Transfusion-transmissible infections in Australia

2014
Surveillance Report

Australian Red Cross BLOOD SERVICE

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Kirby Institute

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2014 Surveillance Report

edited by

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The Kirby Institute

in collaboration with

The Australian Red Cross Blood Service

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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 fourth report that summarises donation testing data and incidence/prevalence trends for transfusion-transmissible infections (TTIs) among Australian blood donors. While the report focuses on data collected during the 2013 calendar year, it also assesses for trends against the previously published data for 2005-2012 contained in the transfusion-transmissible infections 2013 surveillance report. As in last year's report, data on malaria testing and surveillance activity for emerging infections are also included in the 2014 report. Last year we presented summarised data on non-compliance among test-negative blood donors to selective high-risk donor deferral criteria in Australia. This year we provide further data on donor non-compliance from a large national donor survey conducted between November 2012 and April 2013. We also continue to include 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 TTIs remained low in 2013 with the vast majority (81%) identified in first time donors. Reassuringly, the overall infection rate has continued to decline in 2013. Infected first time donors in 2013 mostly had undiagnosed prevalent infections but we continued to identify a small number of recently acquired (incident) infections among repeat donors. Notably, in 2013 there was a modest increase in incidence of HBV, HCV, and HIV infections in donors compared to 2012. 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 was steady in the range 20-25% until 2008 after which it gradually declined to a new low point of 13% in 2011. However, the rate increased again in 2012 to 19% but pleasingly has declined again in 2013 to 15%, suggesting it may have stabilised at a lower level. The importance of monitoring and understanding non-compliance was highlighted in the '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 TTIs and gauging opinion among donors on the donor questionnaire and possible ways to optimise the donor assessment process.

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%, well below the internationally published range (0.8-2.3%). This study also estimated the prevalence of non-compliance among Australian donors deferred for a history of injecting drug use (0.36%) as well as the prevalence of overall non-compliance (i.e. to at least one TTI-risk screening question) (1.65%). 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 submitted a proposal to the Therapeutic Goods Administration (TGA) in support of reducing the deferral period to 6 months for all sexual activity-based deferrals in line with the recommendation of the expert committee. However, after due consideration the TGA did not support the proposal and the existing 12 month deferrals for all sexual activity-based deferrals remain current. The Blood Service is fully committed to ongoing review of donor eligibility criteria given their critical role in protecting both donors and blood product recipients.

Contents

Summary of the main findings

General characteristics of blood donors in Australia

1. Over the period 2005-2013, there were approximately 11.3 million blood donations in Australia with an average of 1.25 million donations per year. Total blood donations remained fairly steady with a slight decline in 2013 (0.13%) compared to 2012 reflecting both a reduced clinical demand for red cells leading to fewer whole blood collections, and continued expansion of automated plasma collections to meet an increasing demand for some plasma products, principally intravenous immunoglobulin.

2. About 2.9% of the Australian population aged between 16-80 years donated blood during 2013.

3. First time and repeat donors comprised 16.3% and 83.7% of all blood donors in Australia over the period 2005-2013, respectively. As in previous years, this ratio remained relatively stable nationally and across all states and territories. Male donors constitute approximately 49.4% of all donors in 2013.

Trends in transfusion-transmissible infections in Australian blood donors

1. A total of 187 blood donors were detected as having a TTI (HBV, HCV, HIV, HTLV or syphilis) in 2013. Only one donor had co-infection (both HBV and HCV positive). More than 90% of these donors were infected with either HBV or HCV. A total of 2 102 TTI-positive donors have been detected in the 2005-2013 period.

2. HIV was the least common TTI among blood donors in 2013; a total of four donors were HIV positive in 2013. Overall in 2005-2013, HIV and HTLV were the least common infections among first time and repeat donors, respectively.

3. Although representing only 16% of the donor population, first time blood donors contributed 80% of TTIs in Australia in 2013.This ratio has been fairly consistent over the period of 2005-2013, 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 2008-2013. Three probable cases of transfusion-transmitted HBV infection were reported in the 2008-2013 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 slightly increased from 83.1 per 100 000 donations in 2012 to 84.4 per 100 000 donations in 2013. Since 2007, of all TTIs, HBV continued to have the highest prevalence among first time donors.

2. While the incidence of HBV increased from 0.3 per 100 000 donor-years of observation in 2012 to 0.95 per 100 000 donor-years of observation in 2013 overall it remained low during the study period.

3. The most common infective risk factor for donors with HBV infection during 2010-2013 was ethnicity/country of birth (86%) which is consistent with the findings of previously published data for the period 2009-2012.

4. In 2013, HBV positive donors were slightly younger (mean age 36 years versus 40 years for all donors), more likely to be male (73% versus 49.4% male donor proportion) and only 14% were born in Australia. These characteristics are consistent with previous years.

HCV infection among Australian blood donors

1. After HBV, HCV was the most common infection found in first time blood donors.

2. HCV prevalence among first time donors decreased by 21.9% from 66.1 per 100 000 donations in 2012 to 51.6 per 100 000 donations in 2013. This continues a decreasing trend among first time donors and is in contrast with population data which shows a slight increase in both number and rate of new HCV diagnoses in 2013 following a steady decline in 2007-2012.

3. HCV had the highest incidence rate among previously negative repeat donors during 2006 to 2013. Following a gradual decline in 2009-2011, the incidence of HCV continued to increase in 2011-2013 (from 1.7 per 100 000 donor-years of observation in 2011 to 4.1 per 100 000 donor-years of observation in 2013). 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 2009-2013.

4. The most common infective risk factor for donors with HCV infection during 2010-2013 was tattoo/piercing (26%) followed by intravenous drug use (21%). In comparison, intravenous drug use (74%) and sexual contact (4%) were the two most dominant routes of exposure in cases of newly acquired HCV infection in the general population in 2013.

5. In 2013, the mean age of donors with HCV infection was 45 years. Like HBV, male donors were over-represented (61% versus 49.4% male donors overall) but in contrast to HBV, the majority (59%) were born in Australia. The key attributes of HCV positive donors in 2013 remained similar to those in 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 2005-2013 remained very low (2 per 100 000 donations) and comparatively much lower than HBV (83.9 per 100 000 donations) and HCV (71.1 per 100 000 donations).

2. Following a steady decline in 2010-2012, the incidence of HIV infection among previously negative repeat donors increased marginally in 2013, from 0.3 per 100 000 donor-years of observation in 2012 to 0.6 per 100 000 donor-years of observation in 2013. The incidence rate of HIV in blood donors remained very low compared to the general population, and showed a fluctuating trend over the past nine years. Following a gradual increase in 2007-2012 the number of diagnoses of newly acquired HIV infection in Australia has slightly reduced in 2013 (350 in 2013 compared to 400 in 2012).[1]

3. The two most common routes of exposure for donors with HIV infection during 2010-2013 were partners with known risk or known to be positive (48%) followed by male-to-male sexual contact (29%).[2] This contrasts with the general population where men who have sex with men accounted for 69.7% of new HIV diagnoses in Australia in 2013. The lower proportion associated with male-to-male sexual contact in blood donors reflects the effectiveness of the 12-month deferral for male-to-male sex.

4. Mean age of HIV positive donors increased in 2013 (47 years) compared to the previous years (between 36 and 37 years). All of the four HIV positive donors were male and most HIV positive donors in 2013 (75%) were born in Australia.

HTLV infection among Australian blood donors

1. Although the prevalence of HTLV among first time donors remained very low during 2005-2012, it increased substantially from 1.7 per 100 000 donations in 2012 to 8.9 per 100 000 donations in 2013. Notably, nine donors were HTLV positive in 2013, all were first time donors.

2. As in 2011-2012, no incident HTLV donor was identified in 2013. There was only one incident case of HTLV among previously negative repeat donors during 2005-2013.

3. The most common infective risk factor for donors with HTLV infection during 2010-2013 was ethnicity or country of birth (80%).

4. In 2013, the mean age of donors with HTLV infection was 45 years. In 2013, 56% of the infected donors were male and most of them (78%) were born overseas.

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1 The Kirby Institute. HIV, viral hepatitis and sexually transmissible infections in Australia Annual Surveillance Report 2014 HIV Supplement. The Kirby Institute, UNSW, NSW 2052

2 Includes declaration form compliant and non-compliant donors (see section *Non-compliance among positive donors*, page 23).

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 2005-2013.

2. The prevalence of active syphilis in first time donors showed an increasing trend during 2005-2013, although there was a reassuring decline in the recent 2-years. The prevalence among repeat donors decreased from 0.4 per 100 000 donations in 2012 to 0.3 per 100 000 donations in 2013.

Malaria testing

1. In 2013, a total 110 866 donations were tested for malaria antibody of which 1 618 (1.5%) were repeat reactive. None of these 1 618 donations had detectable malaria DNA suggesting past infection in the donors.

2. There were no reported cases of transfusion-transmitted malaria during 2013, with the last Australian case occurring in 1991.

Bacterial pre-release testing for platelets

1. Bacterial screening of 124 381 platelets identified 120 (0.1%) as confirmed positive.

2. *Propionibacterium* spp., which are common skin commensals were by far the most frequently isolated organisms (104). These organisms are rarely, if ever associated with septic transfusion reactions in recipients. A small number of clinically significant organisms including *Streptococcus agalactiae* and *Streptococcus pneumoniae* were also detected. No cases of septic transfusion reactions were identified in patients who received platelets.

Emerging infections

1. During 2013 there were several dengue fever outbreaks in northern Queensland. The outbreaks were in Cairns (3 confirmed cases), Port Douglas (12 confirmed and 1 probable case), Innisfail (9 confirmed cases), Townsville (19 confirmed cases), Ingham (4 confirmed cases), Pimlico (3 confirmed cases), and Woree (6 confirmed cases). The final reported outbreak for 2013 was in October in the Miallo/Port Douglas area with 14 confirmed cases and was still ongoing at the end of 2013. In addition, there was an outbreak in 2012 in Cairns that continued until October 2013 with 146 confirmed cases. To mitigate the transmission risk, donations from these areas were restricted to CSL fractionation/processing, a strategy that has been shown to effectively eliminate dengue virus, until the outbreaks were declared over.

2. In 2013, while continuing the fresh component restrictions for recent visitors to North America the Blood Service monitored the risk associated with West Nile virus (WNV) outbreaks in the European Union (EU) and surrounding countries during the European transmission season (July to November 2013). The risk of a donor returning and donating while viraemic was monitored on a weekly basis. As in 2012, the additional level of risk to the Australian blood supply associated with donors returning from these countries during the 2013 WNV transmission season did not exceed the threshold requiring additional donor selection measures.

3. Human cases of infection with a novel coronavirus, now referred to as Middle East respiratory syndrome coronavirus (MERS-CoV) was first reported by 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. From April to December 2013 the number of reported human MERS-CoV cases averaged 16 per month, with approximately 85% of cases being reported in Saudi Arabia. The current risk posed by MERS-CoV to Australia's blood safety appears to be very low, and WHO did not advise any special screening at points of entry with regard to MERS-CoV nor did it recommend the application of any travel or trade restrictions. However the Blood Service continues to closely monitor developments.

4. Human Hendra virus (HeV) infection is an emerging Australian zoonotic disease associated with high mortality. To date all seven recorded cases of HeV transmission to humans has occurred from horses exposed to *Pteropus* bats (flying foxes). While no cases of human HeV infection were recorded in 2013, there were 5 equine cases in NSW and Queensland. In 2013, HeV was detected in South Australian flying foxes for the first time. The second reported case of canine HeV infection in Australia till date was also reported last year in a dog on a property in the NSW region of Macksville (a previous case was reported in 2011 in NSW). In 2013, the world's first commercially available HeV vaccine for horses, Equivac(R) HeV, was launched in Australia. 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. Transfusion transmission has not been reported but is theoretically possible and as a precautionary measure the Blood Service permanently excludes donors with HeV infection.

5. In 2013, the Chinese Centre for Disease Control and Prevention reported the isolation of A(H7N9) virus from 3 human patients with respiratory infections, this was the first report of this avian influenza subtype in humans. Currently the most plausible explanation for the origin of A(H7N9) infection in humans is exposure to a zoonotic avian influenza virus that has spread in poultry in parts of Eastern China. So far the evidence indicates that the A(H7N9) is not easily transmitted human-to-human via airborne secretions but appears to require direct, intimate contact for infection. While it cannot be excluded, based on the current knowledge of A(H7N9) and lack of documented transfusion transmission by known influenza viruses, transfusion transmission is very unlikely. Currently the risk posed to the Australian blood supply from A(H7N9) appears to be very low. However, similar to the MERS-CoV outbreak, the Blood Service is managing the potential risk from A(H7N9) by ongoing monitoring of reports of laboratory-confirmed cases and the geographical location of case clusters and local human-to-human transmission.

Key messages

1. Supporting the effectiveness of donor education and selection, the prevalence of TTIs is substantially lower among both first time blood donors (11 to 58 times) and all donors (120 to 377 times) than in the general population in 2013 and shows a stable or declining trend since 2005.

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

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

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

5. Almost 17% of the positive donors in 2010-2013 were 'non-compliant' in that they had risk factors identified during their post-donation interview that would have deferred them from donating had they disclosed them at the pre-donation interview. The non-compliance rate of 20-25% declined gradually during 2008-2011 to its lowest ever level in 2011 (12.9%) and subsequently appears to have stabilised at a lower threshold, around 15%. 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 large national survey conducted in 2012-2013 showed a comparatively low rate of non-compliance (in the range 0.05 to 0.29%) among TTI test-negative donors for several sexual activity-based donor deferrals. Non-compliance with the 12-month deferral for male-to-male sex (which is the subject of the majority of international research and controversy) was 0.23%. This is markedly lower than published overseas studies which range from 0.8-2.3%. The estimated prevalence of overall non-compliance (i.e. to at least one screening question related to the deferrals for injecting drug use, sex with an injecting drug user, male-to-male sex, sex worker activity/contact and sex with a partner from a high HIV prevalence country) was 1.65%. While these estimates are minimum estimates because non-compliant donors might have chosen not to take the survey or been non-compliant if they did, overall these findings are reassuring and support the effectiveness of the current screening questions.

7. An unexpected and concerning compliance survey finding was that a small number of donors are donating to get tested for infections including HIV - referred to as 'test-seeking' behaviour. Among male donors test-seeking was statistically associated with non-compliance. Test-seeking for TTIs is detrimental to blood safety given a donor could attend while in the window period. Importantly, test-seeking poses an avoidable risk to the blood supply given the availability of free sexually-transmissible infection (STI) testing in Australia.

8. 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 468 000) but comparable to other Blood Services in developed countries. These risk estimates support the claim that Australia's blood supply is among the safest worldwide in respect of transfusion-transmissible infections for which testing is conducted. Despite this, there remains a minimal but real risk of transfusion-transmissible infections which must be carefully considered before any transfusion.

9. Bacterial screening of 124 381 platelets identified 120 (0.1%) as confirmed positive. The majority of organisms identified were slow-growing anaerobic skin flora not usually associated with post-transfusion septic reactions. However, a minority of platelets grew clinically-significant organisms which were likely to have been due to transient or occult bacteraemia in the donor and could have led to potentially serious septic transfusion reactions in the recipient.

