Transfusion-transmissible infections in Australia

2015
Surveillance Report

Australian Red Cross BLOOD SERVICE

UNSW AUSTRALIA

Kirby Institute

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2015 Surveillance Report

edited by

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The Australian Red Cross Blood Service

in collaboration with

The Kirby Institute

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Foreword

This report is jointly produced by the Australian Red Cross Blood Service (Blood Service) and 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 fifth report that summarises donation testing data, and incidence and prevalence trends for transfusion-transmissible infections among Australian blood donors. While it is an important Blood Service resource, it is also intended to be a reference document for organisations and individuals interested in the occurrence of transfusion-transmissible infections in Australia and the effectiveness of the Blood Services' infectious disease blood safety strategy.

Consistent with previous years, the overall number of transfusion transmissible infections detected remained very low in 2014 (n=153, 0.01% of all donations). Of these, 92% were either hepatitis B (HBV) or hepatitis C (HCV). Reflecting the effectiveness of donor selection strategies, the prevalence of infection in first-time donors continues to be substantially (13-35 times) lower than national population prevalence estimates. Only nine (0.06%) of infections in 2014 were determined to be incident (newly acquired) based on a past negative test within the last twelve months for the same transfusion-transmissible infection. 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 donation testing. Notably, for the ten-year period 2005-2014 there was no significant trend observed for incidence rates of any of the transfusion-transmissible infections with rates being stable or declining.

As window period infections cannot be identified by testing but can be avoided if the donor discloses risk behaviour leading to deferral from donation, we are highly reliant on the truthfulness of our donors. Of the transfusion transmissible infections detected in 2014, 25% had risk factors identified in their post-donation interview which were not disclosed in their initial donation interview (termed 'non-compliance'). While this rate had been fairly stable in the past decade, there has been an increasing trend in recent years. Minimising non-compliance is an organisational imperative and previous research supports the use of an audio computer-assisted structured interview (ACASI) as a strategy to improve compliance as well as the donor experience. Accordingly, the Blood Service has commenced a strategic project to assess the operational feasibility of implementing ACASI. Importantly, significant validation and regulatory approval for any selected system would be required before implementation.

Contents

Glossary

Active syphilis

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

Infectious Syphilis

Laboratory or clinical evidence of seroconversion within the last two years.

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 in Australia.

Hepatitis B virus (HBV) positive:

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

Has either tested positive to antibodies to HCV, HCV RNA or both as defined below:

Antibodies to hepatitis C (anti-HCV) Positive: The test detects 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: The most common follow-up test is a qualitative HCV RNA (ribonucleic acid) test. 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 test in the presence of anti-HCV indicates resolved infection.

Injecting drug use

Defined as ever "used drugs" by injection or been injected, even once, with drugs not prescribed by a doctor or a dentist.

Incidence

The rate of newly acquired infection among repeat donors.

Incident donor

A positive repeat donor whose last donation tested negative within the past twelve months for the same transfusion-transmissible infection.

Infective risk factor

A potential route of infection in positive donors reported at the post-donation interview.

Lapsed donor

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

Non-compliance

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

Occult hepatitis B infection (OBI)

The presence of circulating hepatitis B DNA in the absence of detectable HBsAg, excluding the pre-HBsAg window period.

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) 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

A virus, parasite, or other bloodborne infectious agent in donated blood that can be transmitted by transfusion to a recipient.

Window period

The duration of the period from infection to the time of first detection in the bloodstream by a screening test. The window period differs dependent on the infection and the test used.

Summary of the main findings

General characteristics of blood donors in Australia

1. Over the ten-year period 2005-2014, there were approximately 12.5 million blood donations in Australia with an average of 1.2 million donations per year. Although there has been a decrease in the total number of donations since 2009, the trend over the last ten years shows a significant increase (p= 0.01). Total blood donations in 2014 declined by 3.7% (representing 48 939 less donations) compared to 2013 reflecting both a reduced clinical demand for red cells leading to fewer whole blood collections, and continued expansion of automated plasma collections to meet an increasing demand for some plasma products, principally intravenous immunoglobulin.

2. Of the Australian population aged between 16-80 years, 2.5% donated blood during 2014.

3. First-time and repeat donors comprised 16% and 84% of all blood donors in Australia over the period 2005-2014, respectively. As in previous years, this ratio remained relatively stable nationally and across all states and territories. Male donors constitute approximately 50% of all donors in 2014 in comparison to representing 46% of the Australian general population aged 16-80 years.

Trends in transfusion-transmissible infections in Australian blood donors

1. In 2014, a total of 153 blood donors were detected as having a transfusion transmissible infection 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 2005-2014 a total of 2 255 transfusion transmissible infection-positive donors have been detected. In 2014, no donor had more than one transfusion-transmissible infection.

2. The most common transfusion transmissible infection was HBV, followed by HCV. Of all the donations positive for a TTI in 2014, 92% were positive for either HBV or HCV.

3. Overall HTLV was the least common infection among all donors in 2014; just one donor was HTLV positive in 2014. In the ten year period 2005-2014, HIV was the least common infection among first-time donors.

4. Although representing only 13.2% of the donor population, first-time blood donors contributed approximately 66.6% of transfusion transmissible infections in Australia in 2014 (Figure 2). This ratio has declined as compared to 2013 where the first-time blood donors contributed to 82% of the total transfusion transmissible infections. However, this decline is explained by an increase in the proportion of repeat donors during 2014 who had made their last donation prior to 1990 (i.e. they had not previously been tested for HCV).

5. No transfusion-transmitted HIV, HCV, HTLV or syphilis infections were reported in Australia during 2008-2014. 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.

6. In 2014, the prevalence of transfusion-transmissible infections was substantially lower among first-time blood donors (13 to 35 times) compared with national prevalence estimates.

HBV infection among Australian blood donors

1. There were 84 HBV infections detected among all donations in 2014 (65 in first-time donations and 19 in repeat donations).

2. Of all transfusion-transmissible infections detected, HBV continued to have the highest prevalence among first-time donors.

3. The prevalence of HBV infection among first-time donors during 2005-2014 remained stable at 82.9 per 100 000 donations (or 0.08% of the total first-time donations) which was 12 times lower than 1.0% reported nationally.

4. Incident HBV donors continue to be rare with only three recorded nationally in 2014, two in Victoria and one in Western Australia, giving an incidence rate of 0.9 per 100 000 donor-years of observation. Overall, there was no discernible time trend in HBV incidence nationally or in any state/territory during the ten-year study period 2005-2014.

5. The most common infective risk factor for donors with hepatitis B infection during the five year period 2010-2014 was ethnicity/country of birth (83%) which is consistent with the findings of previously published population data for the period 2009-2012.

6. In 2014, HBV positive donors were the same age when compared to all donors (mean age 42 years) but were more likely to be male (65% 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 previous years.

7. Three probable cases of transfusion-transmitted HBV infection were reported in the 2008-2014 period (See Main Findings for details).

HCV infection among Australian blood donors

1. There were 56 HCV infections detected among all donations in 2014 (31 in first donations and 25 in repeat donations).The increased proportion among repeat donors this year is explained by an increase in the number who were screened for HCV for the first time (11 of 25 positive repeat donors).

2. HCV was the second most common infection found in first-time blood donors. Importantly, in 2014 the proportion of HCV positive donors with detectable RNA (indicative of current infection) was only 46% (26 of the 56). This proportion has steadily declined from around 75% when universal HCV RNA testing of blood donations commenced in 2000. This likely reflects the overall decline in HCV notifications in Australia, due to a number of possible factors, including safe injecting practices, the uptake of substitution therapy, and a decrease in the number of people newly initiating injecting.

3. During 2005-2014, there has been a significant decrease in HCV prevalence in first-time donors in Australia ($p<.001$), from 0.1% in 2005 to 0.03% in 2014. This translates into a decrease of 68% from 106 per 100 000 first-time donations in 2005 to 34 per 100 000 first-time donations in 2014. The 0.03% first-time donor prevalence in 2014 is 33 times lower than the 0.9% reported nationally. This decreasing trend is consistent with national HCV new-diagnoses notification data which also shows a decrease in both numbers of notifications (from 12 175 in 2005 to 10 621 in 2014) and rate (from 61 per 100 000 in 2005 to 46 per 100 000 in 2014).

4. Of all transfusion-transmissible infections detected, HCV had the highest incidence rate among previously negative repeat donors during 2005-2014. The incidence rate has fluctuated over time from 1.7 in 2011, to 4.1 in 2013 and was 0.9 per 100 000 donor-years of observation in 2014. Importantly, the fall in 2014 is at least in part due to the application of a stricter incidence definition and should therefore be interpreted with due caution.

5. The most common putative reported infective risk factor for donors with HCV infection during 2011-2014 was a history of tattoo/piercing (25%), followed by injecting drug use (23%). In comparison, injecting drug use (65%) and sexual contact (5%) were the two most dominant routes of exposure in cases of newly acquired hepatitis C infection reported in national notification data in 2014.[1]

6. In 2014, the mean age of HCV positive donors was 48 years compared to 42 years for all donors. Like HBV, male donors were over-represented as compared to all donors (66% versus 50%) but in contrast to hepatitis B, the majority (79%) were born in Australia.

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

1 The Kirby Institute. HIV, viral hepatitis, sexually transmissible infections in Australia Annual Surveillance Report 2015. The Kirby Institute, UNSW, NSW 2052.

HIV infection among Australian blood donors

1. There were seven HIV infections detected among all donations in 2014 (three in first-time donations and four in repeat donations).

2. The prevalence of HIV infection among first-time donors during 2005-2014 remained very low at 2.1 per 100 000 donations (or 0.003% of the total first-time donations) and comparatively much lower than hepatitis B (82.9 per 100 000 donations) and hepatitis C (68.3 per 100 000 donations). The 0.003% HIV prevalence in first-time donors is 30 times lower than the 0.1% prevalence reported nationally.

3. The incidence of HIV infection among previously negative repeat donors remained low and stable over time; 0.8 in 2011, 0.3 in 2012, 0.6 in 2013 and 0.9 per 100 000 donor-years of observation in 2014.

4. The two most common routes of exposure for donors with HIV infection during 2011-2014 were male-to-male sex (38%), followed by heterosexual sex with partners with known risk factors or known to be HIV positive (33%). This compares to the new HIV diagnoses notification data in Australia where men who have sex with men accounted for 70% of new HIV diagnoses in Australia in 2014, followed by heterosexual sex (19%). [1]

5. The mean age of HIV positive donors in 2014 was 36 years (compared to 42 years for all donors. Male donors were over-represented as compared to all donors (79% versus 50%) and 43% were Australian-born.

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

HTLV infection among Australian blood donors

1. There was just one case of HTLV infection detected among all donations in 2014. The donor was a first-time donor.

2. The prevalence of HTLV among first-time donors remained very low and stable during 2005-2014, fluctuating from 0.9 per 100 000 first-time donations in 2005, to 0.8 per 100 000 new donations in 2010, and 1.1 per 100 000 first-time donations in 2014.

3. No incident HTLV donor was identified in 2014 and none have been recorded during the ten-year period 2005-2014.

4. The most common infective risk factor for donors with HTLV infection during 2011-2014 was ethnicity or country of birth (80%). There are no data to compare risk factors in the general population.

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

Active syphilis infection among Australian blood donors

1. There were five active syphilis infections detected among all donations in 2014. Active syphilis is defined by reactivity on treponemal and non-treponemal syphilis testing and/or clinically apparent infection, i.e. excluding past-treated infections.

2. The prevalence of active syphilis in first-time donors has increased over-time, but this trend is not significant. In first-time donors the prevalence was 0 per 100 000 first-time donations in 2005, 3.9 per 100 000 first-time donations in 2010 and 2.2 per 100 000 first-time donations in 2014.

3. Overall, the prevalence of active syphilis among all blood donations (first and repeat) has remained low (overall prevalence of 0.4 per 100 000 donations); although, there has been a significant increase in the ten-year period 2005-2014; from 0 per 100 000 in 2005 to 0.6 per 100 000 in 2010 and 0.4 per 100 000 in 2014.

Donor Compliance

Over 17% of the positive donors in 2010-2014 were ‘non-compliant’ in that they had risk factors identified during their post-donation interview that would have deferred them from donating had they disclosed them at the pre-donation interview. The non-compliance rate has fluctuated in the last four years, from 12.9% in 2011 to 25% in 2014. These findings highlight the importance of ongoing donor education to ensure that the potential donors understand the importance of ‘self-deferral’ to reduce the risk of collecting blood from a potentially infected donor whose infection may not be detected by testing.

Malaria testing

1. In 2014, a total 105 645 donations were tested for malaria antibody of which 1 483 (1.4%) were repeatedly reactive. None had detectable malaria DNA suggesting past infection in these donors.

2. There were no reported cases of transfusion-transmitted malaria during 2014, with the last Australian case occurring in 1991.

Bacterial pre-release testing for platelets

1. Bacterial screening of 118 610 platelets identified 114 (0.1%) as confirmed positive.

2. *Propionibacterium spp.,* which are common skin commensals were by far the most frequently isolated organisms (94). These organisms are rarely, if ever associated with septic transfusion reactions in recipients. Other potentially pathogenic organisms included *Granulicatella sp, Kocuria sp, Coagulase negative staphylococci* and mixed organisms. A small number of clinically significant organisms including *Salmonella enterica, Erisipelotrix rusiopatiae and Streptococci - pneumonia, dysgalactiae and group C.* were also detected. None of the contaminated platelets with clinically significant organisms had been transfused.

3. During 2014, two septic transfusion reactions were identified in patients who received platelets, one receiving pooled platelets contaminated with *Staphylococcus aureus* and the second patient receiving *Bacillus cereus* contaminated platelets. Such cases are rare, being only the second and third cases of transfusion-transmitted bacterial infection associated with the transfusion of platelets since the introduction bacterial screening in 2008.

Emerging infections

1. During 2014 there were several dengue fever outbreaks in northern Queensland involving the Miallo/Port Douglas, Cairns/Innisfail and Charters Towers. These outbreaks spanned January to late June with a total of 200 confirmed cases. To mitigate the transmission risk, donations from these areas were restricted to CSL fractionation/processing until the outbreaks were declared over, a strategy that has been shown to effectively eliminate dengue virus.

2. In 2014, while continuing the fresh component restrictions for recent visitors to North America the Blood Service monitored the risk associated with West Nile virus (WNV) outbreaks in the European Union (EU) and surrounding countries during the European transmission season (July to November 2014). The risk of a donor returning and donating while viraemic was monitored on a weekly basis. As in 2013, the additional level of risk to the Australian blood supply associated with donors returning from these countries during the 2014 WNV transmission season did not exceed the threshold requiring additional donor selection measures.

3. Human cases of infection with a novel coronavirus, now referred to as Middle East respiratory syndrome coronavirus (MERS-CoV) was first reported by the World Health Organization (WHO) in September 2012. MERS-CoV has been classified in the same genus as severe acute respiratory syndrome-related coronavirus (SARS-CoV) which raised initial concerns that the new virus may result in a similar pandemic to SARS in 2003-04. Evidence indicates that, to a limited extent, MERS-CoV can be transmitted between humans. 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. During 2014, approximately 640 cases (compared to 173 in 2013) were reported to WHO with over 90% occurring in Saudi Arabia and the United Arab Emirates. During 2014, the risk posed by MERS-CoV to Australia's blood safety appeared to be very low, and WHO did not advise any special screening at points of entry with regard to MERS-CoV nor did it recommend the application of any travel or trade restrictions. However the Blood Service continues to closely monitor developments.

4. In March 2014, an ebolavirus disease (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 in 2014, were Guinea, Liberia and Sierra Leone. By the end of 2014 the outbreak remained ongoing and approximately 20,000 cases had been reported with 7,900 deaths. Although transfusion-transmission of EBOV has not been reported, it cannot be excluded as ebolaviruses are typically detectable in the blood for about 1-2 weeks during acute infection. However, the risk of transfusion-transmitted ebolavirus infection may be mitigated by the observation that ebolavirus DNA is usually not detectable until symptoms appear, by which time the infected individual would be unlikely to attempt to donate blood. The Blood Service is managing the potential risk from EBOV by ongoing monitoring of reports of laboratory-confirmed cases and 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 eblolavirus are deferred from donating for 8 weeks after leaving the risk area and blood donor deferrals were introduced for cases and close contacts. The risk posed by EBOV to Australia's blood safety appears to be very low.

Key messages

1. Supporting the effectiveness of donor education and selection, the prevalence of transfusion-transmissible infections is substantially lower among first-time blood donors (13 to 35 times) compared with national prevalence estimates in 2014 and shows a stable or declining trend since 2005 (Table 2).

2. The prevalence of transfusion-transmissible infections among first-time donors was much higher than their prevalence among all donors, highlighting the importance of promoting donor education of potential new donors and ensuring first-time donors read the pre-donation information, and understand the importance of 'self-deferral'.

3. The incidence of newly acquired infection measured by the rate of incident donors is also much lower than reported for 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.

4. Infective risk factors identified in blood donors with transfusion-transmissible infections closely parallel those for the general population with no 'unique' risk factors identified to date among blood donors.

5. Donor compliance with deferral periods is an important factor impacting any change in risk to the blood supply. Over 17% of the positive donors in 2010-2014 were '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. This finding further 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.

6. While non-compliance among positive donors has been routinely monitored since 2000 the rate among TTI test-negative donors is more difficult to track. We previously reported results from a large national survey conducted in 2012-2013 which showed a comparatively low rate of non-compliance (in the range 0.05 to 0.29%) among TTI test-negative donors for several sexual activity-based donor deferrals. The study included a multivariate analysis of factors influencing non-compliance which suggested that the use of an audio computer-assisted structured interview (ACASI) might lead to further improvement in the overall compliance rate. The Blood Service has commenced a strategic project to assess the operational feasibility of implementing ACASI. Regulatory approval for any selected system would be required before implementation.

7. The estimated residual risk of transmission for HIV, HCV, HBV, HTLV and syphilis in Australia is very low, less than one in one million per unit transfused for all except HBV. The residual risk of transmission of HBV is higher (approx. 1 in 557,000) but comparable to other Blood Services in developed countries. These risk estimates support the claim that Australia's blood supply is among the safest worldwide in respect of transfusion-transmissible infections for which screening is conducted. Despite this, there remains a minimal but real risk of transfusion-transmissible infections which must be carefully considered before any transfusion.

8. Bacterial screening of 118 612 platelets identified 114 (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.

9. In addition to established transfusion-transmissible infections, emerging infectious diseases continue to demand vigilant surveillance. Mosquito-borne agents such as dengue virus and West Nile virus are currently the principal threats but many other novel or emerging infectious diseases are constantly monitored by the Blood Service to assess their threat to the safety of the blood supply. The worldwide spread of dengue virus continued in 2014 and several seasonal outbreaks in northern Queensland were subject to the routine risk mitigation strategies. Overall, the numbers of reported cases of WNV fever in EU and neighbouring countries was lower in 2014 compared to 2013. While no cases of human Hendra virus infection were recorded in 2014, there were 4 equine cases. In 2014, Middle East respiratory syndrome coronavirus (MERS-CoV) cases continued to be reported, predominantly in the Arabian Peninsula, though no sustained human to human transmission or transfusion transmission has been identified and the risk to the blood supply is assessed as very low. The largest ever outbreak of ebolavirus disease (EVD) was reported in West Africa commencing in March 2104. The Blood Service is managing the potential risk from EBOV by ongoing monitoring of reports of laboratory-confirmed cases and 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 eblolavirus are deferred from donating for 8 weeks after leaving the risk area. The risk posed by EBOV to Australia's blood safety appears to be very low.

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Abbreviations

anti-HBc	antibody to hepatitis B core antigen
anti-HBe	antibody to hepatitis B antigen
anti-HBs	antibody to hepatitis B surface antigen
anti-HeV	antibody to Hendra virus
A(H7N9)	avian influenza H7N9 virus
HBsAg	hepatitis B surface antigen
Blood Service	Australian Red Cross Blood Service
HBeAg	hepatitis B e antigen
HBsAg	hepatitis B surface antigen
HBV	hepatitis B virus
HCV	hepatitis C virus
HeV	Hendra virus
HIV	human immunodeficiency virus
HTLV	human T-cell lymphotropic virus
IDU	intravenous drug user
MERS-CoV	Middle East Respiratory Syndrome coronavirus
NAT	nucleic acid testing
NiV	Nipah virus
OBI	Occult hepatitis B virus infection
SARS-CoV	severe acute respiratory syndrome-related coronavirus
STIs	sexually transmissible infections
TTVI	transfusion-transmissible viral Infections
TTIs	transfusion-transmissible infections
WNV	West Nile virus
WP	window period

Main Findings

Epidemiology of transfusion-transmissible infections in Australia

Blood donors are a subset of the general population, so to provide a context for the report, the following section of the document focuses on the epidemiology of transfusion-transmissible infections in Australia. This includes a brief description of the number of people living with transfusion-transmissible infections in Australia by the end of 2014, trends in the last ten years, notifications of newly diagnosed transfusion-transmissible infections 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 2015.[2]

HBV Infection:

At the end of 2014, an estimated 213 300 people were living with chronic HBV infection in Australia (range 175 000 to 253 000), of whom an estimated 56% were diagnosed with chronic hepatitis B, 38% were born in the Asia-Pacific and 9.3% were among Aboriginal and Torres Strait Islander peoples. There were a total of 6 635 notifications of newly diagnosed HBV infection in Australia in 2014; of these, just over half (54%) were males, and 73% were people aged 30 years and above. Australia has a concentrated hepatitis B epidemic among key populations; migrants from high prevalence countries, particularly South East Asia; men who have sex with men; Aboriginal and Torres Strait Islander peoples; and people who inject drugs. Over the past ten years, the population rate of diagnosis of HBV infection in Australia has declined in younger age groups - 25 – 29 years (from 72 per 100 000 in 2005 to 59 per 100 000 in 2014); 20 – 24 year (58 to 32 per 100 000); and 15 – 19 years (25 to 11 per 100 000). This decline could be attributable to the successful implementation of immunisation programs for HBV and high levels of vaccine coverage in the younger age groups. In addition, there has been a decline in the rate of newly acquired HBV cases (acquired in the past 2 years) in the past ten years by 39% from 1.2 per 100 000 in 2005 to 0.8 per 100 000 in 2014. The estimated prevalence of chronic HBV infection among people born in Australia is 1.0%, which by country of birth is higher than the United Kingdom (0.3%) but lower than many other countries in South East Asia and the Pacific.[2]

HCV Infection:

During 2014, an estimated 230 470 (180 490 – 243 990) people were living with chronic hepatitis C in Australia, of which an estimated 75% or 172 932 (157 055 – 188 865) were diagnosed with chronic hepatitis C. Australia has a concentrated chronic hepatitis C epidemic among key populations; people who inject drugs, prisoners, and people from high prevalence countries and HIV positive men who have sex with men. The rate of diagnosis of HCV infection in 2014 was 46 per 100 000 as compared to 61 in 2005, representing a continuing decline over the past 10 years; suggesting a reduction in transmission related to injection drug use, which has been the main pathway of infection in Australia. In contrast, the rate of hepatitis C diagnosis in the Aboriginal and Torres Strait Islander population increased in 2014, from 119 per 100 000 in 2010 to 164, a rate over four times greater than in the non-Indigenous population (35 per 100 000). Most cases (66%) of newly diagnosed HCV infection were in males and 77% were in people aged 30 years and above.[2]

HIV Infection:

During 2014, an estimated 27 150 (24 630 – 30 310) people were living with HIV (about a tenth of infections compared to HBV and HCV), and an estimated majority (88%) or 23 800 were diagnosed (22,480 – 25,050). Transmission of HIV in Australia continues to occur primarily through sexual contact between men, with 88% of newly acquired cases of HIV infection in Australia in the period 2005 to 2014 involving men who reported sexual contact with men. The annual number of new HIV diagnoses has gradually increased by 13% over the past 10 years, from 953 diagnoses in 2005 to 1 064 in 2012 and stabilised since then with 1 081 cases of HIV infection newly diagnosed in Australia in 2014. Of these newly diagnosed HIV infections, 90% were in males, 70% occurred among men who have sex with men, 5% due to male-to-male sex and injecting drug use, 19% were attributed to heterosexual sex, and 3% to injecting drug use. At 0.1%, the prevalence or overall proportion of people in Australia who have HIV is lower than other comparable high income countries, and countries in the region.[2]

2 The Kirby Institute. *op. cit.*, p 8

HTLV Infection:

HTLV is not a notifiable infection in Australia, and very few studies have examined the epidemiology in Australia. There has been a focus on HTLV-1, due to disease outcomes, including HTLV-1-associated myelopathy and adult T-cell leukemia/lymphoma[3] [4]. Published data on the prevalence of HTLV-1 in Australia has been based on the detection of HTLV-1 antibody through testing in the clinical setting or blood donor screening, rather than population based surveillance. 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.[5] [6] [7] There is no published population based seroprevalence studies. In the absence of information about HTLV-1 prevalence by age and sex, it is not possible to infer the primary modes of transmission in the general population in the Australian setting.

