory, Queensland and Victoria where the prevalence was 6.78, 4.87 and 7.76 per 100 000 donations, respectively (Figure 29). No significant trend was observed for prevalence in first-time donors during the period 2007-2016 in any jurisdiction (Table 34). The prevalence of HTLV infection in first-time donors remained zero in Northern Territory and Tasmania during the ten-year study period, 2007-2016 (Figure 29 and Table 35).

Figure 29 Prevalence of HTLV infection among first time donors by state/territory and year of donation, 2007-2016

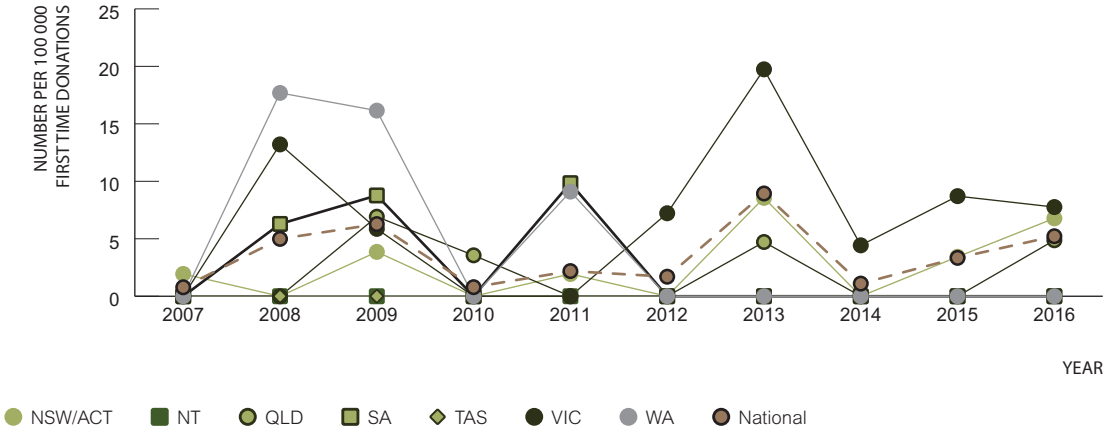


Table 34 Trend in prevalence of HTLV infection in first-time donors, by state and territory, 2007-2016

	Prevalence of HTLV Infections in First-time Donors, 2007-2016	
	IRR (95% CI)	**p-value**
NSW/ACT	*1.17 (0.94-.1.47)*	*0.14*
NT	…	…
QLD	*1.04 (0.76-1.42)*	*0.79*
SA	*0.80 (0.49-1.32)*	*0.4*
TAS	…	…
VIC	*1.08 (0.91-1.27)*	*0.35*
WA	*0.71 (0.47-1.08)*	*0.11*

Table 35 Number and prevalence[1] of HTLV infection among first-time donors, 2007-2016, by state/territory and year of donation

	2007			2008			2009			2010		
State/Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate
NSW/ACT	51 427	1	1.94	48 607	0	0.00	51 821	2	3.86	48 130	0	0.00
NT	759	0	0.00	815	0	0.00	965	0	0.00	799	0	0.00
QLD	28 575	0	0.00	29 498	0	0.00	28 889	2	6.92	28 097	1	3.56
SA	10 886	0	0.00	15 908	1	6.29	11 400	1	8.77	9 284	0	0.00
TAS	2 650	0	0.00	3 936	0	0.00	3 736	0	0.00	3 222	0	0.00
VIC	23 172	0	0.00	30 286	4	13.21	34 133	2	5.86	25 820	0	0.00
WA	11 292	0	0.00	11 307	2	17.69	12 387	2	16.15	11 149	0	0.00
Total	**128 761**	**1**	**0.78**	**140 357**	**7**	**4.99**	**143 331**	**9**	**6.28**	**126 501**	**1**	**0.79**
	2011			2012			2013			2014		
State/Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate
NSW/ACT	51 528	1	1.94	41 780	0	0.00	35 060	3	8.56	30 697	0	0.00
NT	772	0	0.00	937	0	0.00	853	0	0.00	793	0	0.00
QLD	28 839	0	0.00	24 881	0	0.00	21 181	1	4.72	20 043	0	0.00
SA	10 164	1	9.84	8 900	0	0.00	6 417	0	0.00	6 296	0	0.00
TAS	3 587	0	0.00	3 823	0	0.00	3 058	0	0.00	2 538	0	0.00
VIC	31 286	0	0.00	27 718	2	7.22	25 332	5	19.74	22 580	1	4.43
WA	10 992	1	9.10	9 925	0	0.00	8 815	0	0.00	7 972	0	0.00
Total	**137 168**	**3**	**2.19**	**117 964**	**2**	**1.70**	**100 716**	**9**	**8.94**	**90 919**	**1**	**1.10**
	2015			2016			Total 2007-2016					
State/Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate			
NSW/ACT	29 180.00	1.00	3.43	29 485	2	6.78	417 715	10	2.39			
NT	727.00	0.00	0.00	713	0	0.00	8 133	0	0.00			
QLD	18 914.00	0.00	0.00	20 513	1	4.87	249 430	5	2.00			
SA	6 202.00	0.00	0.00	6 824	0	0.00	92 281	3	3.25			
TAS	2 807.00	0.00	0.00	3 037	0	0.00	32 394	0	0.00			
VIC	22 966.00	2.00	8.71	25 762	2	7.76	269 055	18	6.69			
WA	8 942.00	0.00	0.00	9 398	0	0.00	102 179	5	4.89			
Total	**89 738.00**	**3.00**	**3.34**	**95 732**	**5**	**5.22**	**1 171 187**	**41**	**3.50**			

1 Rate per 100 000 First-time donations

* During the period 2007-2016, 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, the prevalence of HTLV infection in first-time donors in 2016 and the ten-year study period 2007-2016 was 5.2 and 3.5 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 2016 and the five-year period 2012-2016 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, 2016, and 2012-2016

	HTLV 2016				HTLV 2012-2016			
	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	*229 726*	*3 (1.31)*	*1 (ref)*	*…*	*1 221 021*	*14 (1.15)*	*1 (ref)*	*…*
Female	*228 406*	*2 (0.88)*	*0.62(0.10-3.79)*	*0.61*	*1 232 932*	*7 (0.57)*	*0.52 (0.21-1.29)*	*0.16*
Age group (years)								
20-29	*104 568*	*2 (1.91)*	*1 (ref)*	*…*	*348 855*	*0 (0)*	*1 (ref)*	*…*
Less than 20	*32 806*	*0 (0)*	*..*	*0.99*	*409 385*	*3 (0.73)*	*…*	*0.99*
30-39	*84 061*	*2 (2.38)*	*1.19 (0.16-8.57)*	*0.85*	*407 699*	*8 (1.96)*	*3.39 (0.89-12.83)*	*0.07*
40-49	*78 090*	*1 (1.28)*	*0.65 (0.05-7.30)*	*0.73*	*422 408*	*6 (1.42)*	*2.56 (0.64-10.28)*	*0.18*
50 and above	*158 607*	*0 (0)*	*..*	*0.99*	*865 606*	*4 (0.46)*	*0.84 (0.18-3.79)*	*0.82*
State/Territory								
NSW	*134 421*	*1 (0.74)*	*1 (ref)*	*…*	*742 406*	*3 (0.4)*	*1 (ref)*	*…*
ACT	*12 030*	*1 (8.31)*	*9.96 (0.62-159.26)*	*0.1*	*64 088*	*4 (6.24)*	*1.77 (0.21-14.73)*	*0.59*
NT	*3 260*	*0 (0)*	*..*	*0.99*	*18 831*	*0 (0)*	*…*	*0.99*
QLD	*91 333*	*1 (1.09)*	*1.47 (0.09-23.62)*	*0.78*	*489 437*	*2 (0.41)*	*0.49 (0.10-2.47)*	*0.39*
SA	*40 366*	*0 (0)*	*..*	*0.99*	*222 369*	*0 (0)*	*…*	*0.99*
TAS	*15 371*	*0 (0)*	*..*	*0.99*	*80 354*	*0 (0)*	*…*	*0.99*
VIC	*119 434*	*2 (1.67)*	*2.12(0.19-23.46)*	*0.53*	*617 064*	*12 (1.94)*	*2.29 (0.86-6.12)*	*0.09*
WA	*41 917*	*0 (0)*	*..*	*0.99*	*219 404*	*0 (0)*	*…*	*0.99*
Total	458 132	5 (1.09)			2 453 953	21 (0.86)		

In 2016, there was no significant association between gender, donors' age group or location and HTLV infection status (Table 36).

Similarly, during the five-year period, 2012-2016, there was no significant association between gender, age & donor location and HTLV infection status (Table 36).

* See methodological notes for details

Risk factors associated with HTLV infected donors

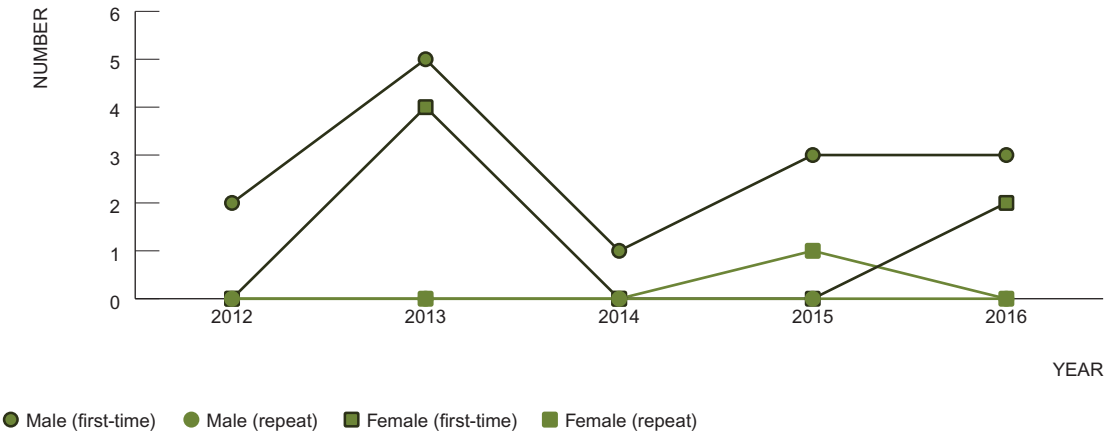
Only 21 donors were positive for HTLV infection during the 2012-2016 period; 20 were first-time donors, with the only repeat positive donor being identified in 2015; 67% were male, and the mean age was 42 years with a wide range (20-68 years) (Table 37). The majority of the HTLV positive donors (86%) were born overseas. Ethnicity or country of birth (81%) 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 (19%). 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 2012-2016.

Table 37 Characteristics of donors positive for HTLV infection by year of donation, 2012–2016

Characteristics	2012	2013	2014	2015	2016	2012-2016
Number of positive donors	2	9	1	4	5	21
Number of positive First-time donors (%)	2 (100%)	9 (100%)	1 (100%)	3 (75%)	5 (100%)	20 (95%)
% male	2 (100%)	5 (56%)	1 (100%)	3 (75%)	3 (60%)	14 (67%)
Mean age (range) in years	32 (27 to 37)	45 (30 to 58)	68	33(30-40)	32 (20-45)	42 (20 to 68)
Number of incident donors	0	0	0	0	0	0
% born in Australia	0 (0%)	2 (22%)	0 (0%)	1(25%)	0 (0%)	3 (14%)
Main reported risk factor	Ethnicity/COB[1]	Ethnicity/COB[1]	Ethnicity/COB[1]	Ethnicity/COB[1]	Ethnicity/COB[1]	Ethnicity/COB[1]
	100%	78%	100%	75%	80%	81%
Second reported risk factor	…	PRP[2]		PRP[2]	PRP[2]	PRP[2]
		22%		25%	20%	19%

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

Figure 30 Donors with HTLV infection by sex and donor status, 2012-2016



No discernible overall trend has been observed for first-time male and female donors and repeat female donors. The number of repeat male donors positive for HTLV has remained zero for the study period 2012-2016 (Figure 30). For more information on the number and percentage of donors with HTLV infection by sex, age group, donor status and country of birth for period 2012-2016, see 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.[16] 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.[17] This is consistent with the finding that ethnicity or country of birth was the likely infective risk in all five HTLV positive donors in 2016.

