

Transfusion-transmissible infections in Australia









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edited by Clive Seed and Tarana Lucky

The Australian Red Cross Blood Service in collaboration with

The Kirby Institute





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Australian governments fully fund the Australian Red Cross Blood Service for the provision of blood products and services to the Australian community.





Foreword

This report is produced jointly by the Australian Red Cross Blood Service and the Surveillance and Evaluation Program for Public Health at the Kirby Institute. This is the third report that summarises available surveillance data and trends for transfusion-transmissible infections among Australian blood donors. While the report focuses on data collected during the 2012 calendar year, it also assesses for trends against the previously published data for 2005-2011 contained in the transfusion-transmissible infections 2012 surveillance report. As in last year's report, data on malaria testing and surveillance activity for emerging infections are also included in the 2013 report. Furthermore, this year we present data on non-compliance among test-negative blood donors to selective high-risk donor deferral criteria in Australia. Summarised results from a large national donor survey conducted between November 2012 and April 2013 are presented. We also include for the first time data on bacterial testing for platelets which provides important information on the risk of transfusion-associated sepsis.

Consistent with previous years, the overall number of transfusion-transmissible infections remained low in 2012 with the vast majority (84%) identified in first time donors. Reassuringly, the overall infection rate has remained fairly stable in 2012 following a gradual decrease in 2008-2011. Infected first time donors in 2012 mostly had undiagnosed prevalent infections but we continued to identify a small number of recently acquired (incident) infections among repeat donors. Notably, in 2012 there was an increase in the number of both prevalent and incident HCV infections. 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. For this reason the pre-donation questionnaire remains a critical safety procedure and its effectiveness is directly dependent on the accuracy (termed 'compliance') of the donor's answers.

Optimal compliance is therefore a blood safety imperative. The non-compliance rate among TTI positive donors gradually declined in 2008-2011 to around 20%, and the rate of 12.9% in 2011 is the lowest recorded to date. However, the rate in 2012 of 19% indicates that 2011 might be considered an 'outlier' with 2012 heralding return to previous levels. The importance of monitoring and understanding non-compliance was highlighted in the <u>*Review of Australian Blood Donor Deferrals relating to sexual activity'* (May 2012). This expert committee recommended that the Blood Service consider reducing the length of the deferral period from 12 to 6 months for a number of existing sexual activity-based deferrals. Importantly, this recommendation was dependent on the Blood Service first considering the impact of the shorter deferral period on the level of compliance to the deferral screening questions. Accordingly, the Blood Service in collaboration with the Kirby Institute conducted targeted research with the aim of estimating the current rate of non-compliance among donors testing negative for transfusion-transmissible infections and gauging opinion among donors on the donor questionnaire and possible ways to optimise the donor assessment process.</u>

A large survey of over 30 000 Australian TTI test-negative blood donors confirmed that non-compliance with sexual activity-based questions is comparatively low, in the range of 0.05 to 0.29% for individual deferral questions. In particular, the prevalence of non-compliance with the current 12-month deferral for male-to-male sex was estimated as 0.23%, which is well below the internationally published range (0.8-2.3%). It must be acknowledged that these estimates should be considered minimum estimates because non-compliant donors may have chosen not to participate or, if they had, were non-compliant on the questionnaire. Overall though these findings are reassuring and support the effectiveness of the current screening questions. Having carefully considered the results of the study the Blood Service has submitted a proposal to the Australian Federal government in support of reducing the deferral period to 6 months for all sexual activity-based deferrals considered by the expert committee. The outcome is pending and if supported would also need endorsement by all Australian jurisdictional governments prior to implementation.





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Summary of the main findings

General characteristics of blood donors in Australia

- 1. Over the period 2005-2012, there were approximately 10 million blood donations in Australia with an average of 1.25 million donations per year. Total blood donations declined (by 3.7%) in 2012 compared to 2011 reflecting both a reduced clinical demand for red cells leading to fewer whole blood collections, and expansion of automated plasma collections to meet an increasing demand for some plasma products, principally intravenous immunoglobulin.
- 2. Consistent with previous years, about 3.2% of the Australian population aged between 16-80 years donated blood during 2012.
- 3. First time and repeat donors comprised 16.6% and 83.4% of all blood donors in Australia over the period 2005-2012, respectively. As in previous years, this ratio remained relatively stable nationally and across all states and territories. Male donors constitute approximately 49.1% of all donors in 2012.

Trends in transfusion-transmissible infections in Australian blood donors

- 1. A total of 215 blood donors were detected as having a transfusion-transmissible infection (HBV, HCV, HIV, HTLV or syphilis) in 2012. None of the donors had co-infections. More than 94% of these donors were infected with either HBV or HCV. A total of 1 915 TTI- positive donors have been detected in the 2005-2012 period.
- 2. HTLV was the least common infection among blood donors in 2012; only two donors, both first time donors were HTLV positive. Overall in 2005-2012, HIV and HTLV were the least common infections among first time and repeat donors, respectively.
- 3. Although representing only 15% of the donor population, first time blood donors contributed 84% of transfusion-transmissible infections in Australia in 2012. This ratio has been fairly consistent over the period of 2005-2012, highlighting the importance of promoting education of potential new donors and appropriate self-deferral.
- 4. No transfusion-transmitted HIV, HCV, HTLV or syphilis infections were reported during 2008-2012. Three probable cases of transfusion-transmitted HBV infection were reported in the 2008-2012 period, two in 2009 associated with the same donor and one further case in 2011.

HBV infection among Australian blood donors

- 1. The prevalence of HBV among first time donors increased from 72.2 per 100 000 donations in 2011 to 83.1 per 100 000 donations in 2012. Of all transfusion-transmissible infections, HBV continued to have the highest prevalence among first time donors since 2007.
- 2. Following an increase during 2009-2011 associated with the introduction of HBV DNA testing, HBV incidence reduced substantially from 1.4 per 100 000 donor-years of observation in 2011 to 0.3 per 100 000 donor-years of observation in 2012.
- 3. The most common infective risk factor for donors with HBV infection during 2009-2012 was ethnicity/country of birth (83%) which is consistent with the findings of previously published data for the period 2008-2011.
- 4. In 2012, HBV positive donors were slightly younger (mean age 37 years versus 40 years for all donors), more likely to be male (74% versus 49% male donor proportion) and only 14% were born in Australia. These characteristics are consistent with previous years.

HCV infection among Australian blood donors

- 1. Following a gradual decline during 2007-2011, HCV prevalence among first time donors increased by 33% from 49.6 per 100 000 donations in 2011 to 66.1 per 100 000 donations in 2012.
- 2. After HBV, HCV was the most common infection found in first time blood donors.
- 3. HCV had the highest incidence rate among previously negative repeat donors during 2006 to 2012. The incidence of HCV increased from 1.7 per 100 000 donor-years of observation in 2011 to 3.6 per 100 000 donor-years of observation in 2012. This is consistent with the findings in the general population where the number of diagnoses of newly acquired HCV infection has shown a slight but gradual increase in 2010-2012.
- 4. The most common infective risk factor for donors with HCV infection during 2009-2012 was intravenous drug use (25%) which was also the predominant route (60%) of exposure in cases of newly acquired HCV infection in the general population in 2012.
- 5. In 2012, the mean age of donors with HCV infection was 44 years. Like HBV, male donors were over-represented (62% versus 49% male donors overall) but in contrast to HBV, the majority (69%) were born in Australia. The key attributes of HCV positive donors in 2012 remained similar to HCV positive donors in the previous three years.

HIV infection among Australian blood donors

- 1. The prevalence of HIV infection among first time donors during 2005-2012 remained very low (2 per 100 000 donations) in comparison to HBV (83.9 per 100 000 donations) and HCV (73.3 per 100 000 donations).
- 2. The incidence of HIV infection among previously negative repeat donors gradually declined over the past three years, from 1.2 per 100 000 donor-years of observation in 2010 to 0.3 per 100 000 donor-years of observation in 2012. Although remaining very low compared to the general population, the incidence rate of HIV in donors increased steadily but not significantly, between 2005 and 2009 then subsequently declined in 2010-2012. Overall, the donor HIV incidence rate was relatively stable in 2005-2012. Diagnoses of newly acquired HIV infection in Australia were also relatively stable in 2005-2010 but have continued to increase in the past three years.
- 3. The two most common routes of exposure for donors with HIV infection during 2009-2012 were partners with known risk or known to be positive (60%) followed by male-to-male sexual contact (15%)¹. This contrasts with the general population where men who have sex with men accounted for 69% of new HIV diagnoses in Australia in 2012. The lower proportion associated with male-to-male sexual contact in blood donors reflects the impact of the 12-month deferral for male-to-male sex.
- 4. As in 2011, HIV positive donors in 2012 were generally younger (36 years versus 40 years for all donors) and male (100% versus 49% male donors overall). Most HIV-positive donors in 2012 (67%) were born in Australia.

HTLV infection among Australian blood donors

- 1. The prevalence of HTLV among first time donors has remained very low over the past eight years. In 2012, only two donors were HTLV-positive and both were first time donors.
- 2. As in 2011, no donor seroconverted for HTLV in 2012. There was only one incident case of HTLV among previously negative repeat donors during 2005-2012.
- 3. The most common infective risk factor for donors with HTLV infection during 2009-2012 was ethnicity or country of birth (60%).
- 4. In 2012, the mean age of donors with HTLV infection was 32 years. Both infected donors in 2012 were male and born overseas.

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¹ Includes declaration form compliant and non-compliant donors (see section Non-compliance among positive donors, page 22).

Active syphilis infection among Australian blood donors

- 1. Overall, the prevalence of active syphilis among all blood donors has remained low (overall prevalence of 0.4 per 100 000 donations) in 2005-2012.
- 2. Following a steady increase in 2007-2011, the prevalence of active syphilis among first time donors has substantially decreased by 83.4% from 2011 to 2012. However, prevalence among repeat donors increased from 0.08 per 100 000 donations in 2011 to 0.4 per 100 000 donations in 2012.

Malaria testing

- 1. In 2012, a total 120 415 donations were tested for malaria antibody of which 2 866 (2.4%) were found to be repeat reactive for malaria antibodies. None of these 2 866 donations had detectable malaria DNA suggesting past infection in the donors.
- 2. There were no reported cases of transfusion-transmitted malaria during 2012, with the last Australian case occurring in 1991.

Bacterial pre-release testing for platelets

- 1. Bacterial screening of 124 241 platelets identified 138 (0.11%) as confirmed positive.
- 2. Propionibacterium spp., which are common skin commensals were by far the most frequently isolated organisms (112/138). These organisms are rarely, if ever associated with septic transfusion reactions in recipients. A small number of organisms including *Staphylococcus aureus, Staphylococcus epidermis, Campylobacter fetus, Aeromonas* sp. and *Serratia marcescens* were also detected, all of which are clinically significant organisms. No cases of septic transfusion reactions were identified in patients who received platelets. One transfusion-associated bacterial infection was recorded in 2012 involving a red cell unit from which *Staphylococcus epidermis* was cultured. The recipient recovered from their infection.
- 3. Routine follow-up of a donor from whom *Enterococcus faecalis* was cultured identified subacute bacterial endocarditis, facilitating early diagnosis and treatment of this donor's life-threatening condition.

Emerging infections

- 1. During 2012 there were four dengue fever outbreaks, two each in Cairns and Townsville. The Cairns outbreaks were in Manunda during February/March (7 confirmed cases) and Mt Sheridan beginning in November (3 cases by the end of December). The Townsville outbreaks were in Mundingburra (1 case in February) and Heatley (7 cases in May/June). To mitigate the transmission risk, donors visiting or residing in these areas were restricted to donating plasma for fractionation only. Restrictions were lifted 28 days after the last case onset date in each location.
- 2. In 2012, 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 2012). The risk of a donor returning and donating while viraemic was monitored on a weekly basis but unlike in 2010 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 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. The current risk posed by MERS-CoV to Australia's blood safety appears to be very low however the Blood Service continues to closely monitor developments.
- 4. The isolation and characterisation of a new paramyxovirus from pteropid bats in Australia, Cedar virus (CedPV) was reported in 2012. Genomic analysis indicated that CedPV shares significant features with the known henipaviruses, Nipah virus (NiV) and Hendra virus (HeV). While no disease association was reported, it was noted that, the discovery of another henipavirus in Australian flying foxes highlights the importance of bats as a significant reservoir of potential zoonotic agents and the need to expand our understanding of virus-bat relationships in general. It remains to be determined whether spill-over of CedPV into other hosts has occurred in the past in Australia, whether CedPV is pathogenic in certain mammalian hosts, and whether CedPV exists in bat populations in geographically diverse regions.

Key messages

- 1. Supporting the effectiveness of donor education and selection, the prevalence of transfusion-transmissible infections is substantially lower among both first time blood donors (11 to 67 times) and all donors (106 to 495 times) than in the general population in 2012 and shows a stable or declining trend since 2005.
- 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 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 viral seroconversion in repeat blood donors is also much lower than in the general population. 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. Almost one-fifth of the positive donors in 2009-2012 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. While the non-compliance rate of 20-25% declined gradually during 2008-2011 to its lowest ever level in 2011 (12.9%), in 2012 it returned to 19.1%. Understanding the reasons for and minimising the rate of non-compliance is important because it reduces 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 no such data existed for TTI test negative donors. Results from a recently conducted large national survey 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. 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%. 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.
- 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 538 000) 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 124 241 platelets identified 138 (0.11%) as confirmed positive. The majority of organisms identified were slow-growing anaerobic skin flora not usually associated with post-transfusion septic reactions. However, a minority of platelets grew clinically-significant organisms which were likely to have been due to transient or occult bacteraemia in the donor and could have led to potentially serious septic transfusion reactions in the recipient. During 2012 one such transfusion-associated bacterial infection was identified associated with a transfused red cell unit from which *Staphylococcus epidermis* was cultured. There was no platelet associated with the source whole blood donation and therefore bacterial testing was not performed. The patient developed a fever and the transfusion was ceased. They received a course of antibiotics and subsequently recovered from the infection. The importance of routinely following up donors with confirmed positive results was highlighted by early diagnosis and treatment of a donor with subacute bacterial endocarditis.
- 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 spread of dengue virus was highlighted in 2012 by the first recorded outbreak of locally acquired cases on Madeira. While the world's first commercially available vaccine against Hendra virus was launched in Australia in late 2012, the isolation and characterisation of a novel henipavirus (Cedar virus) in Australian bats was reported. The new virus is closely related to the Hendra virus but disease association and host range have not been determined. In the Middle East, a human novel coronavirus referred to as Middle East respiratory syndrome coronavirus (MERS-CoV) was reported. MERS-CoV has raised concerns as it is related to SARS-CoV and also causes acute respiratory syndrome.





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Glossary

Active syphilis

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

Apheresis

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

First time donor

A donor who has not previously donated in Australia.

Intravenous drug user

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.

Infective risk factor

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

Non-compliance

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

Occult HBV infection (OBI)

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

Prevalence

The frequency of infection in the first time donor population.

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.