Infectious syphilis:

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 2014 was 1 999. The rate of diagnosis of infectious syphilis among men has increased in the past ten years, from 5.1 per 100 000 in 2005 to 15.9 per 100 000 in 2014 whereas the rate among women has fluctuated and remained low (1.5 per 100 000 in 2014).[8]

Blood donors in Australia

Over 12.5 million donations were tested for transfusion-transmissible infections in Australia during the ten-year period 2005-2014 with an average of 1.2 million donations per year. Overall, the number of blood donations increased by more than 16% over the past ten years, with a 3.7% decrease from 2013 to 2014 (Figure 1). The more recent decrease in total collections in the past two years is attributed to the combined impact of a progressive uptake of patient blood management initiatives with a decrease in clinical demand for red cells leading to a reduction in whole blood collections, and a planned shift in collection strategy to improve overall efficiency by increasing the proportion of machine-based plasma collections. The latter aims to provide the most cost-effective method to increase local plasma production to meet an increasing demand for plasma derived products, particularly intravenous immunoglobulin.

In 2013, 2.9% of the general population who were aged between 16-80 years donated blood in Australia. This proportion declined slightly in 2014 to 2.5%. As in previous years, more than 90% of all donations in 2014 were from repeat donors. Predictably, while first-time blood donors represented only 13.2% of the donor population, they contributed the majority (66.6%) of transfusion-transmissible infections in Australia in 2014, reflecting detection of prevalent infections rather than incident infections. Overall in the past ten years, there has been a steady increase in the proportion of repeat donors among all TTI-positive blood donations in Australia (from 7% in 2005 to 33% in 2014) (Figure 2) - noting that the 2014 figure is explained by an anomaly in the rate of returning 'lapsed' donors undergoing HCV testing for the first time. The increase in repeat donor proportion for the period 2005 to 2013 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 repeat donors is not reflective of an increase in incidence, which has been stable or declining.

3 Gallo RC. History of the discoveries of the first human retroviruses: HTLV-1 and HTLV-2. *Oncogene*. 2005; 24: 5926-30.

4 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.

5 Bastian I, Hinuma Y and Doherty RR. HTLV-I among Northern Territory aborigines. *The Medical journal of Australia*. 1993; 159: 12-6.

6 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. 2014.

7 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.

8 The Kirby Institute. *op. cit.*, p 8

Figure 1 **Number of blood donations in Australia by year of donation, 2005-2014**

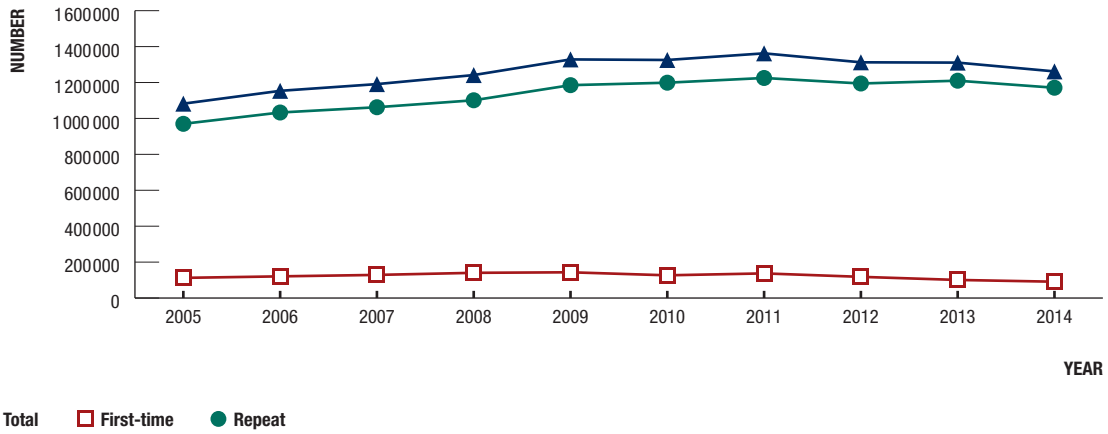
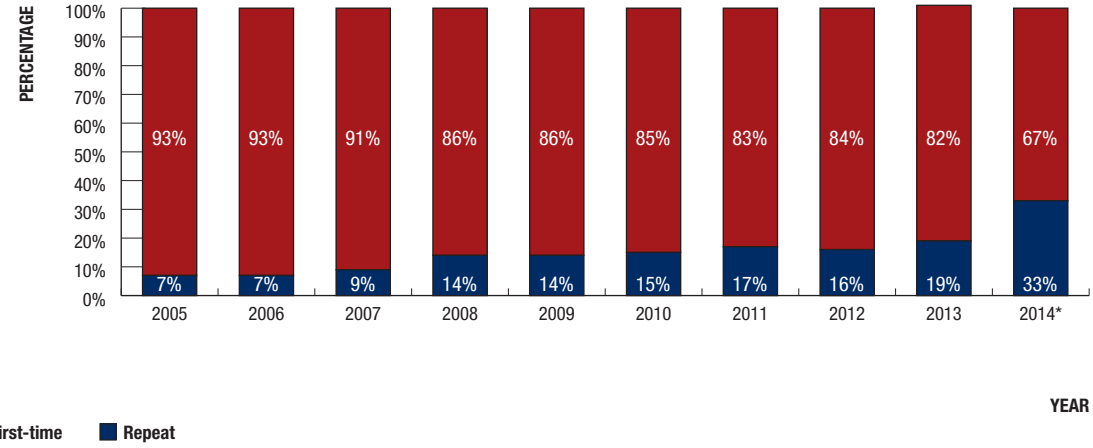


Figure 2 **Percentage of first-time and repeat donations among all positive blood donations in Australia, 2005-2014**



* The increase in the % of repeat donor among all positive blood donations from 19% in 2013 to 33% in 2014 is partly because 11 of the 25 HCV+ repeat donors are 'lapsed' donors who last donated prior to 1990 when HCV screening commenced; and so are 'first-time' tested for HCV. In comparison only 4 of 18 repeat HCV+ donors in 2013 were lapsed.

Among all blood donors who donated in 2014, an equal proportion of males and females contributed donations (50% each). Overall, 36% of donors were from those aged 50 years and above, and the median age of male donors was 43 and 39 years for females; 30% were people residing in New South Wales. Together New South Wales, Queensland and Victoria accounted for more than 76% of all blood donations in Australia in 2014.

Trends in incidence and prevalence of transfusion-transmissible infections

This section focuses on the trends in prevalence and incidence of transfusion-transmissible infections during the ten-year period 2005-2014 overall in Australia and trends observed in state/territory jurisdictions. 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 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 (Supporting Table 27).

In 2014, a total of 153 donors (12 per 100 000 donations) were found positive for at least one of the transfusion-transmissible infections subject to mandatory donation testing. Overall, HBV and HCV were the two most common transfusion-transmissible infections identified in Australian blood donors in 2014, together contributing more than 92% of all infections (Figure 3). Hepatitis B and C were the most common transfusion-transmissible infections in both first-time and repeat donors. TTI-positivity has remained low with a slight but significant* declining trend in overall prevalence during 2005-2014, largely due to declines in hepatitis B and C prevalence in donations (Figure 4).

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

Figure 3 **Number of blood donors with transfusion-transmissible infections in Australia in 2014, by infection**

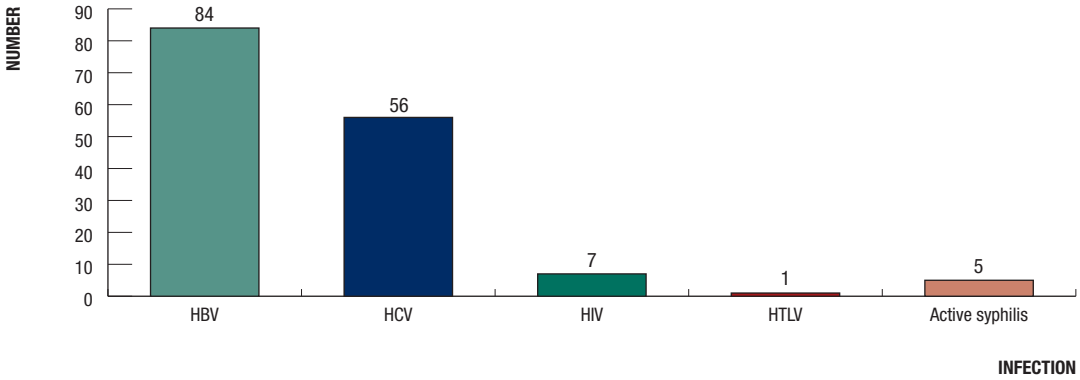
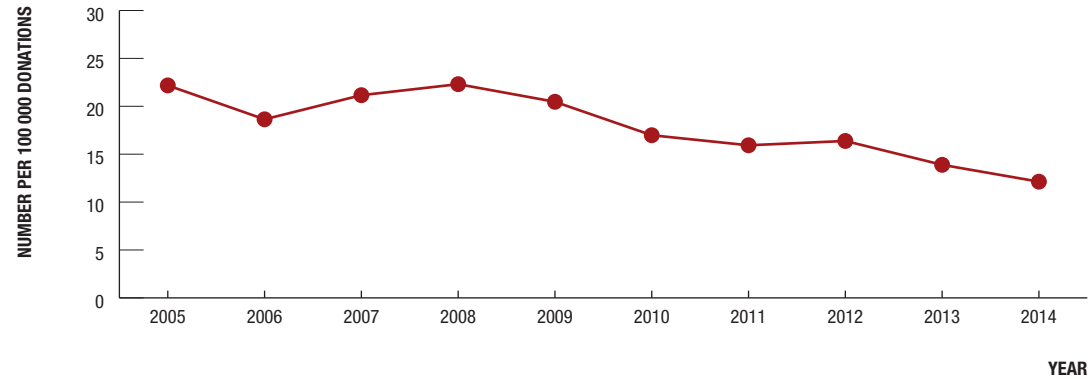


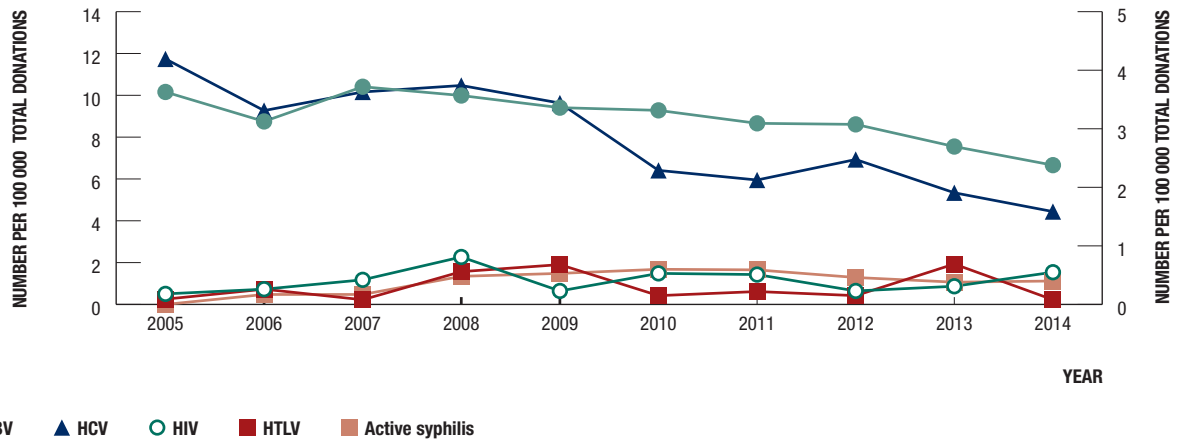
Figure 4 **Prevalence of any transfusion-transmissible infection among all tested donations**



Prevalence among all donors

During the last ten years, the prevalence of HBV and HCV infections among all donors has declined significantly with an overall reduction from 2005 to 2014 of 35% and 62%, respectively (Figure 5). The prevalence of active syphilis infection among all donors has remained low but increased significantly during 2005-2014. Both HIV and HTLV prevalence showed no statistically significant trends over the ten-year period.

Figure 5 **Prevalence of transfusion-transmissible infections in all blood donations in Australia, 2005-2014, by infection* and year of donation**

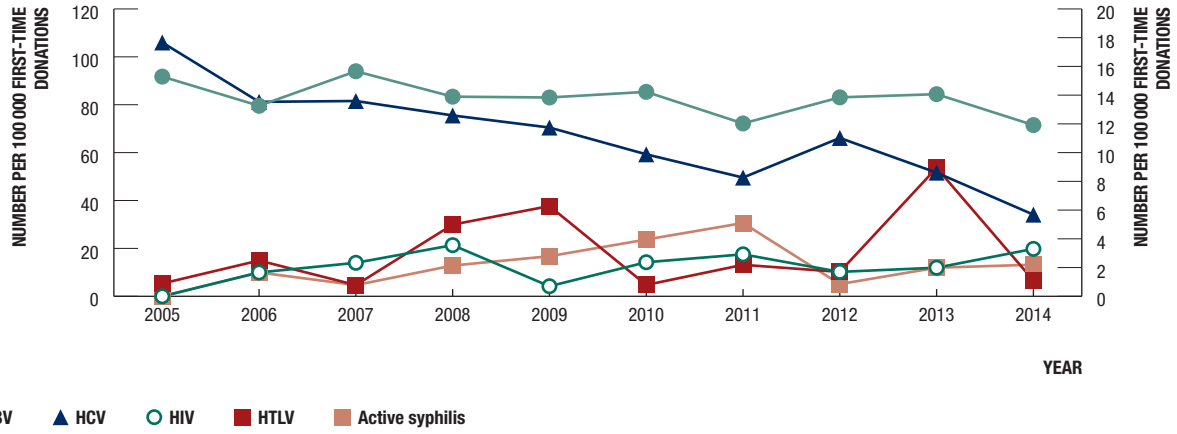


* Prevalence of HIV, HTLV and active syphilis are provided according to the scale on the secondary axis.

Prevalence among first-time donors

Over the ten year period 2005-2014 no significant annual trend was observed in the prevalence of HBV infection among first-time donors, with the rate remaining stable at 82.9 per 100 000 donations (0.08% of the total first-time donations) (Figure 6). During 2005-2014, there has been a significant decrease in HCV prevalence in first-time donors in Australia; from 106 per 100 000 donations in 2005, to 59.2 per 100 000 donations in 2010 and 34 per 100 000 donations in 2014). This translates into a decrease from 0.1% of the total first-time donations in 2005 to 0.03% of the total first-time donations in 2014. 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 hepatitis C infection declined from 61 per 100 000 in 2005 to 46 per 100 000 in 2014.[9] The literature provides evidence for a peak of new HCV seroconversions occurring in 1999.[10] The decline in recent years may be attributed to a range of factors, including positive health behaviour such as safe injecting practices and the uptake of opioid substitution therapy[11], as well as a decline in the number of people newly initiating injecting.[12]

Figure 6 **Prevalence of transfusion-transmissible infections in first-time blood donors in Australia, 2005-2014, by infection[1] and year of donation**



1 Prevalence of HIV, HTLV and active syphilis are provided according to the scale on the secondary axis on the right hand side.

The prevalence of HIV, HTLV and active syphilis in first-time donors remained very low over the past ten years. HIV prevalence remained stable over the nine-year period 2005-2013 period at 2 per 100 000 first-time donations; ranging from 0.0 per 100 000 donations in 2005, to 2.3 per 100 000 donations in 2010 and 2 per 100 000 donations in 2013. However, it increased from 2.0 per 100,000 donations in 2013 to 3.3 per 100,000 donations in 2014. Despite the latter increase, overall, no significant trends were observed in the past ten years. The prevalence of HIV infection among first-time donors during 2005-2014 remained very low at 0.003%, which is encouraging given that the number of newly diagnosed HIV infections in the general Australian population increased steadily in the past decade by 13%, from 953 diagnoses in 2005 to 1 081 cases of newly diagnosed HIV infection in Australia in 2014.[9]

During the ten-year period 2005-2014, HTLV prevalence demonstrated a slight, non-significant increasing trend in first-time donors in Australia; from 0.9 per 100 000 donations in 2005, to 0.8 per 100 000 donations in 2010, and 1.1 per 100 000 donations in 2014. However, there has been an 88% decrease in the prevalence of HTLV in the first-time donors in 2014 (1.1 per 100,000 donations) as compared to 2013 (8.9 per 100 000 donations).

Overall, the prevalence of active syphilis in first-time donors showed an increasing trend during 2005-2014. The prevalence increased steadily from 0.0 per 100 000 first-time donations in 2005, to 3.9 per 100 000 first-time donations in 2010, and 2.2 per 100 000 first-time donations in 2014. It reached the highest level of 5.1 per 100 000 first-time donations in 2011. 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 per 100 000 population in 2010 to 7.6 per 100 000 population in 2013. The rate reached 8.7 per 100,000 population in 2014, corresponding to the highest recorded number of notifications, with 1 999 diagnoses of infectious syphilis.[9]

9 The Kirby Institute. *op. cit.*, p 8

10 Razali K, Amin J, Dore GJ, Law MG and Grp HPW. Modelling and calibration of the hepatitis C epidemic in Australia. Stat Methods Med Res. 2009; 18: 253-70.

11 White B, Dore GJ, Lloyd AR, Rawlinson WD and Maher L. Opioid substitution therapy protects against hepatitis C virus acquisition in people who inject drugs: the HITS-c study. The Medical journal of Australia. 2014; 201: 326-9.

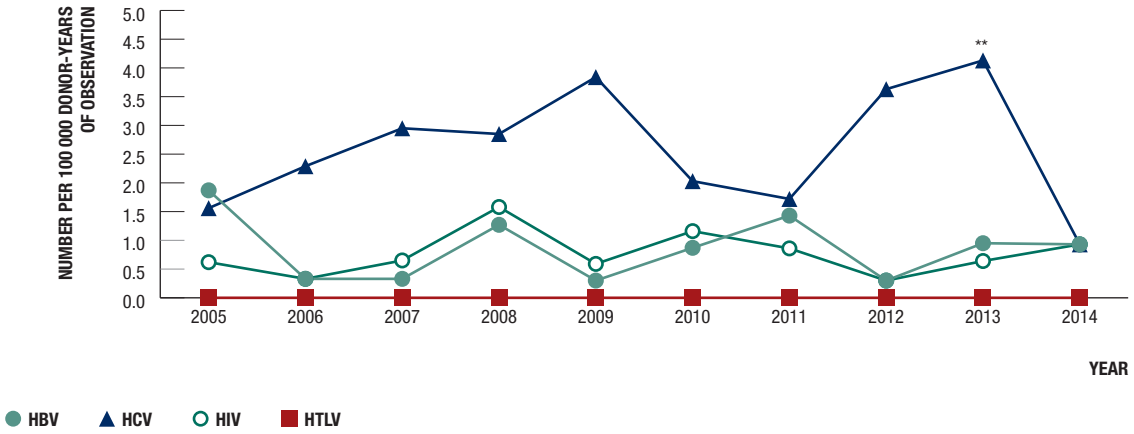
12 The Kirby Institute. HIV, viral hepatitis and sexually transmissible infections in Australia Annual Surveillance Report 2014. The Kirby Institute, The University of New South Wales, Sydney, NSW 2052, 2014.

Incidence in repeat donors

In 2014 a total of nine incident infections were detected with three for each of hepatitis B, hepatitis C and HIV. For the ten-year period 2005-2014 there was no significant trend observed for incidence rates of any of the transfusion-transmissible infections (Figure 7). Due to the application of a new incidence definition from 2014, trends were also analysed for the nine-year period 2005-2013 with no significant change observed. Similarly, no significant annual trend was observed for incidence of HCV over a nine year study period (2005-2013) among people who inject drugs participating in the Australian Needle and Syringe Program Survey, although following a steady decline in 2005-2009 HCV incidence has remained high in the past three years (between 8.1 and 21.4 per 100 person-years).[13] Likewise, no significant trend was observed for the incidence of HIV in a four-year study period among gay and bisexual men attending sexual health services, with the highest incidence recorded in 2011 at 1.32, declining to 0.81 in 2014.[13]

The HTLV incidence among repeat Australian donors in 2014 was zero as it was for the entire ten-year period 2005-2014.

Figure 7 **Incidence of transfusion-transmissible infection in repeat blood donors in Australia, 2005-2014, by infection and year of donation**



** The drop in HCV incidence in repeat blood donors in 2014 is at least in part attributed to the change in the definition of incident donors (formerly 'seroconverters'), previously defined as any donor with a previous negative test for the same infection and now defined as 'positive repeat donors whose last donation tested negative for the same transfusion-transmissible infection within the last twelve months.