Conclusion

- The prevalence of HTLV among first-time donors remained 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.

This page intentionally left blank

Active Syphilis:

Main findings

1. There were 12 active syphilis infections detected among all donations in 2016, the highest number recorded in the past ten years, 2007-2016.

2. The prevalence of active syphilis in first-time donors has shown no significant change over time in the past ten years, 2007-2016. In first-time donors the prevalence per 100 000 first-time donations was 0.7 in 2007, 5.1 in 2011 and 6.2 in 2016.

3. The mean age of donors with active syphilis in 2016 was 37 years (compared to 41.6 years for all donors); and donors with active syphilis were more likely to be male as compared to all donors (58% versus 50%).

4. The most common reported route of exposure by donors with active syphilis during 2014-2016 was having a partner with an unspecified risk (45%).

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 +/- clinically apparent infection (i.e. excluding past treated infections and may also exclude latent syphilis[18]). Infectious syphilis, on the other hand, is defined as syphilis infection of less than two years duration (including primary, secondary and early latent stages[19]). Although the two definitions are slightly different (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 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 2016 was 3 377.[1] The rate of diagnosis of infectious syphilis among men has increased in the past ten years, from 12.2 per 100 000 in 2007 to 25.1 per 100 000 in 2016, whereas the rate among women has fluctuated and remained low between1.5 per 100 000 in 2007 and 3.6 per 100 000 in 2016.[1]

Trends in prevalence

All donations:

In the past ten years, 2007-2016, a total of 64 donors with active syphilis have been detected (33 first-time donors & 31 repeat donors) (Table 38). During the period 2007-2016, the overall prevalence of active syphilis infection among all donations remained very low at 0.5 per 100 000 donations (Table 38); however, the overall prevalence in all donations increased by nearly three-fold from 0.3 per 100 000 donations in 2015 to 1.0 per 100 000 donations in 2016. Of note, the prevalence of active syphilis infection among all donations showed a slight but significant increase during 2005-2014; however, during 2007-2016, no statistically significant trend was observed (Table 39) (Figure 31).

Figure 31 Prevalence of active syphilis in all blood donations in Australia, 2007-2016, by year of donation

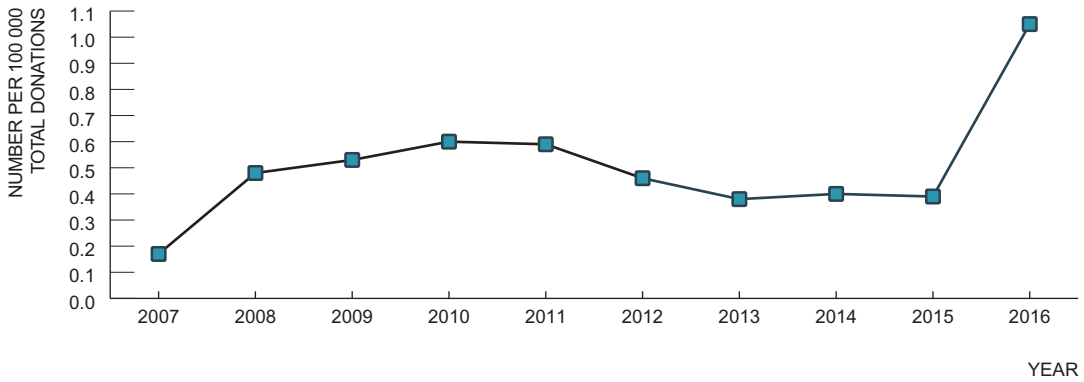


Table 38 The number and prevalence rate of syphilis infection in Australia by state/territory, 2016 and 2007-2016 period

State/Territory of donation	All accepted donations 2016			Syphilis			State/Territory of donation	All accepted donations 2007-2016			Syphilis		
	First time	Repeat	All	First time	Repeat	All		First time	Repeat	All	First time	Repeat	All
NSW/ACT	29 485	314 802	344 287	1	2	3	**NSW/ACT**	417 715	3 586 971	4 004 686	3	11	14
Number (*Number per 100 000 donations)*				*3.39*	*0.64*	*0.87*	Number (*Number per 100 000 donations)*				*0.72*	*0.31*	*0.35*
NT	713	7 333	8 046	0	0	0	**NT**	8 133	98 256	106 389	4	2	6
Number (*Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*	Number (*Number per 100 000 donations)*				*49.18*	*2.04*	*5.64*
QLD	20 513	217 741	238 254	1	2	3	**QLD**	249 430	2 348 812	2 598 242	8	6	14
Number (*Number per 100 000 donations)*				*4.87*	*0.92*	*1.26*	Number (*Number per 100 000 donations)*				*3.21*	*0.26*	*0.54*
SA	6 824	97 701	104 525	0	0	0	**SA**	92 281	1 179 035	1 271 316	4	0	4
Number (*Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*	Number (*Number per 100 000 donations)*				*4.33*	*0.00*	*0.31*
TAS	3 037	40 343	43 380	0	0	0	**TAS**	32 394	413 224	445 618	0	1	1
Number (*Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*	Number (*Number per 100 000 donations)*				*0.00*	*0.24*	*0.22*
VIC	25 762	264 472	290 234	3	2	5	**VIC**	269 055	2 786 026	3 055 081	7	7	14
Number (*Number per 100 000 donations)*				*11.65*	*0.76*	*1.72*	Number (*Number per 100 000 donations)*				*2.60*	*0.25*	*0.46*
WA	9 398	101 389	110 787	1	0	1	**WA**	102 179	1 161 303	1 263 482	7	4	11
Number (*Number per 100 000 donations)*				*10.64*	*0.00*	*0.90*	Number (*Number per 100 000 donations)*				*6.85*	*0.34*	*0.87*
National	95 732	1 043 781	1 139 513	6	6	12	**National**	1 171 187	11 573 627	12 744 814	33	31	64
Number (*Number per 100 000 donations)*				*6.27*	*0.57*	*1.05*	Number (*Number per 100 000 donations)*				*2.82*	*0.27*	*0.50*

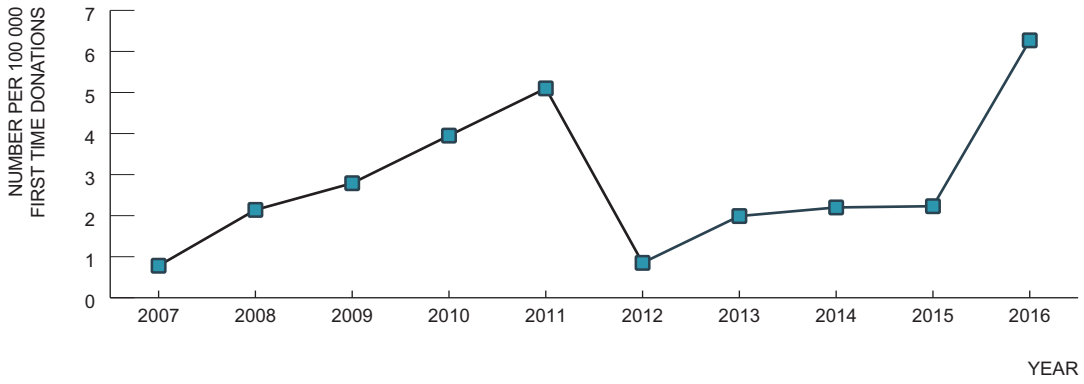
First-time donors:

In the past ten years, 2007-2016, the prevalence of active syphilis in first-time donors remained low, at 2.8 per 100 000 donations (Table 38). Overall, the prevalence of active syphilis in first-time donors showed no significant trend during 2007-2016 (Table 39). The prevalence fluctuated from 0.7 per 100 000 donations in 2007, to 5.1 per 100 000 donations in 2011, dropping sharply to 0.8 per 100 000 donations in 2012, and stabilising during 2013-2015 at around 2 per 100 000 donations (Table 41 & Figure 32). However, it increased by nearly 3-fold to 6.2 per 100 000 donations in 2016 as compared to 2.2 per 100 000 donations in 2015 (Table 41 & Figure 32). By comparison, the rate of diagnoses of infectious syphilis reported through the Australian National Notifiable Diseases Surveillance System was 6.8 per 100 000 population in 2007, gradually declining in 2007-2010 before a steady increase from 5.0 per 100 000 population in 2010 to 8.9 per 100 000 population in 2014. The rate showed a steep increase to 11.8 per 100 000 population in 2015, and 14.3 per 100 000 in 2016 corresponding to the highest recorded number of notifications, with 3 377 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.[19]

Table 39 Trends in prevalence of active syphilis in all donations and first-time donors, 2007-2016

Trends in prevalence of Active Syphilis Infection in all donations and First-time donors in Australia, 2007-2016		
Prevalence	**IRR (95% CI)**	**p-value**
All Donations	*1.05 (0.97-1.15)*	*0.14*
First time Donors	*1.08 (0.95-1.22)*	*0.20*

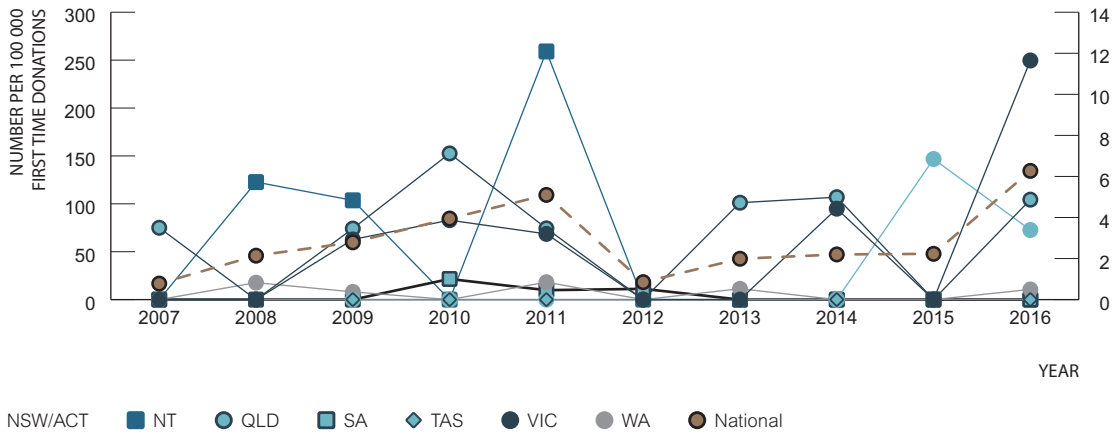
Figure 32 Prevalence of active syphilis in first-time blood donors in Australia, 2007-2016, by year of donation