Seroconverter

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

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

10

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





Abbreviations

anti-HBc	antibody to hepatitis B core antigen
anti-HBe	antibody to hepatitis B e antigen
anti-HBs	antibody to hepatitis B surface antigen
anti-HeV	antibody to Hendra virus
HBsAg	hepatitis B surface antigen
Blood Service	Australian Red Cross Blood Service
CedPV	Cedar virus
CFS	chronic fatigue syndrome
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
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
XMRV	Xenotropic murine leukemia virus- related virus

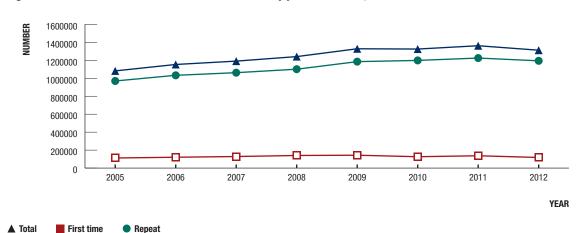


2013 Surveillance Report

Main findings

Blood donors in Australia

About 10 million donations were tested for transfusion-transmissible infections in Australia during 2005-2012 with an average of about 1.2 million donations per year. Overall, the number of blood donations increased by more than 21% over the past eight years, with a decrease (3.7% decrease) from 2011 to 2012 (Figure 1). This recent decrease in total collections 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 meet an increasing demand for plasma derived products, particularly intravenous immunoglobulin. During 2005-2012, about 3.6% of the general population who were aged between 16-80 years donated blood in Australia. This ratio remained fairly similar in 2012 (3.2%). As in previous years, more than 90% of all donations in 2012 were from repeat donors and 84% of all TTI positive donations were made by first time donors.





Among all blood donors who donated in 2012, 51% were female, 32% were younger than 30 years and 30% were from New South Wales. Median ages of both male and female donors in 2012 ranged between 38 and 40 years continuing a trend toward a younger donor base.

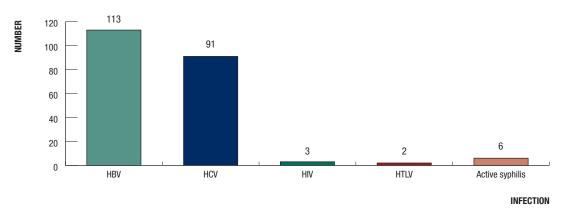
Trends in incidence and prevalence of transfusion-transmissible infections

In 2012, a total of 215 donors (16.4 per 100 000 donations) were found positive for at least one of the transfusion-transmissible infections – HBV, HCV, HIV, HTLV and active syphilis. In 2012, no donors had more than one transfusion-transmissible infection. Overall, HCV and HBV were the two most common infections identified in Australian blood donors in 2012, together contributing more than 94% of all infections (Figure 2). HBV and HCV were the most common infections in first time and repeat donors, respectively. Overall TTI-positivity increased slightly from 15.8 per 100 000 donations in 2011 to 16.4 per 100 000 donations in 2012. However, in general, the presence of any transfusion-transmissible infection among Australian blood donations has remained low with a slight but significantly² declining trend in overall prevalence during 2005-2012.

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² Throughout the document the term 'significant' is used only where a statistical test has a p value <0.05

Figure 2 Number of blood donors with transfusion-transmissible infections in Australia, in 2012, by infection



Among all donors during 2005-2012, the prevalence of HCV infection has been declining significantly with an overall 41% reduction from 2005 to 2012; however, following a steady decrease during 2008-2011, HCV prevalence increased by 16.6% in 2012. The prevalence of active syphilis infection increased significantly in 2005-2012. Both HIV and HTLV prevalence showed a slight, non-significant overall increase and HBV prevalence remained relatively stable. Although not significant, the prevalence of HBV among Australian blood donors has steadily decreased since 2007.

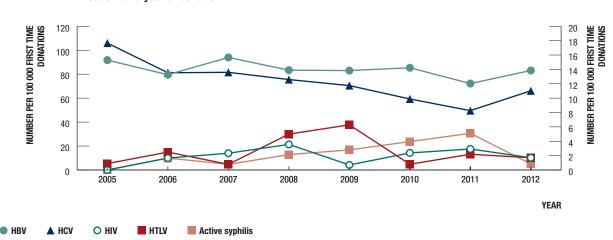


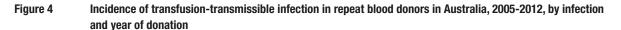
Figure 3 Prevalence of transfusion-transmissible infections in first time blood donors in Australia, 2005-2012, by infection¹ and year of donation

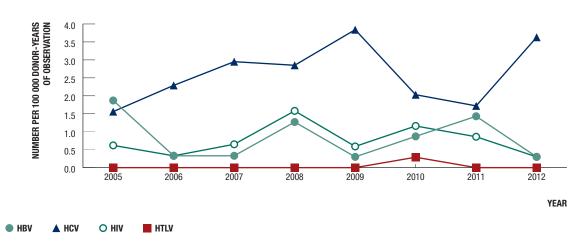
1 Prevalence of HIV, HTLV and active syphilis are provided according to the scale on the secondary axis on the right hand side.

The prevalence of HBV in first time donors increased from 72.2 per 100 000 donations in 2011 to 83.08 per 100 000 donations in 2012 with no significant annual trend observed in the past eight years (Figure 3). During 2005-2012, there has been a significant decrease in HCV prevalence in first time donors in Australia, a trend consistent with the *per capita* rate of diagnosis of HCV infection reported through the National Notifiable Disease Surveillance System³, which also declined since 2006. However, following a steady decline in 2007-2011 the HCV first time donor prevalence increased from 49.5 per 100 000 donations in 2011 to 66.1 per 100 000 donations in 2012. Contrasting this, the population diagnosis rate continued its previously declining rate in 2012. It is too soon to determine if the increase in the first time donor prevalence rate reflects the commencement of an upward trend or is simply natural variation.

In contrast with HBV and HCV, the prevalence of HIV, HTLV and active syphilis in first time donors remained very low over the past eight years. Compared to 2011, prevalence of HIV and HTLV in first time donors reduced in 2012 by 41.9% and 22.5%, respectively. Apart from an increase in 2008, HIV prevalence has been stable over the 2005-2012 period. During 2005-2012, HTLV prevalence demonstrated a slight, non-significant increasing trend in first time donors in Australia. Overall, the prevalence of active syphilis in first time donors showed an increasing trend during 2005-2012 (Figure 3). Reassuringly though, prevalence of active syphilis in first time donors declined substantially from 5.1 per 100 000 donations in 2011 to 1.7 per 100 000 donations in 2012, following a continuing increase in 2007-2011. The annual number of diagnoses of infectious syphilis reported through the National Notifiable Diseases Surveillance System peaked at 1 418 in 2007 and has remained above 1 000 in 2008-2012.

³ The Kirby Institute. HIV, viral hepatitis and sexually transmissible infections in Australia Annual Surveillance Report 2013. The Kirby Institute, the University of New South Wales, 2013.





For the 2005-2012 period there was no significant trend observed for incidence rates of any of the TTIs (Figure 4). Consistent with previous years HCV had the highest TTI incidence rate in 2012. Incidence rates for HIV and HBV decreased substantially from 2011 to 2012. The incidence of HCV among repeat donors increased from 1.72 per 100 000 donor-years of observation in 2011 to 3.63 per 100 000 donor-years of observation in 2012 (Figure 4). Although not significant, there was a slightly increasing trend in HCV incidence in repeat blood donors over the past eight years. Notably, diagnoses of newly acquired HCV infection in the general population has also shown a slight but gradual increase in 2010-2012⁴. Nationally, no significant annual trend was observed for incidence of HIV in 2005-2012 although it has steadily declined since 2010. This is pleasing given the contrast with the general population where there has been a substantial increase in diagnoses of newly acquired HIV infection in 2010-2012. As in 2011, the HTLV incidence among repeat Australian donors in 2012 was zero. During 2005-2012, HTLV incidence remained very low with only one incident case identified in 2010.

Trends in HBV infection by state/territory

In 2012, the prevalence of HBV among first time donors varied markedly across Australia. While the national prevalence was 83.08 per 100 000 donations this ranged from 64.31 to 151.13 per 100 000 donations (Table 1 & Supporting figure 7). From 2011 to 2012, the prevalence of HBV increased in all states/territories except for Northern Territory and Victoria. The greatest increase was observed in Tasmania (from 27.88 per 100 000 donations in 2011) to 78.47 per 100 000 donations in 2012) followed by South Australia (from 29.52 per 100 000 donations in 2011) to 78.65 per 100 000 donations in 2012). Compared to 2011, HBV prevalence among first time donors in 2012 increased by 7.52%, 32.47% and 66.13% in New South Wales/Australian Capital Territory, Queensland and Western Australia, respectively. Overall, Queensland continued to have a lower HBV prevalence than both New South Wales/ Australian Capital Territory and Victoria, the prevalence of HBV in first time donors has been gradually declining over the past three years consistent with a declining diagnosis rate in the general population. Contrasting the declining donor HBV prevalence between 2011 and 2012, the population diagnosis rate in the Northern Territory increased.

Overall, there was no obvious trend in HBV incidence in any state/territory during the eight-year study period 2005-2012 except in Western Australia, showing a non-significant increasing trend (Supporting figure 8) However, a substantial decrease in HBV incidence was observed in all jurisdictions in 2012 compared to 2011. Except for one incident (i.e. seroconverting) donor in Western Australia, incidence was zero in all other states/territories. This is reassuring as there were five incident donors identified in 2011; the majority (four out of five) were HBV DNA positive but HBsAg negative, highlighting the value of implementing HBV NAT during 2010. Among donors in New South Wales/Australian Capital Territory, Northern Territory, South Australia and Tasmania, HBV incidence has been zero since 2008. The decreasing donor incidence is pleasing given that the rate of diagnosis of newly acquired HBV in the general population for 2012 compared to 2011 has increased in all jurisdictions except in New South Wales, Tasmania and Victoria.

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⁴ The Kirby Institute. op.cit.

Trends in HCV infection by state/territory

While nationally the prevalence of HCV in first time donors remained relatively stable throughout the 2005-2012 period with no significant trend, there were some notable jurisdictional increases in 2012 (Supporting figure 9). Queensland (from 45.08 per 100 000 donations in 2011 to 84.4 per 100 000 donations in 2012) followed by Victoria (from 38.36 per 100 000 donations in 2011 to 57.72 per 100 000 donations in 2012) both had marked increases in 2012. These increases were not reflected in the general population data for the rate of newly diagnosed HCV infection in Queensland and Victoria. It is premature to make any assumptions based on a single year increase. Notably, apart from 2012, the declining prevalence trend in first time donors is consistent with the declining rate of newly diagnosed HCV infection which has remained fairly stable or declined over the past decade. Several jurisdictions (including New South Wales and Victoria) recorded further decreases in the rate of new diagnoses of HCV between 2011 and 2012. This bodes well for the future donor prevalence rate given donors are selected directly from the general population.

The incidence of HCV in repeat donors remained very low across all Australian jurisdictions with some variation during the past eight years (Supporting figure 10). In New South Wales/Australian Capital Territory, the rate continued to decline since 2008 (from 2.96 per 100 000 donor-years of observation in 2008 to 0.92 per 100 000 donor-years of observation in 2012). In Tasmania, HCV incidence has been zero since 2010. Apart from a slight increase in 2012, the rate in Western Australia remained relatively stable during the past three years at around 3 per 100 000 donor-years of observation. In contrast, HCV incidence in Queensland and Victoria were approximately five and three times higher in 2012, respectively compared with 2011. There was a corresponding increase (although much smaller) in the 2012 HCV incidence in the Victorian general population. Data on HCV incidence in the general population are not available for Queensland. Importantly, given the low donor incidence rates in all jurisdictions individual year variation should be interpreted with due caution.

Trends in HIV infection by state/territory

The prevalence of HIV infection in first time donors remained substantially lower than HBV and HCV throughout the 2005-2012 period, with the national average prevalence being 1.95 per 100 000 donations (Supporting figure 11). In 2012, the prevalence of HIV in first time donors was zero in all jurisdictions except Victoria where the rate was 7.22 per 100 000 donations. While this was a notable increase in rate given the prevalence was zero in the previous two years it should not be over-interpreted as it represents a raw increase from zero to two HIV infected donors. It is particularly pleasing that the first time donor prevalence rate has remained stable and low given that the number of newly diagnosed HIV infections in the general Australian population continues to increase. Only Victoria and South Australia recorded decreases in 2012 compared with 2011.

Nationally, HIV incidence among repeat donors is showing evidence of a gradual decline since 2010. As with HIV prevalence this contrasts the situation in the general population. The only incident donor in 2012 was South Australian, the first recorded there since 2007. With the exception of Queensland, no clear jurisdictional trend was observed over the 2005-2012 period (Supporting figure 12). The Queensland incidence rate steadily declined by approximately 50% from 2.95 per 100 000 donor-years of observation in 2010 to 1.45 per 100 000 donor-years of observation in 2011 reaching zero in 2012.

Trends in HTLV infection by state/territory

In 2012 HTLV prevalence was zero in all jurisdictions except Victoria with two HTLV-positive, first time donors (Supporting figure 13). For the 2005-2012 period, HTLV prevalence remained low in all jurisdictions without any discernible trend. No incident HTLV donors where reported during 2012 and HTLV incidence has remained very low throughout the 2005-2012 period with the only incident donor identified in 2010.

Trends in active syphilis infection by state/territory

The rate of active syphilis infection in blood donors remained low across Australia during the 2005-2012 period. Prevalence in first time donors was zero in all jurisdictions in 2012 except in South Australia (Supporting figure 14). In both Queensland and Victoria, the prevalence of active syphilis infection in first time donors continued to decline steadily since 2010. Reassuringly, the prevalence of active syphilis infection decreased substantially from 5.1 per 100 000 donations in 2011 to 0.85 per 100 000 donations in 2012. This reverses a previous increasing trend in the five preceding years from 2007 to 2011. This reversal is creditable given recent statistics show that the number and rate of diagnosis of infectious syphilis in the general population has steadily increased in the past three years.⁵ In contrast, active syphilis among repeat donors has increased in 2012 (from 1 repeat donor in 2011 to 5 in 2012). It is too early to determine if this represents a trend or simply natural variation.

⁵ The Kirby Institute. op.cit.