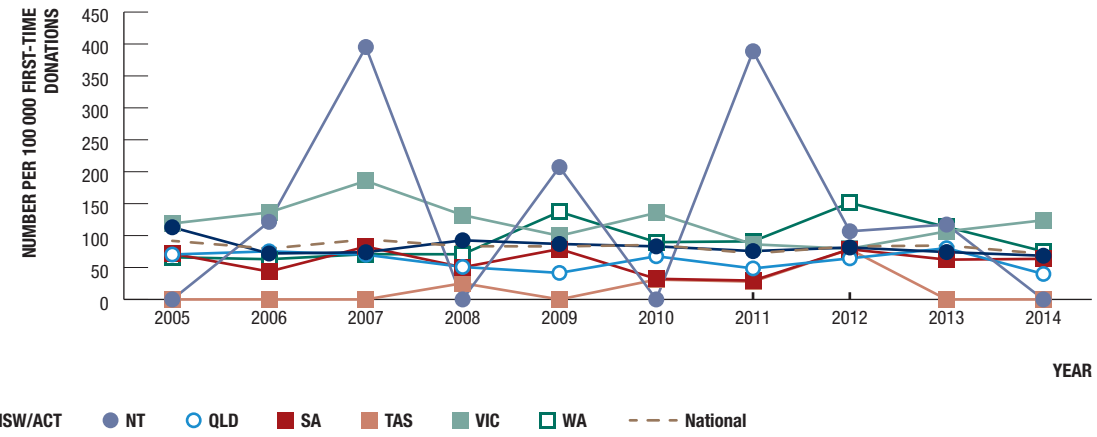
No transfusion-transmitted HIV, HCV, HTLV or syphilis infections were reported in Australia during 2008-2014. Three probable cases of transfusion-transmitted HBV infection were reported in the 2008-2014 period, two in 2009 associated with the same donor and one further case in 2011. In the first two 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 confirmed 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 cases were identified the Blood Service had already commenced planning to implement an upgrade to its existing HIV-HCV 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 testing, the Blood Service identified another donor with HBV screening results consistent with OBI. The recipient of this donation tested positive for hepatitis B after donation 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 level of HBV was too low to undertake sequence analysis. In this case transmission was considered probable and the recipient subsequently cleared the virus.

13 The Kirby Institute. *op. cit.*, p 8

Trends in HBV infection by state/territory

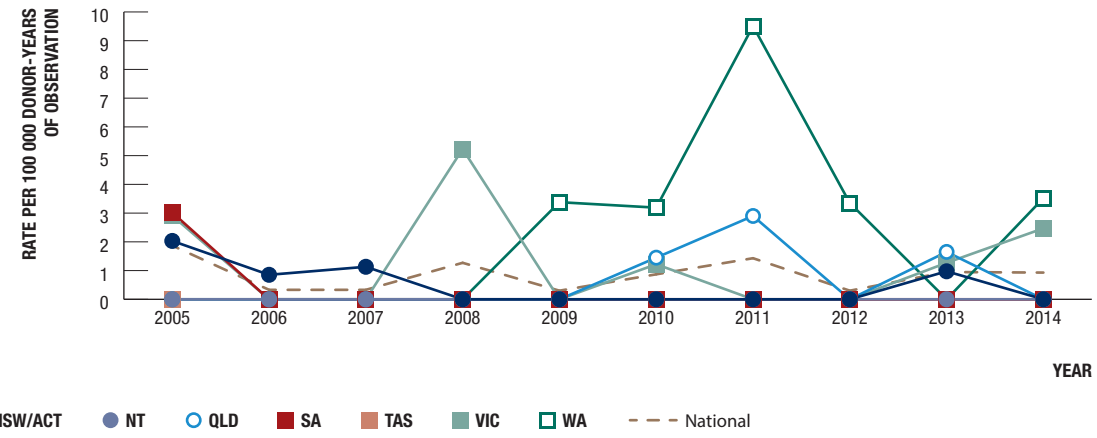
Consistent with previous TTI-surveillance reports the prevalence of HBV infection among first-time donors varied markedly by jurisdiction in 2014. While the national prevalence was 71.5 per 100 000 donations, this ranged from 0 to 115.1 per 100 000 donations across jurisdictions (Table 1 & Figure 8). In 2014, Victoria saw the highest prevalence of HBV infection among first-time donors as compared to the other states (115.1 per 100 000 donations); however a slight but significant decrease in the annual trend was observed in Victoria during 2005-2014 (p-value 0.02); from 118.9 per 100 000 first-time donations in 2005, to 135.5 per 100 000 first-time donations in 2010 and 115.1 per 100 000 first-time donations in 2014. No significant annual trend was observed in the prevalence of hepatitis B infection among first-time donors in the past ten years in any other state.

Figure 8 **Prevalence of HBV among first-time donors by state/territory and year of donation, 2005-2014**



Incident HBV infection continues to be rare with only three incident donors recorded nationally in 2014, two in Victoria and one in Western Australia. Overall, there was no obvious trend in HBV incidence in any state/territory during the ten-year study period 2005-2014 (Figure 9). Due to the application of a new incidence definition from 2014, trends were also analysed for the nine-year period 2005-2013 with no significant change observed in any state or territory. Among donors in Northern Territory and Tasmania, hepatitis B incidence has been zero since 2005.

Figure 9 **Incidence of HBV among repeat donors by state/territory and year of donation, 2005-2014**

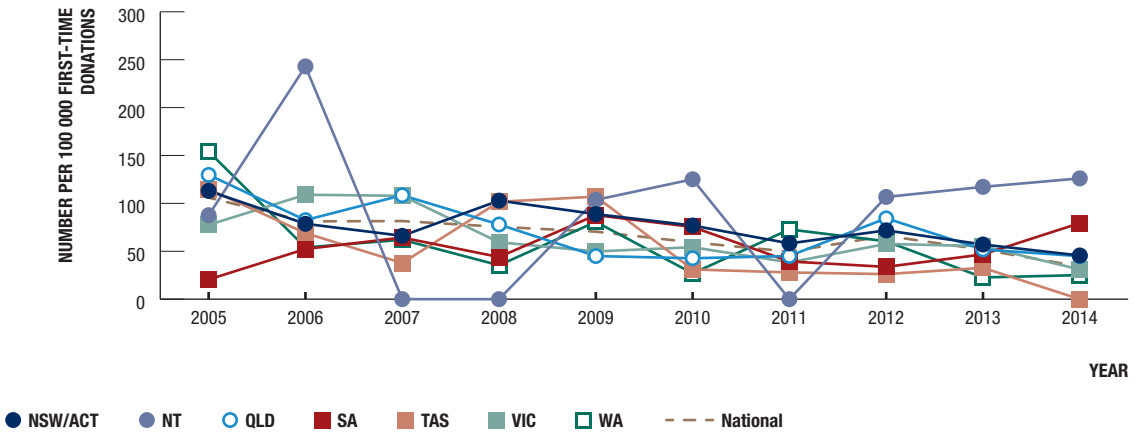


Trends in HCV infection by state/territory

Nationally, the prevalence of HCV in first-time donors has shown a significant declining trend throughout the ten year period 2005-2014. There were some notable jurisdictional decreases in 2005-2014 (Figure 10). There has been a significant decrease in the annual trend in the prevalence of HCV infection among first-time donors in all jurisdictions except the Northern Territory and South Australia; New South Wales/Australian Capital Territory from 113 in 2005, to 77 in 2010, and 39 in 2014; Queensland from 129.6 in 2005, to 42.7 in 2010, and 30 in 2014; Tasmania from 115 in 2005, to 31 in 2010, and 0.0 in 2014; Victoria from 77.5 in 2005, to 54.2 in 2010, and 31 in 2014; and lastly, Western Australia from 154 per 100 000 first-time donations in 2005, to 27 per 100 000 first-time donations in 2010, and 25 per 100 000 first-time donations in 2014.

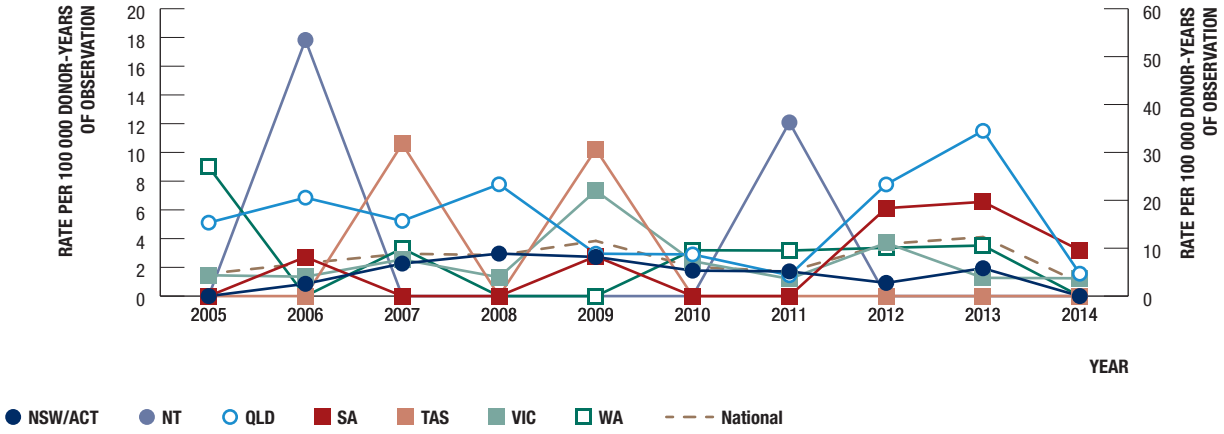
These decreases were also reflected in the general population data. Compared to 2013, the rate of newly diagnosed hepatitis C infection decreased in all jurisdictions in 2014 except for Queensland, which showed an increase from 54.0 per 100 000 in 2013 to 57.5 per 100 000 in 2014.[14]

Figure 10 **Prevalence of HCV among first-time donors by state/territory and year of donation, 2005-2014**



Generally, the incidence of HCV in repeat donors remained very low across all Australian jurisdictions during the past ten years (Figure 11), and no significant annual trend was observed during 2005-2014 study period. Due to the application of a new incidence definition from 2014, trends were also analysed for the nine-year period 2005-2013 with no significant change observed in any state or territory. Notably, in Tasmania, HCV incidence has been zero since 2010. Similarly, the rate in Northern Territory has remained zero in the last three years. The rate in Western Australia has decreased to zero after a relatively stable rate of around 3 per 100 000 donor-years of observation in 2010-2013.

Figure 11 **Incidence of HCV among repeat donors by state/territory[1] and year of donation, 2005-2014**



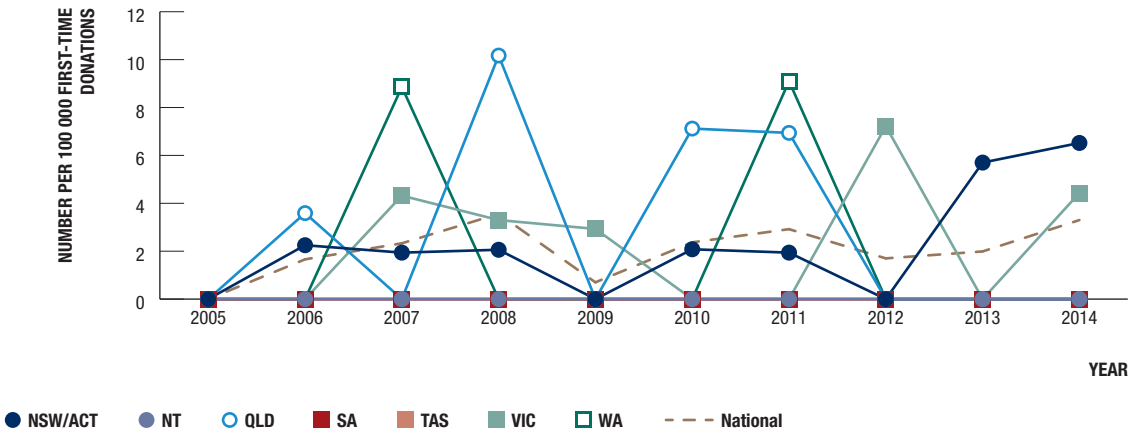
[1] HCV incidence in NT provided according to the scale on the secondary axis on the right hand side.

14 The Kirby Institute. *op. cit.*, p 8

Trends in HIV infection by state/territory

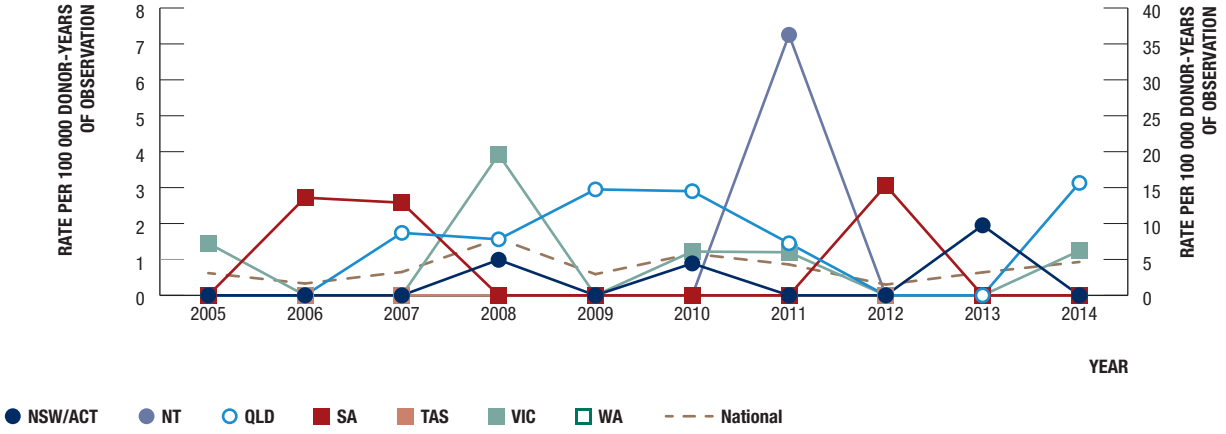
The prevalence of HIV infection in first-time donors remained substantially lower than hepatitis B and hepatitis C throughout the 2005-2014 period, with a national prevalence of 2.0 per 100 000 donations (Supporting table 15). No significant annual trend was observed during 2005-2014 period in any jurisdiction. In 2014, HIV prevalence in the first-time donors was zero in all jurisdictions except New South Wales/Australian Capital Territory and Victoria where the rates were 6.5 per 100 000 donations and 4.4 per 100 000 donations, respectively (Figure 12). Although these differences between jurisdictions are generally consistent with the national epidemiology, they should be interpreted with caution as there were a low number of infections (two in New South Wales and one in Victoria).

Figure 12 Prevalence of HIV among first-time donors by state/territory and year of donation, 2005-2014



Incident HIV infections in blood donors continue to be rare with only three recorded in 2014, two from Queensland and one from Victoria. No incident HIV donors were identified in Tasmania or in Western Australia in the past ten years. No significant annual trend was observed in any jurisdiction during 2005-2014. However, it is interesting to note the Queensland incidence rate steadily declined by approximately 50% from 2.9 per 100 000 donor-years of observation in 2010 to 1.4 per 100 000 donor-years of observation in 2011, and was zero in both 2012 and 2013. However, in 2014 the incidence rate has again increased to 3.13 per 100 000 donor-years of observation. Given this rise equates to only two incident infections it should not be over-interpreted.

Figure 13 Incidence of HIV among repeat donors by state/territory[1] and year of donation, 2005-2014

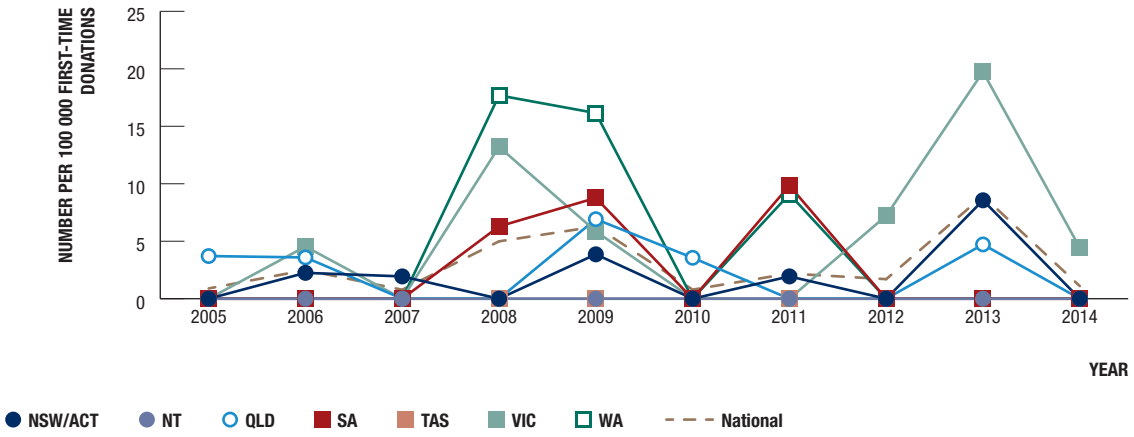


1 HIV incidence in NT provided according to the scale on the secondary axis on the right hand side.

Trends in HTLV infection by state/territory

In 2014, HTLV prevalence was zero in all jurisdictions except Victoria (Figure 14 and Supporting Table 21). No incident HTLV donors where reported during 2014, and HTLV incidence has remained zero in the ten-year period 2005-2014 with the last incident donor identified in 2004.

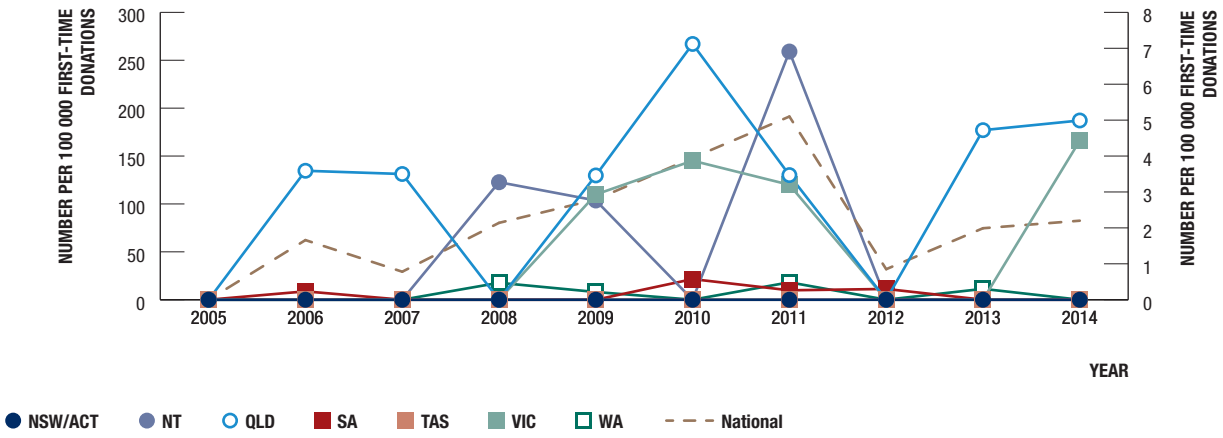
Figure 14 Prevalence of HTLV among first-time donors by state/territory and year of donation, 2005-2014



Trends in active syphilis infection by state/territory

The rate of active syphilis infection in blood donors remained low in 2014 with only five donors (2 first-time and 3 repeat) identified in 2014 (Table 1 and Figure 15). There does not appear to be any clearly discernible trends in the jurisdictional data although the small number of infections prohibits meaningful analysis. In comparison, the trend in the general population over the past five years showed an increase in rates of diagnosis of infectious syphilis in New South Wales, Queensland and Victoria, whereas rates were stable or declined in Western Australia and in the Northern Territory.[15]

Figure 15 Prevalence of active syphilis among first-time donors by state/territory[1] and year of donation, 2005-2014



1 Prevalence in QLD, VIC and at the National level are provided according to the scale on the secondary axis on the right hand side.

15 The Kirby Institute. *op. cit.*, p 8

Table 1 Prevalence of transfusion-transmissible infections in Australia by type of donation and state/territory, 2014

State/Territory of donation	All tested donations			HBV			HCV			HIV			HTLV			Syphilis			Total positive donations		
	First-time	Repeat	All	First-time	Repeat	All	First-time	Repeat	All	First-time	Repeat	All	First-time	Repeat	All	First-time	Repeat	All	First-time	Repeat	All
NSW/ACT	**30 697**	**353 055**	**383 752**	**21**	**5**	**26**	**12**	**6**	**17**	**2**	**0**	**2**	**0**	**0**	**0**	**0**	**0**	**0**	**35**	**11**	**45**
Number (Number per 100 000 donations)				*68.41*	*1.42*	*6.78*	*39.09*	*1.70*	*4.43*	*6.52*	*0.00*	*0.52*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*114.02*	*3.12*	*11.73*
NT	**793**	**8 914**	**9 707**	**0**	**1**	**1**	**1**	**0**	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**1**	**2**
Number (Number per 100 000 donations)				*0.00*	*11.22*	*10.30*	*126.10*	*0.00*	*10.30*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*126.10*	*11.22*	*20.60*
QLD	**20 043**	**239 720**	**259 763**	**8**	**0**	**8**	**6**	**10**	**17**	**0**	**2**	**2**	**0**	**0**	**0**	**1**	**1**	**2**	**15**	**13**	**29**
Number (Number per 100 000 donations)				*39.91*	*0.00*	*3.08*	*29.94*	*4.17*	*6.54*	*0.00*	*0.83*	*0.77*	*0.00*	*0.00*	*0.00*	*4.99*	*0.42*	*0.77*	*74.84*	*5.42*	*11.16*
SA	**6 296**	**116 658**	**122 954**	**4**	**1**	**5**	**3**	**3**	**6**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**7**	**4**	**11**
Number (Number per 100 000 donations)				*63.53*	*0.86*	*4.07*	*47.65*	*2.57*	*4.88*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*111.18*	*3.43*	*8.95*
TAS	**2 538**	**45 788**	**48 326**	**0**	**1**	**1**	**0**	**2**	**2**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**3**	**3**
Number (Number per 100 000 donations)				*0.00*	*2.18*	*2.07*	*0.00*	*4.37*	*4.14*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*6.55*	*6.21*
VIC	**22 580**	**288 753**	**311 333**	**26**	**8**	**34**	**7**	**4**	**11**	**1**	**1**	**2**	**1**	**0**	**1**	**1**	**2**	**3**	**36**	**15**	**51**
Number (Number per 100 000 donations)				*115.15*	*2.77*	*10.92*	*31.00*	*1.39*	*3.53*	*4.43*	*0.35*	*0.64*	*4.43*	*0.00*	*0.32*	*4.43*	*0.69*	*0.96*	*159.43*	*5.19*	*16.38*
WA	**7 972**	**118 014**	**125 986**	**6**	**3**	**9**	**2**	**0**	**2**	**0**	**1**	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**8**	**4**	**12**
Number (Number per 100 000 donations)				*75.26*	*2.54*	*7.14*	*25.09*	*0.00*	*1.59*	*0.00*	*0.85*	*0.79*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*100.35*	*3.39*	*9.52*
National	**90 919**	**1 170 902**	**1 261 821**	**65**	**19**	**84**	**31**	**25***	**56**	**3**	**4**	**7**	**1**	**0**	**1**	**2**	**3**	**5**	**102**	**51**	**153**
Number (Number per 100 000 donations)				*71.49*	*1.62*	*6.66*	*34.10*	*2.14*	*4.44*	*3.30*	*0.34*	*0.55*	*1.10*	*0.00*	*0.08*	*2.20*	*0.26*	*0.40*	*112.19*	*4.36*	*12.13*

* 11 of the 25 HCV positive repeat donors detected in 2014 are 'lapsed' donors and last donated prior to 1990 when HCV screening commenced - so are 'first-time' tested for HCV. In comparison only 4 of 18 repeat HCV positive donors in 2013 were lapsed.