Trends in active syphilis infection by state/territory

The rate of active syphilis infection in blood donors increased sharply in 2016 with a record high of 12 donors identified nationally (6 first-time and 6 repeat donors) (Table 41 & Table 42). In 2016, active syphilis prevalence in first-time donors varied markedly between jurisdictions from zero to 11.6 per 100 000 donations. Remarkably, after remaining zero during the eight-year period, 2007-2014, the prevalence in New South Wales/Australian Capital Territory increased to 6.85 per 100 000 donations in 2015, then decreased to 3.3 per 100 000 donations in 2016 (Figure 33). The prevalence of active syphilis in first-time donors in Victoria, Western Australia and Queensland increased from zero in 2015 to 11.6, 10.6 and 4.8 per 100 000 donations in 2016, respectively. 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, 2007-2016 (Table 40). In comparison, the trend in the general population over the past ten years, 2007-2016, shows an increase in rates of diagnosis of infectious syphilis in all jurisdictions, except Tasmania and Australian Capital Territory.[1]

Figure 33 Prevalence[1] of active syphilis among first time donors by state/territory and year of donation, 2007-2016



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, 2007-2016

	Prevalence of Active Syphilis Infections in First-time Donors, 2007-2016	
	IRR (95% CI)	p-value
NSW/ACT	*2.65 (0.93-7.52)*	*0.06*
NT	*0.79 (0.53-1.18)*	*0.25*
QLD	*1.02 (0.80-1.30)*	*0.85*
SA	*1.00 (0.70-1.41)*	*0.99*
TAS	…	…
VIC	*1.27 (0.95-1.69)*	*0.10*
WA	*0.95 (0.73-1.24)*	*0.76*

Table 41 Number and prevalence[1] of active syphilis among first-time donors, 2007-2016, by state/territory and year of donation

	2007			2008			2009			2010		
State/Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate
NSW/ACT	51 427	0	0.00	48 607	0	0.00	51 821	0	0.00	48 130	0	0.00
NT	759	0	0.00	815	1	122.70	965	1	103.63	799	0	0.00
QLD	28 575	1	3.50	29 498	0	0.00	28 889	1	3.46	28 097	2	7.12
SA	10 886	0	0.00	15 908	0	0.00	11 400	0	0.00	9 284	2	21.54
TAS	2 650	0	0.00	3 936	0	0.00	3 736	0	0.00	3 222	0	0.00
VIC	23 172	0	0.00	30 286	0	0.00	34 133	1	2.93	25 820	1	3.87
WA	11 292	0	0.00	11 307	2	17.69	12 387	1	8.07	11 149	0	0.00
Total	128 761	1	0.78	140 357	3	2.14	143 331	4	2.79	126 501	5	3.95

	2011			2012			2013			2014		
State/Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate
NSW/ACT	51 528	0	0.00	41 780	0	0.00	35 060	0	0.00	30 697	0	0.00
NT	772	2	259.07	937	0	0.00	853	0	0.00	793	0	0.00
QLD	28 839	1	3.47	24 881	0	0.00	21 181	1	4.72	20 043	1	4.99
SA	10 164	1	9.84	8 900	1	11.24	6 417	0	0.00	6 296	0	0.00
TAS	3 587	0	0.00	3 823	0	0.00	3 058	0	0.00	2 538	0	0.00
VIC	31 286	1	3.20	27 718	0	0.00	25 332	0	0.00	22 580	1	4.43
WA	10 992	2	18.20	9 925	0	0.00	8 815	1	11.34	7 972	0	0.00
Total	137 168	7	5.10	117 964	1	0.85	100 716	2	1.99	90 919	2	2.20

	2015			2016			Total 2007-2016		
State/Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate
NSW/ACT	29 180	2	6.85	29 485	1	3.39	417 715	3	0.72
NT	727	0	0.00	713	0	0.00	8 133	4	49.18
QLD	18 914	0	0.00	20 513	1	4.87	249 430	8	3.21
SA	6 202	0	0.00	6 824	0	0.00	92 281	4	4.33
TAS	2 807	0	0.00	3 037	0	0.00	32 394	0	0.00
VIC	22 966	0	0.00	25 762	3	11.65	269 055	7	2.60
WA	8 942	0	0.00	9 398	1	10.64	102 179	7	6.85
Total	89 738	2	2.23	95 732	6	6.27	1 171 187	33	2.82

1 Rate per 100 000 First-time donations

Table 42 Number and rate[1] of active syphilis among repeat donors, 2007-2016, by state/territory and year of donation

	2007			2008			2009			2010		
State/Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate
NSW/ACT	338 173	0	0.00	339 062	1	0.29	372 806	0	0.00	380 014	1	0.26
NT	10 214	0	0.00	11 166	0	0.00	11 158	1	8.96	10 470	1	9.55
QLD	209 556	0	0.00	226 726	0	0.00	242 001	1	0.41	243 837	1	0.41
SA	114 618	0	0.00	118 476	0	0.00	126 855	0	0.00	123 587	0	0.00
TAS	28 019	0	0.00	33 321	1	3.00	37 274	0	0.00	41 484	0	0.00
VIC	252 340	1	0.40	259 052	0	0.00	276 835	0	0.00	278 897	0	0.00
WA	109 425	0	0.00	113 274	1	0.88	118 327	1	0.85	120 646	0	0.00
Total	1 062 345	1	0.09 413	1 101 077	3	0.27	1 185 256	3	0.25	1 198 935	3	0.25

	2011			2012			2013			2014		
State/Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate
NSW/ACT	390 455	1	0.26	377 220	2	0.53	373 670	2	0.54	353 055	0	0.00
NT	10 782	0	0.00	9 673	0	0.00	9 493	0	0.00	8 914	0	0.00
QLD	245 975	0	0.00	237 599	0	0.00	243 042	1	0.41	239 720	1	0.42
SA	124 199	0	0.00	120 720	0	0.00	119 530	0	0.00	116 658	0	0.00
TAS	44 661	0	0.00	46 379	0	0.00	48 953	0	0.00	45 788	0	0.00
VIC	288 085	0	0.00	285 168	1	0.35	292 058	0	0.00	288 753	2	0.69
WA	121 057	0	0.00	117 728	2	1.70	123 298	0	0.00	118 014	0	0.00
Total	1 225 214	1	0.08	1 194 487	5	0.42	1 210 044	3	0.25	1 170 902	3	0.26

	2015			2016			Total 2007-2016			
State/Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate	
NSW/ACT	347 714	2	0.58	314 802	2	0.64	3 586 971	11	0.31	
NT	9 053	0	0.00	7 333	0	0.00	98 256	2	2.04	
QLD	242 615	0	0.00	217 741	2	0.92	2 348 812	6	0.26	
SA	116 691	0	0.00	97 701	0	0.00	1 179 035	0	0.00	
TAS	47 002	0	0.00	40 343	0	0.00	413 224	1	0.24	
VIC	300 366	1	0.33	264 472	2	0.76	2 786 026	7	0.25	
WA	118 145	0	0.00	101 389	0	0.00	1 161 303	4	0.34	
Total	1 181 586	3	0.25	1 043 781	6	0.57	11 573 627	31	0.27	

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 first-time donors in 2016 and the ten-year study period 2007-2016 was 6.2 and 2.8 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 donors positive for active syphilis are available on only 20 donors (3 from 2014, 5 from 2015, and 12 from 2016). 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 active syphilis infection among Australian blood donors in 2016 and the three-year period 2014-2016 separately (Table 36). Of note, during the three-year period, 2014-2016, there were 22 donors positive for active syphilis; however, information is available for only three out of five donors positive for active syphilis in 2014. The remaining two positive donors for active syphilis in 2014 are therefore not included in the demographic factors analyses. Male donors, donors aged between 20-29 years and donors from New South Wales were used as reference groups for comparison of positivity rate by sex, age group and state/territory of donation.

In 2016, there was no significant association between gender, donors' age group or location and active syphilis status. During the three-year period, 2014-2016, there was no association between gender and active syphilis positivity. Similarly, there was no association with state/territory of the donors and active syphilis infection among Australian blood donors during this period. However, there was a significantly lesser risk of active syphilis infection among donors aged 50 years or above as compared to the reference group of 20-29 years. (Table 29).

** See methodological notes for details

Table 43 Association of demographic characteristics with presence of active syphilis infection among blood donors in Australia, 2016, and 2014*-2016

	Active Syphilis 2016				Active Syphilis 2014*-2016			
	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	*229 726*	*7 (3.05)*	*1 (ref)*	*…*	*700 141*	*14 (2)*	*1 (ref)*	*…*
Female	*228 406*	*5 (2.19)*	*0.66 (0.21-2.12)*	*0.49*	*696 803*	*6 (0.86)*	*0.40 (0.15-1.06)*	*0.06*
Age group (years)								
20-29	*104 568*	*6 (5.74)*	*1 (ref)*	*…*	*176 682*	*9 (3.61)*	*1 (ref)*	*…*
Less than 20	*32 806*	*0 (0)*	*…*	*0.99*	*248 977*	*0 (0)*	*…*	*0.99*
30-39	*84 061*	*1 (1.19)*	*0.20 (0.02-1.67)*	*0.13*	*241 408*	*4 (1.66)*	*0.53 (0.16-1.73)*	*0.29*
40-49	*78 090*	*2 (2.56)*	*0.44 (0.08-2.20)*	*0.32*	*237 239*	*3 (1.26)*	*0.42 (0.11-1.56)*	*0.19*
50 and above	*158 607*	*3 (1.89)*	*0.32 (0.08-1.32)*	*0.11*	*492 638*	*4 (0.81)*	*0.27 (0.08-0.89)*	*0.03*
State/Territory								
NSW	*134 421*	*3 (2.23)*	*1 (ref)*	*…*	*416 294*	*6 (1.44)*	*1 (ref)*	*…*
ACT	*12 030*	*0 (0)*	*…*	*0.99*	*35 454*	*1 (2.82)*	*1.78 (0.21-14.84)*	*0.59*
NT	*3 260*	*0 (0)*	*…*	*0.99*	*10 243*	*0 (0)*	*…*	*0.99*
QLD	*91 333*	*3 (3.28)*	*1.44 (0.29-7.14)*	*0.65*	*278 803*	*5 (1.79)*	*1.22 (0.37-4.01)*	*0.73*
SA	*40 366*	*0 (0)*	*…*	*0.99*	*125 209*	*0 (0)*	*…*	*0.99*
TAS	*15 371*	*0 (0)*	*…*	*0.99*	*46 069*	*0 (0)*	*…*	*0.99*
VIC	*119 434*	*5 (4.19)*	*1.80 (0.43-7.56)*	*0.41*	*359 182*	*7 (1.95)*	*1.27 (0.42-3.79)*	*0.66*
WA	*41 917*	*1 (2.39)*	*1.03 (0.10-9.91)*	*0.97*	*125 690*	*1 (0.8)*	*0.51 (0.06-4.25)*	*0.53*
Total	458 132	12 (2.62)			1 396 944	20 (1.43)		

* Information is available on only three out of five donors positive for active syphilis in 2014. The remaining two positive donors for year 2014 are therefore not included in the demographic factors analyses

Risk factors associated with active syphilis infected donors

As noted above, this report presents risk factors data for the five-year period 2012 to 2016. During this period, a total of 33 donors were positive for active syphilis, of which only 20 have standardised risk factor data available (3 from 2014, 5 from 2015, and 12 from 2016), impeding any meaningful analysis for the entire period of 2012-2016; therefore, data for only the 2014-2016 period are presented. Of note, in 2014, five donors were positive for active syphilis; of these, risk factors data are available for only 3 donors. Of the 20 donors (with known standardised risk factor data) positive for active syphilis during 2014-16, 45% were first-time donors, 14 of 20 (70%) were male, and 60% were born in Australia (Table 43). The mean age was 36 (range 24-60). Partner with unspecified risk (45%) was the most frequent likely risk factor for active syphilis positivity. In comparison, in 2016, nationally, 87.3% of infectious syphilis diagnoses were in males and 59.4% were in people aged 20 – 39 years.[1]

Table 44 Characteristics of donors positive for active syphilis by year of donation, 2014-2016

Characteristics	2014*	2015	2016	2012-2016
Number of positive donors	5	5	12	22
Number of positive first-time donors (%)	1 (33%)	2(40%)	6(50%)	9 (45%)^
% male	2 (67%)	5 (100%)	7 (58%)	14 (70%)^
Mean age (range) in years	40 (29-60)	32 (29-60)	37 (24-55)	36 (24-60)^
% born in Australia	1 (33%)	2 (40%)	9 (75%)	12 (60%)^
Main reported risk factor	Partner with unspecified risk	Unknown	Partner with unspecified risk	Partner with unspecified risk
	100%	60%	Unknown	
Second reported risk factor	…	MSM contact & PUSR[1] each	PRP[2]	Unknown
		20%	17%	40%

1 PUSR=Partner with unspecified risk
2 PRP= Partner with known risk/known to be positive
* For 2014 data, information is available for only three out of five donors positive for active syphilis
^ % calculations are based on 20 donors (that have standardised risk data available) as the denominator.