Table 1 Prevalence of transfusion-transmissible infections in Australia by type of donation and state/territory, 2012

	All accepted donations		donations H		HBV HCV		HCV		HIV			HTLV		Syphilis		Total positive donations					
State/Territory of donation	First time	Repeat	All	First time	Repeat	All	First time	Repeat	All	First time	Repeat	All	First time	Repeat	AII	First time	Repeat	All	First time	Repeat	All
NSW/ACT	41 780	377 220	419 000	34	6	40	30	1	31	0	0	0	0	0	0	0	2	2	64	9	73
Number (Number per 100 000 donations)				81.38	1.59	9.55	71.80	0.27	7.40	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.53	0.48	153.18	2.39	17.42
NT	937	9 673	10 610	1	0	1	1	0	1	0	0	0	0	0	0	0	0	0	2	0	2
Number (Number per 100 000 donations)				106.72	0.00	9.43	106.72	0.00	9.43	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	213.45	0.00	18.85
QLD	24 881	237 599	262 480	16	4	20	21	5	26	0	0	0	0	0	0	0	0	0	37	9	46
Number (Number per 100 000 donations)				64.31	1.68	7.62	84.40	2.10	9.91	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	148.71	3.79	17.53
SA	8 900	120 720	129 620	7	0	7	3	2	5	0	1	1	0	0	0	1	0	1	11	3	14
Number (Number per 100 000 donations)				78.65	0.00	5.40	33.71	1.66	3.86	0.00	0.83	0.77	0.00	0.00	0.00	11.24	0.00	0.77	123.60	2.49	10.80
TAS	3 823	46 379	50 202	3	0	3	1	1	2	0	0	0	0	0	0	0	0	0	4	1	5
Number (Number per 100 000 donations)				78.47	0.00	5.98	26.16	2.16	3.98	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	104.63	2.16	9.96
VIC	27 718	285 168	312 886	22	2	24	16	3	19	2	0	2	2	0	2	0	1	1	42	6	48
Number (Number per 100 000 donations)				79.37	0.70	7.67	57.72	1.05	6.07	7.22	0.00	0.64	7.22	0.00	0.64	0.00	0.35	0.32	151.53	2.10	15.34
WA	9 925	117 728	127 653	15	3	18	6	1	7	0	0	0	0	0	0	0	2	2	21	6	27
Number (Number per 100 000 donations)				151.13	2.55	14.10	60.45	0.85	5.48	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.70	1.57	211.59	5.10	21.15
National	117 964	1 194 487	1 312 451	98	15 ¹	113	78	13	91	2	1	3	2	0	2	1	5	6	181	34	215
Number (Number per 100 000 donations)				83.08	1.26	8.61	66.12	1.09	6.93	1.70	0.08	0.23	1.70	0.00	0.15	0.85	0.42	0.46	153.44	2.85	16.38

1 Only one donor seroconverted while the remaining 14 were chronic occult hepatitis B infections identified by HBV DNA testing. These do not contribute to the HBV incidence rate but are considered in the estimation of residual risk (refer 'residual risk estimates' page 86)

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

Consistent with a previous Blood Service study for the period 2000-2006⁶, a marked reduction is evident in the prevalence of HBV, HCV and HIV in blood donors compared with the general population (Table 2). Prevalence of these infections are substantially lower in blood donors than in the general population, with an 11 to 67 times reduction in first time donors and 106 to 495 times reduction among all donors in 2012. As in 2005-2011, the greatest comparative reduction among first time donors (67 times lower) was observed for HIV infection. 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, 2005-2012

Infection	•	Population prevalence (per 100 000 people)		nce in all od donors onations)	Prevalence in bloo (per 100 000 de	d donors	•	ence reduction Il blood donors		ce reduction blood donors
	2005-2011	2012	2005-2011	2012	2005-2011	2012	2005-2011	2012	2005-2011	2012
HBV	850	911	9.50	8.61	83.93	83.08	90 times	106 times	10 times	11 times
HCV	745-1422	1052-1722	8.97	6.93	73.92	66.12	83-159 times	152-248 times	10-19 times	16-26 times
HIV	102	113	0.43	0.23	1.98	1.70	239 times	495 times	52 times	67 times
HTLV ¹	-	-	0.30	0.15	2.75	1.70	-	-	-	-

1 Population prevalence for HTLV is unknown.

Demographic factors associated with transfusion-transmissible infections in blood donors

While the prevalence/incidence data covers 2005-2012, the risk factor analysis is restricted to 2008 to 2012 where 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 2012 was analysed⁷ to determine the association between demographic factors and presence of transfusion-transmissible infections among Australian blood donors (Table 3). Male donors, donors aged less than 20 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, respectively.

HBV positivity and associated demographic risk factors

Overall, there were no significant trends in 2008-2012 for HBV positivity among Australian donors by demographics analysed. However, as in 2011, female donors were less likely to have acquired HBV infection. There were no significant associations with age group or state/territory of donation and HBV infection among Australian blood donors in 2012.

HCV positivity and associated demographic risk factors

Generally, there were no significant trends in 2008-2012 for HCV positivity among Australian donors by demographics analysed. However, like HBV, female donors were significantly less likely (36% less likely compared to male donors) to be HCV positive. Older donors were more likely to be HCV positive compared to those younger than 20 years. Donors aged 30-39 years, 40-49 years and 50 years and above were about 4, 4.9 and 3.9 times more likely to be HCV positive respectively, compared with those younger than 20 years. Overall, these age-groups were also predominant for HCV notifications in the general population in Australia. Together, people aged 30-39 years, 40-49 years and 50-59 years accounted for almost 70% of all new diagnoses of HCV among general Australian population in 2012. This proportion increased in the past five years from 61.5% in 2008 to 68.8% in 2012, suggesting a possible age/cohort effect. As in 2011, there was no association with state/territory of the donor and HCV infection among Australian blood donors in 2012.

HIV and HTLV positivity and associated demographic risk factors

Given the small number of donors with HIV and HTLV infection in 2012 no meaningful analysis was possible.

⁶ Polizzotto MN, Wood EM, Ingham H, Keller AJ. Reducing the risk of transfusion-transmissible viral infection through blood donor selection: the Australian experience 2000 through 2006. *Transfusion*. 2008;48(1):55-63.

⁷ See methodological notes for details

			HBV		HCV		HIV		HTL
	Number of donors	Number of positive donors (Number per 100 000 donors)	IRR ¹ and their 95% Cl ² (Multivariate adjusted)	Number of positive donors (Number per 100 000 donors)	IRR and their 95% Cl (Multivariate adjusted)	Number of positive donors (Number per 100 000 donors)	IRR and their 95% Cl (Multivariate adjusted)	Number of positive donors (Number per 100 000 donors)	IRR and their 95% CI (Multivariate adjusted)
Sex									
Male	269 584	84 (31.16)	1 (ref)	56 (20.77)	1 (ref)	3 (1.11)	1 (ref)	2 (0.74)	1 (ret
Female	278 986	29 (10.39)	0.33 (0.21-0.5)	35 (12.55)	0.64 (0.42-0.97)	0 (0)	-	0 (0)	-
Age group (years)									
Less than 20	59 796	9 (15.05)	1 (ref)	3 (5.02)	1 (ref)	1 (1.67)	1 (ref)	0 (0)	-
20-29	117 384	35 (29.82)	1.94 (0.93-4.04)	11 (9.37)	1.92 (0.53-6.88)	0 (0)	-	1 (0.85)	-
30-39	85 421	26 (30.44)	1.84 (0.86-3.94)	17 (19.9)	3.95 (1.16-13.5)	1 (1.17)	0.49 (0.03-7.83)	1 (1.17)	-
40-49	98 323	16 (16.27)	1 (0.44-2.27)	24 (24.41)	4.88 (1.47-16.22)	0 (0)	-	0 (0)	-
50 and above	187 646	27 (14.39)	0.87 (0.41-1.85)	36 (19.19)	3.81 (1.17-12.39)	1 (0.53)	0.22 (0.01-3.52)	0 (0)	-
State/Territory									
NSW	170 252	37 (21.73)	1 (ref)	32 (18.8)	1 (ref)	0 (0)	1 (ref)	0 (0)	-
ACT	14 503	3 (20.69)	0.93 (0.29-3.01)	0 (0)	-	0 (0)	-	0 (0)	-
NT	4 483	1 (22.31)	0.97 (0.13-7.11)	1 (22.31)	1.18 (0.16-8.63)	0 (0)	-	0 (0)	-
QLD	109 796	20 (18.22)	0.84 (0.49-1.45)	25 (22.77)	1.17 (0.69-1.97)	0 (0)	-	0 (0)	-
SA	51 665	8 (15.48)	0.75 (0.35-1.61)	5 (9.68)	0.49 (0.19-1.26)	1 (1.94)	-	0 (0)	-
TAS	17 516	3 (17.13)	0.86 (0.26-2.78)	2 (11.42)	0.59 (0.14-2.44)	0 (0)	-	0 (0)	-
VIC	131 838	24 (18.2)	0.82 (0.49-1.37)	19 (14.41)	0.75 (0.42-1.32)	2 (1.52)	-	2 (1.52)	-
WA	48 517	17 (35.04)	1.58 (0.89-2.8)	7 (14.43)	0.73 (0.32-1.65)	0 (0)	-	0 (0)	-
Total	548 570	113 (20.6)		91 (16.59)		3 (0.55)		2 (0.36)	

Table 3 Association of demographic characteristics with presence of transfusion-transmissible infection among blood donors in Australia by infection, 2012

1 IRR = Incident Rate Ratio

2 CI = Confidence Intervals

Risk factors associated with infected donors

Standardised national data on risk factors associated with infected donors is available since 2008. Data for the period 2008-2011 was included in the 2011 surveillance report. This report presents data for the period 2009 to 2012. In 2012, 215 donors were confirmed positive for at least one of the transfusion-transmissible infections with a total of 927 confirmed positive donors over the period of 2009-2012. Among them, 29 donors were positive for active syphilis, however no risk factor data was available for these donors. The data on the remaining 898 donors who were positive for any of the other transfusion-transmissible infections (HBV, HCV, HIV and HTLV) were analysed to determine the key attributes of blood donors with transfusion-transmissible infections, stratified by year of donation (Tables 4-7).

Donors with HBV infection, 2009-2012

Of 482 HBV positive donors during 2009-2012, 88% were first time donors, 68% were male, with a mean age of 37 years (Table 4). Most (76%) of the HBV positive donors were born overseas, which reflects the epidemiology of HBV in the general population. There were only ten blood donors who seroconverted for HBV during the last four years, consistent with a low incidence rate. 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 (4%).

Table 4 Attributes of donors positive for HBV infection by year of donation, 2009-2012

Characteristics	2009	2010	2011	2012	2009-2012
Number of positive donors	124	127	118	113	482
Number of positive first time donors (%)	118 (95%)	108 (84%)	99 (83%)	97 (86%)	422 (88%)
% male	79 (63%)	84 (66%)	79 (67%)	84 (74%)	326 (68%)
Mean age (range) in years	34 (16 to 69)	37 (16 to 71)	38 (16 to 77)	37 (16 to 67)	37 (16 to 77)
Number of seroconverters	1	3	5	1	10
% born in Australia	16 (13%)	17 (13%)	15 (13%)	19 (17%)	68 (14%)
Main reported risk factor	Ethnicity/COB ¹	Ethnicity/COB	Ethnicity/COB	Ethnicity/COB	Ethnicity/COB
	77%	83%	85%	89%	83%
Second reported risk factor	Household contact	Partner with known risk or known to be positive	TBP ² ,PRP ³ each	Partner with known risk or known to be positive	Partner with known risk or known to be positive
	6%	4%	3%	4%	4%

COB=Country of birth 1

2 TBP= Tattoo/ Body piercing

PRP= Partner with known risk/known to be positive 3

Donors with HCV infection, 2009-2012

Of 380 donors positive for HCV in 2009-2012, 73% were first time donors (Table 5). The mean age of HCV positive donors was 43 years with a tight range (42-44) over the last four years. Male donors represented more than 60% of all donors with HCV infection but, unlike HBV where birth overseas predominated, the majority (69%) of HCV positive donors were born in Australia. The number of HCV seroconverters (39 donors) was the highest among all transfusion-transmissible infections. Overall, the most important risk factor for HCV positivity was intravenous drug use (25%) followed by tattoo or body piercing (15%).

Characteristics	2009	2010	2011	2012	2009-2012
Number of positive donors	122	86	81	91	380
Number of positive first time donors (%)	83 (68%)	67 (79%)	59 (73%)	67 (7%)	276 (73%)
% male	72 (59%)	53 (62%)	55 (68%)	56 (62%)	236 (62%)
Mean age (range) in years	44 (17 to 71)	42 (16 to 63)	42 (16 to 78)	44 (16 to 66)	43 (16 to 78)
Number of seroconverters	11	10	6	12	39
% born in Australia	90 (74%)	61 (71%)	51 (63%)	62 (68%)	264 (69%)
Main reported risk factor	Intravenous drug use	Tattoo/Body piercing	Intravenous drug use	Tattoo/Body piercing	Intravenous drug use
	35%	21%	21%	31%	25%
Second reported risk factor	Tattoo/Body piercing	Intravenous drug use	Tattoo/Body piercing	Intravenous drug use	Tattoo/Body piercing
	18%	19%	20%	23%	15%

Table 5 Attributes of donors positive for HCV infection by year of donation, 2009-2012

Donors with HIV infection, 2009-2012

In contrast to HBV and HCV infected donors, the majority of HIV infected donors during 2009-2012 were repeat donors (65%) (Table 6). Most were male (75%) of younger age (mean age 36 years) and Australian born (60%). In respect of country of birth, 2011 was notable as the proportion born in Australia (29%) was markedly lower that the average for 2009-2012 (63%). Overall though, the pattern in donors is very similar to new HIV diagnoses in the general population. According to the recent population data, people born in Australia accounted for 62.4% of cases of HIV infection newly diagnosed in 2009-2012, most of the newly diagnosed HIV cases were male (86.5%) with a mean age of 36.8 years⁸. Of 20 HIV positive repeat donors, 10 donors seroconverted for HIV during the last four years. Having a sexual partner with known risk or known to be positive for any transfusion-transmissible infection (60%) and male-to-male sexual contact (15%) were the two most important risk factors for HIV positivity in blood donors during 2009-2012.

Table 6 Attributes of donors positive for HIV infection by year of donation, 2009-2012

Characteristics	2009	2010	2011	2012	2009-2012
Number of positive donors	3	7	7	3	20
Number of positive first time donors (%)	1 (33%)	1 (14%)	4 (57%)	1 (33%)	7 (35%)
% male	2 (67%)	5 (71%)	5 (71%)	3 (100%)	15 (75%)
Mean age (range) in years	38 (26 to 50)	37 (23 to 57)	36 (22 to 62)	36 (19 to 56)	36 (19 to 62)
Number of seroconverters	2	4	3	1	10
% born in Australia	2 (67%)	6 (86%)	2 (29%)	2 (67%)	12 (60%)
Main reported risk factor	Male-to-male sexual contact	Male-to-male sexual contact	Partner with known risk or known to be positive	Partner with known risk or known to be positive	Partner with known risk or known to be positive
	33%	57%	57%	100%	60%
Second reported risk factor	Partner with known risk or known to be positive	Male-to-male sexual contact	Male-to-male sexual contact		Male-to-male sexual contact
	33%	14%	14%		15%

8 The Kirby Institute. op. cit.

Donors with HTLV infection, 2009-2012

Only 16 donors were positive for HTLV infection during the 2009-2012 period, 94% were first time donors and 60% were male, with a mean age of 40 years (Table 7). Most of the HTLV positive donors (80%) were born overseas. There was only one donor who seroconverted for HTLV in 2010. Ethnicity or country of birth (60%) was the most important risk factor for HTLV infection in accepted blood donors in Australia.