10. In addition to established TTIs, emerging infectious diseases continue to demand vigilant surveillance. Mosquito-borne agents such as dengue virus and West Nile virus are currently the principal threats but many other novel or emerging infectious diseases are constantly monitored by the Blood Service to assess their threat to the safety of the blood supply. The worldwide spread of dengue virus continued in 2013 and several seasonal outbreaks in northern Queensland were subject to the routine risk mitigation strategies. Overall, the numbers of reported cases of WNV fever in EU and neighbouring countries was lower in 2013 compared to 2012. While no cases of human Hendra virus infection were recorded in 2013, there were 5 equine cases. 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. No sustained human to human transmission or transfusion transmission has been identified and the risk to the blood supply is assessed as very low. In 2013 the first isolation of A(H7N9) virus from 3 human patients with respiratory infections was reported. Transfusion transmission of this virus has not been reported. While it cannot be excluded, based on the current knowledge of A(H7N9) and lack of documented transfusion transmission by known influenza viruses, it is very unlikely.

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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.

Incident donor

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

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.

Transfusion-transmissible infection
Any infection that can be transmitted to a recipient via transfused blood components.

Window period
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

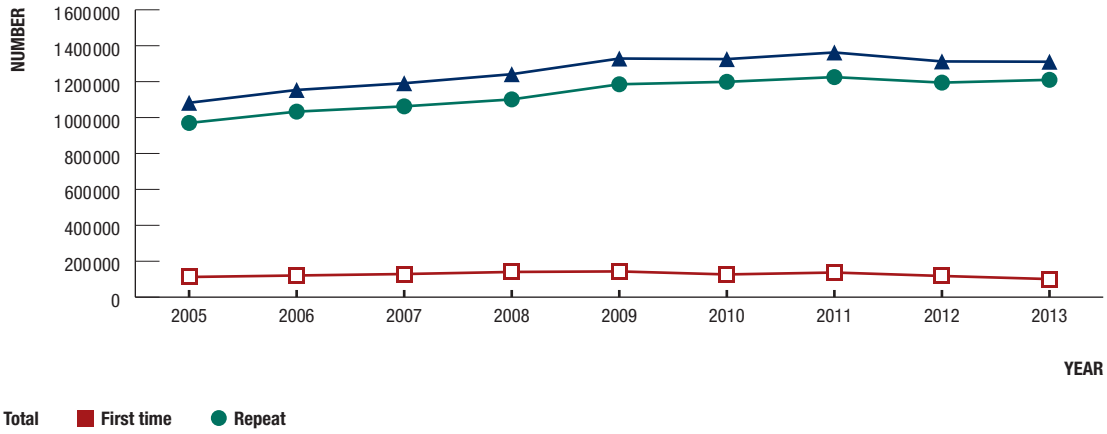
anti-HBc	antibody to hepatitis B core antigen
anti-HBe	antibody to hepatitis B e antigen
anti-HBs	antibody to hepatitis B surface antigen
anti-HeV	antibody to Hendra virus
A(H7N9)	avian influenza H7N9 virus
HBsAg	hepatitis B surface antigen
Blood Service	Australian Red Cross Blood Service
HBeAg	hepatitis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

Main findings

Blood donors in Australia

About 11.3 million donations were tested for TTIs in Australia during 2005-2013 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 nine years, with a slight decrease (0.13% decrease) from 2012 to 2013 (Figure 1). The recent decrease in total collections in the past two years is attributed to the combined impact of a progressive uptake of patient blood management initiatives with a decrease in clinical demand for red cells leading to a reduction in whole blood collections, and a planned shift in collection strategy to improve overall efficiency by increasing the proportion of machine-based plasma collections. The latter aims to provide the most cost-effective method to increase local plasma production to meet an increasing demand for plasma derived products, particularly intravenous immunoglobulin. In 2012, about 3.2% of the general population who were aged between 16-80 years donated blood in Australia. This proportion slightly declined in 2013 (2.9%). As in previous years, more than 90% of all donations in 2013 were from repeat donors and 81% of all TTI positive donations were made by first time donors.

Figure 1 **Number of blood donations in Australia by year of donation, 2005-2013**



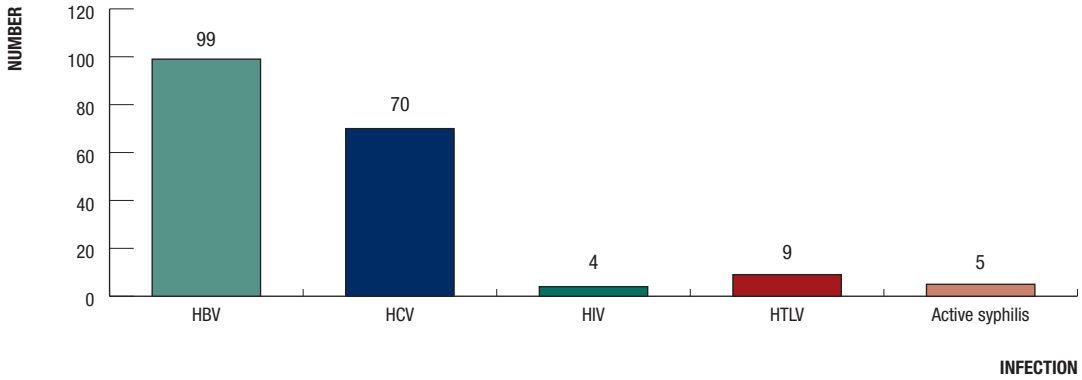
Among all blood donors who donated in 2013, 51% were female and 31% were younger than 30 years. Median ages of both male and female donors in 2013 were 43 and 40 years, respectively.

Trends in incidence and prevalence of transfusion-transmissible infections

In 2013, a total of 187 donors (14.3 per 100 000 donations) were found positive for at least one of the TTIs subject to mandatory donation testing (i.e. HBV, HCV, HIV, HTLV and syphilis). In 2013, only one donor was positive for more than one of these TTIs. Overall, HBV and HCV were the two most common TTIs identified in Australian blood donors in 2013, together contributing more than 90% of all infections (Figure 2). HBV and HCV were the most common TTIs in first time and repeat donors, respectively. Overall TTI-positivity decreased from 16.4 per 100 000 donations in 2012 to 14.3 per 100 000 donations in 2013. In general, the presence of any TTI among Australian blood donations has remained low with a slight but significantly[3] declining trend in overall prevalence during 2005-2013.

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

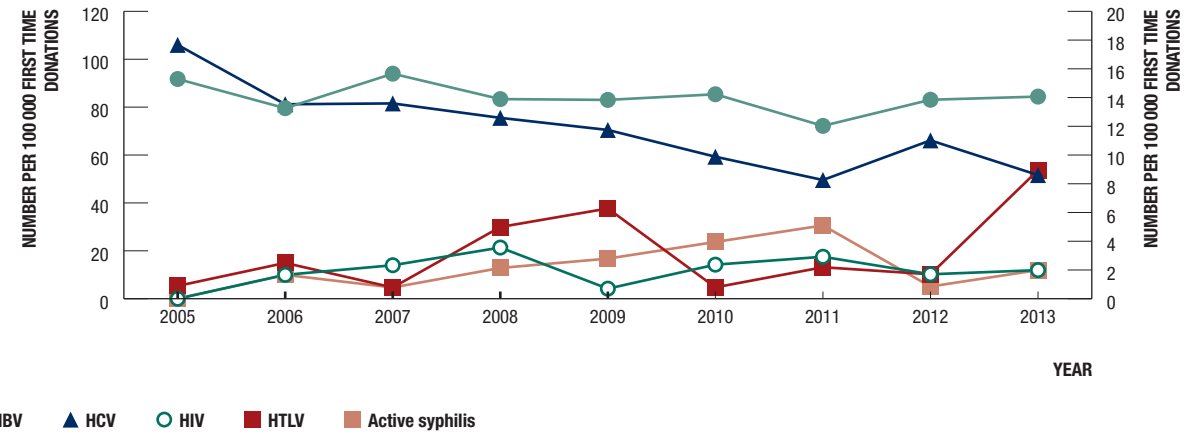
Figure 2 **Number of blood donors with transfusion-transmissible infections in Australia, in 2013, by infection**



Among all donors during 2005-2013, the prevalence of HCV infection has been declining significantly with an overall 51% reduction from 2005 to 2013. The prevalence of active syphilis infection increased significantly in 2005-2011 followed by a fluctuating rate in the past two years. Both HIV and HTLV prevalence showed a slight, non-significant overall increase and HBV prevalence remained relatively stable.

The prevalence of HBV in first time donors increased marginally from 83.1 per 100 000 donations in 2012 to 84.4 per 100 000 donations in 2013 with no significant annual trend observed in the past nine years (Figure 3). During 2005-2013, there has been a significant decrease in HCV prevalence in first time donors in Australia. Following a steady decline in 2007-2011 the HCV prevalence increased in 2012 but has again declined in 2013.This trend is fairly consistent with the *per capita* rate of diagnosis of HCV infection reported through the National Notifiable Disease Surveillance System.[4] The per capita rate increased marginally from 44.5 per 100 000 population in 2012 to 46.3 per 100 000 population in 2013 following a steady decline in 2006-2012.

Figure 3 **Prevalence of transfusion-transmissible infections in first time blood donors in Australia, 2005-2013, by infection[1] and year of donation**



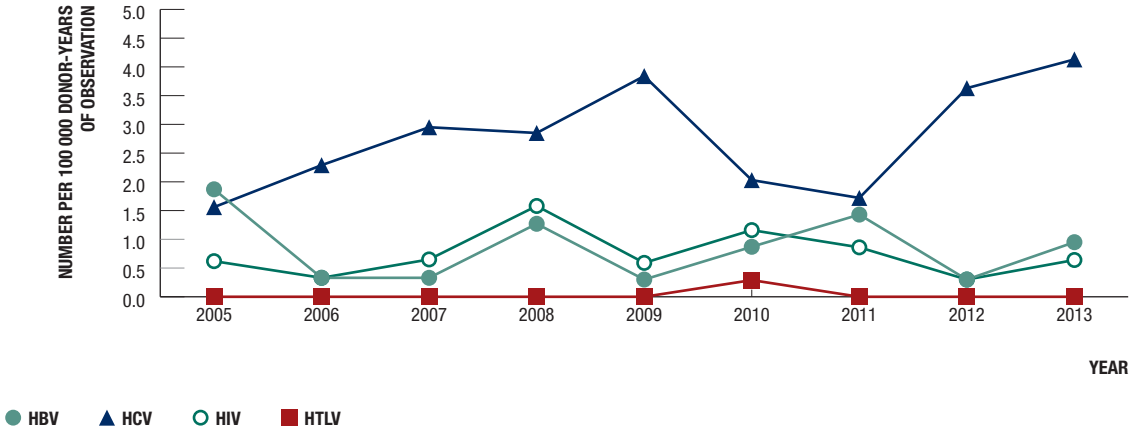
1 Prevalence of HIV, HTLV and active syphilis are provided according to the scale on the secondary axis on the right hand side.

In contrast with HBV and HCV, the prevalence of HIV, HTLV and active syphilis in first time donors remained very low over the past nine years. HIV prevalence has been stable over the 2005-2013 period at around 2 per 100 000 donations. During 2005-2013, HTLV prevalence demonstrated a slight, non-significant increasing trend in first time donors in Australia. Notably, the prevalence of 8.9 per 100 000 donations in 2013 is the highest recorded to date. Despite higher prevalence rates of HIV and HTLV in 2013 compared to 2012, overall no significant trends were observed in the past nine years. Overall, the prevalence of active syphilis in first time donors showed an increasing trend during 2005-2013, although there was a reassuring decline in the recent 2-years (Figure 3). The prevalence increased steadily from 2005 reaching its maximal rate of 5.1 per 100 000 donations in 2011. The prevalence then declined to 0.85 per 100 000 donations in 2012 but increased again in 2013 to 1.99 per 100 000 donations. It is too early to determine the significance, if any, of the 2013 increase. By comparison, the annual number of diagnoses of infectious syphilis reported through the National Notifiable Diseases Surveillance System peaked at 1 418 in

4 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.

2007 (Age standardised rate of 6.8 per 100 000 population). The rate then declined gradually in 2007-2010 before demonstrating a steady increase from 5 per 100 000 population in 2010 to 7.6 per 100 000 population in 2013.

Figure 4 **Incidence of transfusion-transmissible infection in repeat blood donors in Australia, 2005-2013, by infection and year of donation**



For the 2005-2013 period there was no significant trend observed for incidence rates of any of the TTIs, although with the exception of HTLV, incidence rates increased in 2013 compared with 2012 (Figure 4). Consistent with previous years HCV had the highest TTI incidence rate in 2013 which increased marginally from 3.6 per 100 000 donor-years of observation in 2012 to 4.1 per 100 000 donor-years of observation in 2013 (Figure 4). Although not significant, there was a slightly increasing trend in HCV incidence in repeat blood donors over the past nine years. In recent years this parallels diagnoses of newly acquired HCV infection in the general population which have also shown a slight but gradual increase in 2011-2013.[5] Nationally, no significant annual trend was observed for incidence of HIV in 2005-2013 although following a steady decline in 2010-2012 HIV incidence has increased from a low base in 2013-from 0.3 per 100 000 donor-years of observation in 2012 to 0.6 per 100 000 donor-years of observation in 2013. The low and stable donor HIV incidence contrasts with the general population where there has been a steady increase in diagnoses of newly acquired HIV infection in 2007-2012 which plateaued in 2013. As in 2012, the HTLV incidence among repeat Australian donors in 2013 was zero. During 2005-2013, HTLV incidence remained very low with only one incident case identified in 2010.

Trends in HBV infection by state/territory

Consistent with previous TTI-surveillance reports the prevalence of HBV among first time donors varied markedly across Australia in 2013. While the national prevalence was 84.4 per 100 000 donations this ranged from 0 to 117.2 per 100 000 donations in various jurisdictions (Table 1 & Supporting fFigure 7). Compared to 2012, HBV prevalence among first time donors in 2013 decreased by 8.9%, 20.8% and 24.9% in New South Wales/Australian Capital Territory, South Australia and Western Australia, respectively. In contrast, increases were observed in Victoria (from 79.4 per 100 000 donations in 2012 to 106.6 per 100 000 donations in 2013) and Queensland (from 64.3 per 100 000 donations in 2012 to 80.3 per 100 000 donations in 2013). Generally, Queensland recorded a lower HBV prevalence than both New South Wales/Australian Capital Territory and Victoria and the rate remained relatively stable across the study period.

Incident HBV donors continue to be rare with only three recorded nationally in 2013, one each in New South Wales/Australian Capital Territory, Queensland and Victoria. Overall, there was no obvious trend in HBV incidence in any state/territory during the nine-year study period 2005-2013 (Supporting fFigure 8). In Western Australia, following a gradual increase in 2009-2011 the rate steadily declined in the past 3 years. Among donors in Northern Territory, South Australia and Tasmania, HBV incidence has been zero since 2008. The low and stable donor incidence is pleasing and consistent with the continuing declining trend in the rate of newly acquired HBV in the general population. In 2009-2013, the rate has gradually declined from 1.2 to 0.7 per 100 000 population. Compared to 2012, rate of newly acquired HBV has decreased in all jurisdictions except in Australian Capital Territory, Northern Territory and Western Australia.