Conclusion

- Overall, the prevalence of active syphilis among all blood donations during 2007-2016 has remained 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.

Additional information

Main findings

1. Nineteen percent (162 donors) of the TTI-positive donors in 2012-2016 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, 69% (111 donors) were first-time donors.

2. The non-compliance rate of positive donors has fluctuated in the last five years between 14.8 and 25%. The non-compliance rate among TTI-negative donors is not determined on a regular basis; however, results from a large national survey from 2012-13 showed a comparatively lower rate of non-compliance (in the range of 0.05-0.29%). See *Additional Information* section for more information.

3. In 2016, a total of 104 687 donations were tested for malaria antibody of which 1 695 (1.6%) were repeatedly reactive. None of these repeatedly reactive donors had detectable malaria DNA indicative of current infection.

4. There were no reported cases of transfusion-transmitted malaria during 2016, with the last Australian case occurring in 1991.

5. 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.

6. Bacterial testing of 120 941 platelets identified 151 as confirmed positive.

7. *Propionibacterium* spp., which are common skin commensals, were by far the most frequently isolated organisms (121). These organisms are rarely, if ever, associated with septic transfusion reactions in recipients. Other potential contaminants included Coagulase negative staphylococci (21), *Corynebacterium* sp and unidentified gram positive cocci. A small number of clinically significant organisms including one each of *E.coli, Serratia marcescens, Bacteroides thetaiotaomicron, Streptococcus pneumoniae, Streptococcus gallolyticus* and *Clostridium perfringens* were also detected. All contaminated platelets with detected significant organisms were prevented from being transfused. During 2016, there were two septic transfusion reactions reported in recipients of apheresis platelets collected from a single donor contaminated with methicillin sensitive *Staphylococcus aureus.* Both corresponding platelets were negative on bacterial contamination screening.

8. 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, outbreaks of Ebola virus and Zika virus have also been closely monitored during 2016-2017. The risk to the blood supply posed by donors returning from Ebola virus and Zika virus outbreak areas has been managed by deferring donation (or restricting to plasma for fractionation) for an appropriate period.

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 member 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) since this will lead to deferral and no donation will be collected.

Nineteen percent (162 donors) of infected donors in 2012-2016 had risk factors disclosed during their post-donation interview that would have deferred them from donating had they disclosed their risk behaviour at the pre-donation interview (Table 45). Of these, 69% (111 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 13-25%. 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 34). However, the rate since has fluctuated between 15 and 25%.

Figure 34 Rate of reported non-compliance in transfusion-transmissible-infection positive donors, 2008-2016

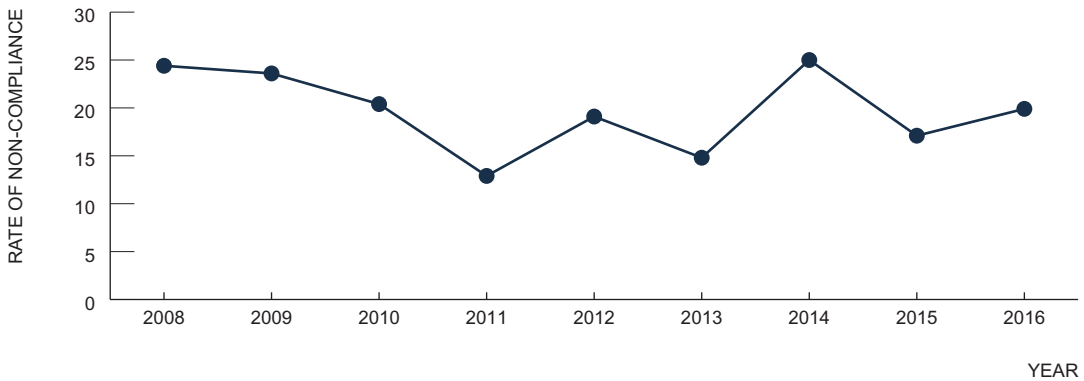


Table 45 Non-compliance category and rate among donors who were positive for HBV, HCV, HIV and HTLV, 2012-2016

Non-compliance by year and reason for deferral	2012	2013	2014	2015*	2016**	2012-2016
Number (%) of non-compliant donors by reasons for deferral						
Intravenous drug use	21 (52.5)	13 (48.2)	19 (51.3)	14 (52)	15 (48.3)	82 (51.9)
Known status/previous positive ^	13 (32.5)	11 (40.7)	10 (27)	10 (37)	17 (54.8)	61 (37.6)
Male-to-male-sexual contact	0	2 (7.4)	2 (5.4)	1 (3.7)	1 (3.2)	6 (3.7)
Partner with known risk or known to be positive	4 (10)	1 (3.7)	4 (10.8)	1 (3.7)	2 (6.4)	12 (7.4)
Others	2 (5)	0 (0)	2 (5.4)	7 (26)	0 (0)	11 (6.7)
Total number (per 100 positive donors) of non-compliant donors by year	**40 (19.1)**	**27 (15)**	**37 (25)**	**27 (17)**	**31 (20%)**	**162 (19)**

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

Unlike previous years where the majority of non-compliant positive donors had a history of injecting drug use, in 2016 the most common risk behaviour identified was known status of previously being positive for a virus (including history of jaundice) (54.8%). It is possible that this might reflect an increasing number of returning/prospective donors with past HCV infection who have successfully undergone treatment with direct acting anti-viral medications. While these donors have undetectable RNA and are 'cured', they have detectable HCV antibodies and therefore are not eligible to donate blood. Overall, during the period 2012-2016, 51.9% of non-compliance was attributed to injecting drug use followed by known status of previously being positive for a virus (37.6%), having a sexual partner with known risk or known to be positive for any transfusion-transmissible infection (7.4%) and male-to-male sexual contact within the last 12 months (3.7%) (Table 45).

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.[20]

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[21] (per unit transfused) were derived for the four transfusion-transmissible viral infections subject to mandatory testing (Table 46). Of note, a revised model was applied to HBV which specifically addresses the risk of occult hepatitis B infection (OBI).[22] 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 46 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 number of window period units collected (per annum)	<1	<1	<1	<1	<1
Residual risk to recipient - per unit transfused	Less than 1 in 1 million	Less than 1 in 1 million	Less than 1 in 1 million	Less than 1 in 1 million	Less than 1 in 1 million

Based on the estimates and assuming approximately 1.3 million donations collected per annum, 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 2005-2016 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 that they have travelled to or been resident in malaria endemic countries, as well as those with a previous history of infection.[23] 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 2016, 104 687 donations were tested for malaria antibody of which 1 695 (1.6%) were found to be repeat reactive for malaria antibodies. This rate of antibody detection is comparable to the 1.4% rate recorded in 2015. None of the 1 695 donations had detectable malaria DNA suggesting past infection in the donors.

Minimising bacterial contamination of blood components

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[24] for platelets and 1:500 000[25] 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.[26] 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%.[27]

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.[28]

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

Bacterial prerelease 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, 14-20 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. However, the culture is maintained for 7 days. Samples flagging as 'reactive' after platelet issue lead to immediate recall and clinician notification in the event they have been transfused. All initially reactive samples are subject to further investigation and follow-up testing.

During 2016, 120 941 platelet units were screened for bacterial contamination (Table 46). Of the 31 782 apheresis units tested, 184 (0.58%) were flagged as initially positive, but only 16 (0.05%) were determined as 'confirmed positive' with an additional 26 (0.08%) classified as 'indeterminate'. The remaining 142 (0.45%) were classified as 'false positive' predominantly associated with anaerobic culture bottles. There were 89 159 pooled platelet units tested of which 520 (0.58%) flagged as initially positive with 135 (0.15%) determined as 'confirmed positive'. A further 124 (0.15%) were classified as 'indeterminate' and the remaining 261 (0.29%) were classified as 'false positive'.

Table 47 Summary of bacterial testing of platelets by BacT/ALERT, 2016

Platelet type	No. components Screened	No. initial positive (%)[1]	No. confirmed positive (%)[2]	No. indeterminate (%)[3]	No. false positive (%)[4]
Pooled platelets	89 159	520 (0.58)	135 (0.15)	124 (0.15)	261 (0.31)
Apheresis platelets	31 782	184 (0.58)	16 (0.05)	26 (0.08)	142 (0.45)
Total	120 941	704 (0.58)	151 (0.12)	150 (0.12)	403 (0.33)

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

Consistent with previous years, *Propionibacterium* spp., which are common skin commensals, were by far the most frequently isolated organisms but have not been associated with septic transfusion reactions in recipients if transfused. 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. They are not clinically significant in the majority of recipients, however, these organisms can

lead to intravascular grafts or catheter-associated bacteraemias or prosthetic device 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, E.coli, Clostridium perfringens, Bacteroides thetaiotaomicron, Staphylococcus aureus*., as well as two *Streptococcus* species: *Strepococcus pneumoniae* and *Streptococcus gallolyticus*. 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. One of the donors of *Streptococcus pneumoniae* contaminated platelets developed respiratory illness post donation. Therefore, microbial detection likely represents transient bacteraemia from a bowel, urinary tract or throat source or contaminated skin in these cases. Externally performed follow-up blood cultures for the donor in which *Clostridium perfringens* was detected grew the same organism. No further information is available.

During 2016, there were two septic transfusion reactions reported in recipients of apheresis platelets collected from a single donor contaminated with methicillin sensitive *Staphylococcus aureus*. Both corresponding platelets were negative on bacterial contamination screening. Isolates from both recipients' blood cultures and the implicated platelet components were typed and found identical. The donor was clinically well both during and post-donation, however was subsequently identified as a nasal carrier of *Staphylococcus aureus*. This isolate was not typed therefore the source of infection remains unproven.

Such cases are rare, being only the fourth and fifth cases of transfusion-transmitted bacterial infection associated with platelets issued by the Blood Service since the introduction of bacterial screening in 2008. The rate of transfusion transmitted bacterial infection associated with platelets issued by the blood service since 2008 is approximately 1 in 332 000,[29] which compares favourably with overseas data where the reported rate in one large US study was is approximately 1 in 107 000.[30]

Table 48 Summary of organisms detected in confirmed positives, 2016 (n=151)

Confirmed positive organisms	Number
Propionibacterium spp.	121
Coagulase negative staphylococci	21
Staphylococcus aureus	1
Streptococcus spp.	2
Serratia marcescens	1
E.coli	1
Clostridium perfringens	1
Bacteroides thetaiotaomicron	1
Unidentified Gram positive coccus	1
Corynebacterium sp	1
Total	151

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 an emerging infection is identified as a clear and present threat to the safety of the blood supply. Where appropriate this will be performed in collaboration with CSL Behring (in their capacity as national plasma fractionator) and the Therapeutic Goods Administration (TGA).