Characteristics	2009	2010	2011	2012	2009-2012
Number of positive donors	9	2	3	2	16
Number of positive first time donors (%)	8 (89%)	1 (50%)	3 (100%)	2 (100%)	14 (94%)
% male	6 (67%)	1 (50%)	1 (33%)	2 (100%)	9 (60%)
Mean age (range) in years	38 (18 to 65)	70 (70)	38 (23 to 46)	32 (27 to 37)	40 (18 to 70)
Number of seroconverters	0	1	0	0	1
% born in Australia	3 (33%)	0 (0%)	0 (0%)	0 (0%)	3 (20%)
Main reported risk factor	Ethnicity/COB	Ethnicity/COB	Ethnicity/COB	Ethnicity/COB	Ethnicity/COB
	44%	50%	66%	100%	60%
Second reported risk factor	BTR ¹ ,HHC ² ,HCE ³ each	-	Tattoo/Body piercing	-	BTR,HHC,HCE,PRP4 each
	11%		33%		7%

Table 7	Attributes of donors positive for HTLV infection by year of donation, 2009-2012
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1 BTR= Blood/tissue recipient

2 HHC=Household contact

3 HCE=Exposure in healthcare setting

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

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).

Consistent with previous years, the most frequent risk factor for HBV positive donors was ethnicity or country of birth which accounted for 89% of the HBV positive donors in 2012. 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^{9,10,11}.

The most frequent risk factor for HCV infection in blood donors in 2012 was tattoo or body piercing, followed by intravenous drug use. In comparison, intravenous drug use and sexual contact were the two most important risk factors for newly acquired HCV infection in the general population in 2012. Nonetheless, the proportion of individuals reporting intravenous drug use among newly acquired HCV infections in the general population¹² (56%) was comparatively higher than in the donor population (23.1%), reflecting the impact of the Blood Services' permanent deferral for intravenous drug use.

As in previous years, the majority of the newly diagnosed HIV infection in the general population was attributed to sexual contact (76.8%). This was consistent with the findings among blood donors, where sexual contact was identified as the primary risk factor for all of the three HIV-positive blood donors in 2012.

⁹ Nguyen VTT, Razali K, Amin J, Law MG, 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(6):922-9.

¹⁰ O'Sullivan BG, Gidding HF, Law M, Kaldor JM, Gilbert GL, Dore GJ. Estimates of chronic hepatitis B virus infection in Australia, 2000. Australian and New Zealand Journal of Public Health. 2004;28(3):212-6.

¹¹ Williams S, Vally H, Fielding J, Cowie B. Hepatitis B prevention in Victoria, Australia – the potential to protect. *Euro Surveillance*. 2011;16(22):pii: 19879.

¹² The Kirby Institute. op. cit.

Due to the scarcity of reliable data on prevalence of key risk factors for HTLV in the Australian population, no meaningful comparison was possible. However, HTLV 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 China¹³. This is consistent with our finding that ethnicity or country of birth was the infective risk in both of the HTLV positive donors in 2012.

	HBV ¹		HC\	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	15.5%	0.0	56.0%	23.1	2.2%	0.0	-	0.0	
Country of birth/Ethnicity	-	88.5	-	5.5	8.6%	0.0	-	100.0	
Sexual contact ³	10.4%	4.4	1.9%	6.6	76.8%	100.0	-	0.0	
Blood or tissue recipient Tattoo or body piercing Exposure in health care setting	_ 0.5% 2.1%	0.0 2.7 1.8	-	5.5 30.8	0.4%	0.0 0.0 0.0	- - -	0.0 0.0 0.0	
			1.3%		-				
			0.0%	5.5	_				
Household contact	2.1%	2.7	0.0%	5.5	-	0.0	-	0.0	
Other blood to blood contact	-	0.0	-	4.4	0.3%	0.0	-	0.0	
Other/undetermined	69.4%	0.0	40.8%	3.3	11.7%	0.0	-	0.0	
No risk factors identified	_	0.0	-	4.4	_	0	_	0	
Not reported	_	0.0	-	5.5	-	0	-	0	

Table 8 Comparison between positive blood donors and the general population in Australia by infection and major risk categories, 2012

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

Non-compliance among positive donors

About one-fifth of the positive donors in 2009-2012 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). This is termed 'non-compliance' with donor selection guidelines and the Blood Service remains highly committed to minimise it by developing improved methods of 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 a donor with a history of risk behaviour for a transfusion-transmissible infection donates blood within the window period, there is a very small but real possibility that infection is not detected by testing and the blood is included in the blood supply. Secondly, even when successfully detected 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.

¹³ Verdonck K, González E, Van Dooren S, Vandamme A-M, Vanham G, Gotuzzo E. Human T-lymphotropic virus 1: recent knowledge about an ancient infection. *The Lancet Infectious Diseases*. 2007;7(4):266-81

Table 9 Non-compliance rate among donors who were positive for HBV, HCV, HIV and HTLV, and reason for non-compliance, 2009-2012

2009	2010	2011	2012	2009-2012					
		Number (%) of non-compliant donors by reasons for deferral							
47 (77)	30 (66.7)	15 (55.6)	21 (52.5)	113 (65.3)					
(16.4)	8 (17.8)	8 (29.6)	13 (32.5)	39 (22.5)					
1 (1.6)	2 (4.4)	0 (0)	0	3 (1.7)					
3 (4.9)	1 (2.2)	3 (11.1)	4 (10)	11 (6.4)					
0 (0)	4 (8.9)	1 (3.7)	2 (5)	7 (4)					
(23.6)	45 (20.4)	27 (12.9)	40 (19.1)	173					
	(16.4) 1 (1.6) 3 (4.9) 0 (0)	(16.4) 8 (17.8) 1 (1.6) 2 (4.4) 3 (4.9) 1 (2.2) 0 (0) 4 (8.9)	(16.4) 8 (17.8) 8 (29.6) 1 (1.6) 2 (4.4) 0 (0) 3 (4.9) 1 (2.2) 3 (11.1) 0 (0) 4 (8.9) 1 (3.7)	(16.4) 8 (17.8) 8 (29.6) 13 (32.5) 1 (1.6) 2 (4.4) 0 (0) 0 3 (4.9) 1 (2.2) 3 (11.1) 4 (10) 0 (0) 4 (8.9) 1 (3.7) 2 (5)					

1 Includes history of hepatitis not further specified

During 2009-2012, a total of 173 TTI positive donors were identified as non-compliant with at least one donor deferral criterion according to current Australian donor selection guidelines. The rate of non-compliance in TTI positive donors appears to have been stable for the past decade in the range 20-25%. The rate observed in the previous Blood Service study¹⁴ for 2000-2006 was 22% and the number of donors and rates for 2008, 2009, 2010 and 2011 were 67 (24.4%), 61 (23.6%), 45 (20.4%) and 27 (12.9%) respectively. 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. However, it has increased to 19.1% in 2012. Consistent with previous years, more than half (52.5%) of non-compliant positive donors in 2012 had a history of injecting drug use, which is a permanent donor deferral criterion in Australia irrespective of time since last episode of injection. Overall, during the period of 2009-2012, 65.3% of non-compliance was attributed to injecting drug use followed by known status of previously being positive for a virus (22.5%), having a sexual partner with known risk or known to be positive for any transfusion-transmissible infection (6.4%) and male-to-male sexual contact within the last 12 months (1.7%).

Non-compliance among negative donors

While the rate of non-compliance among Australian donors with transfusion-transmissible infections has been known since 2000, the rate of non-compliance among TTI-negative donors was unidentified until recently. This rate is the more important because recently infected, window period donors (who would test negative) pose the greatest risk if they fail to self-defer. Anonymous surveys of donors in Hong Kong and Canada^{15,16} estimated non-compliance to deferral questions relating to male-to-male sex among male donors to range from 0.8-2.3%.

In order to estimate the non-compliance rate to existing sexual activity-based deferrals in Australia, the Blood Service, in partnership with the Kirby Institute, has recently conducted an anonymous donor survey. The survey was conducted online between November 2012 and April 2013, targeting a nationally representative sample of donors who had recently made a successful donation. This large, anonymous survey of over 30 000 Australian blood donors confirmed that non-compliance to sexual activity-based questions is comparatively low, ranging from 0.05 to 0.29% per question. Non-compliance to the male-to-male sex deferral question which has been the subject of the majority of international research and controversy was 0.23%¹⁷. This is markedly lower than the published international studies ranging from 0.8-2.3% - all of which were conducted in countries with permanent deferrals in contrast to the 12-month deferral applicable in Australia.

¹⁴ Polizzotto. op. cit.

¹⁵ Lee C-K, Lee KC-K, Lin C-K, Lee S-S. Donors' perspectives on self-deferral of men having sex with men from blood donation. *Transfusion*. 2013; Article first published online: 9 AUG 2013. DOI: 10.1111/trf.12365.

¹⁶ Goldman M, Yi Q-L, Ye X, Tessier L, O'Brien SF. Donor understanding and attitudes about current and potential deferral criteria for high-risk sexual behavior. *Transfusion*. 2011;51(8):1829-34.

¹⁷ Seed CR, Lucky TT, Waller D, Wand H, Lee JF, Wroth S, McDonald A, Pink J, Wilson DP, Keller AJ. Compliance with the current 12-month deferral for male-to-male sex in Australia. *Vox Sang.* 2013.DOI: 10.1111/Vox 12093

Seroconverters

The Blood Service uses the rate of viral seroconversion as a measure of the incidence rate of newly acquired infection in donors which correlates directly with the risk of transmission. During 2005-2012, a total of 112 donors whose previous donation tested negative were positive for that transfusion-transmissible viral infection, designating them as 'seroconverters'. Consistent with 2008-2011, the highest number of viral seroconversions in 2012 occurred for HCV (12 out of 14), accounting for almost 86% of all viral seroconverters. There was a single HIV and HBV seroconversion but none recorded for HTLV.

Similar to the findings from previous years, seroconverters in 2012 were disproportionately male (71.43%). However, unlike 2011, the majority were Australian born (78.57%). The mean age of seroconverters in 2012 was 44 years (53 years for HBV, 46 years for HCV and 19 years for HIV).

Viral residual risk estimates

The rate of viral seroconversion 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 HBV residual risk in Australia results from donors with OBI.¹⁸

Using viral testing data including the number of seroconversions reported for the 2011 and 2012 calendar year periods and applying these to four published risk models, residual risk estimates¹⁹ (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 538 000 compares favourably with estimates from developed countries and is considered 'minimal' on the risk scale, roughly equating with the 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.

Based on the estimates and assuming approximately 1.3 million donations collected per annum, two to three transfusion-transmissions (most likely HBV) would be predicted per annum. The 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 2005-2012 period.

	HBV	HCV	HIV	HTLV	Active syphilis
Estimated rate of collecting infectious unit (per million donations)	<1	<1	<1	<1	<1
Residual Risk to recipient - per unit transfused	Approximately 1 in 538 000	Less than 1 in 1 million			

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 (2011-2012)

Testing for malaria

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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 infection²⁰. 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

¹⁸ Seed CR, 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 Sang.* 2013. doi: 10.1111/vox.12060.

¹⁹ Seed CR, Kiely P, Keller AJ. Residual risk of transfusion transmitted human immunodeficiency virus, hepatitis B virus, hepatitis C virus and human T lymphotrophic virus. *Internal Medicine Journal*. 2005;35(10):592-8.

²⁰ Seed CR, Kee G, Wong T, Law M, Ismay S. Assessing the safety and efficacy of a test-based, targeted donor screening strategy to minimize transfusion transmitted malaria. *Vox Sanguinis*. 2010;98(3p1):e182-e92.

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 malaria antigen and malaria DNA to exclude current infection. Donors positive for one or both supplementary tests are immediately referred for clinical assessment.

In 2012, 120 415 donations were tested for malaria antibody of which 2 866 (2.4%) were found to be repeat reactive for malaria antibodies. None of these 2 866 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 000²¹ for platelets and 1:500 000²² 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.²³ Between 1:1 000 and 1:3 000 platelet units are bacterially contaminated at the time of transfusion which in the absence of screening is estimated to cause life-threatening sepsis in between 10-40% of recipients.

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

1. Pre-donation health screening

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

2. Donor skin disinfection

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

3. Flow diversion techniques

The Blood Service diverts the initial 30mL of blood away from the collection bag which has been shown to reduce the bacterial load in blood components by up to 70%.²⁴

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.²⁵

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

²¹ Eder A, Kennedy JM, Dy BA, Notari EP, Weiss JW, Fang CT, 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(7):1134-1142.

²² Kuehnert MJ, Roth VR, Haley NR, Gregory KR, Elder KV, Schreiber GB, et al. Transfusion-Transmitted Bacterial Infection in the United States, 1998 through 2000. *Transfusion* 2001;41(12):1493-1499.

²³ Wood E: Prevention of bacterial contamination, including initial flow diversion. ISBT Science Series. 2009;4: p. 221-229.

²⁴ 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: p. 2152-2157.

²⁵ Borosak M, Wood E: Bacterial Pre-Release Testing of Platelets - the Australian Red Cross Blood Service Clinical Experience. *Transfusion medicine* and hemotherapy 2011;38: p. 239-241.

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.

During 2012, 124 201 platelet units were screened for bacterial contamination (table 11). Of the 34 749 apheresis units tested 373 (1.07%) were flagged as initially positive however only 15 (0.04%) were determined as 'confirmed positive' with an additional 30 (0.08%) classified as 'indeterminate'. The remaining 328 (0.94%) were classified as 'false positive' predominantly associated with anaerobic culture bottles. There were 89 452 pooled platelet units tested of which 1 106 (1.23%) flagged as initially positive with 123 (0.14%) determined as 'confirmed positive'. A further 99 (0.11%) were classified as 'indeterminate' and the remaining 884 (0.98%) were classified as 'false positive'.

Table 11 Summary of bacterial testing of platelets by BacT/ALERT, 2012

Platelet type	No. components Screened	No. Initial positive ¹ (%)	No. confirmed ² positive (%)	No. indeterminate ³ (%)	No. false positive⁴ (%)	
Pooled platelets	89 452	1 106 (1.23)	123 (0.14)	99 (0.11)	884 (0.98)	
Apheresis platelets	34 749	373 (1.07)	15 (0.04)	30 (0.09)	328 (0.94)	
Total	124 201	1 479 (1.19)	138 (0.11)	129 (0.1)	1 212 (0.98)	

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 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 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

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.

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 *Staphylococcus aureus, Staphylococcus epidermis, Campylobacter fetus, Aeromonas* sp. and *Serratia marcescens*, all 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 skin source in the donor. *Enterococcus faecalis* and *Streptococcus* spp. on the other hand are associated with subacute bacterial endocarditis, and occult bacteraemia would not be uncommon.

During 2012 no cases of septic transfusion reactions were identified in patients who received platelets. However, there was one recorded case of transfusion-associated bacterial sepsis associated with a red cell transfusion from which Staphylococcus epidermis was cultured from the red cell unit. The patient received a red cell transfusion for post-operative anaemia and developed fever but was otherwise stable. The transfusion was ceased. The patient received a course of antibiotics and subsequently recovered from this infection. Both the patient and the red cell pack were cultured and grew *Staphylococcus epidermis*, with the same antibiotic sensitivity profile. No pooled platelet was manufactured from this collection so no pre-release bacterial testing was performed.