5 The Kirby Institute. *op.cit.*

Trends in HCV infection by state/territory

Nationally the prevalence of HCV in first time donors remained relatively stable with some declining trend throughout the 2005-2013 period. There were some notable jurisdictional decreases in 2012-2013 (Supporting fFigure 9). Western Australia (from 60.5 per 100 000 donations in 2012 to 22.7 per 100 000 donations in 2013) followed by Queensland (from 84.4 per 100 000 donations in 2012 to 52 per 100 000 donations in 2013) and New South Wales (from 71.8 per 100 000 donations in 2012 to 57.1 per 100 000 donations in 2013) had marked decreases. However, these decreases were not reflected in the general population data. Compared to 2012, the rate of newly diagnosed HCV infection increased in all jurisdictions in 2013 except for South Australia, Tasmania and Victoria. Notably, apart from 2012, the declining prevalence trend in first time donors is fairly consistent with the declining rate of newly diagnosed HCV infection in the general population which has remained fairly stable or declined over the past decade. Although nationally a slight increase in new HCV diagnoses in the general population has been observed in 2013 compared with 2012, it is premature to make any assumptions based on a single year increase. This bodes well for the future donor prevalence rate given donors are selected directly from the general population.

Generally, the incidence of HCV in repeat donors remained very low across all Australian jurisdictions during the past nine years (Supporting fFigure 10). In New South Wales/Australian Capital Territory, the rate increased from 0.92 per 100 000 donor-years of observation in 2012 to 1.94 per 100 000 donor-years of observation in 2013 after a steady decline in 2008-2012. In Tasmania, HCV incidence has been zero since 2010. Apart from a slight increase in 2012-2013, the rate in Western Australia remained relatively stable during the past four years at around 3 per 100 000 donor-years of observation. The rate in Victoria has returned to 1.3 per 100 000 donor-years of observation in 2013 after an increase in 2012. In contrast, HCV incidence in Queensland continued to increase steadily since 2011 reaching a new high for the 2005-2013 period of 11.5 per 100 000 donor-years of observation. However, only two of the seven incident donors contributing to the 2013 rate were HCV RNA positive indicative of ongoing HCV infection. Data on HCV incidence in the general population are not available for Queensland making it difficult to determine whether the increasing donor incidence is related to a population trend. 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 2005-2013 period, with the national average prevalence being 1.99 per 100 000 donations (Supporting fFigure 11). In 2013, HIV prevalence was zero in all jurisdictions except New South Wales/ Australian Capital Territory where the rate was 5.7 per 100 000 donations. While proportionally this appears to be a notable increase, 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 increased steadily in the past decade reaching a plateau in 2013. Except for Australian Capital Territory, South Australia and Victoria, all other jurisdictions recorded decreases in new HIV diagnoses in 2013 compared with 2012.

Incident HIV infections in blood donors continue to be a rarity with only two recorded in 2013, both from New South Wales/ Australian Capital Territory. With the exception of Queensland, no clear jurisdictional trend is discernible over the 2005-2013 period (Supporting fFigure 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. This is in contrast with the general population data for newly acquired HIV infections in Queensland which shows an increase in the number of newly acquired HIV infections since 2010. Notably, no incident HIV donor cases were identified in Tasmania or in Western Australia in the past nine years.

Trends in HTLV infection by state/territory

In 2013 HTLV prevalence was zero in all jurisdictions except New South Wales/ Australian Capital Territory, Queensland and Victoria (Supporting fFigure 13). For the 2005-2012 period, HTLV prevalence remained relatively low in all jurisdictions without any discernible trend. However, nationally the rate of 8.9 per 100 000 first-time donations in 2013 is the highest prevalence recorded to date. No incident HTLV donors where reported during 2013 and HTLV incidence has remained very low throughout the 2005-2013 period with the only incident donor identified in 2010.

Trends in active syphilis infection by state/territory

Consistent with the national trend for the 2005-2013 period the rate of active syphilis infection in blood donors remained low in 2013 with only five donors (2 first time and 3 repeat) identified in 2013 (Table 1 and Supporting fFigure 14). There does not appear to be any clearly discernible trends in the jurisdictional data although the small number of infections makes trend analysis problematic.

Table 1 **Prevalence of transfusion-transmissible infections in Australia by type of donation and state/territory, 2013**

State/Territory of donation	All accepted donations			HBV			HCV			HIV			HTLV			Syphilis			Total positive donations		
	First time	Repeat	All	First time	Repeat	All	First time	Repeat	All	First time	Repeat	All	First time	Repeat	All	First time	Repeat	All	First time	Repeat	All
NSW/ACT	**35 060**	**373 670**	**408 730**	**26**	**5**	**31**	**20**	**3**	**23**	**2**	**2**	**4**	**3**	**0**	**3**	**0**	**2**	**2**	**51**	**12**	**63**
Number (Number per 100 000 donations)				*74.16*	*1.34*	*7.58*	*57.05*	*0.80*	*5.63*	*5.70*	*0.54*	*0.98*	*8.56*	*0.00*	*0.73*	*0.00*	*0.54*	*0.49*	*145.46*	*3.21*	*15.41*
NT	**853**	**9 493**	**10 346**	**1**	**0**	**1**	**1**	**0**	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**2**	**0**	**2**
Number (Number per 100 000 donations)				*117.23*	*0.00*	*9.67*	*117.23*	*0.00*	*9.67*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*234.47*	*0.00*	*19.33*
QLD	**21 181**	**243 042**	**264 223**	**17**	**1**	**18**	**11**	**8**	**19**	**0**	**0**	**0**	**1**	**0**	**1**	**1**	**1**	**2**	**30**	**10**	**40**
Number (Number per 100 000 donations)				*80.26*	*0.41*	*6.81*	*51.93*	*3.29*	*7.19*	*0.00*	*0.00*	*0.00*	*4.72*	*0.00*	*0.38*	*4.72*	*0.41*	*0.76*	*141.64*	*4.11*	*15.14*
SA	**6 417**	**119 530**	**125 947**	**4**	**1**	**5**	**3**	**3**	**6**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**7**	**4**	**11**
Number (Number per 100 000 donations)				*62.33*	*0.84*	*3.97*	*46.75*	*2.51*	*4.76*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*109.09*	*3.35*	*8.73*
TAS	**3 058**	**48 953**	**52 011**	**0**	**1**	**1**	**1**	**1**	**2**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**2**	**3**
Number (Number per 100 000 donations)				*0.00*	*2.04*	*1.92*	*32.70*	*2.04*	*3.85*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*32.70*	*4.09*	*5.77*
VIC	**25 332**	**292 058**	**317 390**	**27**	**3**	**30**	**14**	**2**	**16**	**0**	**0**	**0**	**5**	**0**	**5**	**0**	**0**	**0**	**46**	**5**	**51**
Number (Number per 100 000 donations)				*106.58*	*1.03*	*9.45*	*55.27*	*0.68*	*5.04*	*0.00*	*0.00*	*0.00*	*19.74*	*0.00*	*1.58*	*0.00*	*0.00*	*0.00*	*181.59*	*1.71*	*16.07*
WA	**8 815**	**123 298**	**132 113**	**10**	**3**	**13**	**2**	**1**	**3**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**1**	**13**	**4**	**17**
Number (Number per 100 000 donations)				*113.44*	*2.43*	*9.84*	*22.69*	*0.81*	*2.27*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*11.34*	*0.00*	*0.76*	*147.48*	*3.24*	*12.87*
National	**100 716**	**1 210 044**	**1 310 760**	**85**	**14**	**99**	**52**	**18**	**70**	**2**	**2**	**4**	**9**	**0**	**9**	**2**	**3**	**5**	**150**	**37**	**187**
Number (Number per 100 000 donations)				*84.40*	*1.16*	*7.55*	*51.63*	*1.49*	*5.34*	*1.99*	*0.17*	*0.31*	*8.94*	*0.00*	*0.69*	*1.99*	*0.25*	*0.38*	*148.93*	*3.06*	*14.27*

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

Consistent with a previous Blood Service study for the period 2000-2006,[6] 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 is substantially lower in blood donors than in the general population, with an 11 to 58 times reduction in first time donors and 120 to 377 times reduction among all donors in 2013. As in 2005-2012, the greatest comparative reduction among first time donors (58 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, 2005-2013

Infection	Population prevalence (per 100 000 people)		Prevalence in all blood donors (per 100 000 donations)		Prevalence in first time blood donors (per 100 000 donations)		Overall prevalence reduction in all blood donors		Prevalence reduction in first time blood donors	
	2005-2012	2013	2005-2012	2013	2005-2012	2013	2005-2012	2013	2005-2012	2013
HBV	858	908	9.38	7.55	83.83	84.40	91 times	120 times	10 times	11 times
HCV	786-1 461	1 038-1 405	8.70	5.34	73.03	51.63	90-168 times	194-263 times	11-20 times	20-27 times
HIV	104	115	0.40	0.31	1.95	1.99	260 times	377 times	53 times	58 times
HTLV[1]	–	–	0.28	0.69	2.63	8.94	–	–	–	–

1 Population prevalence for HTLV is unknown.

Demographic factors associated with transfusion-transmissible infections in blood donors

While the prevalence/incidence data covers 2005-2013, the risk factor analysis is restricted to 2008 to 2013 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 2013 was analysed[7] to determine the association between demographic factors and presence of TTIs among Australian blood donors (Table 3). Male donors, donors aged between 20 and 29 years and donors from New South Wales were used as reference groups for comparison of positivity rate by sex, age group and state/territory of donation, respectively.

HBV positivity and associated demographic risk factors

Overall, there were no significant trends in 2008-2013 for HBV positivity among Australian donors by demographics analysed. However, as in 2012, female donors were less likely to have acquired HBV infection and donors aged 40-49 years and 50 years and above were less likely to be HBV positive compared to those aged between 20 and 29 years. In 2013 there was no significant association between the state/territory of the donor and HBV infection status.

HCV positivity and associated demographic risk factors

Generally, there were no significant trends in 2008-2013 for HCV positivity among Australian donors by demographics analysed. However, while not significant, female donors were less likely (35% less likely compared to male donors) to be HCV positive. Older donors were generally more likely to be HCV positive. Donors aged 40-49 years 2.9 times more likely to be HCV positive compared to donors who were aged between 20 and 29 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 2013. This proportion increased gradually in 2009-2011, however remained stable at around 68% in the past two years. As in 2012, there was no significant association between the state/territory of donor and HCV infection status among Australian blood donors in 2013.

HIV and HTLV positivity and associated demographic risk factors

Given the small number of donors with HIV and HTLV infection in 2013 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

Table 3 Association of demographic characteristics with presence of transfusion-transmissible infection among blood donors in Australia by infection, 2013

		HBV		HCV		HIV		HTLV	
	Number of donors	Number of positive donors (Number per 100 000 donors)	IRR[1] and their 95% CI[2] (Multivariate adjusted)	Number of positive donors (Number per 100 000 donors)	IRR and their 95% CI (Multivariate adjusted)	Number of positive donors (Number per 100 000 donors)	IRR and their 95% CI (Multivariate adjusted)	Number of positive donors (Number per 100 000 donors)	IRR and their 95% CI (Multivariate adjusted)
Sex									
Male	*251 296*	*72 (28.65)*	*1 (ref)*	*43 (17.11)*	*1 (ref)*	*4 (1.59)*	*1 (ref)*	*5 (1.99)*	*1 (ref)*
Female	*257 143*	*27 (10.5)*	*0.35 (0.22-0.54)*	*27 (10.5)*	*0.65 (0.4-1.05)*	*0 (0)*	*..*	*4 (1.56)*	*1.24 (0.42-3.71)*
Age group (years)									
20-29	*112 377*	*27 (24.03)*	*1 (ref)*	*9 (8.01)*	*1 (ref)*	*0 (0)*	*1 (ref)*	*0 (0)*	*1 (ref)*
Less than 20	*43 024*	*16 (37.19)*	*1.64 (0.88-3.05)*	*0 (0)*	*..*	*1 (0.89)*	*..*	*0 (0)*	*..*
30-39	*80 870*	*22 (27.2)*	*1.05 (0.6-1.84)*	*13 (16.08)*	*1.94 (0.83-4.55)*	*1 (1.24)*	*1.16 (0.07-18.61)*	*2 (2.47)*	*..*
40-49	*86 846*	*9 (10.36)*	*0.41 (0.19-0.87)*	*21 (24.18)*	*2.91 (1.33-6.37)*	*0 (0)*	*..*	*4 (4.61)*	*..*
50 and above	*185 322*	*25 (13.49)*	*0.53 (0.31-0.91)*	*27 (14.57)*	*1.76 (0.82-3.74)*	*0 (0)*	*1.08 (0.1-11.91)*	*3 (1.62)*	*..*
State/Territory									
NSW	*155 858*	*28 (198.15)*	*1 (ref)*	*4 (2.57)*	*1 (ref)*	*1 (0.64)*	*1 (ref)*	*0 (0)*	*1 (ref)*
ACT	*14 131*	*3 (1.92)*	*1.24 (0.38-4.07)*	*19 (134.46)*	*–*	*3 (21.23)*	*3.56 (0.37-34.27)*	*3 (21.23)*	*..*
NT	*4 105*	*1 (24.36)*	*1.42 (0.19-10.44)*	*1 (24.36)*	*1.9 (0.25-14.2)*	*0 (0)*	*..*	*0 (0)*	*..*
QLD	*100 838*	*18 (17.85)*	*1.06 (0.58-1.92)*	*19 (18.84)*	*1.47 (0.78-2.78)*	*0 (0)*	*..*	*1 (0.99)*	*2.57 (0.61-10.78)*
SA	*45 495*	*5 (10.99)*	*0.68 (0.26-1.77)*	*6 (13.19)*	*1.01 (0.4-2.54)*	*0 (0)*	*..*	*0 (0)*	*..*
TAS	*16 769*	*1 (5.96)*	*0.37 (0.05-2.74)*	*2 (11.93)*	*0.93 (0.22-3.98)*	*0 (0)*	*..*	*0 (0)*	*..*
VIC	*126 044*	*30 (23.8)*	*1.4 (0.83-2.35)*	*16 (12.69)*	*0.99 (0.51-1.93)*	*0 (0)*	*..*	*5 (3.97)*	*2.06 (0.49-8.65)*
WA	*45 197*	*13 (28.76)*	*1.7 (0.88-3.3)*	*3 (6.64)*	*0.51 (0.15-1.72)*	*0 (0)*	*..*	*0 (0)*	*..*
Total	**508 439**	**99 (19.47)**		**70 (13.77)**		**4 (0.79)**		**9 (1.77)**	

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 and 2009-2012 were included in the 2012 and 2013 surveillance report, respectively. This report presents data for the period 2010 to 2013. In 2013, 187 donors were confirmed positive for at least one of the TTIs with a total of 849 confirmed positive donors over the period of 2010-2013. Among them, 27 donors were positive for active syphilis, however no risk factor data was available for these donors. The data on the remaining 822 donors who were positive for any of the other TTIs (HBV, HCV, HIV and HTLV) were analysed to determine the key attributes of blood donors with TTIs, stratified by year of donation (Tables 4-7).