Comparison of prevalence of transfusion-transmissible infections among blood donors and the general population

This section presents a comparison of prevalence of transfusion-transmissible infections among first-time blood donors and the general population for a combined period of 2005-2013, and then 2014 separately. Subsequently, a discussion is presented on the prevalence reduction in first-time donors as compared to the general population.

The prevalence of HBV, HCV and HIV is much higher in the general population than in blood donors (Table 2), which is consistent with a previous Blood Service study for the period 2000-2006[16] and expected, based on donor screening processes. Prevalence of these infections is substantially lower in blood donors than in the general population, with a 13 to 35 times reduction in first-time donors. 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 2 Comparison of prevalence of transfusion-transmissible infections in blood donors with population prevalence by infection, 2005-2014

Infection	Population prevalence (per 100 000 people)		Prevalence in first-time blood donors (per 100 000 donations)		Prevalence reduction in first-time blood donors	
	2005-2013	2014	2005-2013	2014	2005-2013	2014
HBV	864.31	908.02	83.88	71.49	10 times	13 times
HCV	816-1455	768-1039	71.11	34.10	11-20 times	23-30 times
HIV	105.18	115.58	1.95	3.30	54 times	35 times
HTLV[1]	–	–	3.19	1.10	–	–

1 Population prevalence for HTLV is unknown.

Demographic factors associated with transfusion-transmissible infections in blood donors

The risk factor analysis is restricted to 2008 to 2014, the time period for which standardised national risk factor data is available. Data on the demographic characteristics (sex, age group, state/territory and year of donation) for all blood donors in 2014 was analysed* to determine the association between demographic factors and presence of transfusion-transmissible infections among Australian blood donors (Table 3). 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.

HBV positivity and associated demographic risk factors

Overall, there were no significant trends in 2008-2014 for HBV positivity among Australian donors by demographics analysed. However, as in 2013, female donors were approximately half as likely to be HBV positive. In 2014 there was no significant association between the state/territory, and age group of the donor and HBV infection status.

HCV positivity and associated demographic risk factors

Generally, there were no significant trends in 2008-2014 for HCV positivity among Australian donors by the available demographic information. However, like HBV, female donors were significantly less likely (45.8%) compared to male donors to be HCV positive. Older donors were more likely to be HCV positive. There was no association with state/territory of the donor, age groups, and HCV infection among Australian blood donors in 2014.

HIV and HTLV positivity and associated demographic risk factors

Given the small number of donors with HIV and HTLV infection in 2014 no meaningful analysis was possible.

* See methodological notes for details

16 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.

Table 3 Association of demographic characteristics with presence of transfusion-transmissible infection among blood donors in Australia by infection, 2014

		HBV			HCV			HIV			HTLV	
	Number of donors	Number of positive donors (Number per 100,000 donors)	IRR[1] and their 95% CI[2] (Multivariate adjusted)	p-value	Number of positive donors (Number per 100,000 donors)	IRR[1] and their 95% CI[2] (Multivariate adjusted)	p-value	Number of positive donors (Number per 100,000 donors)	IRR[1] and their 95% CI[2] (Multivariate adjusted)	p-value	Number of positive donors (Number per 100,000 donors)	IRR[1] and their 95% CI[2] (Multivariate adjusted)	p-value
Sex													
Male	*237 152*	*55 (23.19)*	*1 (ref)*	*–*	*37 (15.6)*	*1 (ref)*	*–*	*5 (2.11)*	*1 (ref)*	*–*	*1 (0.42)*	*1 (ref)*	*–*
Female	*237 523*	*29 (12.21)*	*0.52 (0.33-0.82)*	*0.006*	*19 (8)*	*0.54 (0.31-0.94)*	*0.03*	*2 (0.84)*	*0.37 (0.07-1.95)*	*0*	*0 (0)*	*–*	*0.99*
Age group (years)													
20-29	*106 835*	*18 (16.85)*	*1 (ref)*	*–*	*6 (5.62)*	*1 (ref)*	*–*	*3 (2.81)*	*1 (ref)*	*–*	*0 (0)*	*1 (ref)*	*–*
Less than 20	*38 960*	*6 (15.4)*	*0.95 (0.37-2.41)*	*0.92*	*3 (7.7)*	*1.35 (0.33-5.40)*	*0.67*	*0 (0)*	*–*	*0.99*	*0 (0)*	*–*	*1.00*
30-39	*77 555*	*12 (15.47)*	*0.87 (0.42-1.81)*	*0.72*	*4 (5.16)*	*0.88 (0.24-3.12)*	*0.84*	*1 (1.29)*	*0.42 (0.04-4.12)*	*0.46*	*0 (0)*	*–*	*1.00*
40-49	*80 862*	*18 (22.26)*	*1.29 (0.67-2.49)*	*0.43*	*11 (13.6)*	*2.30 (0.85-6.24)*	*0.10*	*2 (2.47)*	*0.84 (0.14-5.07)*	*0.85*	*0 (0)*	*–*	*1.00*
50 and above	*170 463*	*30 (17.6)*	*1.01 (0.56-1.83)*	*0.94*	*32 (18.77)*	*3.12 (1.30-7.48)*	*0.01*	*1 (0.59)*	*0.20 (0.02-1.96)*	*0.16*	*1 (0.59)*	*–*	*0.99*
State/Territory													
NSW	*144 267*	*26 (18.02)*	*1 (ref)*	*–*	*17 (11.78)*	*1 (ref)*	*–*	*1 (0.69)*	*1 (ref)*	*–*	*0 (0)*	*1 (ref)*	*–*
ACT	*11 631*	*0 (0)*	*–*	*0.99*	*1 (8.6)*	*0.76 (0.10-5.72)*	*0.79*	*1 (8.6)*	*11.39 (0.71-182.27)*	*0.08*	*0 (0)*	*–*	*1.00*
NT	*3 541*	*1 (28.24)*	*1.56 (0.21-11.56)*	*0.66*	*1 (28.24)*	*2.63 (0.34-19.80)*	*0.34*	*0 (0)*	*–*	*0.99*	*0 (0)*	*–*	*1.00*
QLD	*95 049*	*8 (8.42)*	*0.46 (0.21-1.02)*	*0.06*	*16 (16.83)*	*1.39 (0.70-2.76)*	*0.34*	*2 (2.1)*	*2.99 (0.27-33.08)*	*0.37*	*0 (0)*	*–*	*1.00*
SA	*43 173*	*5 (11.58)*	*0.64 (0.24-1.67)*	*0.36*	*6 (13.9)*	*1.10 (0.43-2.80)*	*0.83*	*0 (0)*	*–*	*0.99*	*0 (0)*	*–*	*1.00*
TAS	*15 343*	*1 (6.52)*	*0.36 (0.04-2.66)*	*0.31*	*2 (13.04)*	*1.03 (0.23-4.46)*	*0.96*	*0 (0)*	*–*	*0.99*	*0 (0)*	*–*	*1.00*
VIC	*119 927*	*34 (28.35)*	*1.5 (0.94-2.62)*	*0.08*	*11 (9.17)*	*0.78 (0.36-1.67)*	*0.53*	*2 (1.67)*	*2.30 (0.20-25.42)*	*0.49*	*1 (0.83)*	*–*	*1.00*
WA	*41 744*	*9 (21.56)*	*1.19 (0.55-2.54)*	*0.65*	*2 (4.79)*	*0.40 (0.09-1.75)*	*0.22*	*1 (2.4)*	*3.24 (0.20-51.56)*	*0.40*	*0 (0)*	*–*	*1.00*
Total	**474 675**	**84 (17.7)**			**56 (11.8)**			**7 (1.47)**			**1 (0.21)**		

1 IRR = Incident Rate Ratio

2 CI = Confidence Intervals

Risk factors associated with infected donors

Standardised national data on putative risk factors associated with infected donors are available since 2008. 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 instances (e.g. in Australian prisons or high risk countries) is an acknowledged risk for HCV[17] in contrast to tattooing currently performed in Australian commercial tattooing parlours, where the risk is very low.

This report presents data for the four-year period 2011 to 2014. In 2014, 153 donors were confirmed positive for at least one of the transfusion-transmissible infections with a total of 780 confirmed positive donors over the period 2011-2014. Among them, 32 donors were positive for active syphilis, of which only four (all from 2014 – the commencement of data collection) have standardised risk factor data precluding meaningful analysis. The data on the remaining 748 donors who were positive for any of the other transfusion-transmissible infections (HBV, HCV, HIV and HTLV) were analysed to determine the key characteristics of blood donors with transfusion-transmissible infections, stratified by year of donation (Tables 4-7).

Donors with hepatitis B infection, 2011-2014

Of the 414 HBV positive donors during 2011-2014, 84% were first-time donors, 70% were male, and the mean age was 38 years (Table 4). Most (85%) of the HBV positive donors were born overseas, which reflects the epidemiology of hepatitis B in the general population. Ethnicity or country of birth (83%) was the most frequent risk factor for HBV positivity, followed by having a sexual partner with known risk or known to be positive for any transfusion-transmissible infection (6%). There were only 12 incident hepatitis B blood donors in the last four years, consistent with a low incidence rate

Table 4 Characteristics of donors positive for HBV infection by year of donation, 2011-2014

Characteristics	2011	2012	2013	2014	2011-2014
Number of positive donors	118	113	99	84	414
Number of positive first-time donors (%)	99 (83%)	97 (86%)	85 (86%)	67 (80%)	348(84%)
% male	79 (67%)	84 (74%)	72 (73%)	55 (65%)	290 (70%)
Mean age (range) in years	38 (16 to 77)	37 (16 to 67)	36 (16 to 73)	42 (16-69)	38 (16 to 77)
Number of incident donors	5	1	3	3	12
% born in Australia	15 (13%)	19 (17%)	14 (14%)	15 (18%)	63 (15%)
Main reported risk factor	Ethnicity/COB[1]	Ethnicity/COB	Ethnicity/COB	Ethnicity/COB	Ethnicity/COB
	85%	89%	90%	77%	83%
Second reported risk factor	TBP[2],PRP[3] each	Partner with known risk or known to be positive	Other	Partner with known risk or known to be positive	Partner with known risk or known to be positive
	3%	4%	2%	8%	6%

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

Donors with HCV infection, 2011-2014

Of the 298 donors' positive for HCV in 2011-2014, 76% were first-time donors (Table 5). The mean age of HCV positive donors was 43 years with a wide range (16-78) over the last four years. Male donors represented 64% of all donors with hepatitis C infection however, unlike HBV where birth overseas predominated, the majority (66%) of HCV positive donors were born in Australia. Overall, the main risk factor for HCV positivity was tattoo or body piercing (25%) followed by intravenous drug use (23%). The number of incident HCV infections (35 donors) was the highest among all transfusion-transmissible infections.

17 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.

Table 5 Characteristics of donors positive for HCV infection by year of donation, 2011-2014

Characteristics	2011	2012	2013	2014	2011-2014
Number of positive donors	81	91	70	56	298
Number of positive first-time donors (%)	59 (73%)	67 (74%)	52 (74%)	38 (68%)	216 (76%)
% male	55 (68%)	56 (62%)	43 (61%)	37 (66%)	191 (64%)
Mean age (range) in years	42 (16 to 78)	44 (16 to 66)	45 (23 to 66)	48 (18 to 71)	43 (16 to 78)
Number of incident donors	6	12	14	3*	35
% born in Australia	51 (63%)	62 (68%)	41 (59%)	44 (79%)	198 (66%)
Main reported risk factor	Intravenous drug use	Tattoo/Body piercing	Tattoo/Body piercing	Intravenous drug use	Tattoo/Body piercing
	21%	31%	33%	30%	25%
Second reported risk factor	Tattoo/Body piercing	Intravenous drug use	Intravenous drug use	TBP, BTR[1] each	Intravenous drug use
	20%	23%	19%	13%	23%

* The marked decline in the number of HCV incident donors is at least in part attributed to the application of a stricter incidence definition from 2014 - defined as 'positive repeat donors whose last donation tested negative for the same transfusion-transmissible infection within the last twelve months'

1 BTR= Blood/tissue recipient' in the note

Donors with HIV infection, 2011-2014

In contrast to HBV and HCV infected donors, the majority of HIV infected donors during 2011-2014 were repeat donors (57%) (Table 6). Most were male (81%) with a mean age of 39 years.

Male-to-male sexual contact (38%) and having a sexual partner with known risk or known to be positive for any TTI (33%) were the two most common risk factors for HIV positivity in blood donors during 2010-2014. Similarly, male-to-male sexual contact and heterosexual contact accounted for 70% and 19% of the new HIV diagnoses in the general population in 2014, respectively.[18] Of 21 HIV positive donors in the four-year period 2011-2014 9 were incident HIV infections.

Table 6 Characteristics of donors positive for HIV infection by year of donation, 2011-2014

Characteristics	2011	2012	2013	2014	2011-2014
Number of positive donors	7	3	4	7	21
Number of positive first-time donors (%)	4 (57%)	1 (33%)	2 (50%)	2 (29%)	9 (43%)
% male	5 (71%)	3 (100%)	4 (100%)	5 (71%)	17 (81%)
Mean age (range) in years	36 (22 to 62)	36 (19 to 56)	47 (28 to 65)	36 (26 to 56)	39 (19 to 65)
Number of incident donors	3	1	2	3	9
% born in Australia	2 (29%)	2 (67%)	3 (75%)	3 (43%)	10 (48%)
Main reported risk factor	Partner with known risk or known to be positive	Partner with known risk or known to be positive	Male-to-male sexual contact	Male-to-male sexual contact	Male-to-male sexual contact
	57%	100%	75%	43%	38%
Second reported risk factor	Male-to-male sexual contact	–	Ethnicity/COB[1]	COB[1],PRP[2], each	Partner with known risk or known to be positive
	14%		25%	14%	33%

1 COB=Country of birth

2 PRP=Partner with known risk/known to be positive

18 The Kirby Institute. *op. cit.,* p 8

Donors with HTLV infection, 2011-2014

Only 15 donors were positive for HTLV infection during the 2011-2014 period; all were first-time donors, 60% were male, and the mean age was 46 years (Table 7). Most of the HTLV positive donors (87%) were born overseas. Ethnicity or country of birth (80%) was the most common risk factor for HTLV infection in accepted blood donors in Australia. Attributes of HTLV positive donors remained similar over the past four years. Ethnicity or country of birth has remained the main reported risk factor for HTLV positive blood donors during the study period. Comparison data were not available for risk factors in the general population. There were no incident HTLV donors during the four-year period 2011-2014.

Table 7 Characteristics of donors positive for HTLV infection by year of donation, 2011-2014

Characteristics	2011	2012	2013	2014	2011-2014
Number of positive donors	3	2	9	1	15
Number of positive first-time donors (%)	3 (100%)	2 (100%)	9 (100%)	1 (100%)	15 (100%)
% male	1 (33%)	2 (100%)	5 (56%)	1 (100%)	9 (60%)
Mean age (range) in years	38 (23 to 46)	32 (27 to 37)	45 (30 to 58)	68	46 (23 to 70)
Number of incident donors	0	0	0	0	0
% born in Australia	0 (0%)	0 (0%)	2 (22%)	0 (0%)	2 (13%)
Main reported risk factor	Ethnicity/COB[1]	Ethnicity/COB1	Ethnicity/COB[1]	Ethnicity/COB[1]	Ethnicity/COB[1]
	66%	100%	78%	100%	80%
Second reported risk factor	Tattoo/Body piercing	–	Partner with known risk or known to be positive		Partner with known risk or known to be positive
	33%		22%		13%

1 COB=Country of birth

Comparison of major exposure categories between blood donor and the general population

A comparison of major exposure categories between blood donors and the general population was conducted to determine if any unique source of infection exists for Australian donors (Table 8). 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.

Consistent with previous years, the most frequent risk factor for HBV positive donors was ethnicity or country of birth which accounted for 77.4% of the HBV positive donors in 2014. This finding also parallels the general population data that shows that country of birth is the strongest risk factor for chronic HBV infection in Australia.[19] [20] [21] Notably, for 68.6% of the newly acquired HBV infection in general population the risk category was 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).[22]

The most frequent risk factor for HCV infection in blood donors in 2014 was intravenous drug use (IDU), followed by tattoo or body piercing, and blood or tissue recipient. In comparison, intravenous drug use was the most common risk factor for newly acquired HCV infection in the general population in 2014.[22] Notably, for around 30% of the newly acquired HCV infection in the general population the risk category was undetermined (newly acquired HCV is defined as newly diagnosed hepatitis C infection with evidence of acquisition in the 24 months prior to diagnosis - laboratory or clinical evidence). Of note, the enhanced surveillance procedures related to HCV vary by state/territory with no reported risk factor being grouped with undetermined. Nonetheless, the proportion of individuals reporting

19 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.

20 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.

21 Williams S, Vally H, Fielding J and Cowie B. Hepatitis B prevention in Victoria, Australia: the potential to protect. *Euro Surveill*. 2011; 16: 19879.

22 The Kirby Institute. *op. cit.*, p 8

intravenous drug use among newly acquired HCV infections in the general population[23] (65.5%) was comparatively higher than in the donor population (30.4%) in 2014, reflecting the impact of the Blood Services' permanent deferral for intravenous drug use or potentially donor's failure to disclose risk factors both on the Donor Questionnaire and post-donation interview after testing positive.

As in previous years, the majority of the newly diagnosed HIV infection in the general population was attributed to sexual contact (92.7%).[23] This was consistent with the findings among blood donors, where sexual contact was identified as the primary risk factor for the majority of the HIV positive blood donors in 2014.

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.[24] 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.[25] This is consistent with our finding that ethnicity or country of birth was the infective risk in the only HTLV positive donor in 2014.

Table 8 Comparison between positive blood donors and the general population in Australia by infection and major potential risk categories, 2014

	HBV[1]		HCV[1]		HIV[2]		HTLV	
Major risk category	**General population (%)**	**Blood donors (%)**	**General population (%)***	**Blood donors (%)**	**General population (%)**	**Blood donors (%)**	**General population (%)**	**Blood donors (%)**
Intravenous drug use	20.0	1.1	65.5	30.4	2.9	0.0	–	0.0
Country of birth/Ethnicity	0.0	77.4	0.0	1.8	0.6	14.3	–	100.0
Sexual contact[3]	9.1	8.3	4.8	3.6	92.7	57.2	–	0.0
Blood or tissue recipient	0.0	0.0	0.5	12.5	0.0	0.0	–	0.0
Tattoo or body piercing	1.1	3.6	0.2	12.5	0.0	0.0	–	0.0
Exposure in health care setting	0.6	4.8	0.2	5.4	0.0	0.0	–	0.0
Household contact	0.6	2.4	0.0	8.9	0.0	0.0	–	0.0
Other blood to blood contact	0.0	0.0	0.0	3.6	0.0	0.0	–	0.0
Other/undetermined	68.6	0.0	28.9	5.4	3.8	0.0	–	0.0
No risk factors identified	**0.0**	**2.4**	**0.0**	**8.9**	**0.0**	**14.3**		**0.0**
Not reported	**0.0**	**0.0**	**0.0**	**7.1**	**0.0**	**14.3**	**–**	**0.0**

1 Includes exposure categories for newly acquired HBV and newly acquired HCV infections only

2 Includes exposure categories for new HIV diagnoses

3 Includes three sub-groups: Male-to-male sexual contact, Partner with known risk or known to be positive and Engaged in sex work

* The total % for hepatitis C for general population may add to more than 100 due to rounding

Incident donors

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 transfusion-transmissible infection within the last twelve months'. Incident donors were previously defined as repeat donors with any previous negative tests. The term 'incident donor' reflects that the definition encompasses a test pattern indicative of recently acquired in infection.

During 2005-2014, a total of 137 incident donors were identified. The number of HCV incident donors has considerably decreased in 2014 with only three incident infections noted compared to 13 during 2013. This decrease at least in part reflects the stricter definition of incident infection requiring the negative donation to have occurred within the past 12 months. In contrast the change in definition has not noticeably impacted the number of incident hepatitis B or HIV donors.

23 The Kirby Institute. *op. cit.*, p 8

24 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-.

25 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.

Consistent with the findings from previous years, incident donors in 2014 were disproportionately male (77.7%) and the majority were Australian born (66.6%). The mean age of incident donors in 2014 was 34.5 years (37 years for HBV, 34.3 years for HCV and 32.3 years for HIV).

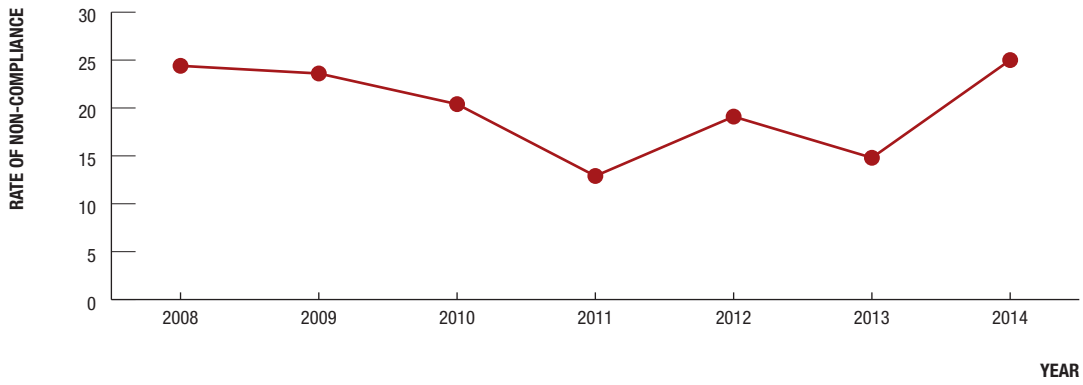
Non-compliance to TTI-related screening questions

Each 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 behaviours related to increased risk of a bloodborne infection. The Blood Service is highly reliant on the donor's complete and truthful answers to all interview questions (i.e. 'compliance'). Subsequent to satisfactorily completing the above assessment process the donor proceeds to 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 transfusion-transmissible infection 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 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 including the use of computerised release systems to minimise this latter risk. These are both avoidable risks if a positive donor appropriately discloses their risk (i.e. complies - leading to deferral) since no donation will be collected.

Over 17% (131 donors) of infected donors in 2011-2014 had risk factors identified during their post-donation interview that would have deferred them from donating had they disclosed their risk behaviour at the pre-donation interview (Table 9). The rate of non-compliance in TTI positive donors appears to have been relatively stable for the past decade in the range 20-25%. The average rate observed in a previous Blood Service study[26] 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 16). However, the rate since has been volatile, increasing to 19.1% in 2012, followed by a fluctuating pattern in the last two years with a decline to 14.8% in 2013, and an increase to 25% in 2014.