Table 12 Summary of bacterial organisms detected in confirmed positives, 2012

Confirmed Positive organisms	Number
Campylobacter fetus	1
Coagulase Negative Staphylococci	14
Propionibacterium spp.	112
Streptococcus spp. ¹	2
Viridans-group Streptococci	1
Staphylococcus aureus	1
Enterococcus faecalis	2
Serratia marcescens	1
Aeromonas sp.	1
Mixed organisms	3
Total	138

1 Other than viridans-group Streptococci

All donors associated with platelets growing clinically significant organisms were followed up and referred for clinical investigation where required. The importance of donor follow-up was highlighted by one case involving the isolation of *Enterococcus faecalis* from a pooled platelet. Subsequent investigation determined that one of the four donors used to manufacture the pooled platelet had subacute bacterial endocarditis. It is noteworthy that bacterial contamination screening by the Blood Service facilitated the early diagnosis and treatment of this donor's life-threatening condition.

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).

2012 summary

Dengue outbreaks in Queensland

Dengue virus transmission by fresh blood components has been demonstrated and thus poses a risk to transfusion safety²⁶. During 2012 there were four dengue fever outbreaks, two each in Cairns and Townsville. The Cairns outbreaks were in Manunda during February/March (7 confirmed cases) and Mt Sheridan beginning in November (3 cases by the end of December). The Townsville outbreaks were in Mundingburra (1 case in February) and Heatley (7 cases in May/June). To mitigate this risk, supplementary donor selection measures and product restrictions were implemented for travel to/residence in affected regions i.e. Mundingburra and Heatley in Townsville and the Cairns suburbs of Mt Sheridan and Manunda. 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 by blood, tissue and organ transplantation has been documented²⁷. 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 2012 transmission season (July to November) in the EU and neighbouring countries there were outbreaks of WNV fever in Greece, Israel, Italy, Montenegro, Russia, Serbia, Tunisia and the Ukraine. The largest outbreaks were in Greece (161 reported cases of WNV fever) and Russia (399 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

²⁶ Teo D, Ng LC, Lam S. Is dengue a threat to the blood supply? Transfusion Medicine. 2009;19(2):66-77.

²⁷ Petersen LR, Busch MP. Transfusion-transmitted arboviruses. Vox Sanguinis. 2010;98(4):495-503.

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 2012 WNV transmission season did not exceed the threshold (established for local dengue outbreaks) that requires cessation of fresh blood component manufacture.

Xenotropic murine leukaemia virus-related virus

Xenotropic murine leukaemia virus-related virus (XMRV) was initially identified in patients with prostate cancer and this finding was supported by some initial studies reporting the detection of XMRV genomic sequences in prostate cancer patients. As well, in 2009 a report was published indicating that XMRV was associated with chronic fatigue syndrome (CFS). However, subsequent studies have not supported an association between XMRV and prostate cancer or CSF and by the end of 2011 the scientific consensus was that the association, if any, between XMRV and CFS has not been established and the initial findings of XMRV genomic sequences may have been due to laboratory contamination. In 2012 two definitive studies demonstrated that there was no evidence for an association between XMRV and either CSF²⁸ or prostate cancer²⁹, and that XMRV is a laboratory contaminant and not a naturally acquired human infection. As a precaution against the possibility that CFS may be caused by an unidentified transfusion-transmissible pathogen, the Blood Service continues to defer donors with current symptoms of CFS and donors with a history of CSF.

Hendra virus

Human Hendra virus (HeV) infection is an emerging Australian zoonotic disease associated with high mortality (4/7 infections fatal)³⁰. 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 2012, there were approximately 10 equine cases across properties in Townsville, Cairns, Ingham, Mackay, Port Douglas and Rockhampton. 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) encouraged 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.

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 horses³¹. Transfusion transmission has not been reported but is theoretically possible and as a precautionary measure the Blood Service permanently excludes donors with HeV infection. In addition, contacts of infected horses are notified that they should not donate blood for a period of at least 6 weeks and thereafter are required to provide documented evidence of lack of anti-HeV seroconversion before being accepted to donate.

Middle East respiratory syndrome coronavirus (MERS-CoV)

Human cases of infection with a novel coronavirus, now referred to as Middle East respiratory syndrome coronavirus (MERS-CoV) was first reported by WHO in September 2012. 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. Most cases have been characterised by severe respiratory illness presenting as pneumonia, and a proportion have developed renal failure. The route of MERS-CoV transmission has not yet been established. However, initial data suggests a zoonotic origin. Evidence also indicates that, to a limited extent, MERS-CoV can be transmitted between humans. To date human-to-human transmission has only been observed in health care facilities and close family contacts. Sustained transmission within communities has not been observed.

By the end of 2012 there had been 9 reported human cases of MERS-CoV, 5 of which were in Saudi Arabia, 2 cases in Qatar and 2 in Jordan. Transfusion transmission of MERS-CoV has not been reported. However, given that infection includes a viraemic phase, the possibility of asymptomatic viraemia and potential transfusion transmission cannot be excluded. The current risk posed by MERS-CoV to Australia's blood safety appears to be very low. The Blood Service

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²⁸ Alter H, et al. - Alter HJ, et al. 2012. A multicenter blinded analysis indicates no association between chronic fatigue syndrome/myalgic encephalomyelitis and either xenotropic murine leukemia virus-related virus or polytropic murine leukemia virus. *mBio* 3(5):e00266-12. doi:10.1128/mBio.00266-12.

²⁹ Lee et al. - Lee D, Das Gupta J, Gaughan C, Steffen I, Tang N, et al. (2012) In-Depth Investigation of Archival and Prospectively Collected Samples Reveals No Evidence for XMRV Infection in Prostate Cancer. *PLoS ONE* 7(9): e44954. doi:10.1371/journal.pone.0044954

³⁰ Young JR, Selvey CE, Symons R. Hendra virus. MJA. 2011;195(5):250-1.

³¹ Tulsiani SM, Graham GC, Moore PR, Jansen CC, Van Den Hurk AF, Moore FAJ, et al. Emerging tropical diseases in Australia. Part 5. Annals of Tropical Medicine and Parasitology, 2011. 105(1): p. 1-11.

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.³²

Cedar virus

The isolation and characterisation of a new paramyxovirus from pteropid bats in Australia, Cedar virus (CedPV) was reported. Genomic analysis indicated that CedPV shares significant features with the known henipaviruses, Nipah virus (NiV) and Hendra virus (HeV). While no disease association was reported, the authors noted that the discovery of another henipavirus in Australian flying foxes highlights the importance of bats as a significant reservoir of potential zoonotic agents and the need to expand our understanding of virus-bat relationships in general. It remains to be determined whether spill-over of CedPV into other hosts has occurred in the past in Australia, whether CedPV is pathogenic in certain mammalian hosts, and whether CedPV exists in bat populations in geographically diverse regions.³³

³² World Health Organisation. Global Alert and Responses. Coronavirus infections. http://www.who.int/csr/disease/coronavirus_infections/en/index.html

³³ Marsh GA, de Jong C, Barr JA, Tachedjian M, Smith C, et al. (2012) Cedar Virus: A Novel Henipavirus Isolated from Australian Bats. *PLoS Pathog* 8(8): e1002836. doi:10.1371/journal.ppat.1002836





- 1. Supporting the effectiveness of donor education and selection, the prevalence of transfusion-transmissible infections is substantially lower among both first time blood donors (11 to 67 times) and all donors (106 to 495 times) than in the general population in 2012 and shows a stable or declining trend since 2005.
- 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 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 viral seroconversion in repeat blood donors is also much lower than in the general population. 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. Almost one-fifth of the positive donors in 2009-2012 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. While the non-compliance rate of 20-25% declined gradually during 2008-2011 to its lowest ever level in 2011 (12.9%), in 2012 it returned to 19.1%. Understanding the reasons for and minimising the rate of non-compliance is important because it reduces 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, no such data existed for TTI test negative donors. Results from a recently conducted large national survey 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. Non-compliance with the 12-month deferral for male-to-male sex, which is the subject of the majority of international research and controversy, showed a non-compliance rate of 0.23%. This is markedly lower than the published overseas studies which range from 0.8-2.3%. 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.
- 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 538 000) 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 124 241 platelets identified 138 (0.11%) as confirmed positive. The majority of organisms identified were slow-growing anaerobic skin flora not usually associated with post-transfusion septic reactions. However, a minority of platelets grew clinically-significant organisms which were likely to have been due to transient or occult bacteraemia in the donor and could have led to potentially serious septic transfusion reactions in the recipient. During 2012 one such transfusion-associated bacterial infection was identified associated with a transfused red cell unit from which *Staphylococcus epidermis* was cultured. There was no platelet associated with the source whole blood donation and therefore bacterial testing was not performed. The patient developed a fever and the transfusion was ceased. They received a course of antibiotics and subsequently recovered from the infection. The importance of routinely following up donors with confirmed positive results was highlighted by early diagnosis and treatment of a donor with subacute bacterial endocarditis.
- 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 spread of dengue virus was highlighted in 2012 by the first recorded outbreak of locally acquired cases on Madeira. While the world's first commercially available vaccine against Hendra virus was launched in Australia in late 2012, the isolation and characterisation of a novel henipavirus (Cedar virus) in Australian bats was reported. The new virus is closely related to the Hendra virus but disease association and host range have not been determined. In the Middle East, a human novel coronavirus referred to as Middle East respiratory syndrome coronavirus (MERS-CoV) was reported. MERS-CoV has raised concerns as it is related to SARS-CoV and also causes acute respiratory syndrome.





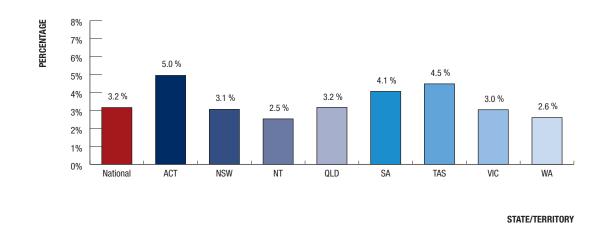
Supporting figures

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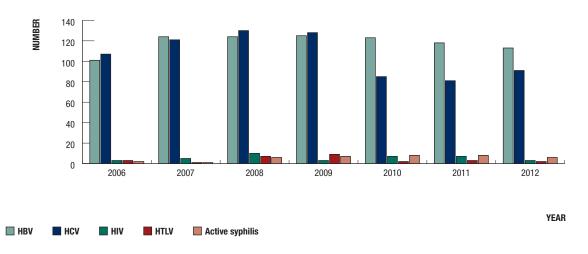
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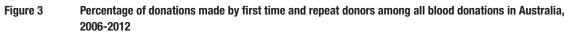
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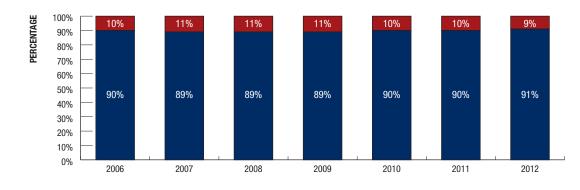


Percentage of age-eligible general population who donated blood in 2012, by state/territory









📕 First time 📃 Repeat

32

Figure 1

YEAR

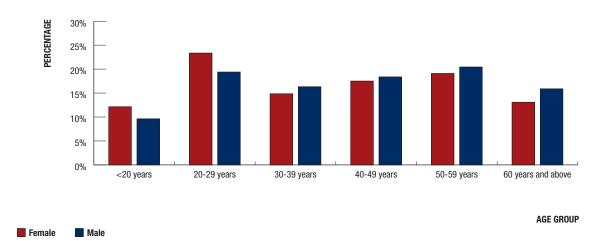
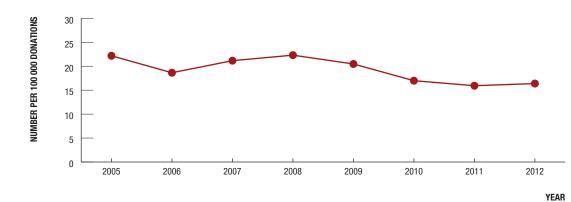
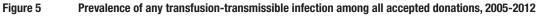
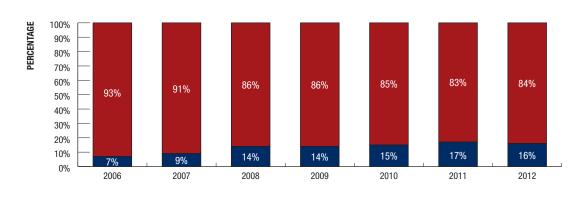


Figure 4 Distribution of blood donors in Australia by age group and sex, 2012







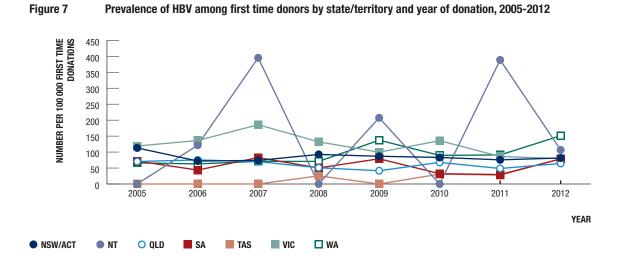
Percentage of first time and repeat donations among all positive blood donations in Australia, 2006-2012

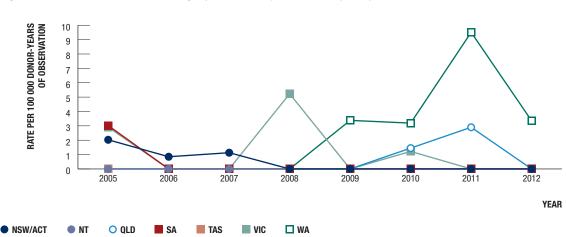
First time

Figure 6

Repeat

YEAR











34

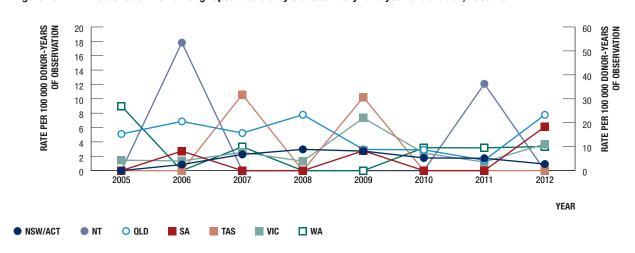


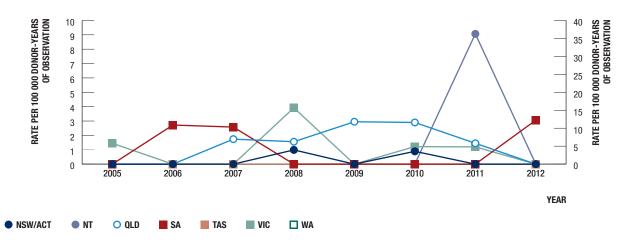
Figure 10 Incidence of HCV among repeat donors by state/territory¹ and year of donation, 2005-2012

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



Figure 11 Prevalence of HIV among first time donors by state/territory and year of donation, 2005-2012



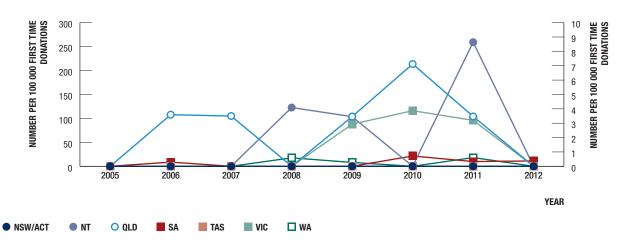


1 HIV incidence in NT provided according to the scale on the secondary axis on the right hand side.



Prevalence of HTLV among first time donors by state/territory and year of donation, 2005-2012