Donors with HBV infection, 2010-2013

Of 457 HBV positive donors during 2010-2013, 85% were first time donors, 70% 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 twelve incident HBV blood donors in the last four years, consistent with a low incidence rate. Ethnicity or country of birth (86%) 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 (3%).

Table 4 Attributes of donors positive for HBV infection by year of donation, 2010-2013

Characteristics	2010	2011	2012	2013	2010-2013
Number of positive donors	127	118	113	99	457
Number of positive first time donors (%)	108 (84%)	99 (83%)	97 (86%)	85 (86%)	386(85%)
% male	84 (66%)	79 (67%)	84 (74%)	72 (73%)	319 (70%)
Mean age (range) in years	37 (16 to 71)	38 (16 to 77)	37 (16 to 67)	36 (16 to 73)	37 (16 to 77)
Number of incident donors	3	5	1	3	12
% born in Australia	17 (13%)	15 (13%)	19 (17%)	14 (14%)	65 (14%)
Main reported risk factor	Ethnicity/COB[1]	Ethnicity/COB	Ethnicity/COB	Ethnicity/COB	Ethnicity/COB
	83%	85%	89%	90%	86%
Second reported risk factor	Partner with known risk or known to be positive	TBP[2],PRP[3] each	Partner with known risk or known to be positive	Other	Partner with known risk or known to be positive
	4%	3%	4%	2%	3%

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

Donors with HCV infection, 2010-2013

Of 328 donors positive for HCV in 2010-2013, 76% were first time donors (Table 5). The mean age of HCV positive donors was 43 years with a tight range (42-45) 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 (66%) of HCV positive donors were born in Australia. The number of incident HCV infections (42 donors) was the highest among all TTIs. Overall, the most important risk factor for HCV positivity was tattoo or body piercing (26%) followed by intravenous drug use (21%).

Table 5 Attributes of donors positive for HCV infection by year of donation, 2010-2013

Characteristics	2010	2011	2012	2013	2010-2013
Number of positive donors	86	81	91	70	328
Number of positive first time donors (%)	67 (79%)	59 (73%)	67 (7%)	52 (74%)	29 (76%)
% male	53 (62%)	55 (68%)	56 (62%)	43 (61%)	207 (63%)
Mean age (range) in years	42 (16 to 63)	42 (16 to 78)	44 (16 to 66)	45 (23 to 66)	43 (16 to 78)
Number of incident donors	10	6	12	14	42
% born in Australia	61 (71%)	51 (63%)	62 (68%)	41 (59%)	215 (66%)
Main reported risk factor	Tattoo/Body piercing	Intravenous drug use	Tattoo/Body piercing	Tattoo/Body piercing	Tattoo/Body piercing
	21%	21%	31%	33%	26%
Second reported risk factor	Intravenous drug use	Tattoo/Body piercing	Intravenous drug use	Intravenous drug use	Intravenous drug use
	19%	20%	23%	19%	21%

Donors with HIV infection, 2010-2013

In contrast to HBV and HCV infected donors, the majority of HIV infected donors during 2010-2013 were repeat donors (62%) (Table 6). Most were male (71%) with a mean age of 39 years and Australian born (62%). In respect of country of birth and mean age, 2011 and 2013 were notable, respectively. The proportion born in Australia in 2011 (29%) was markedly lower that the average for 2010-2013 (62%), and the mean age in 2013 (47 years) was noticeably higher that the average for 2010-2013 (39 years). 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 2010-2013, most of the newly diagnosed HIV cases were male (86.5%) with a mean age of 36.8 years.[8] Of 21 HIV positive donors, there were 10 incident HIV donors during the last four years. Having a sexual partner with known risk or known to be positive for any TTI (48%) and male-to-male sexual contact (29%) were the two most important risk factors for HIV positivity in blood donors during 2010-2013. By comparison, male-to-male sexual contact and heterosexual contact accounted for 64% and 25% of the new HIV diagnoses in the general population in 2013, respectively.[8]

Table 6 Attributes of donors positive for HIV infection by year of donation, 2010-2013

Characteristics	2010	2011	2012	2013	2010-2013
Number of positive donors	7	7	3	4	21
Number of positive first time donors (%)	1 (14%)	4 (57%)	1 (33%)	2 (50%)	8 (38%)
% male	5 (71%)	5 (71%)	3 (100%)	4 (100%)	17 (81%)
Mean age (range) in years	37 (23 to 57)	36 (22 to 62)	36 (19 to 56)	47 (28 to 65)	39 (19 to 65)
Number of incident donors	4	3	1	2	10
% born in Australia	6 (86%)	2 (29%)	2 (67%)	3 (75%)	13 (62%)
Main reported risk factor	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	Male-to-male sexual contact	Partner with known risk or known to be positive
	57%	57%	100%	75%	48%
Second reported risk factor	Male-to-male sexual contact	Male-to-male sexual contact	–	Ethnicity/COB[1]	Male-to-male sexual contact
	14%	14%		25%	29%

1 COB=Country of birth

8 The Kirby Institute. *op. cit.*

Donors with HTLV infection, 2010-2013

Only 16 donors were positive for HTLV infection during the 2010-2013 period, 94% were first time donors and 53% were male, with a mean age of 44 years (Table 7). Most of the HTLV positive donors (77%) were born overseas. There was only one incident HTLV donor in 2010. Ethnicity or country of birth (80%) was the most important risk factor for HTLV infection in accepted blood donors in Australia. Despite the recent increase in HTLV prevalence in first time donors in 2013 compared to previous years, attributes of HTLV positive donors remained fairly similar over the past six years. Ethnicity or country of birth has consistently remained the main reported risk factor for HTLV positive blood donors during the study period.

Table 7 Attributes of donors positive for HTLV infection by year of donation, 2010-2013

Characteristics	2010	2011	2012	2013	2010-2013
Number of positive donors	2	3	2	9	16
Number of positive first time donors (%)	1 (50%)	3 (100%)	2 (100%)	9 (100%)	15 (94%)
% male	1 (50%)	1 (33%)	2 (100%)	5 (56%)	8 (53%)
Mean age (range) in years	70 (70)	38 (23 to 46)	32 (27 to 37)	45 (30 to 58)	44 (23 to 70)
Number of incident donors	1	0	0	0	1
% born in Australia	0 (0%)	0 (0%)	0 (0%)	2 (22%)	2 (13%)
Main reported risk factor	Ethnicity/COB[1]	Ethnicity/COB	Ethnicity/COB	Ethnicity/COB	Ethnicity/COB
	50%	66%	100%	78%	80%
Second reported risk factor	–	Tattoo/Body piercing	–	Partner with known risk or known to be positive	Partner with known risk or known to be positive
		33%		22%	13%

1 COB=Country of birth

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

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

Consistent with previous years, the most frequent risk factor for HBV positive donors was ethnicity or country of birth which accounted for 90% of the HBV positive donors in 2013. 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 2013 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 2013. Nonetheless, the proportion of individuals reporting intravenous drug use among newly acquired HCV infections in the general population[12] (73.7%) was comparatively higher than in the donor population (18.6%) in 2013, reflecting the effectiveness 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 (71.7%). This was consistent with the finding among blood donors, where sexual contact was identified as the primary risk factor for the majority of the HIV positive blood donors in 2013.

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 China.[13] This is consistent with our finding that ethnicity or country of birth was the infective risk in 7 out of the 9 HTLV positive donors in 2013. While there has been an increase in HTLV prevalence in first time donors in 2013 compared to previous years, ethnicity or country of birth has consistently remained the main reported risk factor for HTLV positive blood donors.

Table 8 Comparison between positive blood donors and the general population in Australia by infection and major risk categories, 2013

	HBV[1]		HCV[1]		HIV[2]		HTLV	
Major risk category	**General population (%)**	**Blood donors (%)**	**General population (%)**	**Blood donors (%)**	**General population (%)**	**Blood donors (%)**	**General population (%)**	**Blood donors (%)**
Intravenous drug use	20.9	1.0	73.7	18.6	2.4	0.0	–	0.0
Country of birth/Ethnicity	0.0	89.9	0.0	8.6	2.2	25.0	–	78.0
Sexual contact[3]	12.2	1.0	3.9	11.4	71.7	75.0	–	22.0
Blood or tissue recipient	0.0	0.0	0.5	2.9	0.4	0.0	–	0.0
Tattoo or body piercing	2.3	1.0	1.5	32.9	0.0	0.0	–	0.0
Exposure in health care setting	2.3	1.0	1.5	11.4	0.0	0.0	–	0.0
Household contact	0.0	1.0	0.7	1.4	0.0	0.0	–	0.0
Other blood to blood contact	0.0	0.0	0.0	2.9	0.8	0.0	–	0.0
Other/undetermined	62.2	2.0	18.2	2.9	2.8	0.0	–	0.0
No risk factors identified	**0.0**	**2.0**	**0.0**	**2.9**	**0.0**	**0.0**		**0.0**
Not reported	**0.0**	**1.0**	**0.0**	**4.3**	**0.0**	**0.0**	**–**	**0.0**

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

2 Includes exposure categories for new HIV diagnoses

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

Non-compliance among positive donors

About 17% of the positive donors in 2010-2013 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 optimising methods for ascertaining donor risk behaviour. A donor who does not appropriately report risk behaviour for a transfusion-transmissible infection poses a potential risk to the safety of the blood supply for two reasons. Firstly, if a donor with a history of recent 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, 2010-2013**

	2010	2011	2012	2013	2010-2013
Number (%) of non-compliant donors by reasons for deferral					
Injecting drug user	30 (66.7)	15 (55.6)	21 (52.5)	13 (48.2)	79 (56.8)
Known status/previous positive[1]	8 (17.8)	8 (29.6)	13 (32.5)	11 (40.7)	40 (28.8)
Male-to-male-sexual contact	2 (4.4)	0 (0)	0	2 (7.4)	4 (2.9)
Partner with known risk or known to be positive	1 (2.2)	3 (11.1)	4 (10)	1 (3.7)	9 (6.5)
Others	4 (8.9)	1 (3.7)	2 (5)	0 (0)	7 (5)
Total number (%) of non-compliant donors by year	**45 (20.4)**	**27 (12.9)**	**40 (19.1)**	**27 (14.8)**	**139 (16.9)**

1 Includes history of hepatitis not further specified

During 2010-2013, 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 study[14] 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 increased to 19.1% in 2012 but pleasingly has declined again in 2013 to 15%, suggesting it may have stabilised at a lower level. Consistent with previous years, almost half (48.2%) of non-compliant positive donors in 2013 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 2009-2013, 56.8% of non-compliance was attributed to injecting drug use followed by known status of previously being positive for a virus (28.8%), having a sexual partner with known risk or known to be positive for any transfusion-transmissible infection (6.5%) and male-to-male sexual contact within the last 12 months (2.9%).

Non-compliance among negative donors

While the rate of non-compliance among Australian donors with TTIs has been known since 2000, the rate of non-compliance among TTI-negative donors was unidentified until 2013. 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 the UK and Canada[15,16] estimated non-compliance to deferral questions relating to male-to-male sex among test-negative 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, 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, and aimed to estimate the prevalence of, and likely reasons for, non-compliance among Australian donors with the deferrals for injecting drug use, sex with an injecting drug user, male-to-male sex, sex worker activity/contact and sex with a partner from a high HIV prevalence country.

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 with 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. The estimated prevalence of overall non-compliance (i.e. to at least one screening question) among the survey respondents was 1.65%.[18] Importantly, the selected high-risk behaviours studied were substantially less common (3 to 14 times) in blood donors compared to the general population suggesting that self-deferral

14 Polizzotto. *op. cit.*

15 Grenfell P, Nutland W, McManus S, Datta J, Soldan K, Wellings K. Views and experiences of men who have sex with men on the ban on blood donation: a cross sectional survey with qualitative interviews. *BMJ*. 2011;343.

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, C. R., Lucky, T. T., Waller, D., Wand, H., Lee, J. F., Wroth, S., McDonald, A., Pink, J., Wilson, D. P. and Keller, A. J. (2014), Compliance with the current 12-month deferral for male-to-male sex in Australia. V*ox Sanguinis*. 106: 14–22.

18 Lucky, T. T.A., Seed, C. R., Waller, D., Lee, J. F., McDonald, A., Wand, H., Wroth, S., Shuttleworth, G., Keller, A. J., Pink, J. and Wilson, D. P. (2014), Understanding noncompliance with selective donor deferral criteria for high-risk behaviors in Australian blood donors. *Transfusion*. 54: 1739–1749.

is effective. However, while the estimated non-compliance rate of 1.65% is consistent with published data[19] and would seem reassuringly low, the impact of extrapolation to the annual number of test-negative donors (approximately 600 000) indicates approximately 10 000 non-compliant test-negative donors per year. This makes it imperative to understand the factors impacting non-compliance in order to minimise it. Multivariate analyses of factors influencing non-compliance within the study suggested a focus on using interactive methods of delivering pre-donation information, repeating important information in a simplified manner, and validating the use of an audio computer-assisted structured interview (ACASI).

An unexpected and concerning finding was that a small number of donors are donating to get tested for an infections including HIV - referred to as 'test-seeking' behaviour. Among male donors test-seeking was statistically associated with non-compliance. Test-seeking for TTIs is detrimental to blood safety given a donor could attend while in the window period. Importantly, test-seeking poses an avoidable risk to the blood supply given the availability of free sexually-transmissible infection (STI) testing in Australia. Ultimately, further research on the motivation for test-seeking is indicated.

Incident donors

The Blood Service assesses the incidence rate of newly acquired infection in donors since this correlates directly with the risk of transmission. Incident donors (formerly 'seroconverters') are defined as 'positive repeat donors whose last donation tested negative for the same transfusion-transmissible infection'. The change in nomenclature from seroconverters to incident donors recognises the implementation of nucleic acid tests for HIV, HCV and HBV. In this context it is possible that a previously NAT negative donor may be detected as NAT positive but serologically negative at their most recent donation. Given the donor is serologically negative it is misleading to apply the term 'seroconversion' and thus we have chosen to use the term 'incident donor' reflecting that it encompasses a test pattern indicative of recently acquired in infection.

During 2005-2013, a total of 130 incident donors were identified. Consistent with 2008-2012, the highest number of incident infections in 2013 were HCV (14 out of 18), accounting for almost 72% of the total. A further three HBV and two HIV incident donors were identified but none were recorded for HTLV.

Consistent with the findings from previous years, incident donors in 2013 were disproportionately male (61.1%) and the majority were Australian born (61%). The mean age of incident donors in 2013 was 43 years (38.7 years for HBV, 43.9 years for HCV and 50 years for HIV).