Figure 16 **Rate of non-compliance in transfusion-transmissible-infection positive donors 2008-2014**



Consistent with previous years, the majority of non-compliant positive donors in 2014 had a history of injecting drug use, however, this proportion has been gradually declining over the past five years (from 77% in 2009 to 51.3% in 2014). Notably, this is a permanent donor deferral criterion in Australia irrespective of time since last episode of injection. Overall, during the period of 2011-2014, 51.9% of non-compliance was attributed to injecting drug use followed by known status of previously being positive for a virus (32.1%), having a sexual partner with known risk or known to be positive for any transfusion-transmissible infection (9.16%) and male-to-male sexual contact within the last 12 months (3.1%) (Table 9).

Last year we reported results from a large national survey conducted among our donors in 2012-2013 which showed a comparatively low rate of non-compliance (in the range 0.05 to 0.29%) among TTI test-negative donors for several

26 Polizzotto. *op. cit. p 25*

sexual activity-based donor deferrals.[27] [28] Non-compliance with the 12-month deferral for male-to-male sex (which is the subject of the majority of international research and controversy) was 0.23%. This is markedly lower than published overseas studies which range from 0.8-2.3%. The estimated prevalence of overall non-compliance (i.e. to at least one screening question related to the deferrals for injecting drug use, sex with an injecting drug user, male-to-male sex, sex worker activity/contact and sex with a partner from a high HIV prevalence country) was 1.65%. While these estimates are minimum estimates because non-compliant donors might have chosen not to take the survey or been non-compliant if they did, overall these findings are reassuring and support the effectiveness of the current screening questions.

The study included a multivariate analysis of factors influencing non-compliance which suggested that the use of an audio computer-assisted structured interview (ACASI) might lead to further improvement in the overall compliance rate. The Blood Service has commenced a strategic project to assess the operational feasibility of implementing ACASI. Regulatory approval for any selected system would be required before implementation.

Table 9 Non-compliance rate among donors who were positive for HBV, HCV, HIV and HTLV, and reason for non-compliance, 2011-2014

Non-compliance by year and reason for deferral	2011	2012	2013	2014	2010-2014
Number (%) of non-compliant donors by reasons for deferral*					
Intravenous drug user	15 (55.6)	21 (52.5)	13 (48.2)	19 (51.3)	**68 (51.9)**
Known status/previous positive[1]	8 (29.6)	13 (32.5)	11 (40.7)	10 (27)	**42 (32.1)**
Male-to-male-sexual contact	0 (0)	0	2 (7.4)	2 (5.4)	**4 (3.1)**
Partner with known risk or known to be positive	3 (11.1)	4 (10)	1 (3.7)	4 (10.8)	**12 (9.16)**
Others	1 (3.7)	2 (5)	0 (0)	2 (5.4)	**5 (3.8)**
Total number (per 100 positive donors) of non-compliant donors by year	**27 (12.9)**	**40 (19.1)**	**27 (14.8)**	**37 (25)**	**131 (17.7)**

* Donors whose cause of non-compliance remained unknown have been excluded from these calculations

1 Includes history of hepatitis not further specified

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.[29]

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[30] (per unit transfused) were derived for the four transfusion-transmissible viral infections subject to mandatory testing (Table 10). 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 except for HBV fall below the 'negligible' risk threshold of 1 in 1 million used by the Blood Service to contextualise the risks for transfusion recipients. The HBV residual risk estimate of approximately 1 in 557 000 is similar to comparably derived estimates from developed countries and is considered 'minimal' on the risk scale, roughly equating with the annualised risk of death from a train accident. Further information can be obtained from the following website http://www.transfusion.com.au/adverse_events/risks/estimates.

27 Seed C, Lucky T, Waller D, et al. Compliance with the current 12-month deferral for male-to-male sex in Australia. *Vox sanguinis*. 2014; 106: 14-22.

28 Lucky TT, Seed CR, Waller D, et al. Understanding noncompliance with selective donor deferral criteria for high-risk behaviors in Australian blood donors. *Transfusion*. 2014; 54: 1739-49.

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

30 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.

Table 10 Estimated risk of window period donation/risk of not detecting true infection for HBV, HCV, HIV, HTLV and syphilis in Australian blood donations (2013-2014)

	HBV	HCV	HIV	HTLV	Active syphilis
Estimated rate of collecting infectious unit (per million donations)	2-4	<1	<1	<1	<1
Residual Risk to recipient - per unit transfused	Approximately 1 in 557 000	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, two to four transfusion-transmissions (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 testing commenced in 1993, none for HIV since 1998 and three probable cases of HBV in the 2005-2014 period. It should be noted that no HIV or HCV transfusion-transmissions have been identified since the introduction of NAT testing in 2000.

Testing for malaria

In Australia, donation testing for malaria infection is limited to 'at risk' donors. This includes donors who report at the pre-donation interview travel to or residence in malaria endemic countries, as well as those with a previous history of infection.[31] 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 an estimated 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 2014, 105 645 donations were tested for malaria antibody of which 1 483 (1.4%) were found to be repeat reactive for malaria antibodies. This rate of antibody detection is similar to the 1.5% recorded in 2013. None of these 1 483 donations had detectable malaria DNA suggesting past infection in the donors. Detecting malaria DNA among screened donations is rare, with only three occurrences since malaria testing commenced at the Blood Service in 2005. All three donors were born in malaria endemic countries and had very low parasite loads consistent with 'semi-immunity', a clinical state in which malaria parasites persist at low levels without symptoms of infection.

Minimising bacterial contamination of blood components

The risk of bacterial transmission following transfusion of platelets and red cells is the most common infectious risk of transfusion. International data indicates the risk of clinically apparent reactions to be at least 1:75 000[32] for platelets and 1:500 000[33] 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.[34] 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.

31 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.

32 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.

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

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

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%.[35]

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.[36]

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

Bacterial pre-release testing for platelets

Platelets are manufactured either from 'apheresis' collections or 'pooling' buffy coats from four whole blood collections. A single apheresis donation can result in up to two platelet units whilst pooling results in a single platelet pack. Using a closed system 8-20 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 system. Platelets can be issued immediately after inoculation and the culture maintained for 7 days. Samples flagging as 'reactive' after platelet issue lead to immediate recall and clinician notification in the event they have already been transfused. All initially reactive samples are subject to further investigation and follow-up testing.

Table 11 Summary of bacterial testing of platelets by BacT/ALERT, 2014

Platelet type	No. components Screened	No. Initial positive[1] (%)	No. confirmed positive[2] (%)	No. indeterminate[3] (%)	No. false positive[4] (%)
Pooled platelets	87 977	591 (0.67)	106 (0.12)	83 (0.09)	402 (0.46)
Apheresis platelets	30 633	203 (0.66)	8 (0.03)	23 (0.07)	172 (0.56)
Total	**118 610**	**794 (0.67)**	**114 (0.10)**	**106 (0.09)**	**574 (0.48)**

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

35 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.

36 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.

During 2014, 118 612 platelet units were screened for bacterial contamination (Table 11). Of the 30 633 apheresis units tested 203 (0.66%) were flagged as initially positive however only eight (0.03%) were determined as 'confirmed positive' with an additional 23(0.07%) classified as 'indeterminate'. The remaining 172(0.56%) were classified as 'false positive' predominantly associated with anaerobic culture bottles. There were 87 977 pooled platelet units tested of which 591 (0.67%) flagged as initially positive with 106 (0.12%) determined as 'confirmed positive'. A further 83 (0.09%) were classified as 'indeterminate' and the remaining 402 (0.46%) were classified as 'false positive'.

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. The propensity for Propionibacterium spp. to be contaminants likely relates to their colonisation of hair follicles and deep skin layers which are not reached by skin cleansing agents. The next most frequently isolated organisms, collectively termed coagulase-negative Staphylococci (CNS) are also common skin commensals, and often not clinically significant. However, these organisms can lead to intravascular catheter-associated bacteraemias, particularly in immunocompromised patients and prosthetic-device infections.

A minority of platelets grew clinically significant organisms (Table 12) 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 *Salmonella* and *Streptococci,* both of which are clinically significant. In almost all cases where a clinically significant organism was detected, associated blood components were recalled and discarded prior to transfusion, thus preventing potential septic transfusion reactions. As our donors were all clinically well during their donation, detection likely represents transient bacteraemia from a bowel or throat source in the donor.

During 2014, two septic transfusion reactions were identified in patients who received platelets. One patient received pooled platelets contaminated with *Staphylococcus aureus*, the second patient received *Bacillus cereus* contaminated platelets. Both corresponding platelets were negative on initial bacterial contamination screening prior to dispatch but bacteria were identified on recalled, untransfused portions of the implicated blood components. Such cases are rare, being only the second and third cases of transfusion-transmitted bacterial infection associated with the transfusion of platelets since the introduction 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 250,000, which compares favourably with overseas data where the rate is approximately 1 in 75,000.[37]

Table 12 Summary of bacterial organisms detected in confirmed positives, 2014

Confirmed positive organisms	Number
Propionibacterium spp.	94
Coagulase Negative Staphylococci	9
Streptococcus sp	4
Granulicatella adjacens	1
Salmonella enterica	1
Erysipelotrix rusiopatiae	1
Kocuria sp	1
Mixed organisms	3
Total	**114**

All donors associated with platelet pools growing clinically significant organisms were followed up and referred for clinical investigation where required.

Surveillance for emerging infections

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

37 The American Red Cross experience. *op. cit., p 33*

2014 summary

Dengue outbreaks in Queensland

Dengue virus transmission by fresh blood components has been demonstrated and thus poses a risk to transfusion safety.[38] During 2014 there were two dengue fever outbreaks that carried over from late 2013.[39] One was in Miallo/ Port Douglas with 17 confirmed cases, the last case reported on 4th January. The second outbreak was in Cairns/ Innisfail with 136 confirmed cases, the last case reported 31st March. There were two other outbreaks that started and finished in 2014. The first was in Townsville where there were 18 confirmed cases with the first case reported in late January and the last case reported in late June. The second outbreak was in Charters Towers where there were 29 confirmed cases with the first case reported in early April and the last case in mid-June. Donations from these areas were restricted to CSL fractionation/processing until the outbreaks were declared over, a strategy that has been shown to effectively eliminate dengue virus.

West Nile virus (WNV)

Outbreaks in Europe and Blood Service risk assessment

Transmission of West Nile virus (WNV) by blood, tissue and organ transplantation has been documented.[40] 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 2014 transmission season (May to November) in the EU and neighboring countries there were outbreaks of WNV fever in Austria, Greece, Hungary, Israel, Italy, Romania, Bosnia and Herzegovina, Palestine, Russian Federation and Serbia. The total number of reported West Nile fever cases was 210 with the largest outbreaks in Serbia (76 reported cases) and the Russian Federation (29 cases). The total number of reported West Nile virus fever cases in 2014 was substantially less than 2013 (785 cases) and 2012 (937 cases). The Blood Service monitored these outbreaks based on regular updates of WNV cases provided by the European Centre for Disease Prevention and Control (ECDC), and the Hellenic Centre for Disease Control and Prevention (HCDCP-KEELPNO). The Blood Service performed weekly risk modelling to estimate the risk of a donor returning from these countries and donating while infectious (i.e. viraemic). This modelling indicated that the additional level of risk to the Australian blood supply associated with donors returning from these countries during the 2014 WNV transmission season did not exceed the threshold (established for local dengue outbreaks) that requires cessation of fresh blood component manufacture.[41]

Hendra virus

Human Hendra virus (HeV) infection is an emerging Australian zoonotic disease associated with high mortality (4/7 infections fatal).[42] To date all seven recorded cases of HeV transmission to humans has occurred from *Pteropus* bats (flying foxes) via horses. While no cases of human HeV infection were recorded in 2014, there were 4 reported equine cases, 3 in Queensland and 1 in New South Wales.[43] [44] 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 would be predicted that the risk of human infection would progressively decline as the number of susceptible horses diminishes as a consequence of vaccination. However, the reporting of equine cases in 2013 (7 cases) and 2014 indicates a need for wider uptake of the vaccine. The primary mode of human exposure to HeV is thought to be from the respiratory secretions and/or blood of infected horses. HeV has been isolated from the nasopharyngeal secretions, saliva, urine, foetal material and organs of horses. 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.

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38 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.

39 Queensland Government. Queensland notifiable conditions data 2015. Available at: https://www.health.qld.gov.au/ph/cdb/sru_data.asp Access Date: September 9th 2015. In: Health. Q, (ed.).

40 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.

41 European Centre for Disease Prevention and Control (ECDC). West Nile virus fever maps. Historical data 2014. Available at: http://ecdc.europa.eu/en/healthtopics/west_nile_fever/West-Nile-fever-maps/Pages/historical-data.aspx Access Date: 9th September, 2015.

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

43 ProMED mail. Available at: http://www.promedmail.org/ Access Date: 9th September, 2015.

44 Queensland Government. Department of Agriculture and Fisheries. Departmental News. Available at: https://www.daf.qld.gov.au/services/news-and-updates/animals/news/new-hendra-virus-case-confirmed-in-gladstone-area Access date: 9th September, 2015.

Middle East respiratory syndrome coronavirus (MERS-CoV)

Human cases of infection with Middle East respiratory syndrome coronavirus (MERS-CoV) was 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 similar pandemic as 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 human MERS-CoV has not yet been established. However, during 2014 published reports suggested a zoonotic origin, particularly transmission from dromedary camels. Evidence also indicates that, to a limited extent, MERS-CoV can be transmitted between humans, specifically in health care facilities and close family contacts. Sustained transmission within communities has not been observed. By the end of 2012 there had only been 9 reported human cases of MERS-CoV, 5 of which were in Saudi Arabia, 2 cases in Qatar and 2 in Jordan. Subsequently, reported human cases substantially increased to approximately 170 in 2013 and 640 in 2014. From 2012 to 2014 most cases (approximately 86%) have been reported in Saudi Arabia, followed by the United Arab Emirates (approximately 8%). A small number of imported cases have been reported in countries outside the Middle East. 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. During 2014, neither the ECDC nor WHO advised special screening at points of entry or travel/trade restrictions be applied due to the MERS-CoV outbreak. The current risk posed by MERS-CoV to Australia's blood safety appears to be very low. The Blood Service is managing the potential risk from MERS-CoV by ongoing monitoring of reports of laboratory-confirmed cases and the geographical location of case clusters and local human-to-human transmission.[45] [46]

Ebola viruses

There are 5 known species of the Ebolavirus genus which belongs to the Filoviridae family and are referred to collectively as ebolaviruses. The first reported outbreak of ebolavirus disease (EVD) was reported in 1976 in Sudan and Democratic Republic of the Congo. Between 1976 and 2013 there were 20 reported EVD outbreaks, all in equatorial African countries. Ebola virus infection causes sever 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 in 2014, were Guinea, Liberia and Sierra Leone. By the end of 2014 the outbreak remained ongoing and approximately 20 000 cases of ebolavirus disease (EVD) had been reported with 7,900 deaths. Outside of Africa, the UK, Spain and the USA each reported a single imported case in 2014. The current risk posed by EBOV to Australia's blood safety appears to be very low. Although transfusion-transmission of EBOV has not been reported, it cannot be excluded as ebolaviruses are typically detectable in the blood for about 1-2 weeks during acute infection. However, the risk of transfusion-transmitted ebolavirus infection may be mitigated by the observation that ebolavirus DNA is usually not detectable until symptoms appear, by which time the infected individual would be unlikely to attempt to donate blood. The Blood Service is managing the potential risk from EBOV by ongoing monitoring of reports of laboratory-confirmed cases and 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 eblolavirus are deferred from donating for 8 weeks after leaving the risk area.[47] [48]

45 European Centre for Disease Prevention and Control (ECDC). MERS-CoV factsheet. August 2014. Available at: http://ecdc.europa.eu/en/healthtopics/coronavirus-infections/mers-factsheet/Pages/default.aspx Access Date: 9th September, 2015.

46 European Centre for Disease Prevention and Control (ECDC). Epidemiological update: Middle East respiratory syndrome coronavirus (MERS-CoV), November, 2014. Available at: http://ecdc.europa.eu/en/press/news/_layouts/forms/News_DispForm.aspx?ID=1102&List=8db7286c-fe2d-476c-9133-18ff4cb1b568&Source=http%3A%2F%2Fecdc%2Eeuropa%2Eeu%2Fen%2Fpress%2Fepidemiological%5Fupdates%2FPages%2Fepidemiological%5Fupdates%2Easpx%3Fp%3D2 Access Date: 9th September, 2015

47 World Health Organisation. Ebola virus disease. Fact sheet N°103. August 2015. Available at: http://www.who.int/mediacentre/factsheets/fs103/en/ Accessed Date: 9th September, 2015.

48 World Health Organisation. Ebola Response Roadmap Situation Report. December 2014. Available at: http://apps.who.int/iris/bitstream/10665/146763/1/roadmapsitrep_31Dec14_eng.pdf?ua=1&ua=1 Access Date: 9th September, 2015.

Conclusions

1. Supporting the effectiveness of donor education and selection, the prevalence of transfusion-transmissible infections is substantially lower among first-time blood donors (13 to 35 times) than in the general population in 2014 and shows a stable or declining trend since 2005.
2. The prevalence of transfusion-transmissible infections among first-time-donations was much higher than the prevalence among all donations, highlighting the importance of promoting donor education of potential new donors and ensuring first-time donors read the pre-donation information and understand the importance of 'self-deferral'.
3. The incidence of newly acquired infection measured by the rate of incident donors is also much lower than results from specific at-risk populations in Australia. This supports the general effectiveness of the donor questionnaire and specifically that repeat donors understand what constitutes 'risk behaviour' for acquiring transfusion-transmissible infections.
4. Infective risk factors identified in blood donors with transfusion-transmissible infections closely parallel those for the general population with no 'unique' risk factors identified to date among blood donors.
5. The non-compliance rate has increased to 25% in 2014, the highest recorded to date; again, highlighting 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.
6. While non-compliance among positive donors has been routinely monitored since 2000 the rate among TTI test-negative donors is more difficult to track. We previously reported no such data existed for TTI test negative donors. Results from a large national survey conducted in 2012-2013 which showed a comparatively low rate of non-compliance (in the range 0.05 to 0.29%) among TTI test-negative donors for several sexual activity-based donor deferrals. The study included a multivariate analysis of factors influencing non-compliance which suggested that the use of an audio computer-assisted structured interview (ACASI) might lead to further improvement in the overall compliance rate. The Blood Service has commenced a strategic project to assess the operational feasibility of implementing ACASI. Regulatory approval for any selected system would be required before implementation.
7. The estimated residual risk of transmission for HIV, HCV, HBV, HTLV and syphilis in Australia is very low, less than one in one million per unit transfused for all except HBV. The residual risk of transmission of HBV is higher (approx. 1 in 557 000) but comparable to other Blood Services in developed countries. This supports the claim that Australia's blood supply is among the safest worldwide in respect of transfusion-transmissible infections for which testing is conducted. Despite this, there remains a minimal but real risk of transfusion-transmissible infections which must be carefully considered before any transfusion.
8. Bacterial screening of 118 612 platelets identified 114 (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.
9. In addition to established transfusion-transmissible infections, emerging infectious diseases continue to demand vigilant surveillance. Mosquito-borne agents such as dengue virus and West Nile virus are currently the principal threats but many other novel or emerging infectious diseases are constantly monitored by the Blood Service to assess their threat to the safety of the blood supply. The worldwide spread of dengue virus continued in 2014 and several seasonal outbreaks in northern Queensland were subject to the routine risk mitigation strategies. Overall, the numbers of reported cases of WNV fever in EU and neighbouring countries was lower in 2014 compared to 2013. While no cases of human Hendra virus infection were recorded in 2014, there were 4 equine cases. In 2014, Middle East respiratory syndrome coronavirus (MERS-CoV) cases continued to be reported, predominantly in the Arabian Peninsula. No sustained human to human transmission or transfusion transmission has been identified and the risk to the blood supply is assessed as very low. The largest ever outbreak of ebolavirus disease (EVD) was reported in West Africa commencing in March 2014. The Blood Service is managing the potential risk from EBOV by ongoing monitoring of reports of laboratory-confirmed cases and 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 eblolavirus are deferred from donating for 8 weeks after leaving the risk area and blood donor deferrals were introduced for cases and close contacts. The risk posed by EBOV to Australia's blood safety appears to be very low.