Figure 14 Prevalence of active syphilis among first time donors by state/territory¹ and year of donation, 2005-2012



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



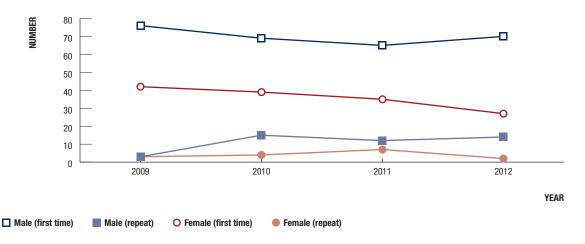


Figure 13

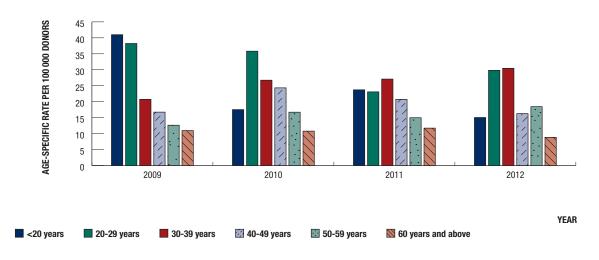


Figure 16 Rate of HBV infection among blood donors by age group and year of donation, 2009-2012

Figure 17 Donors with HBV infection by region of birth, 2012 (n=113)

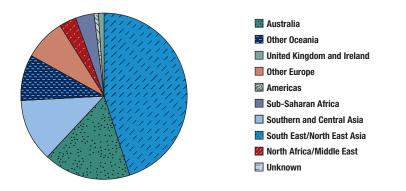
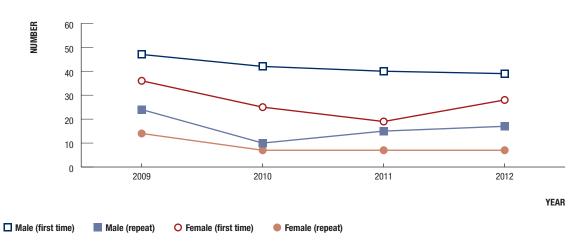


Figure 18 Donors with HCV infection by sex and donor status, 2009-2012



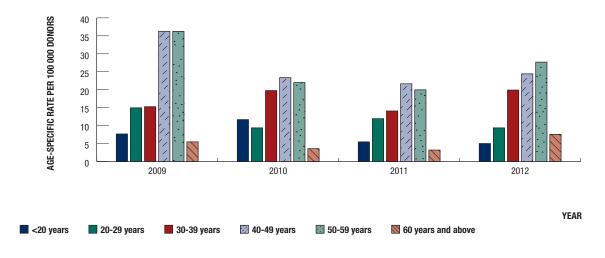
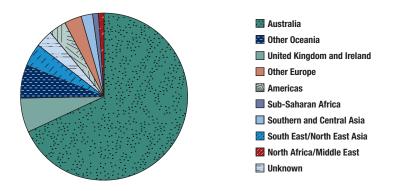
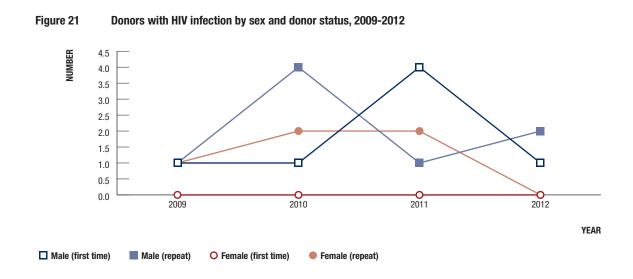


Figure 19 Rate of HCV infection among blood donors by age group and year of donation, 2009-2012

Figure 20 Donors with HCV infection by region of birth, 2012 (n=91)





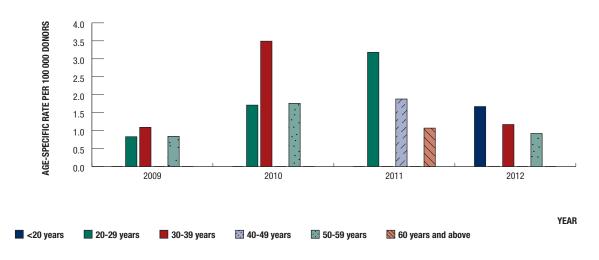


Figure 22 Rate of HIV infection among blood donors by age group and year of donation, 2009-2012



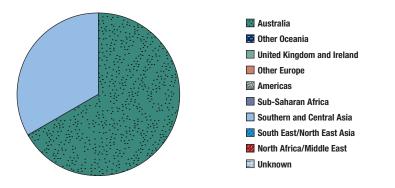
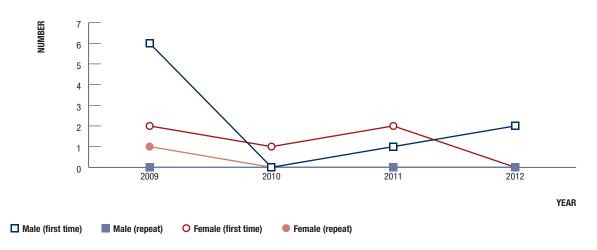


Figure 24 Donors with HTLV infection by sex and donor status, 2009-2012



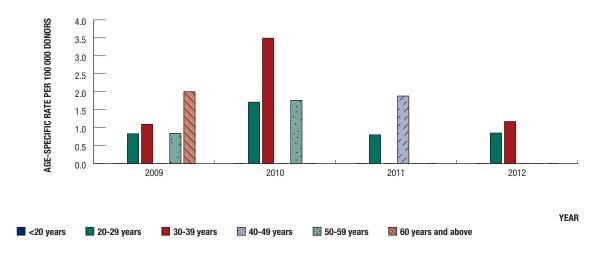
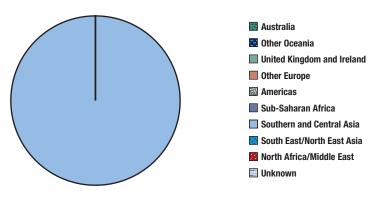


Figure 25 Rate of HTLV infection among blood donors by age group and year of donation, 2009-2012

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Transfusion- Transmissible infection	Mandatory screening tests	Test Target	Year of introduction	Median window period estimate	Estimated risk of window period donation (per million transfusion)
Syphilis	<i>Treponema pallidum</i> Haemagglutination Assay (TPHA)	Antibodies to Treponema pallidum	~1949	45 days	<1 in 1 million
	HBsAg ¹	Hepatitis B surface antigen (HBsAg)	1970	38 days	-
HBV	Nucleic Acid Test for HBV	HBV DNA	2010	23.9 days	Approx. 1 in 538 000
	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	_
ніх	Nucleic Acid Test for HIV-1 ²	HIV-1 RNA	2000	5.6 days	<1 in 1 million
	anti-HCV ¹	Antibody to HCV	1990	66 days	-
нси	Nucleic Acid Test for HCV 2	hepatitis C RNA	2000	3.1 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

Table 1 Screening tests for transfusion-transmissible infections

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 by Novartis HIV-1/HCV/HBV Procleix Ultrio assay using a fully automated testing system (Procleix Tigris).

Table 2 The number and rate of transfusion-transmissible infections in Australia by type of donations and state/territory, 2005-2012

	All a	ccepted dona	tions		HBV			HCV			ні			HTLV			Syphilis			Total positi donations	
State/Territory of donation	First time	Repeat	All	First time	Repeat	All	First time	Repeat	All	First time	Repeat	AII	First time	Repeat	All	First time	Repeat	AII	First time	Repeat	All
NSW/ACT	380 271	2 842 493	3 222 764	324	29	353	310	33	343	5	3	8	5	1	6	0	5	5	644	71	715
Number (Number per 100 000 donations)				85.2	1.02	10.95	81.52	1.16	10.64	1.31	0.11	0.25	1.31	0.04	0.19	0	0.18	0.16	169.35	2.5	22.19
NT	7 011	80 821	87 832	10	1	11	6	2	8	0	1	1	0	0	0	4	2	6	20	6	26
Number (Number per 100 000 donations)				142.63	1.24	12.52	85.58	2.47	9.11	0	1.24	1.14	0	0	0	57.05	2.47	6.83	285.27	7.42	29.6
QLD	223 640	1 827 588	2 051 228	135	12	147	171	38	209	8	7	15	5	0	5	6	2	8	325	59	384
Number (Number per 100 000 donations)				60.36	0.66	7.17	76.46	2.08	10.19	3.58	0.38	0.73	2.24	0	0.24	2.68	0.11	0.39	145.32	3.23	18.72
SA	87 751	929 561	1 017 312	51	7	58	46	13	59	0	3	3	3	0	3	5	0	5	105	23	128
Number (Number per 100 000 donations)				58.12	0.75	5.7	52.42	1.4	5.8	0	0.32	0.29	3.42	0	0.29	5.7	0	0.49	119.66	2.47	12.58
TAS	27 337	284 441	311 778	6	0	6	18	3	21	0	0	0	0	0	0	0	1	1	24	4	28
Number (Number per 100 000 donations)				21.95	0	1.92	65.84	1.05	6.74	0	0	0	0	0	0	0	0.35	0.32	87.79	1.41	8.98
VIC	213 777	2 104 393	2 318 170	254	16	270	141	21	162	5	6	11	9	0	9	3	2	5	412	45	457
Number (Number per 100 000 donations)				118.82	0.76	11.65	65.96	1	6.99	2.34	0.29	0.47	4.21	0	0.39	1.4	0.1	0.22	192.72	2.14	19.71
WA	87 255	900 896	988 151	81	12	93	58	10	68	2	0	2	5	0	5	5	4	9	151	26	177
Number (Number per 100 000 donations)				92.83	1.33	9.41	66.47	1.11	6.88	2.29	0	0.2	5.73	0	0.51	5.73	0.44	0.91	173.06	2.89	17.91
National	1 027 042	8 970 193	9 997 235	861	77	938	750	120	870	20	20	40	27	1	28	23	16	39	1 681	234	1 915
Number (Number per 100 000 donations)				83.83	0.86	9.38	73.03	1.34	8.7	1.95	0.22	0.4	2.63	0.01	0.28	2.24	0.18	0.39	163.67	2.61	19.16

 Table 3
 Number and prevalence¹ of HBV infection among first time donors, 2006-2012, by state/territory and year of donation

		2006			2007			2008			2009	
State/ Territory	Donations	Positive	Rate									
NSW/ACT	44 499	32	71.91	51 427	38	73.89	48 607	45	92.58	51 821	45	86.84
NT	823	1	121.51	759	3	395.26	815	0	0.00	965	2	207.25
QLD	27 873	21	75.34	28 575	20	69.99	29 498	15	50.85	28 889	12	41.54
SA	11 457	5	43.64	10 886	9	82.67	15 908	8	50.29	11 400	9	78.95
TAS	2 899	0	0.00	2 650	0	0.00	3 936	1	25.41	3 736	0	0.00
VIC	22 016	30	136.26	23 172	43	185.57	30 286	40	132.07	34 133	34	99.61
WA	11 116	7	62.97	11 292	8	70.85	11 307	8	70.75	12 387	17	137.24
Total	120 683	96	79.55	128 761	121	93.97	140 357	117	83.36	143 331	119	83.02

		2010			2011			2012		Tot	tal 2006-2012	
State/ Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate
NSW/ACT	48 130	40	83.11	51 528	42	81.51	41 780	34	81.38	337 792	276	81.71
NT	799	0	0.00	772	3	388.60	937	1	106.72	5 870	10	170.36
QLD	28 097	19	67.62	28 839	13	45.08	24 881	16	64.31	196 652	116	58.99
SA	9 284	3	32.31	10 164	3	29.52	8 900	7	78.65	77 999	44	56.41
TAS	3 222	1	31.04	3 587	1	27.88	3 823	3	78.47	23 853	6	25.15
VIC	25 820	35	135.55	31 286	27	86.30	27 718	22	79.37	194 431	231	118.81
WA	11 149	10	89.69	10 992	10	90.98	9 925	15	151.13	78 168	75	95.95
Total	126 501	108	85.37	137 168	99	72.17	117 964	98	83.08	914 765	758	82.86

1 Rate per 100 000 first time donations

 Table 4
 Number and rate¹ of HBV infection among repeat donors, 2006-2012, by state/territory and year of donation

		2006			2007			2008			2009	
State/ Territory	Donations	Positive	Rate									
NSW/ACT	333 250	5	1.50	338 173	3	0.89	339 062	1	0.29	372 806	1	0.27
NT	8 496	0	0.00	10 214	0	0.00	11 166	0	0.00	11 158	0	0.00
QLD	216 496	0	0.00	209 556	0	0.00	226 726	1	0.44	242 001	1	0.41
SA	107 934	0	0.00	114 618	0	0.00	118 476	1	0.84	126 855	0	0.00
TAS	28 726	0	0.00	28 019	0	0.00	33 321	0	0.00	37 274	0	0.00
VIC	238 684	0	0.00	252 340	0	0.00	259 052	4	1.54	276 835	1	0.36
WA	99 376	0	0.00	109 425	0	0.00	113 274	0	0.00	118 327	3	2.54
Total	1 032 962	5	0.48	1 062 345	3	0.28	1 101 077	7	0.64	1 185 256	6	0.51

		2010			2011			2012		Tot	tal 2006-2012	
State/ Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate
NSW/ACT	380 014	4	1.05	390 455	5	1.28	377 220	6	1.59	2 530 980	25	0.99
NT	10 470	1	9.55	10 782	0	0.00	9 673	0	0.00	71 959	1	1.39
QLD	243 837	3	1.23	245 975	3	1.22	237 599	4	1.68	1 622 190	12	0.74
SA	123 587	3	2.43	124 199	2	1.61	120 720	0	0.00	836 389	6	0.72
TAS	41 484	0	0.00	44 661	0	0.00	46 379	0	0.00	259 864	0	0.00
VIC	278 897	3	1.08	288 085	4	1.39	285 168	2	0.70	1 879 061	14	0.75
WA	120 646	1	0.83	121 057	5	4.13	117 728	3	2.55	799 833	12	1.50
Total	1 198 935	15	1.25 ²	1 225 214	19	1.55 ²	1 194 487	15	1.26 ²	8 000 276	70	0.87

1 Rate per 100 000 repeat donations

2 The increase is attributed to the introduction of HBV NAT which identified additional acute HBsAg negative and chronic occult HBV cases

	Yea	ar of donatio	on									
_	200	09	20 ⁻	10	20	11	201	2		2009	-2012	
 Donor status	М	F	М	F	М	F	М	F	М	F	Total	%
First time donors												
<20 years	10	6	5	4	6	7	3	6	24	23	47	9.8
20-29 years	29	16	23	17	17	12	28	7	97	52	149	30.9
30-39 years	12	6	16	6	17	5	18	6	63	23	86	17.8
40-49 years	10	7	15	4	16	4	10	5	51	20	71	14.7
50-59 years	10	3	7	5	5	5	11	2	33	15	48	10.0
60 years and above	5	4	3	3	4	1	0	1	12	9	21	4.4
Repeat donors												
<20 years	0	0	0	0	0	0	0	0	0	0	0	0.0
20-29 years	0	1	0	2	0	0	0	0	0	3	3	0.6
30-39 years	1	0	1	0	3	0	2	0	7	0	7	1.5
40-49 years	1	0	6	0	2	0	1	0	10	0	10	2.1
50-59 years	0	2	6	1	6	2	7	0	19	5	24	5.0
60 years and above	1	0	2	1	3	3	4	2	10	6	16	3.3
Total	79	45	84	43	79	39	84	29	326	156	482	100