Viral residual risk estimates

The rate of incident donors can be used to estimate the risk of collecting a unit of blood from a donor with very early infection (window period) which might test negative. Individuals donating in the window period (incident infections) generally pose the majority of the risk in terms of transmission because they may be missed by testing whereas long standing (prevalent) infections are readily detected by modern screening tests. The exception is HBV where chronically infected donors with occult HBV infection (OBI) may contribute a substantial risk. Highlighting this, a model developed by the Blood Service estimated that the majority (55%) of the HBV residual risk in Australia results from donors with OBI.[20]

Using viral testing data including the number of incident donors reported for the 2012 and 2013 calendar year periods and applying these to four published risk models, residual risk estimates[21] (per unit transfused) were derived for the four transfusion-transmissible viral infections subject to mandatory testing (Table 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 468 000 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.

19 Williams AE, Thomson RA, Schreiber GB, et al. Estimates of infectious disease risk factors in US blood donors. JAMA.1997;277:967-72.

20 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 ;105: p. 290-298.

21 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.

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 (2012-2013)**

	HBV	HCV	HIV	HTLV	Active syphilis
Estimated rate of collecting infectious unit (per million donations)	2-3	<1	<1	<1	<1
Residual Risk to recipient - per unit transfused	Approximately 1 in 468 000	Less than 1 in 1 million	Less than 1 in 1 million	Less than 1 in 1 million	Less than 1 in 1 million

Based on the estimates and assuming approximately 1.3 million donations collected per annum, two to 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 2005-2013 period.

Testing for malaria

In Australia, donation testing for malaria infection is limited to 'at risk' donors. This includes donors who report at the pre-donation interview travel to or reside in malaria endemic countries, as well as those with a previous history of infection.[22] The availability of malaria antibody testing results in significant recovery of valuable fresh blood components (red blood cells and platelets) as prior to the commencement of testing such donors were restricted to donating plasma for fractionation only, for 1-3 years. Annually an estimated 65 000 red cells and 7 000 platelets are 'recovered' as a result of non-reactive malaria antibody test results. Since malaria antibodies can indicate both recent and past infection all antibody repeat reactive donors are also tested for malaria antigen and malaria DNA to exclude current infection. Donors positive for one or both supplementary tests are immediately referred for clinical assessment.

In 2013, 110 866 donations were tested for malaria antibody of which 1 618 (1.5%) were found to be repeat reactive for malaria antibodies. None of these 1 618 donations had detectable malaria DNA suggesting past infection in the donors. Detecting malaria DNA among screened donations is rare, with only three occurrences since malaria testing commenced at the Blood Service in 2005. All three donors were born in malaria endemic countries and had very low parasite loads consistent with 'semi-immunity', a clinical state in which malaria parasites persist at low levels without symptoms of infection.

Minimising bacterial contamination of blood components

The risk of bacterial transmission following transfusion of platelets and red cells is the most common infectious risk of transfusion. International data indicates the risk of clinically apparent reactions to be at least 1:75 000[23] for platelets and 1:500 000[24] 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.[25] 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.

22 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.

23 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.

24 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.

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

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%.[26]

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.[27]

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

Bacterial pre-release testing for platelets

Platelets are manufactured either from 'apheresis' collections or 'pooling' buffy coats from four whole blood collections. A single apheresis donation can result in up to two platelet units whilst pooling results in a single platelet pack. Using a closed system 8-20 mL is removed from platelet packs no earlier than 24 hours after collection and samples are inoculated into aerobic and anaerobic culture bottles and incubated on the BacT/ALERT system. Platelets can be issued immediately after inoculation and the culture maintained for 7 days. Samples flagging as 'reactive' after platelet issue lead to immediate recall and clinician notification in the event they have already been transfused. All initially reactive samples are subject to further investigation and follow-up testing.

Table 11 Summary of bacterial testing of platelets by BacT/ALERT, 2013

Platelet type	No. components screened	No. initial positive[1] (%)	No. confirmed positive[2] (%)	No. indeterminate[3] (%)	No. false positive[4] (%)
Pooled platelets	91 567	596 (0.65)	109 (0.12)	80 (0.09)	407 (0.44)
Apheresis platelets	32 814	189 (0.58)	11 (0.03)	18 (0.05)	159 (0.48)
Total	**124 381**	**785 (0.63)**	**120 (0.10)**	**98 (0.08)**	**566 (0.46)**

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

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

During 2013, 124 381 platelet units were screened for bacterial contamination (Table 11). Of the 32 814 apheresis units tested 189 (0.56%) were flagged as initially positive however only 11 (0.03%) were determined as 'confirmed positive' with an additional 18 (0.05%) classified as 'indeterminate'. The remaining 159 (0.48%) were classified as 'false positive' predominantly associated with anaerobic culture bottles. There were 91 567 pooled platelet units tested of which 596 (0.65%) flagged as initially positive with 109 (0.12%) determined as 'confirmed positive'. A further 80 (0.09%) were classified as 'indeterminate' and the remaining 407 (0.44%) were classified as 'false positive'.

Propionibacterium spp., which are common skin commensals were by far the most frequently isolated organisms but have not been associated with septic transfusion reactions in recipients. The propensity for *Propionibacterium* spp. to be contaminants likely relates to their colonisation of hair follicles and deep skin layers which are not reached

26 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.

27 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.

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 *Streptococcus agalactiae and Streptococcus pneumonia,* both of which are clinically significant. In almost all cases where a clinically significant organism was detected, associated blood components were recalled and discarded prior to transfusion, thus preventing potential septic transfusion reactions. As our donors were all clinically well during their donation, detection likely represents transient bacteraemia from a bowel or throat source in the donor.

During 2013, no cases of septic transfusion reactions were identified in patients who received platelets.

Table 12 Summary of bacterial organisms detected in confirmed positives, 2013

Confirmed positive organisms	Number
Propionibacterium spp.	104
Coagulase Negative Staphylococci	12
Streptococcus agalactiae	1
Streptococcus equi	1
Streptococcus pneumoniae	1
Mixed organisms	1
Total	**120**

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

Surveillance for emerging infections

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

2013 summary

Dengue outbreaks in Queensland

Dengue virus transmission by fresh blood components has been demonstrated and thus poses a risk to transfusion safety.[28] During 2013 there were several dengue fever outbreaks in northern Queensland.[29] In February there were 3 reported outbreaks: Cairns (Edge Hill) with 3 confirmed cases and Port Douglas with 12 confirmed and 1 probable case (both declared over in May), and Innisfail with 9 confirmed cases which was declared over in July. In March there were 2 reported outbreaks: Townsville (Cranbrook, South Townsville, Kirwan, Wulguru, Mundingburra, Rosslea, Railway Estate, West End) with 19 confirmed cases and declared over in August, and Ingham with 4 confirmed cases and declared over in July. In May there was an outbreak in Pimlico with 3 confirmed cases and declared over in August. In June there was an outbreak in Woree with 6 confirmed cases which was declared over in September. The final reported outbreak for 2013 was in October in the Miallo/Port Douglas area with 14 confirmed cases and was still ongoing at the end of 2013. In addition, there was an outbreak in 2012 in Cairns (Whitfield, Manoora, Parramatta Park, Edge Hill, Manunda, Holloways Beach, White Rock, Kewarra Beach, Bungalow, Bentley Park, Earlville) that continued until October 2013 with 146 confirmed cases. 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.

28 Lanteri MC and Busch MP. Dengue in the context of "safe blood" and global epidemiology: to screen or not to screen? *Transfusion*. 2012; 52:1634-1639.

29 Queensland Health. Queensland Notifiable Conditions Data. Weekly reports for 2013. http://www.health.qld.gov.au/ph/cdb/sru_data.asp Accessed 27 July 2014

West Nile virus (WNV)

Outbreaks in Europe and Blood Service risk assessment

Transmission of West Nile virus (WNV) by blood, tissue and organ transplantation has been documented.[30] 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 2013 transmission season (July to November) in the EU and neighbouring countries there were outbreaks of WNV fever in Bosnia and Herzegovina, Croatia, Czech Republic, the Former Yugoslav Republic of Macedonia, Greece, Hungary, Israel, Italy, Montenegro, Romania, Russian Federation, Serbia, Tunisia and the Ukraine.[31] The largest outbreaks were in Serbia (302 reported cases of WNV fever), the Russian Federation (177 cases) and Greece (86 cases). There was a total of 785 reported cases in 2013 compared with 937 cases in 2012. The most notable changes in 2013 compared to 2012 were a dramatic increase in reported cases in Serbia (302 vs 69, respectively) and the Russian Federation (177 vs 447, respectively). The Blood Service monitored these outbreaks based on regular updates of WNV cases provided by the European Centre for Disease Prevention and Control (ECDC). The Blood Service performed weekly risk modelling to estimate the risk of a donor returning from these countries and donating while infectious (i.e. viraemic). This modelling indicated that the additional level of risk to the Australian blood supply associated with donors returning from these countries during the 2013 WNV transmission season did not exceed the threshold (established for local dengue outbreaks) that requires cessation of fresh blood component manufacture.

Hendra virus

Human Hendra virus (HeV) infection is an emerging Australian zoonotic disease associated with high mortality (4/7 infections fatal).[32] To date all seven recorded cases of HeV transmission to humans has occurred from *Pteropus* bats (flying foxes) via horses. Last year, the world's first commercially available HeV vaccine for horses, Equivac(R) HeV, was launched in Australia.[33]

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, faecal material and organs of horses.[34] 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.

While no cases of human HeV infection were recorded in 2013, there were 5 equine cases across properties in NSW (Macksville and Somerset) and Queensland (Mackay region, Atherton Tablelands and Gold Coast hinterland).[35,36,37,38,39] In 2013, HeV was detected in South Australian flying foxes for the first time, highlighting the geographical spread of the virus in bats.[40] However, it should be noted that HeV has not been identified in horses in Victoria or South Australia. In addition, in 2013 HeV was detected in a dog on a property in the NSW region of Macksville and this was only the second reported case of canine HeV infection

30 Marka A, Diamantidis A, Papa A, Valiakos G et al. West Nile Virus State of the Art Report of MALWEST Project. *Int J Environ Res Public Health*. 2013;10:6534-610.

31 European Centre for Disease Control and Prevention. West Nile virus fever. Table on cases 2012, and Table on cases 2013. http://www.ecdc.europa.eu/en/healthtopics/west_nile_fever/West-Nile-fever-maps/Pages/2013-table.aspx Accessed 27 July 2014.

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

33 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.

34 NSW Department of Primary Industries. Agriculture. Hendra virus. http://www.dpi.nsw.gov.au/agriculture/livestock/horses/health/general/hendra-virus Accessed 27 July 2014.

35 ProMED-mail. Hendra virus, equine - Australia: (QL), RFI. ProMED mail 2013; 24 Jan: 20130124.1512182 http://www.promedmail.org . Accessed 28 July 2014.

36 ProMED-mail. Hendra virus, equine - Australia: (02) (QL). ProMED mail 2013; 24 Feb: 20130224.1557005 http://www.promedmail.org . Accessed 28 July 2014.

37 ProMED-mail. Hendra virus, equine - Australia (06): (QL)). ProMED mail 2013; 26 Jun: 20130626.1792190 http://www.promedmail.org . Accessed 28 July 2014.

38 ProMED-mail. Hendra virus, equine - Australia (08): (QL, NS). ProMED mail 2013; 12 Jul: 20130712.1820724 http://www.promedmail.org . Accessed 28 July 2014.

39 ProMED-mail. Hendra virus, equine - Australia (10): (QL, NS). ProMED mail 2013; 25 Aug: 20130825.1900419 http://www.promedmail.org . Accessed 28 July 2014.

40 ProMED-mail. Hendra virus, equine - Australia (09): (NS) dog affected. ProMED mail 2013; 21 Jul: 20130721.1837123 http://www.promedmail.org . Accessed 04 August 2014.

(a previous case was reported in 2011 in NSW).[41] At present there is no evidence that HeV can be transmitted from dogs to horses or humans.

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. Based on an analysis of laboratory-confirmed cases during 2013, common symptoms at presentation were fever (98%), fever with chills or rigors (87%), cough (83%), shortness of breath (72%) and myalgia (32%). Grastrointestinal symptoms have also been common, including diarrhoea (26%), vomiting (21%) and abdominal pain (17%) and a proportion have developed renal failure.[42] The route of MERS-CoV transmission has not yet been established. However, initial data suggests a zoonotic origin as the virus is most closely related to two bat coronaviruses.[43] 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. Between April 2012 and March 2013 there were only 16 reported human cases of MERS-CoV. However, from April to December 2013 the number of reported human MERS-CoV cases averaged 16 per month.[44] Approximately 85% of cases were reported in Saudi Arabia. However, the potential for MERS-CoV to be spread by human travel was indicated by the observation that during 2013 a number of imported human MERS-CoV cases were reported in France, Tunisia, the UK (with limited local transmission in these 3 countries), Italy and Germany.[45] The locally transmitted cases were patients who had not been to the Middle East but had been in close contact with laboratory-confirmed or probable cases with a Middle East connection. Transfusion transmission of MERS-CoV has not been reported. However, given that infection includes a viraemic phase, the possibility of asymptomatic viraemia and potential transfusion transmission cannot be excluded. During 2013, the risk posed by MERS-CoV to Australia's blood safety appeared to be very low. During 2013 the European Centre for Disease Prevention and Control (ECDC)[46] assessed that the risk of MERS-CoV infections in Europe was low, particularly given the lack of evidence for sustained human-to-human transmission, and WHO did not advise any special screening at points of entry with regard to MERS-CoV nor did it recommend the application of any travel or trade restrictions. The Blood Service is managing the potential risk from MERS-CoV by ongoing monitoring of reports of laboratory-confirmed cases and the geographical location of case clusters and local human-to-human transmission.

Avian influenza H7N9 virus – A(H7N9)

On 31 March 2013, the Chinese Centre for Disease Control and Prevention reported the isolation of A(H7N9) virus from 3 human patients with respiratory infections. This was the first report of this avian influenza subtype in humans.[47] The H7 subtypes are usually restricted to birds and the H7N9 subtype has previously been reported in birds in the Netherlands, Japan and US. The clinical features in humans infected with the influenza A(H7N9) virus appear to be similar, although not identical, to those seen in patients infected with H5N1 or pandemic H1N1

41 ProMED-mail. Hendra virus, bats - Australia: (SA) 1st detection. ProMED mail 2013; 19 Jan: 20130119.1505446 http://www.promedmail.org . Accessed 28 July 2014.

42 Assiri A, Al-Tawfiq JA, Al-Rabeeah AA et al. Epidemiological, demographic, and clinical characteristics of 47 cases of Middle East respiratory syndrome coronavirus disease from Saudi Arabia: a descriptive study. *Lancet Infect Dis.* 2013; 13:752-61.

43 Cotten M, Watson SJ, Kellam P et al. Transmission and evolution of the Middle East respiratory syndrome coronavirus in Saudi Arabia: a descriptive genomic study. *Lancet*. 2013; Sep 19. pii: S0140-6736(13)61887-5. doi: 10.1016/S0140-6736(13)61887-5.

44 Penttinen PM, Kaasik-Aaslav K, Friaux A et al. Taking stock of the first 133 MERS coronavirus cases globally – is the epidemic changing? *Euro Surveill.* 2013;18(39):pii=20596. Available online: http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=20596.

45 WHO. Global Alert and Response (GAR). Coronavirus Infections. http://www.who.int/csr/don/archive/disease/coronavirus_infections/en/ (Accessed 28 July 2014).