Supporting figures

Figure 1 **Percentage of age-eligible general population who donated blood in 2014, by state/territory**

Figure 2 **Number of blood donors with transfusion-transmissible infections in Australia, by infection and year of donation, 2005-2014**

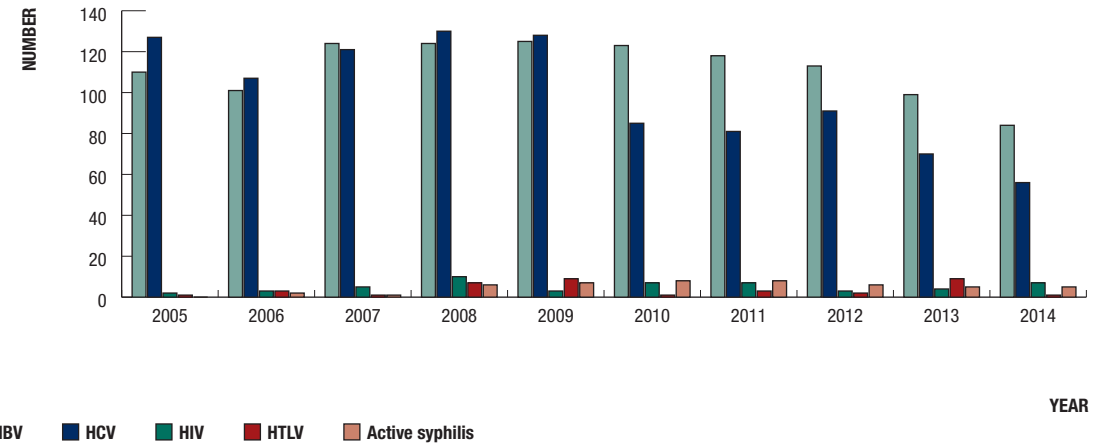


Figure 3 **Percentage of donations made by first-time and repeat donors among all blood donations in Australia, 2008-2014**

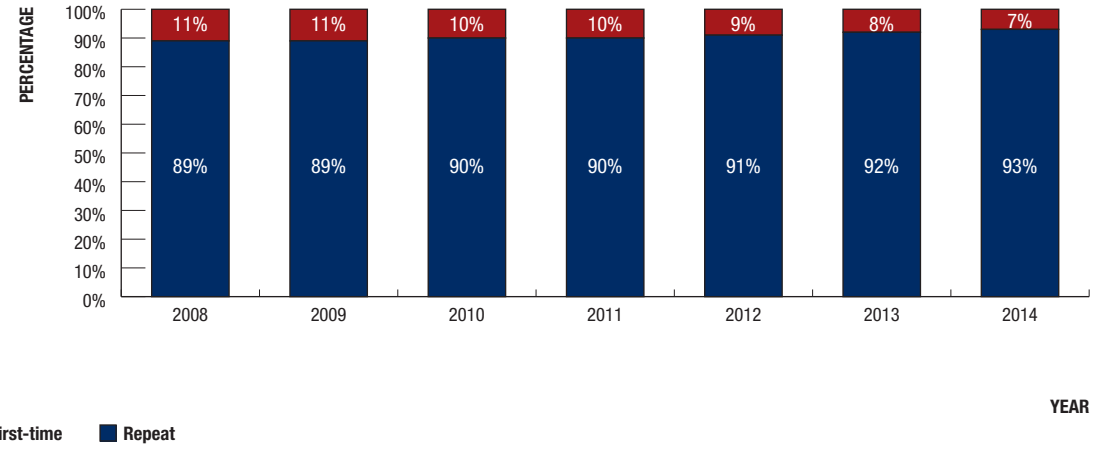


Figure 4 Distribution of blood donors in Australia by age group and sex, 2014

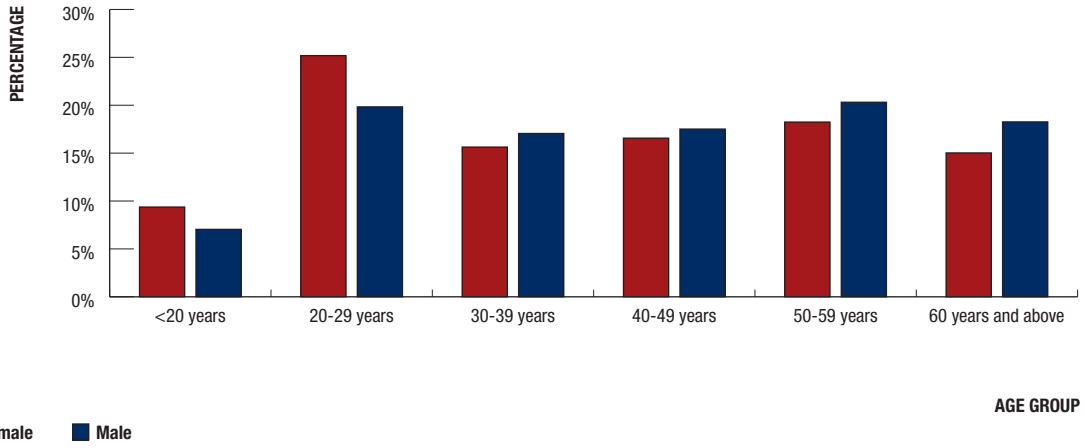


Figure 5 Donors with HBV infection by sex and donor status, 2010-2014

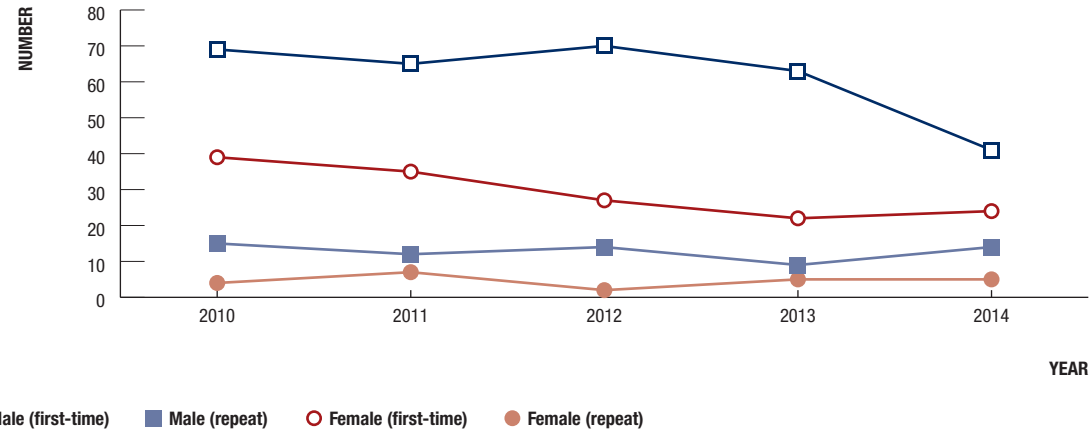


Figure 6 Rate of HBV infection among blood donors by age group and year of donation, 2010-2014

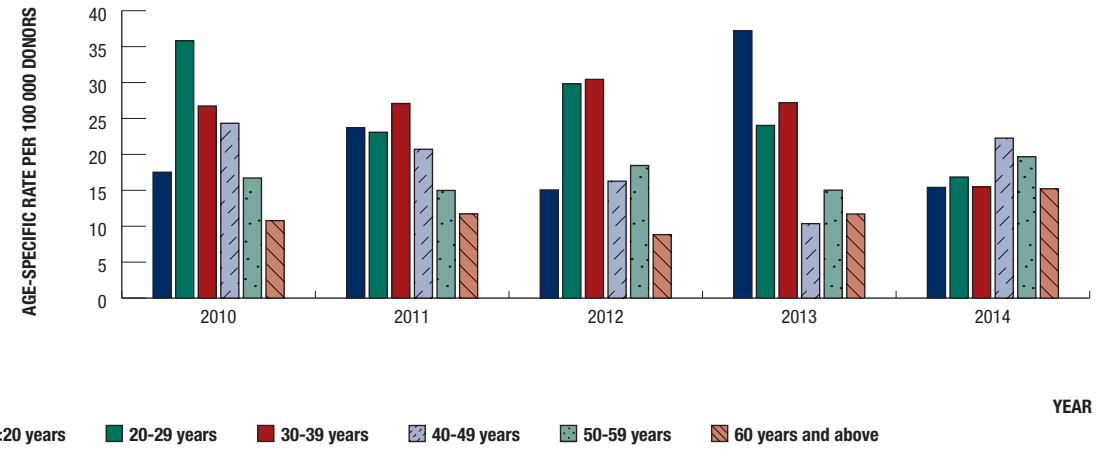


Figure 7 Donors with HBV infection by country/region of birth, 2014 (n=84)

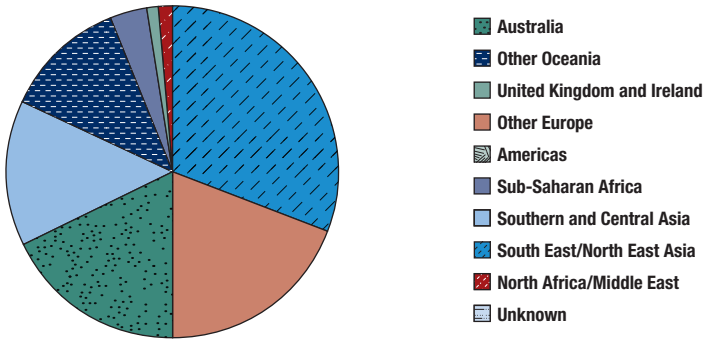


Figure 8 Donors with HCV infection by sex and donor status, 2010-2014

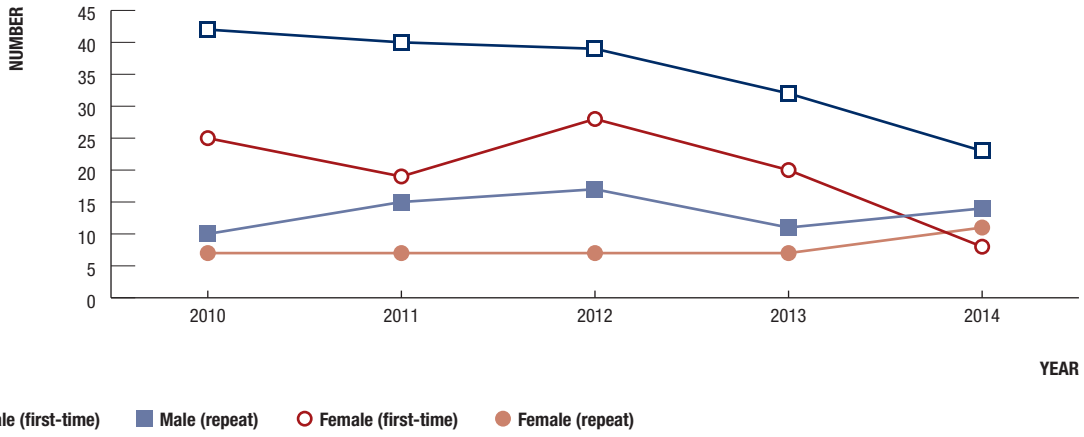


Figure 9 Rate of HCV infection among blood donors by age group and year of donation, 2010-2014

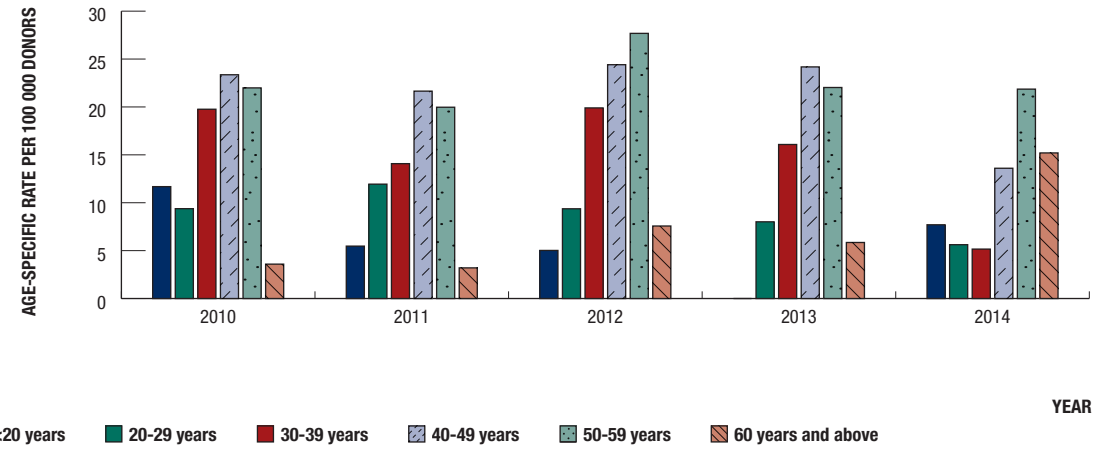


Figure 10 Donors with HCV infection by country/region of birth, 2014 (n=56)

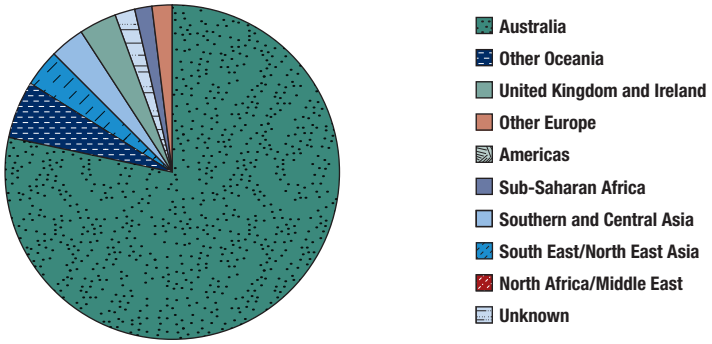


Figure 11 Donors with HIV infection by sex and donor status, 2010-2014

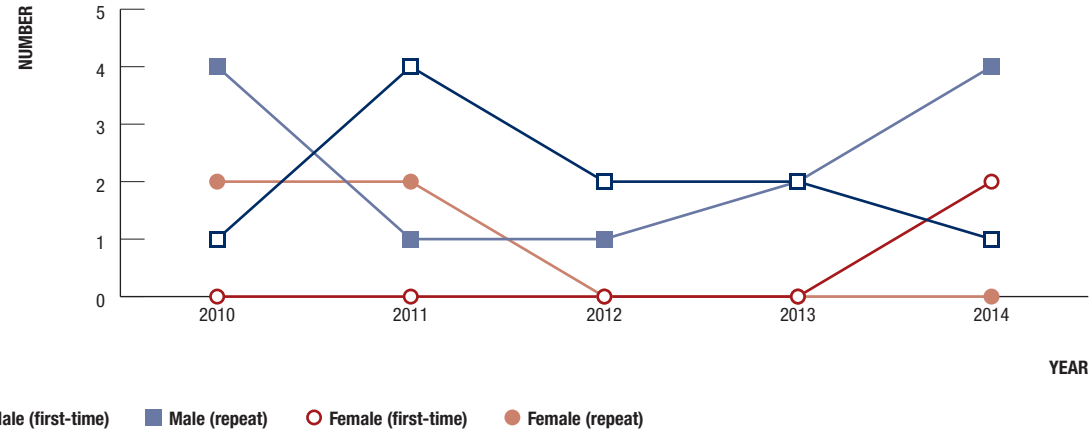


Figure 12 Rate of HIV infection among blood donors by age group and year of donation, 2010-2014

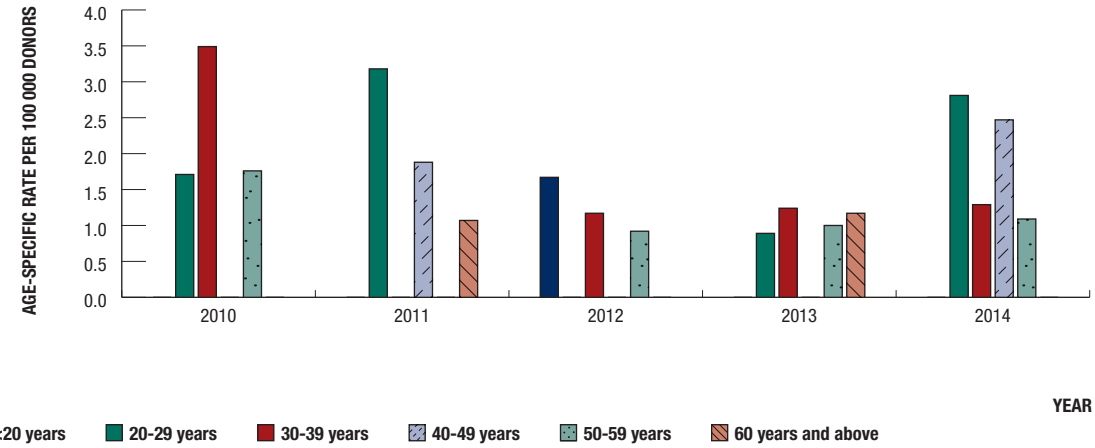


Figure 13 Donors with HIV infection by country/region of birth, 2014 (n=7)

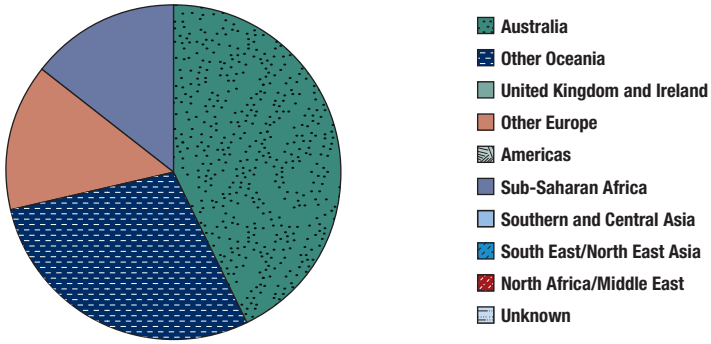


Figure 14 Donors with HTLV infection by sex and donor status, 2010-2014

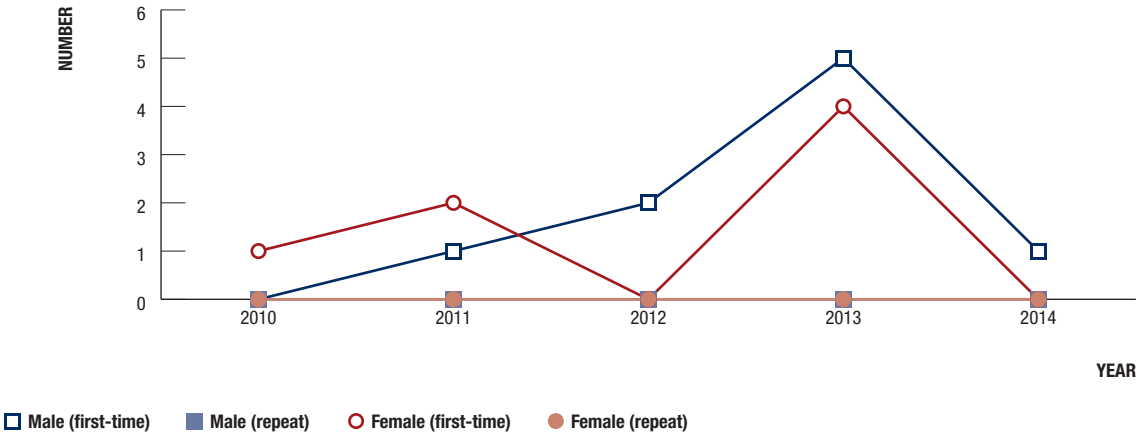
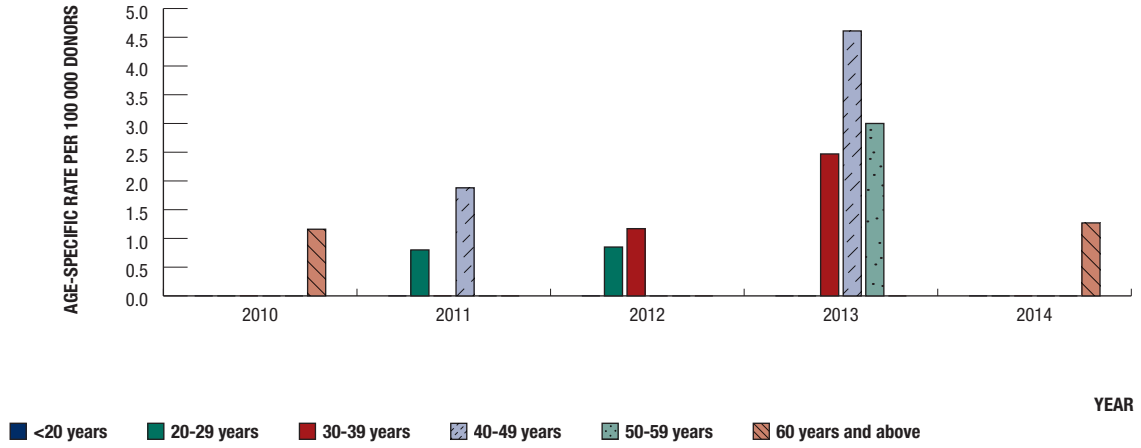


Figure 15 Rate of HTLV infection among blood donors by age group and year of donation, 2010-2014



Supporting tables

Table 1 Screening tests for transfusion-transmissible infections

Transfusion-Transmissible infection	Mandatory screening tests	Test Target	Year of introduction	Median window period estimate	Estimated residual risk (per unit transfused)
Syphilis	*Treponema pallidum* Haemagglutination Assay (TPHA)	Antibodies to *Treponema pallidum*	~1949	45 days	<1 in 1 million
HBV	HBsAg[1]	Hepatitis B surface antigen (HBsAg)	1970	38 days	–
	Nucleic Acid Test for HBV	HBV DNA	2010	15.1 days	Approx. 1 in 557 000
HIV	anti-HIV-1[1] anti-HIV-2[1]	Antibody to both HIV-1 and HIV-2 (anti-HIV-1/2)	1985 (HIV-1) 1993 (HIV-1/HIV-2)	22 days	–
	Nucleic Acid Test for HIV-1[2]	HIV-1 RNA	2000	5.9 days	<1 in 1 million
HCV	anti-HCV[1]	Antibody to HCV	1990	66 days	–
	Nucleic Acid Test for HCV[2]	hepatitis C RNA	2000	2.6 days	<1 in 1 million
HTLV	anti-HTLV-1[1] anti-HTLV-2[1]	Antibody to both HTLV-1 and HTLV-2	1993	51 days	<1 in 1 million

1 Currently Abbott PRISM (Abbott Diagnostics, Wiesbaden-Delkenheim, Germany) Chemiluminescent Immunoassay system.

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

Table 2 The number and rate of transfusion-transmissible infections in Australia by type of donations and state/territory, 2005-2014

State/Territory of donation	All tested donations			HBV			HCV			HIV			HTLV			Syphilis			Total positive donations		
	First-time	Repeat	All	First-time	Repeat	All	First-time	Repeat	All	First-time	Repeat	All	First-time	Repeat	All	First-time	Repeat	All	First-time	Repeat	All
NSW/ACT	**446 028**	**3 569 218**	**4 015 246**	**371**	**39**	**410**	**342**	**42**	**383**	**9**	**5**	**14**	**8**	**0**	**8**	**0**	**7**	**7**	**730**	**93**	**823**
Number (Number per 100 000 donations)				*83.18*	*1.09*	*10.21*	*76.68*	*1.18*	*9.54*	*2.02*	*0.14*	*0.35*	*1.79*	*0.00*	*0.20*	*0.00*	*0.20*	*0.17*	*163.67*	*2.61*	*20.50*
NT	**8 657**	**99 228**	**107 885**	**11**	**2**	**13**	**8**	**2**	**10**	**0**	**1**	**1**	**0**	**0**	**0**	**4**	**2**	**6**	**23**	**7**	**30**
Number (Number per 100 000 donations)				*127.06*	*2.02*	*12.05*	*92.41*	*2.02*	*9.27*	*0.00*	*1.01*	*0.93*	*0.00*	*0.00*	*0.00*	*46.21*	*2.02*	*5.56*	*265.68*	*7.05*	*27.81*
QLD	**264 864**	**2 310 350**	**2 575 214**	**160**	**13**	**173**	**188**	**56**	**245**	**8**	**9**	**17**	**6**	**0**	**6**	**8**	**4**	**12**	**370**	**82**	**453**
Number (Number per 100 000 donations)				*60.41*	*0.56*	*6.72*	*70.98*	*2.42*	*9.51*	*3.02*	*0.39*	*0.66*	*2.27*	*0.00*	*0.23*	*3.02*	*0.17*	*0.47*	*139.69*	*3.55*	*17.59*
SA	**100 585**	**1 168 621**	**1 269 206**	**59**	**9**	**68**	**52**	**19**	**71**	**0**	**3**	**3**	**3**	**0**	**3**	**5**	**0**	**5**	**119**	**31**	**150**
Number (Number per 100 000 donations)				*58.66*	*0.77*	*5.36*	*51.70*	*1.63*	*5.59*	*0.00*	*0.26*	*0.24*	*2.98*	*0.00*	*0.24*	*4.97*	*0.00*	*0.39*	*118.31*	*2.65*	*11.82*
TAS	**33 453**	**382 347**	**415 800**	**6**	**2**	**8**	**19**	**6**	**25**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**1**	**25**	**9**	**34**
Number (Number per 100 000 donations)				*17.94*	*0.52*	*1.92*	*56.80*	*1.57*	*6.01*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.26*	*0.24*	*74.73*	*2.35*	*8.18*
VIC	**264 441**	**2 688 509**	**2 952 950**	**307**	**27**	**334**	**162**	**27**	**189**	**6**	**7**	**13**	**15**	**0**	**15**	**4**	**4**	**8**	**494**	**65**	**559**
Number (Number per 100 000 donations)				*116.09*	*1.00*	*11.31*	*61.26*	*1.00*	*6.40*	*2.27*	*0.26*	*0.44*	*5.67*	*0.00*	*0.51*	*1.51*	*0.15*	*0.27*	*186.81*	*2.42*	*18.93*
WA	**104 885**	**1 147 492**	**1 252 377**	**97**	**18**	**115**	**62**	**11**	**73**	**2**	**1**	**3**	**5**	**0**	**5**	**6**	**4**	**10**	**172**	**34**	**206**
Number (Number per 100 000 donations)				*92.48*	*1.57*	*9.18*	*59.11*	*0.96*	*5.83*	*1.91*	*0.09*	*0.24*	*4.77*	*0.00*	*0.40*	*5.72*	*0.35*	*0.80*	*163.99*	*2.96*	*16.45*
National	**1 228 474**	**11 390 281**	**12 618 755**	**1 011**	**110**	**1 121**	**833**	**163**	**996**	**25**	**26**	**51**	**37**	**0**	**38**	**27**	**22**	**49**	**1 933**	**322**	**2 255**
Number (Number per 100 000 donations)				*82.30*	*0.97*	*8.88*	*67.81*	*1.43*	*7.89*	*2.04*	*0.23*	*0.40*	*3.01*	*0.00*	*0.30*	*2.20*	*0.19*	*0.39*	*157.35*	*2.83*	*17.87*