2016-2017 Summary:

Dengue outbreaks in Queensland

Dengue virus transmission by fresh blood components has been demonstrated and thus poses a risk to blood safety.[31] In 2017 to 12 June there were 5 reported dengue outbreaks in Queensland. In early January, there were 6 confirmed cases on Boigu Island (closed 21 April 2017). In February, there were 6 confirmed cases in Innisfail (closed 25 May 2017), 1 confirmed case in Townsville (closed 27 April 2017) and 2 confirmed cases in Cairns (closed 12 May 2017). On 31 March, a confirmed case was reported on Masig (Yorke) Island and the outbreak remains open at 16 June 2017 (outbreaks are closed 3 months after the onset date of the last confirmed case).[32] To mitigate the potential risk to blood safety, supplementary donor selection measures and product restrictions were implemented for travel to/residence in affected areas associated with the Cairns and Innisfail outbreaks. Donations from these areas were restricted to CSL fractionation/processing until the outbreaks were declared over, a strategy that has been shown to effectively manage the blood safety risk for dengue virus. Restrictions were not required for the Masig and Boigu Islands outbreak due to the remoteness of the locations and absence of donor centres in these regions.

West Nile virus (WNV)

Transmission of West Nile virus (WNV) by blood, tissue and organ transplantation has been documented.[33] 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 2016 transmission season, 225 cases of West Nile fever in humans were reported in the EU: 93 in Romania, 76 in Italy, 44 in Hungary, five in Austria, three in Spain, two in Bulgaria, and one each in Cyprus and Croatia. In neighbouring countries, 267 cases have been reported: 135 in Russia, 84 in Israel, 41 in Serbia, two in Syria, two in Turkey, and one each in Egypt, Tunisia and Ukraine. The total number of reported confirmed/probable West Nile fever cases in 2016 was 481. This compares with 315, 210, 785 and 937 cases in 2015, 2014, 2013 and 2012, respectively. The 2017 season is ongoing but at 29 September, 206 cases have been recorded in 7 countries. 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 level of risk to the Australian blood supply associated with donors returning from these countries during the 2016 and 2017 (to date) WNV transmission season was very small and did not exceed the threshold (established for local dengue outbreaks) that requires cessation of fresh blood component manufacture.[34, 35]

Hendra virus

Human Hendra virus (HeV) infection is an emerging Australian zoonotic disease associated with high mortality (4/7 infections fatal).[36] To date all seven recorded cases of HeV transmission to humans have occurred from *Pteropus* bats (flying foxes) via horses. No cases of human HeV infection were recorded in 2015, 2016 or 2017 to date (5 October, 2017), while there were 2 reported equine cases in 2015 (1 in Queensland and 1 in New South Wales), 1 in 2016 (New South Wales), and 4 (1 in Queensland and 3 in NSW) in 2017 to date (5 October, 2017).[37-40] 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 will 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. In April 2017, the Queensland government indicated that HeV vaccination would not be mandatory. 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.[36] 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 followed by transmission to dromedary camels and subsequent overflow from camels to humans. Although it is likely that zoonotic transmission is the starting point of most clusters, human-to-human transmission is the most common mode of transmission for MERS-CoV.[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. The number of MERS-CoV cases may differ depending on the source of information. Based on case numbers reported by FluTrakers, only 9 cases were reported in 2012. Subsequently, reported human cases substantially increased to approximately 170 in 2013, 640 in 2014, 680 in 2015, declining to 250 in 2016 and 202 in 2017 by 30 September (manually calculated from numbers reported on FluTrakers). Since 2012, 27 countries have reported human cases of MERS-CoV infection with approximately 82% reported from Saudi Arabia. In its most recent Global Summary and Risk Assessment (July 2017) the WHO maintained its 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.[42] 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.[43, 44]

Ebola viruses

There are 5 known species of the *Ebolavirus* genus which belongs to the *Filoviridae* family, referred to collectively as ebolaviruses. The first reported outbreak of Ebola virus 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). A total of 28 646 confirmed, probable and suspected cases have been reported in Guinea, Liberia and Sierra Leone, with 11 312 deaths. The current risk posed by EBOV to Australia's blood safety is considered negligible. Although transfusion-transmission of EBOV has not been reported, it cannot be excluded as ebolaviruses are typically detectable in the blood for about 1-2 weeks during acute infection. However, the risk of transfusion-transmitted ebolavirus infection may be mitigated by the observation that ebolavirus DNA is usually not detectable until symptoms appear, by which time the infected individual would be unlikely to attempt to donate blood. The Blood Service manages the potential risk from EBOV by ongoing monitoring of reports of laboratory-confirmed cases, the geographical location of case clusters and local human-to-human transmission, respectively. Additionally, donors who have travelled to countries defined as risk areas for ebolaviruses are deferred from donating for 6 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 15 June, 2017 a total of 566 135 suspected ZIKV cases and 213 081 confirmed cases had been reported by countries and territories in the Americas. Countries with the highest number of reported suspected/confirmed cases were Brazil (224 670/134 057), Colombia (98 161/9 802), Venezuela (59 965/2 413), Martinique (36 680/21), Honduras (32 130/302) and Guadeloupe (30 845/382).[49]

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 substantially increased to 102 but has declined in 2017 with only 5 cases reported to 23 September. For the 101 cases where the risk country was identified, 50 (49.5%) were acquired in the Americas and 51 (50.5%) in the Pacific region. All reported confirmed cases of ZIKV in Australia have been imported cases.[50] 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 adequate evidence to conclude that ZIKV infection is a causative agent of congenital brain abnormalities and a trigger for Guillain-Barre syndrome (GBS).[52] ZIKV is considered to be transfusion-transmissible as infection includes an asymptomatic viraemic phase and 4 probable cases of transfusion-transmitted ZIKV infection have been reported.[53-56]

In response to the potential risk of ZIKV to blood safety in Australia, the Blood Service has implemented a number of donor deferrals. All countries that have reported autochthonous cases of ZIKV transmission are subject to donor travel deferrals related to either malaria (120 days), or DENV, CHIKV or WNV (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 in Australia of competent mosquito vectors and rarity of reported transfusion-transmission cases worldwide,[57, 58] ZIKV is a negligible risk to blood safety in Australia.

Yellow fever virus (YFV)

YFV is a mosquito-borne virus (arbovirus) classified as a member of the *Flaviviridae* family and *Flavivirus* genus. Between 5% and 50% of YFV infections are subclinical. For clinical infections, there is an incubation period of 3-6 days followed by the abrupt onset of symptoms. The clinical spectrum of yellow fever (YF) symptoms can range from mild and non-specific to severe and fatal. During the acute phase of infection symptoms typically include fever, muscle pain and nausea and resolve within 3-4 days. In about 15-20% of patients illness reappears with more severe symptoms including high fever, vomiting and jaundice. Some may also experience bleeding from mouth, nose or stomach. This severe phase of infection can have a mortality rate of up to 50%.[59, 60] In 2016 there were major outbreaks of YF in Angola (3 137 suspected cases to 10 June 2016) and Democratic Republic of the Congo (700 suspected cases to 31 May 2016).[61, 62] From December 2016 to June 2017 there has been an ongoing outbreak in Brazil. Since the beginning of the outbreak in December 2016 up to 18 May 2017, there have been 3 192 suspected cases of yellow fever reported of which 758 were confirmed, 1 812 discarded and 622 remained under investigation. A relatively small number of cases continued to be reported and by 2 August a total of 798 confirmed cases had been reported.[63] The case fatality rate (CFR) among confirmed cases was 34 per cent.[64] Transfusion-transmitted YFV infection has not been reported. However, there has been one report indicating transfusion-transmission of YF vaccine virus based on an analysis of 5 recipients who were accidentally transfused with blood products from donors who had received the YF vaccine 4 days prior to donation. Three of the recipients developed IgM antibody to YFV 26-36 days after transfusion.[65] In addition, given that human YFV infections may be asymptomatic or not recognised, there is the potential for transfusion-transmission from viraemic but asymptomatic donors. All countries reported by WHO with a risk of YF transmission have a geographical malarial restriction (120 days) except for Trinidad and Tobago which has a dengue restriction.[66] Given the defined geographical range of YF, the absence of reported cases in Australia and travel restrictions for YF-endemic countries, YFV is not an immediate threat to blood safety in Australia.

Hepatitis E virus (HEV)

In 2014, the first probable transfusion-transmission of HEV occurred in Australia.[67]

HEV can lead to chronic infection in immunosuppressed patients such as transplant recipients. The Blood Service has recently published the results of our recently completed HEV RNA prevalence study.[68] HEV is a known transfusion-transmissible agent. HEV infection has increased in prevalence in many developed nations. A high proportion of HEV infections in donors are asymptomatic and therefore the exclusion of unwell donors has only limited effectiveness in preventing transfusion-transmission (TT). Because of this, and the high prevalence in donors in Europe, countries such as the UK have implemented HEV blood donor screening to protect transfusion recipients. However, there is treatment for chronic infection that will result in cure in the vast majority of infected patients.

During 2016 we collected and tested 74 131 whole blood samples for HEV and only one sample was confirmed to be positive. This is the lowest reported prevalence in blood donors world-wide and, taking into account transmission factors and symptoms, we estimated the risk of an adverse outcome in Australia is approximately 1 in 3.5 million components transfused.

The risk of TT-HEV in Australia is low. As a result of our low prevalence, the expectation that complications due to TT would be exceedingly rare and feedback from clinician and government stakeholders, the Blood Service has concluded that HEV blood donor screening is not currently warranted in Australia. The vast majority of confirmed HEV infections in Australia are acquired through overseas travel, especially to developing countries. Blood donors are generally ineligible to donate fresh components on return from these countries because of deferrals related to the risk of malaria.

All reports of suspected TT-HEV should be reported to the Blood Service for further evaluation. The Blood Service will continue to monitor the risk of HEV in Australia and will review our assessment if required.

Conclusion

- Since the recorded high of 25% in 2014, the non-compliance rate among TTI-positive donors has shown a decreasing trend, 17% in 2015 and 19% in 2016. This is encouraging, but the rate highlights the importance of promoting donor education to ensure that the potential donors understand the importance of 'self-deferral' to reduce the risk of collecting blood from a potentially infected donor whose infection may not be detected by testing.
- While non-compliance among positive donors has been routinely monitored since 2000, the rate among TTI test-negative donors is more difficult to track. Results from a large national survey conducted in 2012-2013 showed a comparatively low rate of non-compliance (in the range 0.05 to 0.29%) among TTI test-negative donors for several sexual activity-based donor deferrals.
- The estimated residual risk of transmission for HIV, HCV, HBV, HTLV and syphilis are all less than 1 in 1 million per unit transfused, which is considered a 'negligible' risk.
- Bacterial screening of 120 941 platelets identified 151 (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 2016, there were two septic transfusion reactions reported in recipients of double apheresis 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 2016-2017. The risk to the blood supply posed by donors returning from Ebola virus and Zika virus outbreak areas has been managed by deferring donation (or restricting to plasma for fractionation) for an appropriate period.