46 European Centre for Disease Prevention and Control. Updated Rapid Risk Assessment. Severe respiratory disease associated with Middle East respiratory syndrome coronavirus (MERS-CoV). Eighth update, 06 November, 2013.

47 Kageyama T, Fujisaki S, Takashita E et al. Genetic analysis of novel avian A(H7N9) influenza viruses isolated from patients in China, February to April 2013. *Euro Surveill*. 2013;18(15):pii=20453. Available online: http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=20453

influenza A virus subtypes.[48,49,50,51,52] The incubation period from exposure to the appearance of symptoms has been estimated at 5 days (interquartile range of 2-8 days). Clinical findings indicated that fever and cough were the most common presenting symptoms and 97% of symptomatically infected individuals had findings consistent with pneumonia. Acute respiratory distress syndrome (ARDS) was the most frequent (72%) complication followed by shock (26%), acute kidney injury (16%) and rhabdomyolysis (10%). Reports have indicated a fatality rate of approximately 30% with a median period from the onset of illness to death of 14 days (range 6-58 days). Individuals older than 50 years appear to be at increased risk of infection and experience more severe illness. There is some evidence that a substantial proportion of mild infections are not diagnosed.

Currently the most plausible explanation for the origin of A(H7N9) infection in humans is exposure to a zoonotic avian influenza virus that has spread in poultry in parts of Eastern China. Many of the human cases of A(H7N9) virus appear to have a link with live bird markets but to date no human cases or animal infections of A(H7N9) have been detected on poultry farms. So far the evidence indicates that the A(H7N9) is not easily transmitted human-to-human via airborne secretions from sneezing and coughing but appears to require direct, intimate contact for infection. Transfusion transmission of the avian influenza A(H7N9) virus has not been reported but cannot be excluded as A(H7N9) has been detected in patients. During 2013 the risk posed to the Australian blood supply from A(H7N9) appeared to be very low.[53,54] Very few cases were reported outside of mainland China and there is no evidence of sustained human-to-human spread and no indication that international spread of the virus in humans or animals has occurred. WHO did not advise special screening of points of entry with regard to A(H7N9) and did not recommend any travel or trade restrictions.[55] Similarly, the ECDC did not recommend travel or trade restrictions with China and existing deferral criteria for blood safety should stay unchanged.[56] Similar to the MERS-CoV outbreak, the Blood Service is managing the potential risk from A(H7N9) by ongoing monitoring of reports of laboratory-confirmed cases and the geographical location of case clusters and local human-to-human transmission.

48 Gao HN, Lu HZ, Cao B et al. Clinical findings in 111 cases of influenza A (H7N9) virus infection. *New Engl J Med*. 2013; DOI: 10.1056/NEJMoa1305584.

49 Cowling BJ, Jin L, Lau EH et al. Comparative epidemiology of human infections with avian influenza A H7N9 and H5N1 viruses in China: a population-based study of laboratory-confirmed cases. Lancet. 2013; 382:129-137.

50 Yu X, Zhang X, He Y et al. Mild infection of a novel H7N9 avian influenza virus in children in Shanghai. *Emerg Microbes Infect*. 2013; 2,e41; doi:10.1038/emi.2013.41.

51 Ip DK, Liao Q, Wu P et al. Detection of mild to moderate influenza A/H7N9 infection by China's national sentinel surveillance system for influenza-like illness: case series. *BMJ*. 2013;346:f3693.

52 Yu L, Wang Z, Chen Y et al. Clinical, virological, and histopathological manifestations of fatal human infections by avian influenza A(H7N9) virus. *Clin Infect Dis*. 2013; 57:1449-1457.

53 Bai T, Zhou J and Shu Y. Serologic study for influenza A(H7N9) among high-risk groups in China. *New Engl J Med*. 2013; DOI: 10.1053/NEJMc1305865.

54 Ai J, Huang Y, Xu K et al. Case-control study of risk factors for human infection with influenza A(H7N9) virus in Jiangsu Province, China, 2013. *Euro Surveill*. 013;18(26):pii=20510. Available online: http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=20510 .

55 World Health Organisation Risk Assessment. Human infections with avian influenza A(H7N9) virus. 10 May 2013.

56 European Centre for Disease Control and Prevention. Updated Rapid Risk Assessment. Human infection with a novel avian influenza virus, A(HH7N9) – China. 8 May 2013.

Conclusions

1. Supporting the effectiveness of donor education and selection, the prevalence of TTIs is substantially lower among both first time blood donors (11 to 58 times) and all donors (120 to 377 times) than in the general population in 2013 and shows a stable or declining trend since 2005.

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

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

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

5. Almost 17% of the positive donors in 2010-2013 were 'non-compliant' in that they had risk factors identified during their post-donation interview that would have deferred them from donating had they disclosed them at the pre-donation interview. The non-compliance rate of 20-25% declined gradually during 2008-2011 to its lowest ever level in 2011 (12.9%) and subsequently appears to have stabilised at a lower threshold, around 15%. 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 large national survey in 2012-2013 showed a comparatively low rate of non-compliance (in the range 0.05 to 0.29%) among TTI test-negative donors for several sexual activity-based donor deferrals. Non-compliance with the 12-month deferral for male-to-male sex (which is the subject of the majority of international research and controversy) was 0.23%. This is markedly lower than published overseas studies which range from 0.8-2.3%. The estimated prevalence of overall non-compliance (i.e. to at least one screening question related to the deferrals for injecting drug use, sex with an injecting drug user, male-to-male sex, sex worker activity/ contact and sex with a partner from a high HIV prevalence country) was 1.65%. While these estimates are minimum estimates because non-compliant donors might have chosen not to take the survey or been non-compliant if they did, overall these findings are reassuring and support the effectiveness of the current screening questions.

7. An unexpected and concerning compliance survey finding was that a small number of donors are donating to get tested for infections including HIV - referred to as 'test-seeking' behaviour. Among male donors test-seeking was statistically associated with non-compliance. Test-seeking for TTIs is detrimental to blood safety given a donor could attend while in the window period. Importantly, test-seeking poses an avoidable risk to the blood supply given the availability of free sexually-transmissible infection (STI) testing in Australia.

8. 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 468 000) 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 TTIs for which testing is conducted. Despite this, there remains a minimal but real risk of TTIs which must be carefully considered before any transfusion.

9. Bacterial screening of 124 381 platelets identified 120 (0.1%) as confirmed positive. The majority of organisms identified were slow-growing anaerobic skin flora not usually associated with post-transfusion septic reactions. However, a minority of platelets grew clinically-significant organisms which were likely to have been due to transient or occult bacteraemia in the donor and could have led to potentially serious septic transfusion reactions in the recipient.

10. In addition to established TTIs, emerging infectious diseases continue to demand vigilant surveillance. Mosquito-borne agents such as dengue virus and West Nile virus are currently the principal threats but many other novel or emerging infectious diseases are constantly monitored by the Blood Service to assess their threat to the safety of the blood supply. The worldwide spread of dengue virus continued in 2013 and with several seasonal outbreaks in northern Queensland were subject to the routine risk mitigation strategies. Overall, the number of reported cases of WNV fever in EU and neighbouring countries was lower in 2013 compared to 2012. While no cases of human Hendra virus infection were recorded in 2013, there were 5 equine cases. The world's first commercially available vaccine against Hendra virus was launched in Australia in late 2012. 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. While between April 2012 and March 2013 there were only 16 reported human cases of MERS-CoV, from April to December 2013 the number of reported human MERS-CoV cases averaged 16 per month. No sustained human to human transmission or transfusion transmission has been identified and the risk to the blood supply is assessed as very low. In 2013 the first isolation of A(H7N9) virus from 3 human patients with respiratory infections was reported. Transfusion transmission of the avian influenza A(H7N9) virus has not been reported. While it cannot be excluded, based on the current knowledge of A(H7N9) and lack of documented transfusion transmission by known influenza viruses, it is very unlikely.

Supporting figures

Figure 1 **Percentage of age-eligible general population who donated blood in 2013, by state/territory**

Figure 2 **Number of blood donors with transfusion-transmissible infections in Australia, by infection and year of donation, 2007-2013**

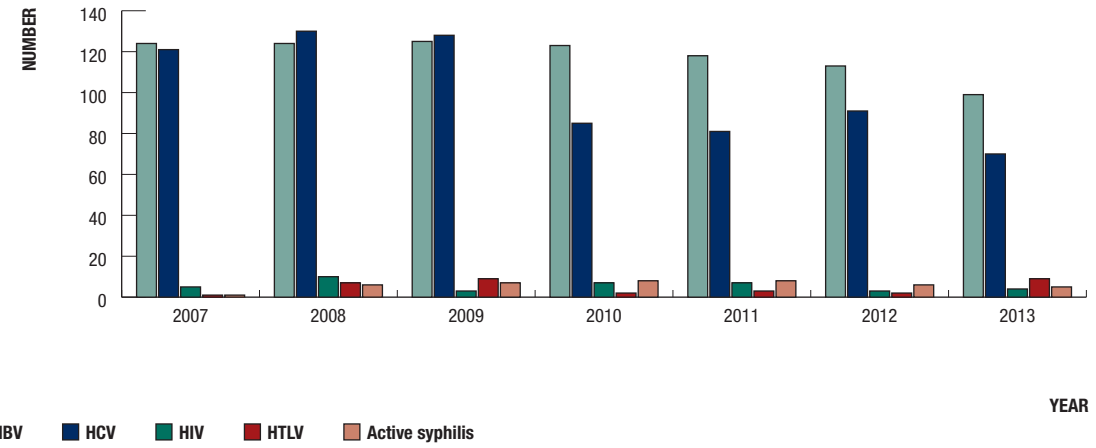


Figure 3 **Percentage of donations made by first time and repeat donors among all blood donations in Australia, 2007-2013**

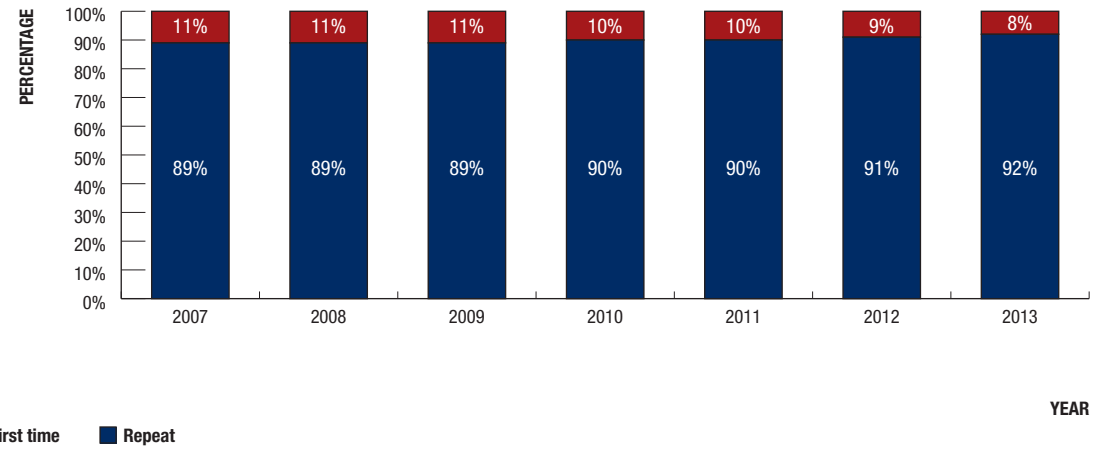


Figure 4 **Distribution of blood donors in Australia by age group and sex, 2013**

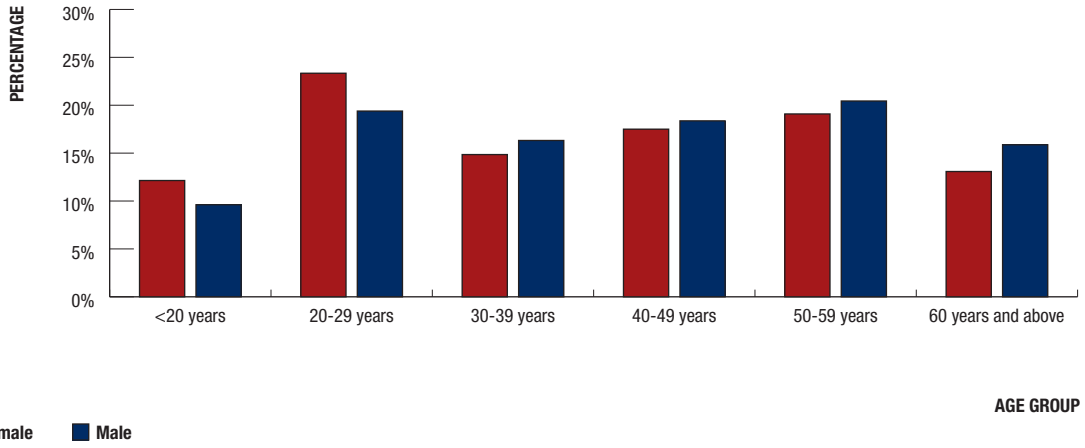


Figure 5 **Prevalence of any transfusion-transmissible infection among all accepted donations, 2005-2013**

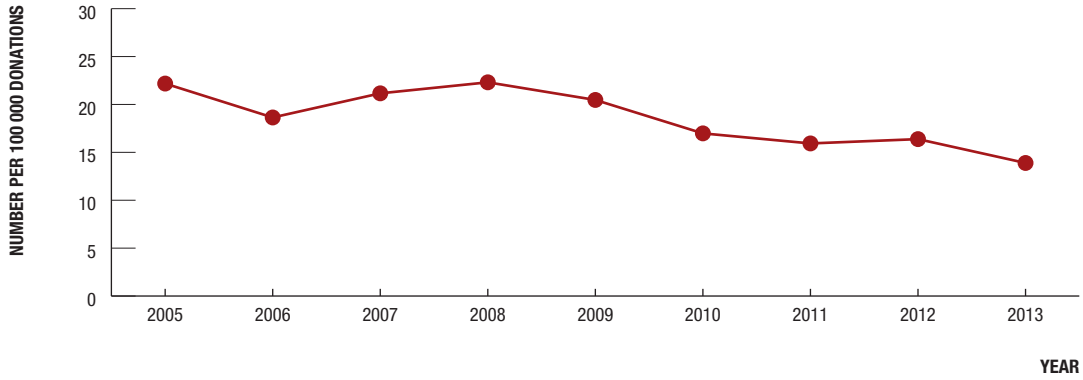


Figure 6 **Percentage of first time and repeat donations among all positive blood donations in Australia, 2007-2013**