Table 5 Number and percentage of donors with HBV infection, 2009-2012, by year of donation, sex and age group

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        Table 6
        Number and percentage of donors with HBV infection, 2009-2012, by year of donation and region of birth<sup>1</sup>
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	200	9	201	0	201	1	201	2	2009-2	2012
Region of birth	Number	%								
Australia	3	33	0	0	0	0	0	0	3	19
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	0	0	0	0	1	33	0	0	1	6
Sub-Saharan Africa	0	0	0	0	0	0	0	0	0	0
South East/North East Asia	1	11	0	0	0	0	0	0	1	6
Southern and Central Asia	2	22	0	0	0	0	2	100	4	25
North America	0	0	0	0	0	0	0	0	0	0
South/Central America and the Caribbean	0	0	1	50	0	0	0	0	1	6
Total with a reported country of birth	6	67	1	50	1	33	2	100	10	63
Not reported	3	33	1	50	2	67	0	0	6	38
Total	9	100	2	100	3	100	2	100	16	100

1 Region of birth from the Australian Bureau of Statistics.

	:	2009	2	2010	:	2011	2	2012		Total (20	009-2012)	
Exposure categories	Male	Female	Total	%								
Ethnicity/Country of birth	63	32	62	34	56	32	66	24	247	122	369	87.4
Intravenous drug user	1	0	0	0	0	0	0	0	1	0	1	0.2
Tattoo/Piercing	1	1	0	0	1	1	0	2	2	4	6	1.4
Partners with any risks or known to be positive	2	2	1	0	1	0	1	1	5	3	8	1.9
Male-to-male sexual contact	0	0	0	0	0	0	0	0	0	0	0	0.0
Exposure in health care setting	1	2	0	0	0	0	0	0	1	2	3	0.7
Engaged in sex work	0	0	0	0	0	0	0	0	0	0	0	0.0
Blood or tissue recipient	1	1	2	1	0	0	0	0	3	2	5	1.2
Household contact	3	4	0	0	0	0	3	0	6	4	10	2.4
Other blood to blood contact	1	0	0	1	0	0	0	0	1	1	2	0.5
Other	1	0	0	0	1	0	0	0	2	0	2	0.5
No risk factors identified	1	0	1	1	0	0	0	0	2	1	3	0.7
Not reported	1	0	3	2	6	1	0	0	10	3	13	3.1
Total	76	42	69	39	65	34	70	27	280	142	422	100

 Table 7
 Number and percentage of HBV infection among first time donors, 2009-2012, by exposure category and sex

Table 8Number and percentage of HBV infection among repeat donors, 2009-2012, by exposure category and sex

	2	2009	2	2010	:	2011	:	2012		Total (20	009-2012)	
Exposure categories	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	Total	%
Ethnicity/Country of birth	0	1	9	1	10	2	8	2	27	6	33	55.0
Intravenous drug user	1	1	1	0	0	0	0	0	2	1	3	5.0
Tattoo/Piercing	0	0	1	0	0	1	1	0	2	1	3	5.0
Partners with any risks or known to be positive	2	0	3	1	1	1	2	0	8	2	10	16.7
Male-to-male sexual contact	0	0	0	0	0	0	0	0	0	0	0	0.0
Exposure in health care setting	0	0	1	1	1	0	2	0	4	1	5	8.3
Engaged in sex work	0	0	0	0	0	0	1	0	1	0	1	1.7
Blood or tissue recipient	0	0	0	0	0	0	0	0	0	0	0	0.0
Household contact	0	1	0	0	0	0	0	0	0	1	1	1.7
Other blood to blood contact	0	0	0	1	0	0	0	0	0	1	1	1.7
Other	0	0	0	0	2	0	0	0	2	0	2	3.3
No risk factors identified	0	0	0	0	0	1	0	0	0	1	1	1.7
Not reported	0	0	0	0	0	0	0	0	0	0	0	0.0
Total	3	3	15 ¹	4	14 ¹	5	14 ¹	2	46	14	60	100

1 The increase is attributed to the introduction of HBV NAT which identified chronic occult HBV cases among repeat donors

Table 9 Number and prevalence¹ of HCV infection among first time donors, 2006-2012, by state/territory and year of donation

		2006			2007			2008			2009	
State/ Territory	Donations	Positive	Rate									
NSW/ACT	44 499	35	78.65	51 427	34	66.11	48 607	50	102.87	51 821	46	88.77
NT	823	2	243.01	759	0	0.00	815	0	0.00	965	1	103.63
QLD	27 873	23	82.52	28 575	31	108.49	29 498	23	77.97	28 889	13	45.00
SA	11 457	6	52.37	10 886	7	64.30	15 908	7	44.00	11 400	10	87.72
TAS	2 899	2	68.99	2 650	1	37.74	3 936	4	101.63	3 736	4	107.07
VIC	22 016	24	109.01	23 172	25	107.89	30 286	18	59.43	34 133	17	49.81
WA	11 116	6	53.98	11 292	7	61.99	11 307	4	35.38	12 387	10	80.73
Total	120 683	98	81.20	128 761	105	81.55	140 357	106	75.52	143 331	101	70.47

		2010			2011			2012		Tot	tal 2006-2012	
State/ Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate
NSW/ACT	48 130	37	76.88	51 528	30	58.22	41 780	30	71.80	337 792	262	77.56
NT	799	1	125.16	772	0	0.00	937	1	106.72	5 870	5	85.18
QLD	28 097	12	42.71	28 839	13	45.08	24 881	21	84.40	196 652	136	69.16
SA	9 284	7	75.40	10 164	4	39.35	8 900	3	33.71	77 999	44	56.41
TAS	3 222	1	31.04	3 587	1	27.88	3 823	1	26.16	23 853	14	58.69
VIC	25 820	14	54.22	31 286	12	38.36	27 718	16	57.72	194 431	126	64.80
WA	11 149	3	26.91	10 992	8	72.78	9 925	6	60.45	78 168	44	56.29
Total	126 501	75	59.29	137 168	68	49.57	117 964	78	66.12	914 765	631	68.98

1 Rate per 100 000 first time donations

 Table 10
 Number and rate¹ of HCV infection among repeat donors, 2006-2012, by state/territory and year of donation

		2006			2007			2008			2009	
State/ Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate
NSW/ACT	333 250	1	0.30	338 173	7	2.07	339 062	11	3.24	372 806	6	1.61
NT	8 496	1	11.77	10 214	0	0.00	11 166	0	0.00	11 158	0	0.00
QLD	216 496	4	1.85	209 556	3	1.43	226 726	8	3.53	242 001	9	3.72
SA	107 934	2	1.85	114 618	0	0.00	118 476	2	1.69	126 855	4	3.15
TAS	28 726	0	0.00	28 019	1	3.57	33 321	0	0.00	37 274	1	2.68
VIC	238 684	1	0.42	252 340	3	1.19	259 052	2	0.77	276 835	7	2.53
WA	99 376	0	0.00	109 425	2	1.83	113 274	1	0.88	118 327	0	0.00
Total	1 032 962	9	0.87	1 062 345	16	1.51	1 101 077	24	2.18	1 185 256	27	2.28

		2010			2011			2012		To	tal 2006-2012	
State/Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate
NSW/ACT	380 014	3	0.79	390 455	3	0.77	377 220	1	0.27	2 530 980	32	1.26
NT	10 470	0	0.00	10 782	1	9.27	9 673	0	0.00	71 959	2	2.78
QLD	243 837	4	1.64	245 975	3	1.22	237 599	5	2.10	1 622 190	36	2.22
SA	123 587	0	0.00	124 199	1	0.81	120 720	2	1.66	836 389	11	1.32
TAS	41 484	0	0.00	44 661	0	0.00	46 379	1	2.16	259 864	3	1.15
VIC	278 897	2	0.72	288 085	2	0.69	285 168	3	1.05	1 879 061	20	1.06
WA	120 646	1	0.83	121 057	3	2.48	117 728	1	0.85	799 833	8	1.00
Total	1 198 935	10	0.83	1 225 214	13	1.06	1 194 487	13	1.09	8 000 276	112	1.40

1 Rate per 100 000 repeat donations

	Yea	r of donatio	n									
_	200)9	201	0	201	1	201	12		2009	-2012	
Donor status	М	F	М	F	М	F	М	F	М	F	Total	%
First time donors												
<20 years	0	3	6	0	2	1	1	2	9	6	15	3.9
20-29 years	10	4	6	3	8	6	7	4	31	17	48	12.6
30-39 years	9	2	9	5	11	2	9	6	38	15	53	13.9
40-49 years	12	13	12	7	12	4	9	4	45	28	73	19.2
50-59 years	14	12	9	8	6	5	12	11	41	36	77	20.3
60 years and above	2	2	0	2	1	1	1	1	4	6	10	2.6
Repeat donors												
<20 years	0	0	1	0	0	0	0	0	1	0	1	0.3
20-29 years	1	3	1	1	1	0	0	0	3	4	7	1.8
30-39 years	3	0	1	2	0	0	2	0	6	2	8	2.1
40-49 years	11	3	3	1	5	2	8	3	27	9	36	9.5
50-59 years	9	7	5	2	8	5	4	3	26	17	43	11.3
60 years and above	1	1	1	1	1	0	3	1	6	3	9	2.4
Total	72	50	54	32	55	26	56	35	237	143	380	100

Table 11 Number and percentage of donors with HCV infection, 2009-2012, by year of donation, sex and age group

 Table 12
 Number and percentage of donors with HCV infection, 2009-2012, by year of donation and region of birth¹

	200	9	201	0	201	1	201	2	2009-2	2012
Region of birth	Number	%								
Australia	90	74	61	71	51	63	62	68	264	69
Overseas born										
Other Oceania	4	3	2	2	4	5	6	7	16	4
United Kingdom and Ireland	5	4	2	2	3	4	6	7	16	4
Other Europe	6	5	5	6	2	2	3	3	16	4
Middle East/North Africa	3	2	1	1	0	0	1	1	5	1
Sub-Saharan Africa	1	1	1	1	0	0	1	1	3	1
South East/North East Asia	7	6	2	2	11	14	4	4	24	6
Southern and Central Asia	4	3	4	5	3	4	2	2	13	3
North America	0	0	1	1	1	1	3	3	5	1
South/Central America and the Caribbean	1	1	2	2	0	0	0	0	3	1
Total with a reported country of birth	121	99	81	94	75	93	88	97	365	96
Not reported	1	1	5	6	6	7	3	3	15	4
Total	122	100	86	100	81	100	91	100	380	100

1 Region of birth from the Australian Bureau of Statistics.

	:	2009	2	2010	:	2011	:	2012		Total (20	009-2012)	
Exposure categories	Male	Female	Total	%								
Ethnicity/Country of birth	7	2	8	2	10	1	3	2	28	7	35	14.5
Intravenous drug user	19	10	10	4	7	2	10	4	46	20	66	27.4
Tattoo/Piercing	5	9	8	7	8	3	0	0	21	19	40	16.6
Partners with any risks or known to be positive	1	4	1	2	1	1	0	0	3	7	10	4.1
Male-to-male sexual contact	0	0	0	0	0	0	0	0	0	0	0	0.0
Exposure in health care setting	5	1	1	1	0	2	2	0	8	4	12	5.0
Engaged in sex work	0	1	0	0	0	0	0	0	0	1	1	0.4
Blood or tissue recipient	7	6	2	5	5	2	4	1	18	14	32	13.3
Household contact	2	2	5	2	1	4	2	2	10	10	20	8.3
Other blood to blood contact	0	0	2	0	3	2	0	0	5	2	7	2.9
Other	1	0	2	0			1	0	4	0	4	1.7
No risk factors identified	0	1	1	0	2	0	0	1	3	2	5	2.1
Not reported	0	0	2	2	3	2	0	0	5	4	9	3.7
Total	47	36	42	25	40	19	22	10	151	90	241	100

 Table 13
 Number and percentage of HCV infection among first time donors, 2009-2012, by exposure category and sex

Table 14 Number and percentage of HCV infection among repeat donors, 2009-2012, by exposure category and sex

	2	2009	:	2010	:	2011	:	2012		Total (20	009-2012)	
Exposure categories	Male	Female	Total	%								
Ethnicity/Country of birth	0	0	0	0	0	0	0	0	0	0	0	0.0
Intravenous drug user	9	4	1	1	7	1	0	1	17	7	24	25.0
Tattoo/Piercing	4	4	2	1	3	2	5	3	14	10	24	25.0
Partners with any risks or known to be positive	1	2	1	2	0	0	1	0	3	4	7	7.3
Male-to-male sexual contact	0	0	0	0	0	0	0	0	0	0	0	0.0
Exposure in health care setting	1	1	1	1	0	2	2	1	4	5	9	9.4
Engaged in sex work	0	0	0	0	0	0	0	0	0	0	0	0.0
Blood or tissue recipient	5	1	2	1	0	2	0	0	7	4	11	11.5
Household contact	0	0	1	0	2	0	0	1	3	1	4	4.2
Other blood to blood contact	2	0	0	0	0	0	1	0	3	0	3	3.1
Other	0	0	1	0	0	0	0	0	1	0	1	1.0
No risk factors identified	2	2	1	1	0	0	0	1	3	4	7	7.3
Not reported	0	0	0	1	3	0	2	0	5	1	6	6.3
Total	24	14	10	8	15	7	11	7	60	36	96	100

Table 15 Number and prevalence¹ of HIV infection among first time donors, 2006-2012, by state/territory and year of donation

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

		2010			2011			2012		То	tal 2006-2012	
State/ Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate
NSW/ACT	48 130	1	2.08	51 528	1	1.94	41 780	0	0.00	337 792	5	1.48
NT	799	0	0.00	772	0	0.00	937	0	0.00	5 870	0	0.00
QLD	28 097	2	7.12	28 839	2	6.94	24 881	0	0.00	196 652	8	4.07
SA	9 284	0	0.00	10 164	0	0.00	8 900	0	0.00	77 999	0	0.00
TAS	3 222	0	0.00	3 587	0	0.00	3 823	0	0.00	23 853	0	0.00
VIC	25 820	0	0.00	31 286	0	0.00	27 718	2	7.22	194 431	5	2.57
WA	11 149	0	0.00	10 992	1	9.10	9 925	0	0.00	78 168	2	2.56
Total	126 501	3	2.37	137 168	4	2.92	117 964	2	1.70	914 765	20	2.19

1 Rate per 100 000 first time donations

Table 16 Number and rate¹ of HIV infection among repeat donors, 2006-2012, by state/territory and year of donation