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

This page intentionally left blank

Appendices

Appendix B

Table B 1 Number and percentage of donors with HBV infection, 2012-2016, by year of donation, sex and age group

	Year of donation													
	2012		2013		2014		2015		2016		2012-2016			
Donor status	M	F	M	F	M	F	M	F	M	F	M	F	Total	%
First time donors														
<20 years	3	6	9	7	3	2	6	2	2	1	23	18	41	9.0
20-29 years	28	7	18	7	9	6	14	5	10	7	79	32	111	24.3
30-39 years	18	6	16	4	9	3	18	6	17	2	78	21	99	21.7
40-49 years	10	5	9	0	7	7	6	5	7	2	39	19	58	12.7
50-59 years	11	2	8	3	9	3	5	3	6	1	39	12	51	11.2
60 years and above	0	1	3	1	4	3	1	1	7	0	15	6	21	4.6
Repeat donors														
<20 years	0	0	0	0	0	1	0	0	0	0	0	1	1	0.2
20-29 years	0	0	0	2	2	1	0	0	0	0	2	3	5	1.1
30-39 years	2	0	1	1	0	0	2	0	2	0	7	1	8	1.8
40-49 years	1	0	0	0	3	1	1	0	3	1	8	2	10	2.2
50-59 years	7	0	4	0	4	2	3	1	5	2	23	5	28	6.1
60 years and above	4	2	4	2	5	0	2	3	1	0	16	7	23	5.0
Total	84	29	72	27	55	29	58	26	60	16	329	127	456	100

Table B 2 Number and percentage of donors with HBV infection, 2012-2016, by year of donation and country/ region of birth*

	2012		2013		2014		2015		2016		2012- 2016	
Region of birth	Number	%	Number	%	Number	%	Number	%	Number	%	Number	%
Australia	19	17	14	14	15	18	8	10	5	7	61	13.0
Overseas born												
Other Oceania	10	9	14	14	10	12	8	10	10	13	52	11.0
United Kingdom and Ireland	1	1	1	1	1	1	0	0	0	0	3	1.0
Other Europe	9	8	10	10	16	19	2	2	6	8	43	9.0
Middle East/North Africa	4	4	2	2	1	1	5	6	9	12	21	5.0
Sub-Saharan Africa	4	4	3	3	3	4	3	4	4	5	17	4.0
South & North East Asia	51	45	43	43	26	31	36	43	32	42	188	41.0
Southern and Central Asia	14	12	10	10	12	14	22	26	10	13	68	15.0
North America	0	0	0	0	0	0	0	0	0	0	0	0.0
South/Central America and the Caribbean	1	1	0	0	0	0	0	0	0	0	1	0.0
Total with a reported country of birth	113	100	97	98	84	100	84	100	76	100	454	100.0
Not reported	0	0	2	2	0	0	0	0	0	0	2	0.0
Total	113	100	99	100	84	100	84	100	76	100	456	100

* Region of birth from the Australian Bureau of Statistics

Table B 3 Number and percentage of hepatitis B infection among first time donors, 2012-2016, by potential reported exposure category and sex

	2012		2013		2014		2015		2016		Total (2012-2016)			
Exposure categories	M	F	M	F	M	F	M	F	M	F	M	F	Total	%
Ethnicity/Country of birth	66	24	59	22	35	19	50	19	47	13	257	97	354	92.9
Intravenous drug user	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Tattoo/Piercing	0	2	0	0	1	2	0	0	0	0	1	4	5	1.3
Partners with any risks or known to be positive	1	1	0	0	4	0	0	1	0	0	5	2	7	1.8
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	1	1	0	0	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	3	0	1	0	0	2	0	1	0	0	4	3	7	1.8
Other blood to blood contact	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Other	0	0	2	0	0	0	0	1	1	0	3	1	4	1.0
No risk factors identified	0	0	0	0	0	0	0	0	1	0	1	0	1	0.3
Not reported	0	0	1	0	0	0	0	0	0	0	1	0	1	0.3
Total	70	27	63	22	41	24	50	22	49	13	273	108	381	100

Table B 4 Number and percentage of hepatitis B infection among repeat donors, 2012-2016 by potential reported exposure category and sex

	2012		2013		2014		2015		2016		Total (2012-2016)			
Exposure categories	M	F	M	F	M	F	M	F	M	F	M	F	Total	%
Ethnicity/Country of birth	8	2	6	2	8	3	6	3	11	3	39	13	52	69.3
Intravenous drug user	0	0	0	1	1	0	0	0	0	0	1	1	2	2.7
Tattoo/Piercing	1	0	1	0	0	0	0	0	0	0	2	0	2	2.7
Partners with any risks or known to be positive	2	0	1	0	3	0	1	0	0	0	7	0	7	9.3
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	2	0	0	1	1	1	0	1	0	0	3	3	6	8.0
Engaged in sex work	1	0	0	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	0	0	0	0	0	0	1	0	0	0	1	0	1	1.3
No risk factors identified	0	0	1	1	1	1	0	0	0	0	2	2	4	5.3
Not reported	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Total	14	2	9	5	14	5	8	4	11	3	56	19	75	100

Appendices

Appendix C

Table C 1 Number and percentage of donors with HCV infection, 2012-2016, by year of donation, sex and age group

	Year of donation													
	2012		2013		2014		2015		2016		2012-2016			
Donor status	M	F	M	F	M	F	M	F	M	F	M	F	Total	%
First time donors														
<20 years	1	2	0	0	0	3	3	1	0	0	4	6	10	2.9
20-29 years	7	4	5	2	2	0	3	5	2	2	19	13	32	9.4
30-39 years	9	6	9	2	3	0	3	2	8	1	32	11	43	12.7
40-49 years	9	4	7	6	4	3	4	2	4	3	28	18	46	13.6
50-59 years	12	11	10	7	10	1	12	4	9	8	53	31	84	24.8
60 years and above	1	1	1	3	4	1	3	1	9	0	18	6	24	7.1
Repeat donors														
<20 years	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
20-29 years	0	0	2	0	1	3	1	1	1	0	5	4	9	2.7
30-39 years	2	0	1	1	0	1	1	1	1	1	5	4	9	2.7
40-49 years	8	3	4	4	2	2	0	2	2	2	16	13	29	8.6
50-59 years	4	3	3	2	6	3	8	4	2	1	23	13	36	10.6
60 years and above	3	1	1	0	5	2	1	0	2	2	12	5	17	5.0
Total	56	35	43	27	37	19	39	23	40	20	215	124	339	100

Table C 2 Number and percentage of donors with HCV infection, 2012-2016, by year of donation and country/ region of birth*

	2012		2013		2014		2015		2016		2012- 2016	
Region of birth	Number	%	Number	%	Number	%	Number	%	Number	%	Number	%
Australia	62	68	41	59	44	79	43	69	40	67	230	67.8
Overseas born												
Other Oceania	6	7	4	6	3	5	1	2	4	7	18	5.3
United Kingdom and Ireland	6	7	6	9	2	4	4	6	2	3	20	5.9
Other Europe	3	3	7	10	1	2	1	2	2	3	14	4.1
Middle East/North Africa	1	1	0	0	0	0	0	0	2	3	3	0.9
Sub-Saharan Africa	1	1	1	1	1	2	1	2	0	0	4	1.2
South & North East Asia	4	4	4	6	2	4	3	5	3	5	16	4.7
Southern and Central Asia	2	2	4	6	2	4	6	10	3	5	17	5.0
North America	3	3	1	1	0	0	1	2	0	0	5	1.5
South/Central America and the Caribbean	0	0	0	0	0	0	0	0	0	0	0	0.0
Total with a reported country of birth	88	97	68	97	55	98	60	97	56	93	327	96.0
Not reported	3	3	2	3	1	2	2	3	4	7	12	4.0
Total	91	100	70	100	56	100	62	100	60	100	339	100

* Region of birth from the Australian Bureau of Statistics

Table C 3 Number and percentage of HCV infection among first time donors, 2012-2016, by potential reported exposure category and sex

	2012		2013		2014		2015		2016		Total (2012-2016)			
Exposure categories	M	F	M	F	M	F	M	F	M	F	M	F	Total	%
Ethnicity/Country of birth	3	2	3	2	1	0	0	0	4	1	11	5	16	6.7
Intravenous drug user	10	4	9	2	10	1	5	1	8	3	42	11	53	22.2
Tattoo/Piercing*	9	11	10	6	5	0	10	8	6	4	40	29	69	28.9
Partners with any risks or known to be positive	1	4	1	6	0	1	0	1	1	0	3	12	15	6.3
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	2	0	4	1	0	0	3	0	2	4	11	5	16	6.7
Engaged in sex work	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Blood or tissue recipient	4	1	0	1	0	2	1	2	4	1	9	7	16	6.7
Household contact	2	2	0	1	0	2	4	0	1	0	7	5	12	5.0
Other blood to blood contact	2	1	1	0	1	0			1	0	5	1	6	2.5
Other**	3	0	0	1	1	1	1	1	3	1	8	4	12	5.0
No risk factors identified	0	0	1	0	2	1	4	2	2	0	9	3	12	5.0
Not reported	3	3	3	0	3	0	0	0	0	0	9	3	12	5.0
Total	39	28	32	20	23	8	28	15	32	14	154	85	239	100

* Four out of 10 first time male donors positive for HCV in 2015 also had imprisonment as a risk factor alongside tattoo/piercing
** One out of 3 First-time male donors positive for HCV in 2012, and in 2016 in the 'Other" category also had imprisonment as a risk factor

Table C 4 Number and percentage of HCV infection among repeat donors, 2012-2016, by potential reported exposure category and sex

	2012		2013		2014		2015		2016		Total (2012-2016)			
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	6	1	2	0	4	2	8	0	4	1	24	4	28	28.0
Tattoo/Piercing	5	3	3	4	1	1	1	3	1	1	11	12	23	23.0
Partners with any risks or known to be positive	1	0	2	0	0	1	0	2	1	1	4	4	8	8.0
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	2	1	1	2	2	1	0	0	0	1	5	5	10	10.0
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	1	0	2	3	0	0	1	0	4	3	7	7.0
Household contact	0	1	0	0	2	1	0	0	0	0	2	2	4	4.0
Other blood to blood contact	1	0	1	0	1	0	0	0	0	0	3	0	3	3.0
Other	0	0	1	0	0	1	2	1	0	0	3	2	5	5.0
No risk factors identified	0	1	0	1	1	1	0	2	1	2	2	7	9	9.0
Not reported	2	0	0	0	1	0	0	0	0	0	3	0	3	3.0
Total	17	7	11	7	14	11	11	8	8	6	61	39	100	100

Appendices

Appendix D

Table D 1 Number and percentage of donors with HIV infection, 2012-2016, by year of donation, sex and age group

	Year of donation													
	2012		2013		2014		2015		2016		2012-2016			
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	0	1	0	1	0	0	1	0	0	2	1	3	15.8
30-39 years	1	0	0	0	0	1	0	0	0	0	1	1	2	10.5
40-49 years	0	0	0	0	0	1	0	0	0	0	0	1	1	5.3
50-59 years	1	0	1	0	0	0	0	0	0	1	2	1	3	15.8
60 years and above	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Repeat donors														
<20 years	1	0	0	0	0	0	0	0	0	0	1	0	1	5.3
20-29 years	0	0	0	0	2	0	0	0	0	0	2	0	2	10.5
30-39 years	0	0	1	0	0	0	1	0	1	0	3	0	3	15.8
40-49 years	0	0	0	0	1	0	0	0	0	0	1	0	1	5.3
50-59 years	0	0	0	0	1	0	0	0	1	0	2	0	2	10.5
60 years and above	0	0	1	0	0	0	0	0	0	0	1	0	1	5.3
Total	3	0	4	0	5	2	1	1	2	1	15	4	19	100

Table D 2 Number and percentage of donors with HIV infection, 2012-2016, by year of donation and country/region of birth*