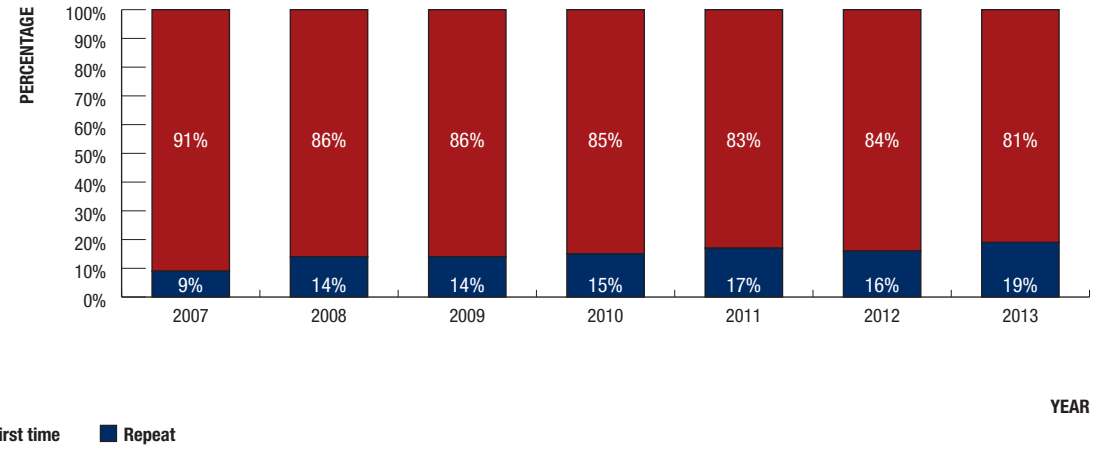


Figure 7 Prevalence of HBV among first time donors by state/territory and year of donation, 2005-2013

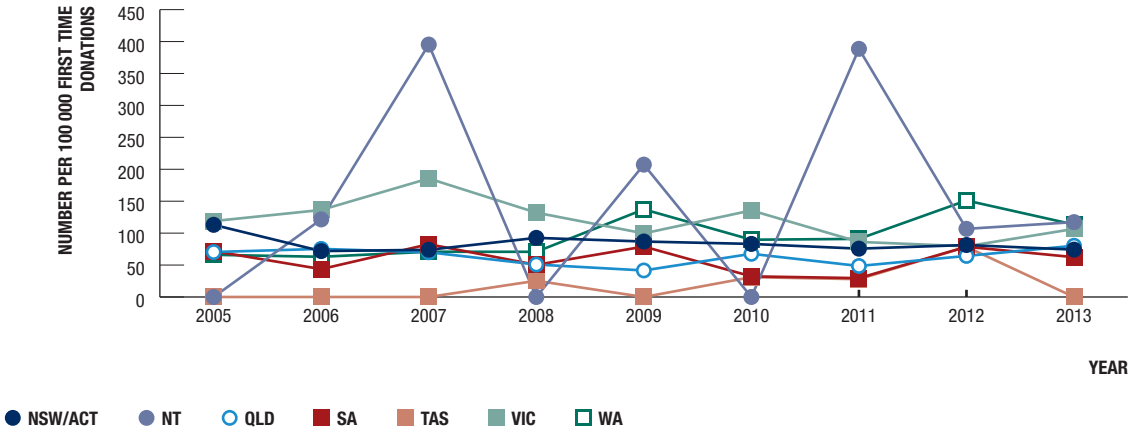


Figure 8 Incidence of HBV among repeat donors by state/territory and year of donation, 2005-2013

Figure 9 Prevalence of HCV among first time donors by state/territory and year of donation, 2005-2013

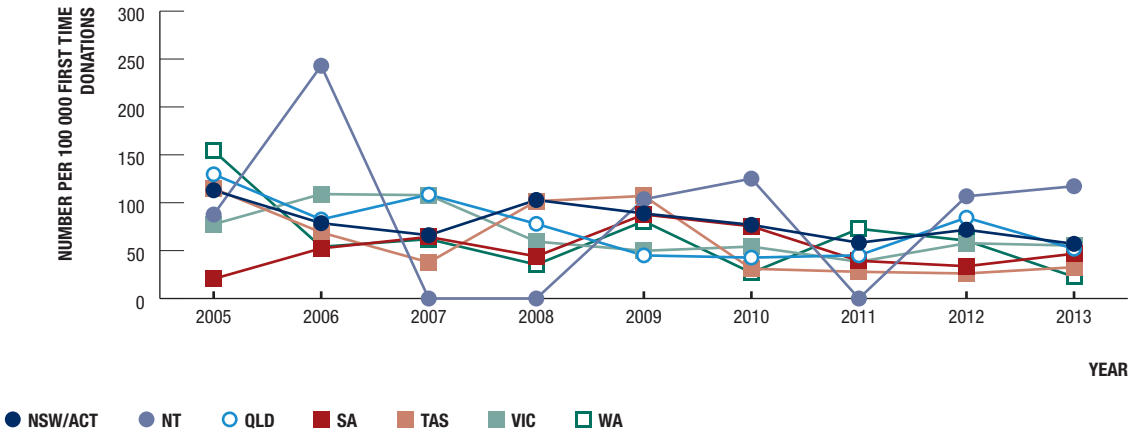
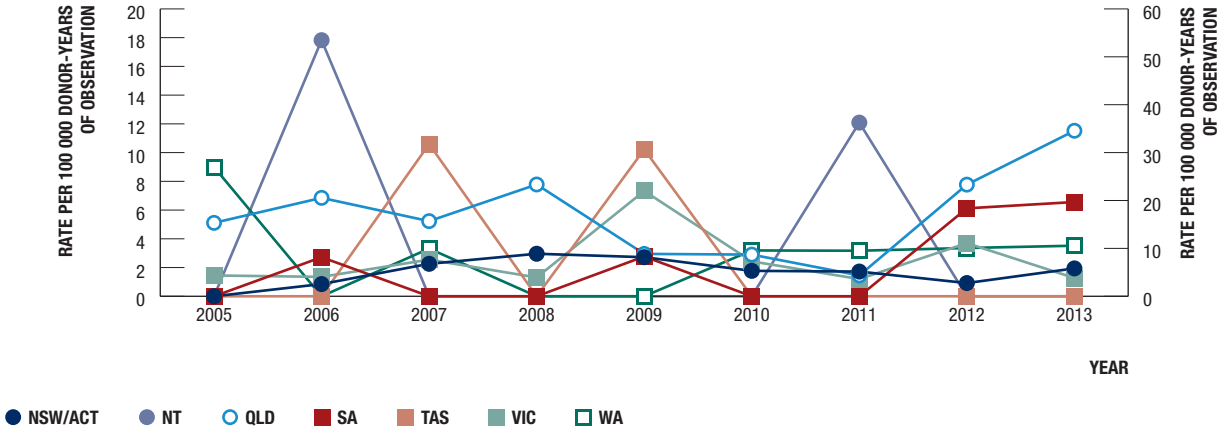


Figure 10 **Incidence of HCV among repeat donors by state/territory[1] and year of donation, 2005-2013**



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, 2005-2013**

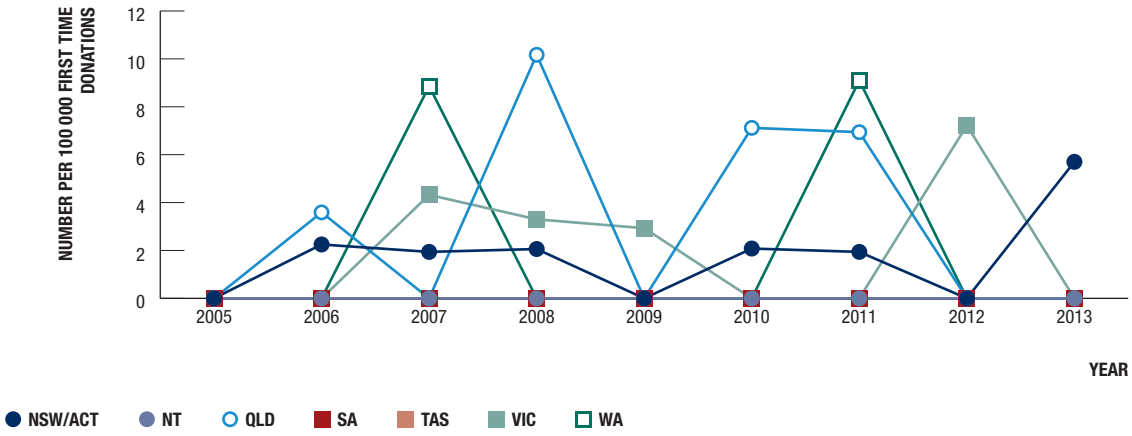
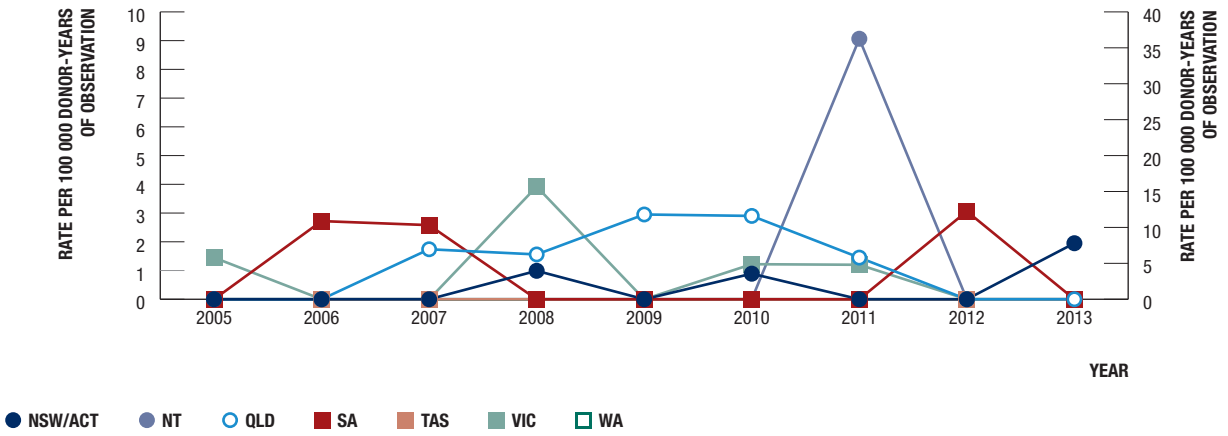


Figure 12 **Incidence of HIV among repeat donors by state/territory[1] and year of donation, 2005-2013**



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

Figure 13 Prevalence of HTLV among first time donors by state/territory and year of donation, 2005-2013

Figure 14 Prevalence of active syphilis among first time donors by state/territory[1] and year of donation, 2005-2013

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

Figure 15 Donors with HBV infection by sex and donor status, 2010-2013

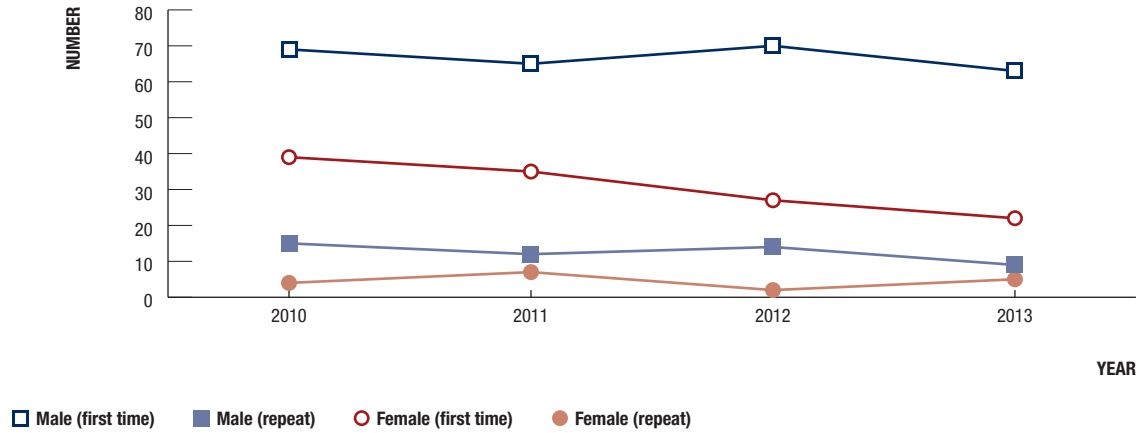


Figure 16 Rate of HBV infection among blood donors by age group and year of donation, 2010-2013

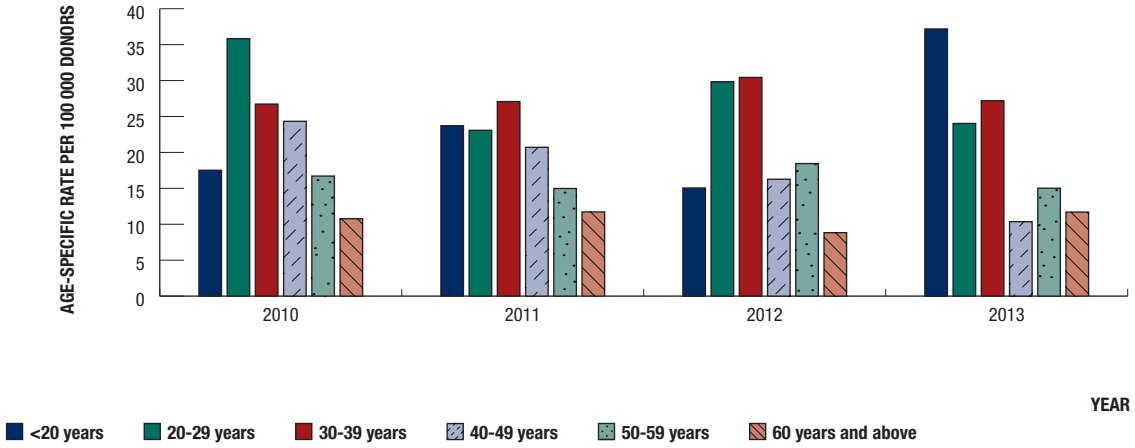


Figure 17 Donors with HBV infection by region of birth, 2013 (n=99)

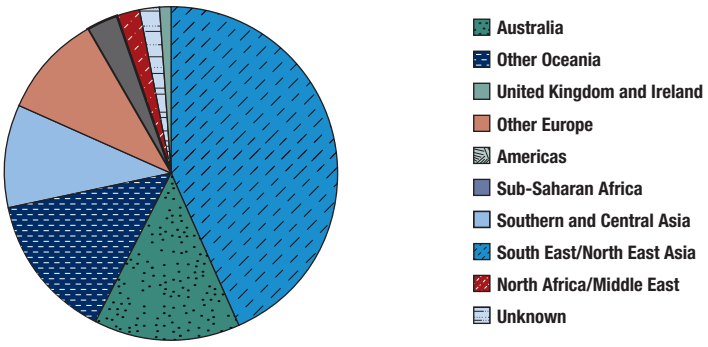


Figure 18 Donors with HCV infection by sex and donor status, 2010-2013

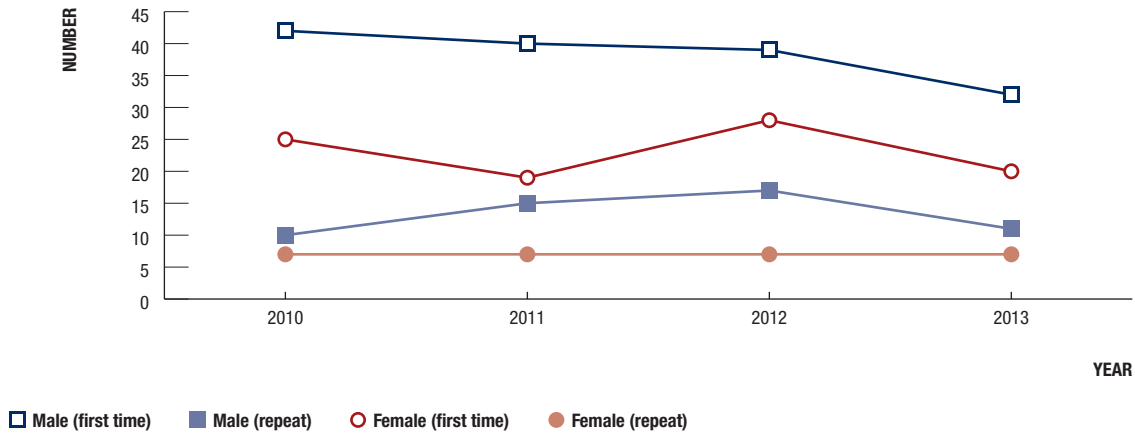


Figure 19 Rate of HCV infection among blood donors by age group and year of donation, 2010-2013