Table 3 Number and prevalence[1] of HBV infection among first-time donors, 2005-2014, by state/territory and year of donation

	2005			2006			2007			2008		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	42 479	48	113.00	44 499	32	71.91	51 427	38	73.89	48 607	45	92.58
NT	1 141	0	0.00	823	1	121.51	759	3	395.26	815	0	0.00
QLD	26 988	19	70.40	27 873	21	75.34	28 575	20	69.99	29 498	15	50.85
SA	9 752	7	71.78	11 457	5	43.64	10 886	9	82.67	15 908	8	50.29
TAS	3 484	0	0.00	2 899	0	0.00	2 650	0	0.00	3 936	1	25.41
VIC	19 346	23	118.89	22 016	30	136.26	23 172	43	185.57	30 286	40	132.07
WA	9 087	6	66.03	11 116	7	62.97	11 292	8	70.85	11 307	8	70.75
Total	**112 277**	**103**	**91.74**	**120 683**	**96**	**79.55**	**128 761**	**121**	**93.97**	**140 357**	**117**	**83.36**
	2009			**2010**			**2011**			**2012**		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	51 821	45	86.84	48 130	40	83.11	51 528	42	81.51	41 780	34	81.38
NT	965	2	207.25	799	0	0.00	772	3	388.60	937	1	106.72
QLD	28 889	12	41.54	28 097	19	67.62	28 839	13	45.08	24 881	16	64.31
SA	11 400	9	78.95	9 284	3	32.31	10 164	3	29.52	8 900	7	78.65
TAS	3 736	0	0.00	3 222	1	31.04	3 587	1	27.88	3 823	3	78.47
VIC	34 133	34	99.61	25 820	35	135.55	31 286	27	86.30	27 718	22	79.37
WA	12 387	17	137.24	11 149	10	89.69	10 992	10	90.98	9 925	15	151.13
Total	**143 331**	**119**	**83.02**	**126 501**	**108**	**85.37**	**137 168**	**99**	**72.17**	**117 964**	**98**	**83.08**
	2013			**2014**			**Total 2005-2014**		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	35 060	25	71.31	30 697	21	68.41	446 028	370	82. 95
NT	853	1	117.23	793	0	0.00	8 657	11	127. 06
QLD	21 181	17	80.26	20 043	8	39.91	264 864	160	60. 41
SA	6 417	4	62.33	6 296	4	63.53	100 464	59	58. 73
TAS	3 058	0	0.00	2 538	0	0.00	32 933	6	18. 22
VIC	25 332	25	98.69	22 580	26	115.15	261 689	305	116. 55
WA	8 815	10	113.44	7 972	6	75.26	104 042	97	93. 23
Total	**100 716**	**82**	**81.42**	**90 919**	**65**	**71.49**	**1 218 677**	**1008**	**82. 71**

1 Rate per 100 000 first-time donations

Table 4 Number and rate[1] of HBV infection among repeat donors, 2005-2014, by state/territory and year of donation

	2005			2006			2007			2008		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	311 513	4	1.28	333 250	5	1.50	338 173	3	0.89	339 062	1	0.29
NT	8 862	0	0.00	8 496	0	0.00	10 214	0	0.00	11 166	0	0.00
QLD	205 398	0	0.00	216 496	0	0.00	209 556	0	0.00	226 726	1	0.44
SA	93 172	1	1.07	107 934	0	0.00	114 618	0	0.00	118 476	1	0.84
TAS	24 577	0	0.00	28 726	0	0.00	28 019	0	0.00	33 321	0	0.00
VIC	225 332	2	0.89	238 684	0	0.00	252 340	0	0.00	259 052	4	1.54
WA	101 063	0	0.00	99 376	0	0.00	109 425	0	0.00	113 274	0	0.00
Total	**969 917**	**7**	**0.72**	**1 032 962**	**5**	**0.48**	**1 062 345**	**3**	**0.28**	**1 101 077**	**7**	**0.64**
	2009			**2010**			**2011**			**2012**		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	372 806	1	0.27	380 014	4	1. 05	390 455	5.00	1.28	377 220	6	1.59
NT	11 158	0	0.00	10 470	1	9. 55	10 782	0.00	0.00	9 673	0	0.00
QLD	242 001	1	0.41	243 837	3	1. 23	245 975	3.00	1.22	237 599	4	1.68
SA	126 855	0	0.00	123 587	3	2. 43	124 199	2.00	1.61	120 720	0	0.00
TAS	37 274	0	0.00	41 484	0	0.00	44 661	0.00	0.00	46 379	0	0.00
VIC	276 835	1	0.36	278 897	3	1. 08	288 085	4.00	1.39	285 168	2	0.70
WA	118 327	3	2.54	120 646	1	0. 83	121 057	5.00	4.13	117 728	3	2.55
Total	**1 185 256**	**6**	**0.51**	**1 198 935**	**15[2]**	**1. 25**	**1 225 214**	**19.00**	**1.55**	**1 194 487**	**15**	**1.26**
	2013			**2014**			**Total 2005-2014**					
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**			
NSW/ACT	373 670	4	1.07	353 055	5	1. 42	3 569 218	38	1.06			
NT	9 493	0	0.00	8 914	1	11. 22	99 228	2	2.02			
QLD	243 042	1	0.41	239 720	0	0.00	2 310 350	13	0.56			
SA	119 530	1	0.84	116 658	1	0.86	1 165 749	9	0.77			
TAS	48 953	1	2.04	45 788	1	2. 18	379 182	2	0.53			
VIC	292 058	2	0.68	288 753	8	2. 77	2 685 204	26	0.97			
WA	123 298	3	2.43	118 014	3	2. 54	1 142 208	18	1.58			
Total	**1 210 044**	**12**	**0.99**	**1 170 902**	**19**	**1. 62**	**1 1351 139**	**108**	**0.95**			

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

Table 5 Number and percentage of donors with HBV infection, 2011-2014, by year of donation, sex and age group

	Year of donation											
	2011		2012		2013		2014		2011-2014			
Donor status	**M**	**F**	**M**	**F**	**M**	**F**	**M**	**F**	**M**	**F**	**Total**	**%**
First-time donors												
<20 years	6	7	3	6	9	7	3	2	21	22	43	10.4
20-29 years	17	12	28	7	18	7	9	6	72	32	104	25.1
30-39 years	17	5	18	6	16	4	9	3	60	18	78	18.8
40-49 years	16	4	10	5	9	0	7	7	42	16	58	14.0
50-59 years	5	5	11	2	8	3	9	3	33	13	46	11.1
60 years and above	4	1	0	1	3	1	4	3	11	6	17	4.1
Repeat donors												
<20 years	0	0	0	0	0	0	0	1	0	1	1	0.2
20-29 years	0	0	0	0	0	2	2	1	2	3	5	1.2
30-39 years	3	0	2	0	1	1	0	0	6	1	7	1.7
40-49 years	2	0	1	0	0	0	3	1	6	1	7	1.7
50-59 years	6	2	7	0	4	0	4	2	21	4	25	6.0
60 years and above	3	3	4	2	4	2	5	0	16	7	23	5.6
Total	**79**	**39**	**84**	**29**	**72**	**27**	**55**	**29**	**290**	**124**	**414**	**100**

Table 6 Number and percentage of donors with HBV infection, 2011-2014, by year of donation and country/region of birth[1]

	2011		2012		2013		2014		2011-2014	
Region of birth	**Number**	**%**	**Number**	**%**	**Number**	**%**	**Number**	**%**	**Number**	**%**
Australia	15	13	19	17	14	14	15	18	48	12
Overseas born										
Other Oceania	*15*	*13*	*10*	*9*	*14*	*14*	*10*	*12*	*49*	*12*
United Kingdom and Ireland	*2*	*2*	*1*	*1*	*1*	*1*	*1*	*1*	*5*	*1*
Other Europe	*5*	*4*	*9*	*8*	*10*	*10*	*16*	*19*	*40*	*10*
Middle East/North Africa	*10*	*8*	*4*	*4*	*2*	*2*	*1*	*1*	*17*	*4*
Sub-Saharan Africa	*4*	*3*	*4*	*4*	*3*	*3*	*3*	*4*	*14*	*3*
South East Asia	*45*	*38*	*51*	*45*	*43*	*43*	*26*	*31*	*165*	*40*
Southern and Central Asia	*14*	*12*	*14*	*12*	*10*	*10*	*12*	*14*	*50*	*12*
North America	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*
South/Central America and the Caribbean	*0*	*0*	*1*	*1*	*0*	*0*	*0*	*0*	*1*	*0*
Total with a reported country of birth	**110**	**93**	**113**	**100**	**97**	**98**	**84**	**100**	**404**	**98**
Not reported	**8**	**7**	**0**	**0**	**2**	**2**	**0**	**0**	**10**	**2**
Total	**118**	**100**	**113**	**100**	**99**	**100**	**84**	**100**	**414**	**100**

1 Region of birth from the Australian Bureau of Statistics.

Table 7 **Number and percentage of HBV infection among first-time donors, 2011-2014, by potential reported exposure category and sex**

	2011		2012		2013		2014		Total (2011-2014)			
Exposure categories	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Total**	**%**
Ethnicity/Country of birth	56	32	66	24	59	22	35	19	216	97	313	90.5
Intravenous drug user	0	0	0	0	0	0	0	0	0	0	0	0.0
Tattoo/Piercing	1	1	0	2	0	0	1	2	2	5	7	2.0
Partners with any risks or known to be positive	1	0	1	1	0	0	4	0	6	1	7	2.0
Male-to-male sexual contact	0	0	0	0	0	0	0	0	0	0	0	0.0
Exposure in health care setting	0	0	0	0	0	0	1	1	1	1	2	0.6
Engaged in sex work	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
Household contact	0	0	3	0	1	0	0	2	4	2	6	1.7
Other blood to blood contact	0	0	0	0	0	0	0	0	0	0	0	0.0
Other	1	0	0	0	2	0	0	0	3	0	3	0.9
No risk factors identified	0	0	0	0	0	0	0	0	0	0	0	0.0
Not reported	6	1	0	0	1	0	0	0	7	1	8	2.3
Total	**65**	**34**	**70**	**27**	**63**	**22**	**41**	**24**	**239**	**107**	**346**	**100**

Table 8 **Number and percentage of HBV infection among repeat donors, 2011-2014 by potential reported exposure category and sex**

	2011		2012		2013		2014		Total (2011-2014)			
Exposure categories	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Total**	**%**
Ethnicity/Country of birth	10	2	8	2	6	2	8	3	32	9	41	60.3
Intravenous drug user	0	0	0	0	0	1	1	0	1	1	2	2.9
Tattoo/Piercing	0	1	1	0	1	0	0	0	2	1	3	4.4
Partners with any risks or known to be positive	1	1	2	0	1	0	3	0	7	1	8	11.8
Male-to-male sexual contact	0	0	0	0	0	0	0	0	0	0	0	0.0
Exposure in health care setting	1	0	2	0	0	1	1	1	4	2	6	8.8
Engaged in sex work	0	0	1	0	0	0	0	0	1	0	1	1.5
Blood or tissue recipient	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
Other blood to blood contact	0	0	0	0	0	0	0	0	0	0	0	0.0
Other	2	0	0	0	0	0	0	0	2	0	2	2.9
No risk factors identified	0	1	0	0	1	1	1	1	2	3	5	7.4
Not reported	0	0	0	0	0	0	0	0	0	0	0	0.0
Total	**14**	**5**	**14**	**2**	**9**	**5**	**14**	**5**	**51**	**17**	**68**	**100**

Table 9 Number and prevalence[1] of HCV infection among first-time donors, 2005-2014, by state/territory and year of donation

	2005			2006			2007			2008		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	42 479	48	113.00	44 499	35	78.65	51 427	34	66.11	48 607	50	102.87
NT	1 141	1	87.64	823	2	243.01	759	0	0.00	815	0	0.00
QLD	26 988	35	129.69	27 873	23	82.52	28 575	31	108.49	29 498	23	77.97
SA	9 752	2	20.51	11 457	6	52.37	10 886	7	64.30	15 908	7	44.00
TAS	3 484	4	114.81	2 899	2	68.99	2 650	1	37.74	3 936	4	101.63
VIC	19 346	15	77.54	22 016	24	109.01	23 172	25	107.89	30 286	18	59.43
WA	9 087	14	154.07	11 116	6	53.98	11 292	7	61.99	11 307	4	35.38
Total	**112 277**	**119**	**105.99**	**120 683**	**98.00**	**81**	**128 761**	**105**	**81.55**	**140 357**	**106**	**75.52**
	2009			**2010**			**2011**			**2012**		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	51 821	46	88.77	48 130	37	76.88	51 528	30	58.22	41 780	30	71.80
NT	965	1	103.63	799	1	125.16	772	0	0.00	937	1	106.72
QLD	28 889	13	45.00	28 097	12	42.71	28 839	13	45.08	24 881	21	84.40
SA	11 400	10	87.72	9 284	7	75.40	10 164	4	39.35	8 900	3	33.71
TAS	3 736	4	107.07	3 222	1	31.04	3 587	1	27.88	3 823	1	26.16
VIC	34 133	17	49.81	25 820	14	54.22	31 286	12	38.36	27 718	16	57.72
WA	12 387	10	80.73	11 149	3	26.91	10 992	8	72.78	9 925	6	60.45
Total	**143 331**	**101**	**70.47**	**126 501**	**75**	**59.29**	**137 168**	**68**	**49.57**	**117 964**	**78**	**66.12**
	2013			**2014**			**Total 2005-2014**					
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**			
NSW/ACT	35 060	20	57.05	30 697	12	39.09	446 028	342	76.68			
NT	853	1	117.23	793	1	126.10	8 657	8	92.41			
QLD	21 181	11	51.93	20 043	6	29.94	264 864	188	70.98			
SA	6 417	3	46.75	6 296	3	47.65	100 464	52	51.76			
TAS	3 058	1	32.70	2 538	0	0.00	32 933	19	57.69			
VIC	25 332	14	55.27	22 580	7	31.00	261 689	162	61.91			
WA	8 815	2	22.69	7 972	2	25.09	104 042	62	59.59			
Total	**100 716**	**52**	**51.63**	**90 919**	**31**	**34.10**	**1 218 677**	**833**	**68.35**			

1 Rate per 100 000 first-time donations

Table 10 Number and rate[1] of HCV infection among repeat donors, 2005-2014, by state/territory and year of donation

	2005			2006			2007			2008		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	311 513	1	0.32	333 250	1	0.30	338 173	7	2.07	339 062	11	3.24
NT	8 862	0	0.00	8 496	1	11.77	10 214	0	0.00	11 166	0	0.00
QLD	205 398	2	0.97	216 496	4	1.85	209 556	3	1.43	226 726	8	3.53
SA	93 172	2	2.15	107 934	2	1.85	114 618	0	0.00	118 476	2	1.69
TAS	24 577	0	0.00	28 726	0	0.00	28 019	1	3.57	33 321	0	0.00
VIC	225 332	1	0.44	238 684	1	0.42	252 340	3	1.19	259 052	2	0.77
WA	101 063	2	1.98	99 376	0	0.00	109 425	2	1.83	113 274	1	0.88
Total	**969 917**	**8.00**	**1**	**1 032 962**	**9**	**0.87**	**1 062 345.00**	**16**	**2**	**1 101 077**	**24**	**2.18**

	2009			2010			2011			2012		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	372 806	6	1.61	380 014	3	0.79	390 455	3	0.77	377 220	1	0.27
NT	11 158	0	0.00	10 470	0	0.00	10 782	1	9.27	9 673	0	0.00
QLD	242 001	9	3.72	243 837	4	1.64	245 975	3	1.22	237 599	5	2.10
SA	126 855	4	3.15	123 587	0	0.00	124 199	1	0.81	120 720	2	1.66
TAS	37 274	1	2.68	41 484	0	0.00	44 661	0	0.00	46 379	1	2.16
VIC	276 835	7	2.53	278 897	2	0.72	288 085	2	0.69	285 168	3	1.05
WA	118 327	0	0.00	120 646	1	0.83	121 057	3	2.48	117 728	1	0.85
Total	**1 185 256**	**27**	**2.28**	**1 198 935**	**10**	**0.83**	**1 225 214**	**13**	**1.06**	**1 194 487**	**13**	**1.09**

	2013			2014			Total 2005-2014		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	373 670	3	0.80	353 055	6	1.70	3 569 218	42	1.18
NT	9 493	0	0.00	8 914	0	0.00	99 228	2	2.02
QLD	243 042	8	3.29	239 720	10	4.17	2310 350	56	2.42
SA	119 530	3	2.51	116 658	3	2.57	1165 749	19	1.63
TAS	48 953	1	2.04	45 788	2	4.37	379 182	6	1.58
VIC	292 058	2	0.68	288 753	4	1.39	2685 204	27	1.01
WA	123 298	1	0.81	118 014	0	0.00	1142 208	11	0.96
Total	**1 210 044**	**18**	**1.49**	**1 170 902**	**25**	**2.14**	**11 351 139**	**163**	**1.44**

1 Rate per 100 000 first-time donations

Table 11 Number and percentage of donors with HCV infection, 2011-2014, by year of donation, sex and age group

	Year of donation											
	2011		2012		2013		2014		2011-2014			
Donor status	M	F	M	F	M	F	M	F	M	F	Total	%
First-time donors												
<20 years	2	1	1	2	0	0	0	3	3	6	9	3.0
20-29 years	8	6	7	4	5	2	2	0	22	12	34	11.4
30-39 years	11	2	9	6	9	2	3	0	32	10	42	14.1
40-49 years	12	4	9	4	7	6	4	3	32	17	49	16.4
50-59 years	6	5	12	11	10	7	10	1	38	24	62	20.8
60 years and above	1	1	1	1	1	3	4	1	7	6	13	4.4
Repeat donors												
<20 years	0	0	0	0	0	0	0	0	0	0	0	0.0
20-29 years	1	0	0	0	2	0	1	3	4	3	7	2.3
30-39 years	0	0	2	0	1	1	0	1	3	2	5	1.7
40-49 years	5	2	8	3	4	4	2	2	19	11	30	10.1
50-59 years	8	5	4	3	3	2	6	3	21	13	34	11.4
60 years and above	1	0	3	1	1	0	5	2	10	3	13	4.4
Total	**55**	**26**	**56**	**35**	**43**	**27**	**37**	**19**	**191**	**107**	**298**	**100**

Table 12 Number and percentage of donors with HCV infection, 2011-2014, by year of donation and country/region of birth[1]

	2011		2012		2013		2014		2011-2014	
Region of birth	Number	%	Number	%	Number	%	Number	%	Number	%
Australia	51	63	62	68	41	59	44	79	198	66
Overseas born										
Other Oceania	4	5	6	7	4	6	3	5	17	6
United Kingdom and Ireland	3	4	6	7	6	9	2	4	17	6
Other Europe	2	2	3	3	7	10	1	2	13	4
Middle East/North Africa	0	0	1	1	0	0	0	0	1	0
Sub-Saharan Africa	0	0	1	1	1	1	1	2	3	1
South East Asia	11	14	4	4	4	6	2	4	21	7
Southern and Central Asia	3	4	2	2	4	6	2	4	11	4
North America	1	1	3	3	1	1	0	0	5	2
South/Central America and the Caribbean	0	0	0	0	0	0	0	0	0	0
Total with a reported country of birth	**75**	**93**	**88**	**97**	**68**	**97**	**55**	**98**	**286**	**96**
Not reported	**6**	**7**	**3**	**3**	**2**	**3**	**1**	**2**	**12**	**4**
Total	**81**	**100**	**91**	**100**	**70**	**100**	**56**	**100**	**298**	**100**

1 Region of birth from the Australian Bureau of Statistics.

Table 13 Number and percentage of HCV infection among first-time donors, 2011-2014, by potential reported exposure category and sex

	2011		2012		2013		2014		Total (2011-2014)			
Exposure categories	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Total**	**%**
Ethnicity/Country of birth	10	1	3	2	3	2	1	0	17	5	22	12.6
Intravenous drug user	7	2	10	4	9	2	10	1	36	9	45	25.9
Tattoo/Piercing	8	3	0	0	10	6	5	0	23	9	32	18.4
Partners with any risks or known to be positive	1	1	0	0	1	6	0	1	2	8	10	5.7
Male-to-male sexual contact	0	0	0	0	0	0	0	0	0	0	0	0.0
Exposure in health care setting	0	2	2	0	4	1	0	0	6	3	9	5.2
Engaged in sex work	0	0	0	0	0	0	0	0	0	0	0	0.0
Blood or tissue recipient	5	2	4	1	0	1	0	2	9	6	15	8.6
Household contact	1	4	2	2	0	1	0	2	3	9	12	6.9
Other blood to blood contact	3	2	0	0	1	0	1	0	5	2	7	4.0
Other			1	0	0	1	1	1	2	2	4	2.3
No risk factors identified	2	0	0	1	1	0	2	1	5	2	7	4.0
Not reported	3	2	0	0	3	0	3	0	9	2	11	6.3
Total	**40**	**19**	**22**	**10**	**32**	**20**	**23**	**8**	**117**	**57**	**174**	**100**

Table 14 Number and percentage of HCV infection among repeat donors, 2011-2014, by potential reported exposure category and sex

	2011		2012		2013		2014		Total (2011-2014)			
Exposure categories	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Total**	**%**
Ethnicity/Country of birth	0	0	0	0	0	0	0	0	0	0	0	0.0
Intravenous drug user	7	1	0	1	2	0	4	2	13	4	17	20.5
Tattoo/Piercing	3	2	5	3	3	4	1	1	12	10	22	26.5
Partners with any risks or known to be positive	0	0	1	0	2	0	0	1	3	1	4	4.8
Male-to-male sexual contact	0	0	0	0	0	0	0	0	0	0	0	0.0
Exposure in health care setting	0	2	2	1	1	2	2	1	5	6	11	13.3
Engaged in sex work	0	0	0	0	0	0	0	0	0	0	0	0.0
Blood or tissue recipient	0	2	0	0	1	0	2	3	3	5	8	9.6
Household contact	2	0	0	1	0	0	2	1	4	2	6	7.2
Other blood to blood contact	0	0	1	0	1	0	1	0	3	0	3	3.6
Other	0	0	0	0	1	0	0	1	1	1	2	2.4
No risk factors identified	0	0	0	1	0	1	1	1	1	3	4	4.8
Not reported	3	0	2	0	0	0	1	0	6	0	6	7.2
Total	**15**	**7**	**11**	**7**	**11**	**7**	**14**	**11**	**51**	**32**	**83**	**100**