	2012		2013		2014		2015		2016		2012- 2016	
Region of birth	Number	%	Number	%	Number	%	Number	%	Number	%	Number	%
Australia	2	67	3	75	3	43	1	50	2	67	11	58.0
Overseas born												
Other Oceania	0	0	0	0	2	29	0	0	0	0	2	11.0
United Kingdom and Ireland	0	0	0	0	0	0	0	0	0	0	0	0.0
Other Europe	0	0	0	0	1	14	0	0	1	33	2	11.0
Middle East/North Africa	0	0	0	0	0	0	0	0	0	0	0	0.0
Sub-Saharan Africa	0	0	0	0	1	14	0	0	0	0	1	5.0
South & North East Asia	0	0	1	25	0	0	1	50	0	0	2	11.0
Southern and Central Asia	1	33	0	0	0	0	0	0	0	0	1	5.0
North America	0	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	0.0
Total with a reported country of birth	3	100	4	100	7	100	2	100	3	100	19	100
Not reported	0	0	0	0	0	0	0	0	0	0	0	0
Total	3	100	4	100	7	100	2	100	3	100	19	100

* Region of birth from the Australian Bureau of Statistics

Table D 3 Number and percentage of HIV infection among first time donors, 2012-2016, by potential reported exposure category and sex

	2012		2013		2014		2015		2016		Total (2012-2016)			
Exposure categories	M	F	M	F	M	F	M	F	M	F	M	F	Total	%
Ethnicity/Country of birth	0	0	1	0	0	1	0	0	0	0	1	1	2	25.0
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	1	0	0	0	0	0	0	0	0	1	1	1	2	25.0
Male-to-male sexual contact	0	0	1	0	1	0	0	0	0	0	2	0	2	25.0
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	1	0	0	0	1	1	12.5
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	1	0	0	0		0	1	1	12.5
Total	1	0	2	0	1	2	0	1	0	1	4	4	8	100

Table D 4 Number and percentage of HIV infection among repeat donors, 2012-2016, by potential reported exposure category and sex

	2012		2013		2014		2015		2016		Total (2012-2016)			
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	1	0	0	0	1	0	0	0	0	0	2	0	2	18.2
Male-to-male sexual contact	1	0	2	0	2	0	0	0	1	0	6	0	6	54.5
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	1	0	1	0	1	0	3	0	3	27.3
Not reported	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Total	2	0	2	0	4	0	1	0	2	0	11	0	11	100

Appendices

Appendix E

Table E 1 Number and percentage of donors with HTLV infection, 2012-2016, by year of donation, sex and age group

	Year of donation													
	2012		2013		2014		2015		2016		2012-2016			
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	1	0	0	0	0	0	0	0	2	0	3	0	3	14.3
30-39 years	1	0	1	1	0	0	2	0	1	1	5	2	7	33.3
40-49 years	0	0	3	1	0	0	1	0	0	1	4	2	6	28.6
50-59 years	0	0	1	2	0	0	0	0	0	0	1	2	3	14.3
60 years and above	0	0	0	0	1	0	0	0	0	0	1	0	1	4.8
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	1	0	0	0	1	1	4.8
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	2	0	5	4	1	0	3	1	3	2	14	7	21	100

Table E 2 Number and percentage of donors with HTLV infection, 2012-2016, by year of donation and country/region of birth*

	2012		2013		2014		2015		2016		2012- 2016	
Region of birth	Number	%	Number	%	Number	%	Number	%	Number	%	Number	%
Australia	0	0	2	22	0	0	1	25	0	0	3	14.3
Overseas born												
Other Oceania	0	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	0.0
Other Europe	0	0	0	0	0	0	0	0	0	0	0	0.0
Middle East/North Africa	0	0	5	56	1	100	1	25	1	20	8	38.1
Sub-Saharan Africa	0	0	0	0	0	0	0	0	0	0	0	0.0
South East Asia	0	0	1	11	0	0	0	0	2	40	3	14.3
Southern and Central Asia	2	100	1	11	0	0	2	50	2	40	7	33.3
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	2	100	9	100	1	100	4	100	5	100	21	100.0
Not reported	0	0	0	0	0	0	0	0	0	0	0	0.0
Total	2	100	9	100	1	100	4	100	5	100	21	100

* Region of birth from the Australian Bureau of Statistics

Table E 3 Number and percentage of HTLV infection among first time donors, 2012-2016, by potential reported exposure category and sex

	2012		2013		2014		2015		2016		Total (2012-2016)			
Exposure categories	M	F	M	F	M	F	M	F	M	F	M	F	Total	%
Ethnicity/Country of birth	2	0	5	2	1	0	3	0	3	1	14	3	17	85.0
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	0	0	2	0	0	0	0	0	1	0	3	3	15.0
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	2	0	5	4	1	0	3	0	3	2	14	6	20	100

Supporting information for transfusion-transmissible infections surveillance report

Blood donation: from volunteer to recipient

In Australia, blood donations from each state and territory are processed and tested at one of the Blood Service's four 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 first-time donation is processed and undergoes mandatory tests for specific transfusion-transmissible infections (TTIs) including HIV, HBV, HCV, HTLV and syphilis. From September 2016, repeat donors donating plasma for fractionation only no longer require testing for syphilis and HTLV resulting in a different test denominator for these TTIs. Additional testing for other transfusion-transmissible infections (e.g. malaria) as well as testing for bacteria is performed on selected donations. Donations positive for mandatory screening tests are quarantined and subsequently discarded. Confirmatory testing is conducted to determine the infectious status of the donor and if positive, they are recalled for follow-up testing and counselling.

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

The 'tiered' safety approach

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

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

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

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

4. Where available, physical and/or chemical measures are applied to inactivate viruses and other infectious agents (pathogen 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 used for the manufacture of fresh blood components is tested for hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus (HIV), human T- lymphotropic virus (HTLV) and *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.[69] During 2010, the Blood Service implemented NAT for HBV DNA as a mandatory screen for all blood donations in addition to the existing HBV test (HBsAg), which reduced the HBV window period from approximately 38 to 24 days.[70] 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 the risk of not detecting a recently infected donor but importantly the WP is not eliminated. Thus, despite state-of-the-art donation testing there remains a small but nonzero risk of transmission from donors with very recently acquired infection, who may test negative if they donate during the window period.

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

The Blood Service has collected and periodically presented data about detected infections in Australian blood donors since its establishment in 1996. In 2011, a review of available data pertaining to TTIs in Australia was jointly produced by the Australian Red Cross Blood Service and the Surveillance and Evaluation Program for Public Health at the Kirby Institute. This was the first of what have now been established as annual reports that summarise data and trends for detected infections among Australian blood donors. The 2011 report included data for the period of 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 2016, with a steady or declining trend for all infections. Infected first-time donors in 2016 mostly had undiagnosed prevalent infections but we continued to identify a small number of recently acquired (incident) infections among repeat donors.

This is the seventh 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 2007-2016 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 2007 to 2016. Anonymous donor data for all donors who donated blood between January 2007 and December 2016 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 2007-2016. Demographic factors associated with TTIs in blood donors were analysed for donations made in 2016 and were compared with the findings from 2012-2016. 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 were combined and risk modelling conducted to derive estimates of the risk of transmission for HCV, HBV, HIV 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 2015-2016 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, 2007-2016, was calculated as follows:

$$\text{Incidence per 100 000 donor-years of observation} = \left(\frac{\text{Total number of incident donors in 2007-2016}}{\text{Average* of 2007-2016 total donor-years of observation}} \right) \times 100\,000$$

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:

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

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

* due to unavailability of the exact DYO for the period 2007-2016, an average DYO was taken to calculate the incidence over the ten-year period, 2007-2016.

Residual risk estimates

Estimates were derived based on minor refinement to the method described in earlier studies.[21, 71] An additional refinement since 2015 is a revised model applied to HBV which specifically addresses the risk of occult hepatitis B infection (OBI).[22] 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, 2007-2016. Poisson regression analysis was used to calculate incidence rate ratios (IRRs) and their 95% confidence intervals. A p-value of less than 0.05 was considered statistically significant.

The trend in the total number of donations for the period 2007-2016 was examined by linear regression analysis. A p-value of less than 0.05 was considered 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 2016, and ten-year period, 2007-2016 (for HBV, HCV, HIV and HTLV), and for the three-year period 2014-2016 (for active syphilis). The association between demographic factors and presence of any transfusion-transmissible infections (HBV, HCV, HIV, HTLV and active syphilis) among Australian blood donors were assessed using multivariate Poisson regression model for each infection separately. The predictor variables were analysed simultaneously thus adjusting for all variables in the model. A p-value of less than 0.05 was considered statistically significant.

References:

1. Kirby Institute. HIV, viral hepatitis and sexually transmissible infections in Australia: annual surveillance report 2017. Sydney: Kirby Institute, UNSW Sydney; 2017.
2. Tohme RA and Holmberg SD. Transmission of hepatitis C virus infection through tattooing and piercing: a critical review. *Clinical infectious diseases*. 2012; 54: 1167-78.
3. Kiely P, Margaritis AR, Seed CR and Yang H. Hepatitis B virus nucleic acid amplification testing of Australian blood donors highlights the complexity of confirming occult hepatitis B virus infection. *Transfusion*. 2014; 54: 2084-91.
4. Polizzotto MN, Wood EM, Ingham H and Keller AJ. Reducing the risk of transfusion-transmissible viral infection through blood donor selection: the Australian experience 2000 through 2006. *Transfusion*. 2008; 48: 55-63.
5. Nguyen VTT, Razali K, Amin J, Law MG and Dore GJ. Estimates and projections of hepatitis B-related hepatocellular carcinoma in Australia among people born in Asia-Pacific countries. *Journal of gastroenterology and hepatology*. 2008; 23: 922-9.
6. O'Sullivan BG, Gidding HF, Law M, Kaldor JM, Gilbert GL and Dore GJ. Estimates of chronic hepatitis B virus infection in Australia, 2000. *Australian and New Zealand journal of public health*. 2004; 28: 212-6.
7. Williams S, Vally H, Fielding J and Cowie B. Hepatitis B prevention in Victoria, Australia: the potential to protect. *Euro Surveill*. 2011; 16: 19879.
8. The Kirby Institute. Bloodborne viral and sexually transmitted infections in Aboriginal and Torres Strait Islander people: Surveillance and Evaluation Report 2017. The Kirby Institute, UNSW Sydney.
9. Razali K, Amin J, Dore G, Law M and Group HPW. Modelling and calibration of the hepatitis C epidemic in Australia. *Statistical Methods in Medical Research*. 2009; 18: 253-70.
10. Gallo RC. History of the discoveries of the first human retroviruses: HTLV-1 and HTLV-2. *Oncogene*. 2005; 24: 5926-30.
11. Feuer G and Green PL. Comparative biology of human T-cell lymphotropic virus type 1 (HTLV-1) and HTLV-2. *Oncogene*. 2005; 24: 5996-6004.
12. Bastian I, Hinuma Y and Doherty RR. HTLV-I among Northern Territory aborigines. *The Medical journal of Australia*. 1993; 159: 12-6.
13. Einsiedel L, Spelman T, Goeman E, Cassar O, Arundell M and Gessain A. Clinical associations of Human T-lymphotropic Virus type 1 infection in an indigenous Australian population. *PLoS Negl Trop Dis*. 2014; 8: e2643.
14. Davies J, Jabbar Z, Gagan F and Baird RW. Blood-borne viruses in the haemodialysis-dependent population attending Top End Northern Territory facilities 2000–2009. *Nephrology*. 2012; 17: 501-7.
15. Einsiedel LJ, Pham H, Woodman RJ, Pepperill C and Taylor KA. The prevalence and clinical associations of HTLV-1 infection in a remote Indigenous community. *The Medical journal of Australia*. 2016; 205: 305.
16. May J, Stent G and Schnagl R. Antibody to human T-cell lymphotropic virus type I in Australian aborigines. *The Medical journal of Australia*. 1988; 149: 104-.
17. Verdonck K, González E, Van Dooren S, Vandamme A-M, Vanham G and Gotuzzo E. Human T-lymphotropic virus 1: recent knowledge about an ancient infection. *The Lancet infectious diseases*. 2007; 7: 266-81.
18. Ratnam S. The laboratory diagnosis of syphilis. *Canadian Journal of Infectious Diseases and Medical Microbiology*. 2005; 16: 45-51.