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

		2010			2011			2012		Tot	tal 2006-2012	
State/ Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate
NSW/ACT	380 014	1	0.26	390 455	0	0.00	377 220	0	0.00	2 530 980	2	0.08
NT	10 470	0	0.00	10 782	1	9.27	9 673	0	0.00	71 959	1	1.39
QLD	243 837	2	0.82	245 975	1	0.41	237 599	0	0.00	1 622 190	7	0.43
SA	123 587	0	0.00	124 199	0	0.00	120 720	1	0.83	836 389	3	0.36
TAS	41 484	0	0.00	44 661	0	0.00	46 379	0	0.00	259 864	0	0.00
VIC	278 897	1	0.36	288 085	1	0.35	285 168	0	0.00	1 879 061	5	0.27
WA	120 646	0	0.00	121 057	0	0.00	117 728	0	0.00	799 833	0	0.00
Total	1 198 935	4	0.33	1 225 214	3	0.24	1 194 487	1	0.08	8 000 276	18	0.22

1 Rate per 100 000 repeat donations

	Yea	r of donatio	n									
_	200	9	201	0	201	1	201	2		2009	-2012	
Donor status	М	F	М	F	М	F	М	F	М	F	Total	%
First time donors												
<20 years	0	0	0	0	0	0	0	0	0	0	0	0.0
20-29 years	1	0	0	0	3	0	0	0	4	0	4	20.0
30-39 years	0	0	1	0	0	0	1	0	2	0	2	10.0
40-49 years	0	0	0	0	1	0	0	0	1	0	1	5.0
50-59 years	0	0	0	0	0	0	1	0	1	0	1	0.0
60 years and above	0	0	0	0	0	0	0	0	0	0	0	0.0
Repeat donors												
<20 years	0	0	0	0	0	0	1	0	1	0	1	5.0
20-29 years	0	0	1	1	0	1	0	0	1	2	3	15.0
30-39 years	0	1	2	0	0	0	0	0	2	1	3	15.0
40-49 years	0	0	0	0	0	1	0	0	0	1	1	5.0
50-59 years	1	0	1	1	0	0	0	0	2	1	3	20.0
60 years and above	0	0	0	0	1	0	0	0	1	0	1	5.0
Total	2	1	5	2	5	2	3	0	15	5	20	100

Table 17 Number and percentage of donors with HIV infection, 2009-2012, by year of donation, sex and age group

Table 18 Number and percentage of donors with HIV infection, 2009-2012, by year of donation and region of birth¹

	200	9	201	0	201	1	201	2	2009-2	2012
Region of birth	Number	%								
Australia	2	67	6	86	2	29	2	67	12	60
Overseas born										
Other Oceania	0	0	1	14	0	0	0	0	1	5
United Kingdom and Ireland	0	0	0	0	1	14	0	0	1	5
Other Europe	0	0	0	0	1	14	0	0	1	5
Middle East/North Africa	0	0	0	0	0	0	0	0	0	0
Sub-Saharan Africa	0	0	0	0	0	0	0	0	0	0
South East/North East Asia	1	33	0	0	1	14	0	0	2	10
Southern and Central Asia	0	0	0	0	0	0	1	33	1	5
North America	0	0	0	0	0	0	0	0	0	0
South/Central America and the Caribbean	0	0	0	0	1	14	0	0	1	5
Total with a reported country of birth	3	100	7	100	6	86	3	100	19	95
Not reported	0	0	0	0	1	14	0	0	1	5
Total	3	100	7	100	7	100	3	100	20	100

1 Region of birth from the Australian Bureau of Statistics

	:	2009	2	2010	:	2011	:	2012		Total (20	009-2012)	
Exposure categories	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	0	1	0	3	0	1	0	5	0	5	62.5
Male-to-male sexual contact	1	0	0	0	1	0	1	0	3	0	3	37.5
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	0	1	0	4	0	2	0	8	0	8	100

 Table 19
 Number and percentage of HIV infection among first time donors, 2009-2012, by exposure category and sex

Table 20 Number and percentage of HIV infection among repeat donors, 2009-2012, by exposure category and sex

	2	2009	:	2010	:	2011	:	2012		Total (20	009-2012)	
Exposure categories	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	2	2	0	1	1	0	3	4	7	58.3
Male-to-male sexual contact	0	0	1	0	0	0	0	0	1	0	1	8.3
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	1	0	1	0	0	0	2	0	2	16.7
Other	0	0	0	0	0	0	0	0	0	0	0	0.0
No risk factors identified	1	0	0	0	0	0	0	0	1	0	1	8.3
Not reported	0	0	0	0	0	1	0	0	0	1	1	8.3
Total	1	1	4	2	1	2	1	0	7	5	12	100

Table 21 Number and prevalence¹ of HTLV infection among first time donors, 2006-2011, by state/territory and year of donation

		2006			2007			2008			2009	
State/ Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate
NSW/ACT	44 499	1	2.25	51 427	1	1.94	48 607	0	0.00	51 821	2	3.86
NT	823	0	0.00	759	0	0.00	815	0	0.00	965	0	0.00
QLD	27 873	1	3.59	28 575	0	0.00	29 498	0	0.00	28 889	2	6.92
SA	11 457	0	0.00	10 886	0	0.00	15 908	1	6.29	11 400	1	8.77
TAS	2 899	0	0.00	2 650	0	0.00	3 936	0	0.00	3 736	0	0.00
VIC	22 016	1	4.54	23 172	0	0.00	30 286	4	13.21	34 133	2	5.86
WA	11 116	0	0.00	11 292	0	0.00	11 307	2	17.69	12 387	2	16.15
Total	120 683	3	2.49	128 761	1	0.78	140 357	7	4.99	143 331	9	6.28

		2010			2011			2012		То	tal 2006-2012	
State/ Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Prevalence	Donations	Positive	Prevalence
NSW/ACT	48 130	0	0.00	51 528	1	1.94	41 780	0	0.00	337 792	5	1.48
NT	799	0	0.00	772	0	0.00	937	0	0.00	5 870	0	0.00
QLD	28 097	1	3.56	28 839	0	0.00	24 881	0	0.00	196 652	4	2.03
SA	9 284	0	0.00	10 164	1	9.84	8 900	0	0.00	77 999	3	3.85
TAS	3 222	0	0.00	3 587	0	0.00	3 823	0	0.00	23 853	0	0.00
VIC	25 820	0	0.00	31 286	0	0.00	27 718	2	7.22	194 431	9	4.63
WA	11 149	0	0.00	10 992	1	9.10	9 925	0	0.00	78 168	5	6.40
Total	126 501	1	0.79	137 168	3	2.19	117 964	2	1.70	914 765	26	2.84

1 Rate per 100 000 first time donations

	Yea	r of donatio	n									
_	200	9	2010) ¹	201	1	201	2		2009	-2012	
Donor status	М	F	М	F	М	F	М	F	М	F	Total	%
First time donors												
<20 years	1	0	0	0	0	0	0	0	1	0	1	6.7
20-29 years	1	1	0	0	0	1	1	0	2	2	4	26.7
30-39 years	3	0	0	0	0	0	1	0	4	0	4	26.7
40-49 years	0	0	0	0	1	1	0	0	1	1	2	13.3
50-59 years	1	1	0	0	0	0	0	0	1	1	2	13.3
60 years and above	0	0	0	1	0	0	0	0	0	1	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	1	0	0	0	0	0	0	0	1	1	6.7
60 years and above	0	0	0	0	0	0	0	0	0	0	0	0.0
Total	6	3	0	1	1	2	2	0	9	6	15	100

Table 22 Number and percentage of donors with HTLV infection, 2009-2012, by year of donation, sex and age group

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

	200	9	201	0	201	1	201	2	2009-2	2012
Region of birth	Number	%								
Australia	3	33	0	0	0	0	0	0	3	19
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	0	0	0	0	1	33	0	0	1	6
Sub-Saharan Africa	0	0	0	0	0	0	0	0	0	0
South East/North East Asia	1	11	0	0	0	0	0	0	1	6
Southern and Central Asia	2	22	0	0	0	0	2	100	4	25
North America	0	0	0	0	0	0	0	0	0	0
South/Central America and the Caribbean	0	0	1	50	0	0	0	0	1	6
Total with a reported country of birth	6	67	1	50	1	33	2	100	10	63
Not reported	3	33	1	50	2	67	0	0	6	38
Total	9	100	2	100	3	100	2	100	16	100

Table 23 Number and percentage of donors with HTLV infection, 2009-2012, by year of donation and region of birth¹

1 Region of birth from the Australian Bureau of Statistics

	2	2009	2	2010	:	2011	:	2012		Total (20	009-2012)	
Exposure categories	Male	Female	Total	%								
Ethnicity/Country of birth	3	1	0	1	1	1	2	0	6	3	9	64.3
Intravenous drug user	0	0	0	0	0	0	0	0	0	0	0	0.0
Tattoo/Piercing	0	0	0	0	0	1	0	0	0	1	1	7.1
Partners with any risks or known to be positive	0	0	0	0	0	0	0	0	0	0	0	0.0
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	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	1	0	0	0	0	0	0	0	1	1	7.1
Household contact	1	0	0	0	0	0	0	0	1	0	1	7.1
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	2	0	0	0	0	0	0	0	2	0	2	14.3
Total	6	2	0	1	1	2	2	0	9	5	14	100

 Table 24
 Number and percentage of HTLV infection among first time donors, 2009-2012, by exposure category and sex

Table 25 Number and prevalence¹ of active syphilis among first time donors, 2006-2012, by state/territory and year of donation

		2006			2007			2008			2009	
State/ Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate
NSW/ACT	44 499	0	0.00	51 427	0	0.00	48 607	0	0.00	51 821	0	0.00
NT	823	0	0.00	759	0	0.00	815	1	122.70	965	1	103.63
QLD	27 873	1	3.59	28 575	1	3.50	29 498	0	0.00	28 889	1	3.46
SA	11 457	1	8.73	10 886	0	0.00	15 908	0	0.00	11 400	0	0.00
TAS	2 899	0	0.00	2 650	0	0.00	3 936	0	0.00	3 736	0	0.00
VIC	22 016	0	0.00	23 172	0	0.00	30 286	0	0.00	34 133	1	2.93
WA	11 116	0	0.00	11 292	0	0.00	11 307	2	17.69	12 387	1	8.07
Total	120 683	2	1.66	128 761	1	0.78	140 357	3	2.14	143 331	4	2.79

		2010			2011			2012		To	tal 2006-2012	
State/ Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Prevalence	Donations	Positive	Prevalence
NSW/ACT	48 130	0	0.00	51 528	0	0.00	41 780	0	0.00	337 792	0	0.00
NT	799	0	0.00	772	2	259.07	937	0	0.00	5 870	4	68.14
QLD	28 097	2	7.12	28 839	1	3.47	24 881	0	0.00	196 652	6	3.05
SA	9 284	2	21.54	10 164	1	9.84	8 900	1	11.24	77 999	5	6.41
TAS	3 222	0	0.00	3 587	0	0.00	3 823	0	0.00	23 853	0	0.00
VIC	25 820	1	3.87	31 286	1	3.20	27 718	0	0.00	194 431	3	1.54
WA	11 149	0	0.00	10 992	2	18.20	9 925	0	0.00	78 168	5	6.40
Total	126 501	5	3.95	137 168	7	5.10	117 964	1	0.85	914 765	23	2.51

1 Rate per 100 000 first time donations

 Table 26
 Number and rate¹ of active syphilis among repeat donors, 2006-2012, by state/territory and year of donation

		2006			2007			2008			2009	
State/ Territory	Donations	Positive	Rate									
NSW/ACT	311 513	0	0.00	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	0	0.00	226 726	0	0.00
SA	93 172	0	0.00	107 934	0	0.00	114 618	0	0.00	118 476	0	0.00
TAS	24 577	0	0.00	28 726	0	0.00	28 019	0	0.00	33 321	1	3.00
VIC	225 332	0	0.00	238 684	0	0.00	252 340	1	0.40	259 052	0	0.00
WA	101 063	0	0.00	99 376	0	0.00	109 425	0	0.00	113 274	1	0.88
Total	969 917	0	0.00	1 032 962	0	0.00	1 062 345	1	0.09	1 101 077	3	0.27

		2010			2011			2012		To	tal 2006-2012	
State/ Territory	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate	Donations	Positive	Rate
NSW/ACT	380 014	1	0.26	390 455	1	0.26	377 220	2	0.53	2 530 980	5	0.20
NT	10 470	1	9.55	10 782	0	0.00	9 673	0	0.00	71 959	2	2.78
QLD	243 837	1	0.41	245 975	0	0.00	237 599	0	0.00	1 622 190	2	0.12
SA	123 587	0	0.00	124 199	0	0.00	120 720	0	0.00	836 389	0	0.00
TAS	41 484	0	0.00	44 661	0	0.00	46 379	0	0.00	259 864	1	0.38
VIC	278 897	0	0.00	288 085	0	0.00	285 168	1	0.35	1 879 061	2	0.11
WA	120 646	0	0.00	121 057	0	0.00	117 728	2	1.70	799 833	4	0.50
Total	1 198 935	3	0.25	1 225 214	1	0.08	1 194 487	5	0.42	8 000 276	16	0.20

1 Rate per 100 000 repeat donations





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:

Age-specific rate of HBV infection among donors aged 20-29 years =	Number of donors with HBV infection aged 20-29 years) x 100 000
	Total number of donors aged 20-29 years	

Donor-years of observation

Data on interval between each donation by all donors who donated at least twice in 2008-2010 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 within the previous 12 months
- 5. Male-to-male sexual contact within the previous 12 months
- 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 within the previous 12 months* and *Male-to-male sexual contact within the previous 12 months* 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 within the previous 12 months
 - c. Male-to-male sexual contact within the previous 12 months
- 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

Please note that unlike general population the risk categories namely *Engaged in sex work* and *Male-to-male sexual contact* are time restricted for blood donors in Australia. Any history of engagement in sex work within the past 12 months and history of male-to-male sexual contact within the past 12 months are defined as the risk factors for transfusion-transmissible infections in blood donors.

Incidence

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

Incidence per 100 000 donor-years of observation =
$$\begin{pmatrix} Number of seroconverters \\ \hline Total donor-years of observation \end{pmatrix} x 100 000$$

Newly acquired infection

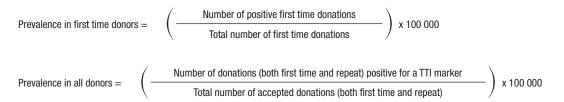
Newly acquired infection was defined as newly diagnosed infection with evidence of a previous negative or indeterminate test result.

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:



Residual risk estimates

Estimates were derived based on minor refinement to the method described in earlier studies^{34,35}. An additional refinement since 2011 is a new model applied to HBV which specifically addresses the risk of occult hepatitis B infection (OBI).³⁶

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 seroconversion (i.e., positive donors who have previously tested negative at the Blood Service for the same viral marker) in the repeat donor (RD) population as a measure of viral incidence (i.e. the rate of newly acquired infection).

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

Two of the WP-based models also incorporate the average inter-donation interval for all seroconverters (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 2012. 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.

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 2012. The association between demographic factors and presence of any transfusion-transmissible viral infections (HBV, HCV, HIV and HTLV) among Australian blood donors were assessed using multivariate Poisson regression model for each infection separately.

³⁴ Seed CR, Kiely P, Keller AJ. op. cit. 2005

³⁵ Seed Clive R, Cheng A, Ismay Susan L, Bolton Wayne V, Kiely P, Cobain Trevor J, 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(10):1365-72.

³⁶ Seed CR, 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 Sang.* 2013. doi: 10.1111/vox.12060.

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