Table 15 Number and prevalence[1] of HIV infection among first-time donors, 2005-2014, by state/territory and year of donation

	2005			2006			2007			2008		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	42 479	0	0	44 499	1	2.25	51 427	1	1.94	48 607	1	2.06
NT	1 141	0	0	823	0	0.00	759	0	0.00	815	0	0.00
QLD	26 988	0	0	27 873	1	3.59	28 575	0	0.00	29 498	3	10.17
SA	9 752	0	0	11 457	0	0.00	10 886	0	0.00	15 908	0	0.00
TAS	3 484	0	0	2 899	0	0.00	2 650	0	0.00	3 936	0	0.00
VIC	19 346	0	0	22 016	0	0.00	23 172	1	4.32	30 286	1	3.30
WA	9 087	0	0	11 116	0	0.00	11 292	1	8.86	11 307	0	0.00
Total	**112 277**	**0**	**0**	**120 683**	**2**	**1.66**	**128 761**	**3**	**2.33**	**140 357**	**5**	**3.56**
	2009			**2010**			**2011**			**2012**		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	51 821	0	0.00	48 130	1	2.08	51 528	1	1.94	41 780	0	0.00
NT	965	0	0.00	799	0	0.00	772	0	0.00	937	0	0.00
QLD	28 889	0	0.00	28 097	2	7.12	28 839	2	6.94	24 881	0	0.00
SA	11 400	0	0.00	9 284	0	0.00	10 164	0	0.00	8 900	0	0.00
TAS	3 736	0	0.00	3 222	0	0.00	3 587	0	0.00	3 823	0	0.00
VIC	34 133	1	2.93	25 820	0	0.00	31 286	0	0.00	27 718	2	7.22
WA	12 387	0	0.00	11 149	0	0.00	10 992	1	9.10	9 925	0	0.00
Total	**143 331**	**1**	**0.70**	**126 501**	**3**	**2.37**	**137 168**	**4**	**2.92**	**117 964**	**2**	**1.70**
	2013			**2014**			**Total 2005-2014**					
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**			
NSW/ACT	35 060	2	5.70	30 697	2	6.52	446 028	9	2.02			
NT	853	0	0.00	793	0	0.00	8 657	0	0.00			
QLD	21 181	0	0.00	20 043	0	0.00	264 864	8	3.02			
SA	6 417	0	0.00	6 296	0	0.00	100 464	0	0.00			
TAS	3 058	0	0.00	2 538	0	0.00	32 933	0	0.00			
VIC	25 332	0	0.00	22 580	1	4.43	261 689	6	2.29			
WA	8 815	0	0.00	7 972	0	0.00	104 042	2	1.92			
Total	**100 716**	**2**	**1.99**	**90 919**	**3**	**3.30**	**1 218 677**	**25**	**2.05**			

1 Rate per 100 000 first-time donations

Table 16 Number and rate[1] of HIV infection among repeat donors, 2005-2014, by state/territory and year of donation

	2005			2006			2007			2008		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	311 513	1	0.32	333 250	0	0.00	338 173	0	0.00	339 062	1	0.29
NT	8 862	0	0.00	8 496	0	0.00	10 214	0	0.00	11 166	0	0.00
QLD	205 398	0	0.00	216 496	0	0.00	209 556	1	0.48	226 726	1	0.44
SA	93 172	0	0.00	107 934	1	0.93	114 618	1	0.87	118 476	0	0.00
TAS	24 577	0	0.00	28 726	0	0.00	28 019	0	0.00	33 321	0	0.00
VIC	225 332	1	0.44	238 684	0	0.00	252 340	0	0.00	259 052	3	1.16
WA	101 063	0	0.00	99 376	0	0.00	109 425	0	0.00	113 274	0	0.00
Total	**969 917**	**2.00**	**0.21**	**1 032 962.00**	**1**	**0.10**	**1 062 345**	**2**	**0.19**	**1 101 077**	**5**	**0.45**

	2009			2010			2011			2012		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	372 806	0	0.00	380 014	1	0.26	390 455	0	0.00	377 220	0	0.00
NT	11 158	0	0.00	10 470	0	0.00	10 782	1	9.27	9 673	0	0.00
QLD	242 001	2	0.83	243 837	2	0.82	245 975	1	0.41	237 599	0	0.00
SA	126 855	0	0.00	123 587	0	0.00	124 199	0	0.00	120 720	1	0.83
TAS	37 274	0	0.00	41 484	0	0.00	44 661	0	0.00	46 379	0	0.00
VIC	276 835	0	0.00	278 897	1	0.36	288 085	1	0.35	285 168	0	0.00
WA	118 327	0	0.00	120 646	0	0.00	121 057	0	0.00	117 728	0	0.00
Total	**1 185 256**	**2**	**0.17**	**1 198 935**	**4**	**0.33**	**1 225 214**	**3**	**0.24**	**1 194 487**	**1**	**0.08**

	2013			2014			Total 2005-2014		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	373 670	2	0.54	353 055	0	0.00	3 569 218	5	0.14
NT	9 493	0	0.00	8 914	0	0.00	99 228	1	1.01
QLD	243 042	0	0.00	239 720	2	0.83	2 310 350	9	0.39
SA	119 530	0	0.00	116 658	0	0.00	1 165 749	3	0.26
TAS	48 953	0	0.00	45 788	0	0.00	379 182	0	0.00
VIC	292 058	0	0.00	288 753	1	0.35	2 685 204	7	0.26
WA	123 298	0	0.00	118 014	1	0.85	1 142 208	1	0.09
Total	**1 210 044**	**2**	**0.17**	**1 170 902**	**4**	**0.34**	**11 351 139**	**26**	**0.23**

1 Rate per 100 000 first-time donations

Table 17 Number and percentage of donors with HIV infection, 2011-2014, by year of donation, sex and age group

	Year of donation											
	2011		2012		2013		2014		2011-2014			
Donor status	**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
20-29 years	3	0	0	0	1	0	1	0	5	0	5	23.8
30-39 years	0	0	1	0	0	0	0	1	1	1	2	9.5
40-49 years	1	0	0	0	0	0	0	1	1	1	2	9.5
50-59 years	0	0	1	0	1	0	0	0	2	0	2	9.5
60 years and above	0	0	0	0	0	0	0	0	0	0	0	0.0
Repeat donors												
<20 years	0	0	1	0	0	0	0	0	1	0	1	4.8
20-29 years	0	1	0	0	0	0	2	0	2	1	3	14.3
30-39 years	0	0	0	0	1	0	0	0	1	0	1	4.8
40-49 years	0	1	0	0	0	0	1	0	1	1	2	9.5
50-59 years	0	0	0	0	0	0	1	0	1	0	1	4.8
60 years and above	1	0	0	0	1	0	0	0	2	0	2	9.5
Total	**5**	**2**	**3**	**0**	**4**	**0**	**5**	**2**	**17**	**4**	**21**	**100**

Table 18 Number and percentage of donors with HIV infection, 2011-2014, by year of donation and country/region of birth[1]

	2011		2012		2013		2014		2011-2014	
Region of birth	**Number**	**%**	**Number**	**%**	**Number**	**%**	**Number**	**%**	**Number**	**%**
Australia	2	29	2	67	3	75	3	43	10	48
Overseas born										
Other Oceania	0	0	0	0	0	0	2	29	2	10
United Kingdom and Ireland	1	14	0	0	0	0	0	0	1	5
Other Europe	1	14	0	0	0	0	1	14	2	10
Middle East/North Africa	0	0	0	0	0	0	0	0	0	0
Sub-Saharan Africa	0	0	0	0	0	0	1	14	1	5
South East Asia	1	14	0	0	1	25	0	0	2	10
Southern and Central Asia	0	0	1	33	0	0	0	0	1	5
North America	0	0	0	0	0	0	0	0	0	0
South/Central America and the Caribbean	1	14	0	0	0	0	0	0	1	5
Total with a reported country of birth	**6**	**86**	**3**	**100**	**4**	**100**	**7**	**100**	**20**	**95**
Not reported	**1**	**14**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**5**
Total	**7**	**100**	**3**	**100**	**4**	**100**	**7**	**100**	**21**	**100**

1 Region of birth from the Australian Bureau of Statistics

Table 19 **Number and percentage of HIV infection among first-time donors, 2011-2014, by potential reported exposure category and sex**

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

Table 20 **Number and percentage of HIV infection among repeat donors, 2011-2014, by potential reported exposure category and sex**

	2011		2012		2013		2014		Total (2011-2014)			
Exposure categories	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Total**	**%**
Ethnicity/Country of birth	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
Tattoo/Piercing	0	0	0	0	0	0	0	0	0	0	0	0.0
Partners with any risks or known to be positive	0	1	1	0	0	0	1	0	2	1	3	30.0
Male-to-male sexual contact	0	0	0	0	2	0	2	0	4	0	4	40.0
Exposure in health care setting	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
Blood or tissue recipient	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
Other blood to blood contact	1	0	0	0	0	0	0	0	1	0	1	10.0
Other	0	0	0	0	0	0	0	0	0	0	0	0.0
No risk factors identified	0	0	0	0	0	0	1	0	1	0	1	10.0
Not reported	0	1	0	0	0	0	0	0	0	1	1	10.0
Total	**1**	**2**	**1**	**0**	**2**	**0**	**4**	**0**	**8**	**2**	**10**	**100**

Table 21 Number and prevalence[1] of HTLV infection among first-time donors, 2005-2014, by state/territory and year of donation

	2005			2006			2007			2008		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	42 479	0	0.00	44 499	1	2.25	51 427	1	1.94	48 607	0	0.00
NT	1 141	0	0.00	823	0	0.00	759	0	0.00	815	0	0.00
QLD	26 988	1	3.71	27 873	1	3.59	28 575	0	0.00	29 498	0	0.00
SA	9 752	0	0.00	11 457	0	0.00	10 886	0	0.00	15 908	1	6.29
TAS	3 484	0	0.00	2 899	0	0.00	2 650	0	0.00	3 936	0	0.00
VIC	19 346	0	0.00	22 016	1	4.54	23 172	0	0.00	30 286	4	13.21
WA	9 087	0	0.00	11 116	0	0.00	11 292	0	0.00	11 307	2	17.69
Total	**112 277**	**1.00**	**1**	**120 683.00**	**3**	**2**	**128 761**	**1**	**0.78**	**140 357**	**7**	**4.99**
	2009			**2010**			**2011**			**2012**		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	51 821	2	3.86	48 130	0	0.00	51 528	1	1.94	41 780	0	0.00
NT	965	0	0.00	799	0	0.00	772	0	0.00	937	0	0.00
QLD	28 889	2	6.92	28 097	1	3.56	28 839	0	0.00	24 881	0	0.00
SA	11 400	1	8.77	9 284	0	0.00	10 164	1	9.84	8 900	0	0.00
TAS	3 736	0	0.00	3 222	0	0.00	3 587	0	0.00	3 823	0	0.00
VIC	34 133	2	5.86	25 820	0	0.00	31 286	0	0.00	27 718	2	7.22
WA	12 387	2	16.15	11 149	0	0.00	10 992	1	9.10	9 925	0	0.00
Total	**143 331**	**9**	**6.28**	**126 501**	**1**	**0.79**	**137 168**	**3**	**2.19**	**117 964**	**2**	**1.70**
	2013			**2014**			**Total 2005-2014**					
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**			
NSW/ACT	35 060	3	8.56	30 697	0	0.00	446 028	8	1.79			
NT	853	0	0.00	793	0	0.00	8 657	0	0.00			
QLD	21 181	1	4.72	20 043	0	0.00	264 864	6	2.27			
SA	6 417	0	0.00	6 296	0	0.00	100 464	3	2.99			
TAS	3 058	0	0.00	2 538	0	0.00	32 933	0	0.00			
VIC	25 332	5	19.74	22 580	1	4.43	261 689	15	5.73			
WA	8 815	0	0.00	7 972	0	0.00	104 042	5	4.81			
Total	**100 716**	**9**	**8.94**	**90 919**	**1**	**1.10**	**1 218 677**	**37**	**3.04**			

1 Rate per 100 000 first-time donations

Table 22 Number and percentage of donors with HTLV infection, 2011-2014, by year of donation, sex and age group

	Year of donation											
	2011		2012		2013		2014		2011-2014			
Donor status	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
20-29 years	0	1	1	0	0	0	0	0	1	1	2	13.3
30-39 years	0	0	1	0	1	1	0	0	2	1	3	20.0
40-49 years	1	1	0	0	3	1	0	0	4	2	6	40.0
50-59 years	0	0	0	0	1	2	0	0	1	2	3	20.0
60 years and above	0	0	0	0	0	0	1	0	1	0	1	6.7
Repeat donors												
<20 years	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
30-39 years	0	0	0	0	0	0	0	0	0	0	0	0.0
40-49 years	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
60 years and above	0	0	0	0	0	0	0	0	0	0	0	0.0
Total	**1**	**2**	**2**	**0**	**5**	**4**	**1**	**0**	**9**	**6**	**15**	**100**

1 Age of one HTLV positive repeat male donor in 2010 was unknown

Table 23 Number and percentage of donors with HTLV infection, 2011-2014, by year of donation and country/region of birth[1]

	2011		2012		2013		2014		2011-2014	
Region of birth	Number	%	Number	%	Number	%	Number	%	Number	%
Australia	0	0	0	0	2	22	0	0	2	13
Overseas born										
Other Oceania	0	0	0	0	0	0	0	0	0	0
United Kingdom and Ireland	0	0	0	0	0	0	0	0	0	0
Other Europe	0	0	0	0	0	0	0	0	0	0
Middle East/North Africa	1	33	0	0	5	56	1	100	7	47
Sub-Saharan Africa	0	0	0	0	0	0	0	0	0	0
South East Asia	0	0	0	0	1	11	0	0	1	7
Southern and Central Asia	0	0	2	100	1	11	0	0	3	20
North America	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
Total with a reported country of birth	**1**	**33**	**2**	**100**	**9**	**100**	**1**	**100**	**13**	**87**
Not reported	**2**	**67**	**0**	**0**	**0**	**0**	**0**	**0**	**2**	**13**
Total	**3**	**100**	**2**	**100**	**9**	**100**	**1**	**100**	**15**	**100**

1 Region of birth from the Australian Bureau of Statistics

Table 24 **Number and percentage of HTLV infection among first-time donors, 2011-2014, by potential reported exposure category and sex**

	2011		2012		2013		2014		Total (2011-2014)			
Exposure categories	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Total**	**%**
Ethnicity/Country of birth	1	1	2	0	5	2	1	0	9	3	12	80.0
Intravenous drug user	0	0	0	0	0	0	0	0	0	0	0	0.0
Tattoo/Piercing	0	1	0	0	0	0	0	0	0	1	1	6.7
Partners with any risks or known to be positive	0	0	0	0	0	2	0	0	0	2	2	13.3
Male-to-male sexual contact	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
Engaged in sex work	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
Household contact	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
Other	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
Not reported	0	0	0	0	0	0	0	0	0	0	0	0.0
Total	**1**	**2**	**2**	**0**	**5**	**4**	**1**	**0**	**9**	**6**	**15**	**100**

Table 25 Number and prevalence[1] of active syphilis among first-time donors, 2005-2014, by state/territory and year of donation

	2005			2006			2007			2008		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	42 479	0	0.00	44 499	0	0.00	51 427	0	0.00	48 607	0	0.00
NT	1 141	0	0.00	823	0	0.00	759	0	0.00	815	1	122.70
QLD	26 988	0	0.00	27 873	1	3.59	28 575	1	3.50	29 498	0	0.00
SA	9 752	0	0.00	11 457	1	8.73	10 886	0	0.00	15 908	0	0.00
TAS	3 484	0	0.00	2 899	0	0.00	2 650	0	0.00	3 936	0	0.00
VIC	19 346	0	0.00	22 016	0	0.00	23 172	0	0.00	30 286	0	0.00
WA	9 087	0	0.00	11 116	0	0.00	11 292	0	0.00	11 307	2	17.69
Total	**112 277**	**0.00**	**0.00**	**120 683.00**	**2**	**2**	**128 761**	**1**	**0.78**	**140 357**	**3**	**2.14**

	2009			2010			2011			2012		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	51 821	0	0.00	48 130	0	0.00	51 528	0	0.00	41 780	0	0.00
NT	965	1	103.63	799	0	0.00	772	2	259.07	937	0	0.00
QLD	28 889	1	3.46	28 097	2	7.12	28 839	1	3.47	24 881	0	0.00
SA	11 400	0	0.00	9 284	2	21.54	10 164	1	9.84	8 900	1	11.24
TAS	3 736	0	0.00	3 222	0	0.00	3 587	0	0.00	3 823	0	0.00
VIC	34 133	1	2.93	25 820	1	3.87	31 286	1	3.20	27 718	0	0.00
WA	12 387	1	8.07	11 149	0	0.00	10 992	2	18.20	9 925	0	0.00
Total	**143 331**	**4**	**2.79**	**126 501**	**5**	**3.95**	**137 168**	**7**	**5.10**	**117 964**	**1**	**0.85**

	2013			2014			Total 2005-2014		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	35 060	0	0.00	30 697	0	0.00	446 028	0	0.00
NT	853	0	0.00	793	0	0.00	8 657	4	46.21
QLD	21 181	1	4.72	20 043	1	4.99	264 864	8	3.02
SA	6 417	0	0.00	6 296	0	0.00	100 464	5	4.98
TAS	3 058	0	0.00	2 538	0	0.00	32 933	0	0.00
VIC	25 332	0	0.00	22 580	1	4.43	261 689	4	1.53
WA	8 815	1	11.34	7 972	0	0.00	104 042	6	5.77
Total	**100 716**	**2**	**1.99**	**90 919**	**2**	**2.20**	**1 218 677**	**27**	**2.22**

1 Rate per 100 000 first-time donations

Table 26 Number and rate[1] of active syphilis among repeat donors, 2005-2014, by state/territory and year of donation

	2005			2006			2007			2008		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	311 513	0	0	333 250	0	0	338 173	0	0	339 062	1	0.29
NT	8 862	0	0	8 496	0	0	10 214	0	0	11 166	0	0.00
QLD	205 398	0	0	216 496	0	0	209 556	0	0	226 726	0	0.00
SA	93 172	0	0	107 934	0	0	114 618	0	0	118 476	0	0.00
TAS	24 577	0	0	28 726	0	0	28 019	0	0	33 321	1	3.00
VIC	225 332	0	0	238 684	0	0	252 340	1	0.396290719	259 052	0	0.00
WA	101 063	0	0	99 376	0	0	109 425	0	0	113 274	1	0.88
Total	**969 917**	**0**	**0**	**1 032 962**	**0**	**0**	**1 062 345**	**1**	**0.094131379**	**1 101 077**	**3**	**0.27**
	2009			**2010**			**2011**			**2012**		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	372 806	0	0.00	380 014	1	0.26	390 455	1	0.26	377 220	2	0.53
NT	11 158	1	8.96	10 470	1	9.55	10 782	0	0.00	9 673	0	0.00
QLD	242 001	1	0.41	243 837	1	0.41	245 975	0	0.00	237 599	0	0.00
SA	126 855	0	0.00	123 587	0	0.00	124 199	0	0.00	120 720	0	0.00
TAS	37 274	0	0.00	41 484	0	0.00	44 661	0	0.00	46 379	0	0.00
VIC	276 835	0	0.00	278 897	0	0.00	288 085	0	0.00	285 168	1	0.35
WA	118 327	1	0.85	120 646	0	0.00	121 057	0	0.00	117 728	2	1.70
Total	**1 185 256**	**3**	**0.25**	**1 198 935**	**3**	**0.25**	**1 225 214**	**1**	**0.08**	**1 194 487**	**5**	**0.42**
	2013			**2014**			**Total 2005-2014**					
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**			
NSW/ACT	373 670	2	0.54	353 055	0	0.00	3569 218	7	0.20			
NT	9 493	0	0.00	8 914	0	0.00	99 228	2	2.02			
QLD	243 042	1	0.41	239 720	1	0.42	2310 350	4	0.17			
SA	119 530	0	0.00	116 658	0	0.00	1165 749	0	0.00			
TAS	48 953	0	0.00	45 788	0	0.00	379 182	1	0.26			
VIC	292 058	0	0.00	288 753	2	0.69	2 685 204	4	0.15			
WA	123 298	0	0.00	118 014	0	0.00	1 142 208	4	0.35			
Total	**1 210 044**	**3**	**0.25**	**1 170 902**	**3**	**0.26**	**11 351 139**	**22**	**0.19**			

1 Rate per 100 000 first-time donations

Table 27 Trends in incidence and prevalence of transfusion-transmissible infections in Australia, 2005-2014

Prevalence of Transfusion-Transmissible Infections in All Donors, 2005-2014

	IRR (95% CI)	p-value
All infections	*0.94 (0.92-0.95)*	*0.00*
HBV	*0.96 (0.94-0.98)*	*0.00*
HCV	*0.9 (0.88-0.92)*	*0.00*
HIV	*1.02 (0.93-1.13)*	*0.58*
HTLV	*1.02 (0.91-1.15)*	*0.63*
Syphilis	*1.11 (1.01-1.23)*	*0.03*

Prevalence of Transfusion-Transmissible Infections in First-Time Donors, 2005-2014

	IRR (95% CI)	p-value
HBV	*0.98 (0.96-1.00)*	*0.13*
HCV	*0.91 (0.88-0.93)*	*0.00*
HIV	*1.08 (0.93-1.25)*	*0.28*
HTLV	*1.07 (0.95-1.21)*	*0.23*
Syphilis	*1.11 (0.97-1.28)*	*0.11*

Incidence of Transfusion-Transmissible Infections in Repeat Donors, 2005-2014

	IRR (95% CI)	p-value
HBV	*0.97 (0.85-1.11)*	*0.72*
HCV	*1.01 (0.93-1.09)*	*0.75*
HIV	*1.01 (0.88-1.16)*	*0.86*

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 2013-2014 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:

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

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:

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

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

Residual risk estimates

Estimates were derived based on minor refinement to the method described in earlier studies.[49] [50] An additional refinement since 2011 is a new model applied to HBV which specifically addresses the risk of occult hepatitis B infection (OBI).[51] 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 first-time donor 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 year 2014. Poisson regression analysis was used to calculate incidence rate ratios (IRRs) and their 95% confidence intervals. A p-value of less than 0.05 was considered as statistically significant. The trend in the total number of donations for the period 2005-2014 was examined by linear regression analysis.

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 2014. The association between demographic factors and presence of any transfusion-transmissible infections (HBV, HCV, HIV and HTLV) among Australian blood donors were assessed using multivariate Poisson regression model for each infection separately.

49 Seed CR, Kiely P, Keller AJ. *op. cit.* 2005. page 32

50 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.

51 Seed C and Kiely P. *op. cit.*, 2013. page 32

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