19. Australian Government DoH. Syphilis - infectious (primary, secondary and early latent), less than 2 years duration case definition, Available at: http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-surveil-nndss-casedefs-cd_syphl2.htm Access date: September 12, 2016. 2015.

20. Seed C and Kiely P. A method for estimating the residual risk of transfusion-transmitted HBV infection associated with occult hepatitis B virus infection in a donor population without universal ant-HBc screening. *Vox sanguinis*. 2013; 105: 290-8.

21. Seed C, Kiely P and Keller A. Residual risk of transfusion transmitted human immunodeficiency virus, hepatitis B virus, hepatitis C virus and human T lymphotrophic virus. *Internal medicine journal*. 2005; 35: 592-8.

22. Seed C, Kiely P, Hoad V and Keller A. Refining the risk estimate for transfusion-transmission of occult hepatitis B virus. *Vox Sanguinis*. 2017; 112: 3-8.

23. Seed C, Kee G, Wong T, Law M and Ismay S. Assessing the safety and efficacy of a test-based, targeted donor screening strategy to minimize transfusion transmitted malaria. *Vox sanguinis*. 2010; 98: e182-e92.

24. Eder AF, Kennedy JM, Dy BA, et al. Bacterial screening of apheresis platelets and the residual risk of septic transfusion reactions: the American Red Cross experience (2004-2006). *Transfusion*. 2007; 47: 1134-42.

25. Kuehnert MJ, Roth VR, Haley NR, et al. Transfusion-transmitted bacterial infectionin the United States, 1998 through 2000. *Transfusion*. 2001; 41: 1493-9.

26. Wood E. Prevention of bacterial contamination, including initial flow diversion. *ISBT Science Series*. 2009; 4: 221-9.

27. Satake M, Mitani T, Oikawa S, et al. Frequency of bacterial contamination of platelet concentrates before and after introduction of diversion method in Japan. *Transfusion*. 2009; 49: 2152-7.

28. Borosak M and Wood E. Bacterial pre-release testing of platelets–the Australian Red Cross Blood Service clinical experience. *Transfusion Medicine and Hemotherapy*. 2011; 38: 239-41.

29. Thyer J, Perkowska-Guse Z, Ismay S, et al. Bacterial Testing of Platelets-Has it Prevented Transfusion-Transmitted Bacterial Infections in Australia? *Vox Sanguinis. 2017 Sep 26. PubMed PMID: 28952159.*

30. Benjamin R, Dy B, Perez J, Eder A and Wagner S. Bacterial culture of apheresis platelets: a mathematical model of the residual rate of contamination based on unconfirmed positive results. *Vox sanguinis*. 2014; 106: 23-30.

31. Lanteri MC and Busch MP. Dengue in the context of "safe blood" and global epidemiology: to screen or not to screen? *Transfusion*. 2012; 52: 1634-9.

32. Queensland Government Queensland Health. Health Alerts - Dengue outbreaks. Available at: https://www.health.qld.gov.au/news-alerts/health-alerts/dengue/default.asp Access Date: On regular basis.

33. Marka A, Diamantidis A, Papa A, et al. West Nile virus state of the Art report of MALWEST project. *International journal of environmental research and public health*. 2013; 10: 6534-610.

34. European Centre for Disease Prevention and Control (ECDC). West Nile virus fever maps. Historical data by Year. Available at: http://ecdc.europa.eu/en/healthtopics/west_nile_fever/West-Nile-fever-maps/Pages/historical-data.aspx Access Date: June 16, 2017.

35. European Centre for Disease Prevention and Control (ECDC). Epidemiological update: West Nile virus transmission season in Europe, 2016. Available at: https://ecdc.europa.eu/en/news-events/epidemiological-update-west-nile-virus-transmission-season-europe-2016 Access Date: June 16, 2017.

36. Young JR, Selvey CE and Symons R. Hendra virus. *The Medical journal of Australia*. 2011; 195: 250.

37. Queensland Government Department News. New Hendra virus case confirmed in Gold Coast Hinterland. Available at: https://www.daf.qld.gov.au/about-us/news-and-updates/biosecurity/news/new-hendra-virus-case-confirmed-in-gold-coast-hinterland Access Date: June 16, 2017.

38. Queensland Government Department of Agriculture and Fisheries. Hendra virus. Available at: https://www.daf.qld.gov.au/animal-industries/animal-health-and-diseases/a-z-list/hendra-virus. Access date: August 17, 2017

39. ProMED mail. Available at: http://www.promedmail.org/ Access Date: 16th June, 2017.

40. New South Wales Government Department of Primary Industries. Hendra Virus. Available at: http://www.dpi.nsw.gov.au/animals-and-livestock/horses/health-and-disease/hendra-virus Access Date: 16th June, 2017.

41. Mohd HA, Al-Tawfiq JA and Memish ZA. Middle East Respiratory Syndrome Coronavirus (MERS-CoV) origin and animal reservoir. *Virology journal*. 2016; 13: 1.

42. World Health Organisation. WHO MERS-CoV Global Summary and Assessment of Risk. Available at: http://www.who.int/emergencies/mers-cov/risk-assessment-july-2017.pdf?ua=1 Access date: October 6, 2017. 2017.

43. European Centre for Disease Prevention and Control (ECDC). Rapid Risk Assessment. Severe respiratory disease associated with Middle East respiratory syndrome coronavirus (MERS-CoV) Availbale at: http://ecdc.europa.eu/en/publications/Publications/MERS-CoV-rapid-risk-assessment-August-2015.pdf Access Date: October 12, 2016.

44. World Health Organisation. Emergencies preparedness, response. Middle East respiratory syndrome coronavirus (MERS-CoV) – Saudi Arabia. Available at: http://www.who.int/csr/don/13-june-2017-mers-saudi-arabia/en/ Access Date: June 13, 2017.

45. World Health Organisation. Ebola virus disease. Fact sheet. Available at: http://www.who.int/mediacentre/factsheets/fs103/en/ Access date: 16th June, 2017.

46. World Health Organisation. Situation Report. Ebola Virus Disease June 2016. Available at: http://apps.who.int/iris/bitstream/10665/208883/1/ebolasitrep_10Jun2016_eng.pdf?ua=1 Access Date: June 16, 2017.

47. Musso D and Gubler DJ. Zika virus. *Clinical microbiology reviews*. 2016; 29: 487-524.

48. Chang C, Ortiz K, Ansari A and Gershwin ME. The Zika outbreak of the 21st century. *Journal of autoimmunity*. 2016; 68: 1-13.

49. Pan American Health Organization / World Health Organization. Zika suspected and confirmed cases reported by countries and territories in the Americas Cumulative cases, 2015–2017. Updated as of June 15, 2017. Washington, D.C.: PAHO/WHO; 2017. Pan American Health Organization, www.paho.org. Access date: June 16, 2017.

50. Australian Government Department of Health. Zika virus - notifications of Zika virus infection (Zika). Available at: http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-zika-notifications.htm Access date: June 19, 2017.

51. Plourde A and Bloch E. A Literature Review of Zika Virus. *Emerging infectious diseases*. 2016; 1185-92.

52. Atif M, Azeem M, Sarwar MR and Bashir A. Zika virus disease: a current review of the literature. *Infection*. 2016; 44: 695-705.

53. Musso D, Stramer SL and Busch MP. Zika virus: a new challenge for blood transfusion. *The Lancet*. 2016; 387: 1993-4.

54. Barjas-Castro ML, Angerami RN, Cunha MS, et al. Probable transfusion-transmitted Zika virus in Brazil. *Transfusion*. 2016; 56: 1684-8.

55. Motta IJ, Spencer BR, Cordeiro da Silva SG, et al. Evidence for transmission of Zika virus by platelet transfusion. *New England Journal of Medicine*. 2016; 375: 1101-3.

56. Jimenez A, Shaz BH and Bloch EM. Zika Virus and the Blood Supply: What Do We Know? *Transfusion Medicine Reviews*. 2017; 31: 1-10.

57. Hall-Mendelin S, Pyke AT, Moore PR, et al. Assessment of Local Mosquito Species Incriminates Aedes aegypti as the Potential Vector of Zika Virus in Australia. *PLoS Negl Trop Dis*. 2016; 10: e0004959.

58. Baggoley C, Knope K, Colwell A and Firman J. Zika preparedness in Australia. *The Medical journal of Australia*. 2016; 204: 249.

59. Gardner CL and Ryman KD. Yellow fever: a reemerging threat. *Clinics in laboratory medicine*. 2010; 30: 237-60.

60. World Health Organisation. Yellow Fever. Emergencies preparedness, response. Available at: http://www.who.int/csr/disease/yellowfev/en/ Access Date: June 19, 2017.

61. World Health Organisation. Yellow fever – Angola. Emergencies preparedness, response. Available at: http://www.who.int/csr/don/14-june-2016-yellow-fever-angola/en/ Access Date: June 19, 2017.

62. World Health Organisation. Yellow fever – Democratic Republic of the Congo. Emergencies preparedness, response. Available at: http://www.who.int/csr/don/02-june-2016-yellow-fever-drc/en/ Access Date: June 19, 2017.

63. World Health Organisation. Yellow Fever. Available at http://www.paho.org/hq/index.php?option=com_topics&view=article&id=69&Itemid=40784&lang=en Access date: October 6, 2017.

64. Pan American Health Organization / World Health Organization. Epidemiological Update Yellow Fever, 24 May 2017. Available at: file:///C:/Users/Lkhawar/Downloads/2017-may-24-phe-epi-update-yellow-fever.pdf Access Date: June 19, 2017.

65. Centers for Disease Control and Prevention. Transfusion-Related Transmission of Yellow Fever Vaccine Virus California, 2009. Morbidity and Mortality Weekly Report (MMWR) 2010 / 59(02);34-37. Available at: https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5902a2.htm Access Date: June 19, 2017.

66. World Health Organisation. International Travel and Health, Annex 1 – Update – As of 16 February 2017. Countries with risk of yellow fever transmission and countries requiring yellow fever vaccination. Available at: http://www.who.int/ith/2017-ith-annex1.pdf?ua=1&ua=1 Access Date: June 19, 2017.

67. Hoad VC, Gibbs T, Ravikumara M, et al. First confirmed case of transfusion-transmitted hepatitis E in Australia. *The Medical journal of Australia*. 2017; 206: 289.

68. Hoad V, Seed C, Fryk J, et al. Hepatitis E virus RNA in Australian blood donors: prevalence and risk assessment. *Vox Sanguinis*. 2017; 112(7): 614-21.

69. Busch MP, Glynn SA, Stramer SL, et al. A new strategy for estimating risks of transfusion-transmitted viral infections based on rates of detection of recently infected donors. *Transfusion*. 2005; 45: 254-64.

70. Kleinman SH and Busch MP. Assessing the impact of HBV NAT on window period reduction and residual risk. *Journal of clinical virology*. 2006; 36: S23-S9.

71. Seed CR, Cheng A, Ismay SL, et al. Assessing the accuracy of three viral risk models in predicting the outcome of implementing HIV and HCV NAT donor screening in Australia and the implications for future HBV NAT. *Transfusion*. 2002; 42: 1365-72.

This page intentionally left blank

Design: **Il Razzo** Telephone: **0407 210 388** E- mail: **admin@ilrazzo.com.au**