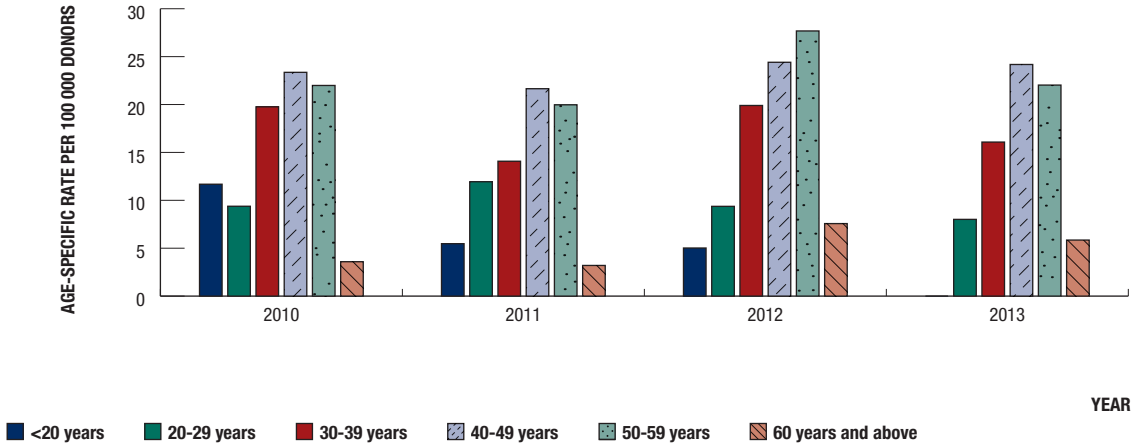


Figure 20 Donors with HCV infection by region of birth, 2013 (n=70)

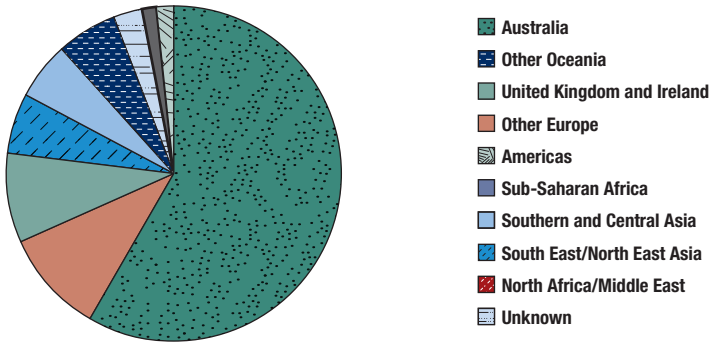


Figure 21 Donors with HIV infection by sex and donor status, 2010-2013

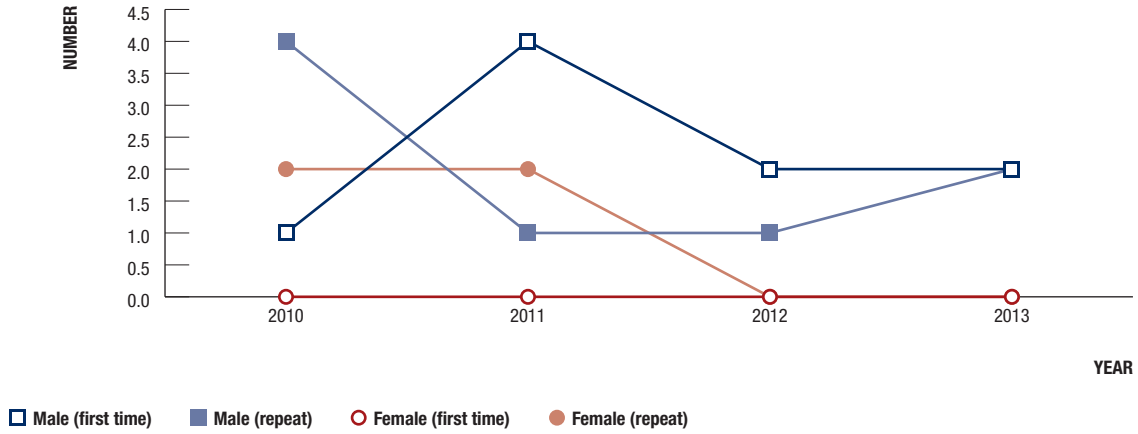


Figure 22 Rate of HIV infection among blood donors by age group and year of donation, 2010-2013

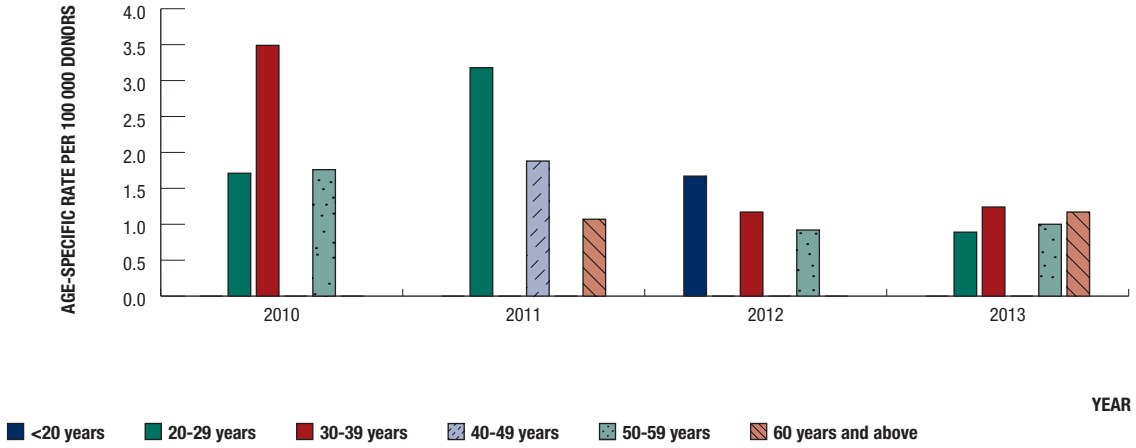


Figure 23 Donors with HIV infection by region of birth, 2013 (n=4)

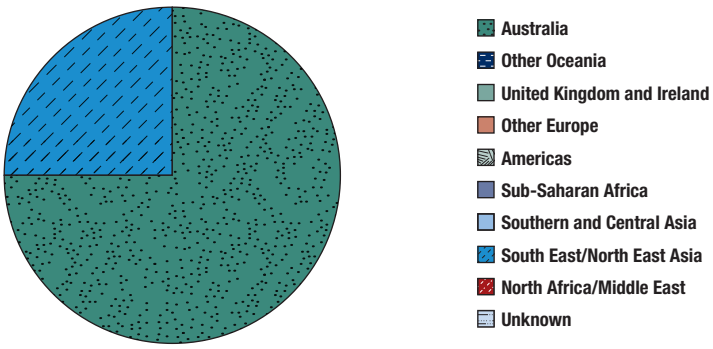


Figure 24 Donors with HTLV infection by sex and donor status, 2010-2013

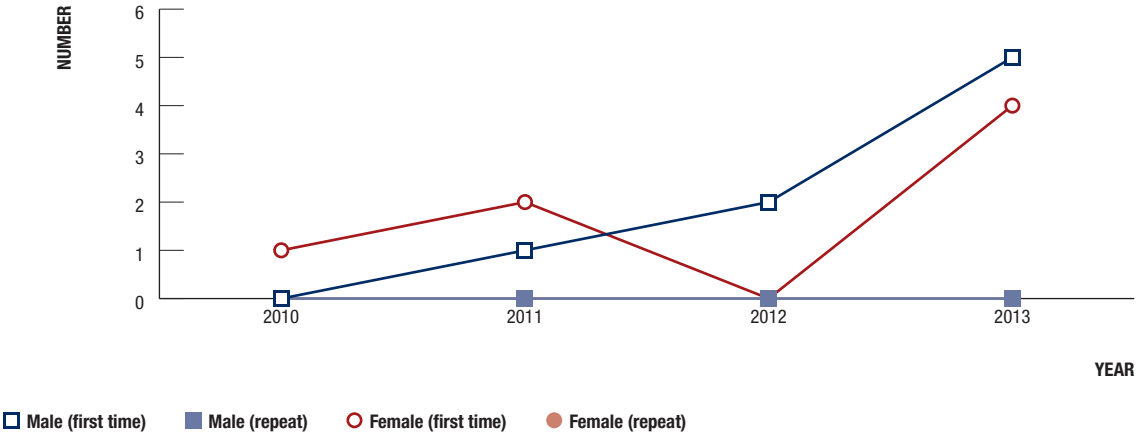


Figure 25 Rate of HTLV infection among blood donors by age group and year of donation, 2010-2013

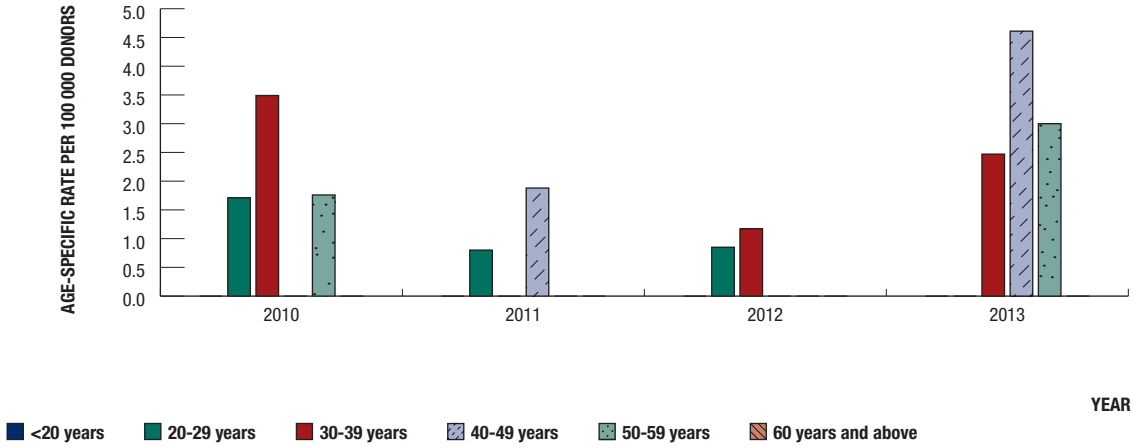
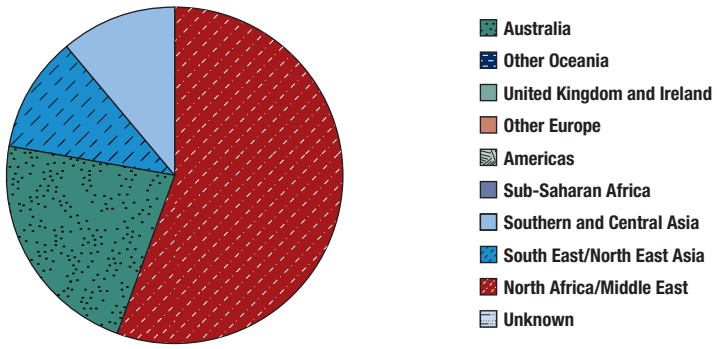


Figure 26 Donors with HTLV infection by region of birth, 2013 (n=9)



Supporting tables

Table 1 Screening tests for transfusion-transmissible infections

Transfusion-Transmissible infection	Mandatory screening tests	Test Target	Year of introduction	Median window period estimate	Estimated risk of window period donation (per million transfusion)
Syphilis	*Treponema pallidum* Haemagglutination Assay (TPHA)	Antibodies to *Treponema pallidum*	~1949	45 days	<1 in 1 million
HBV	HBsAg[1]	Hepatitis B surface antigen (HBsAg)	1970	38 days	–
	Nucleic Acid Test for HBV	HBV DNA	2010	15.1 days	Approx. 1 in 468 000
HIV	anti-HIV-1[1] anti-HIV-2[1]	Antibody to both HIV-1 and HIV-2 (anti-HIV-1/2)	1985 (HIV-1) 1993 (HIV-1/HIV-2)	22 days	–
	Nucleic Acid Test for HIV-1[2]	HIV-1 RNA	2000	5.9 days	<1 in 1 million
HCV	anti-HCV[1]	Antibody to HCV	1990	66 days	–
	Nucleic Acid Test for HCV 2	hepatitis C RNA	2000	2.6 days	<1 in 1 million
HTLV	anti-HTLV-1[1] anti-HTLV-2[1]	Antibody to both HTLV-1 and HTLV-2	1993	51 days	<1 in 1 million

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

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

Table 2 The number and rate of transfusion-transmissible infections in Australia by type of donations and state/territory, 2005-2013

State/Territory of donation	All accepted donations			HBV			HCV			HIV			HTLV			Syphilis			Total positive donations		
	First time	Repeat	All	First time	Repeat	All	First time	Repeat	All	First time	Repeat	All	First time	Repeat	All	First time	Repeat	All	First time	Repeat	All
NSW/ACT	**415 331**	**3 216 163**	**3 631 494**	**350**	**34**	**384**	**3**	**36**	**366**	**7**	**5**	**12**	**8**	**1**	**9**	**0**	**7**	**7**	**695**	**83**	**778**
Number (Number per 100 000 donations)				*84.27*	*1.06*	*10.57*	*0.72*	*1.12*	*10.08*	*1.69*	*0.16*	*0.33*	*1.93*	*0.03*	*0.25*	*0.00*	*0.22*	*0.19*	*167.34*	*2.58*	*21.42*
NT	**7 864**	**90 314**	**98 178**	**11**	**1**	**12**	**7**	**2**	**9**	**0**	**1**	**1**	**0**	**0**	**0**	**4**	**2**	**6**	**22**	**6**	**28**
Number (Number per 100 000 donations)				*139.88*	*1.11*	*12.22*	*89.01*	*2.21*	*9.17*	*0.00*	*1.11*	*1.02*	*0.00*	*0.00*	*0.00*	*50.86*	*2.21*	*6.11*	*279.76*	*6.64*	*28.52*
QLD	**244 821**	**2 070 630**	**2 315 451**	**152**	**13**	**165**	**182**	**46**	**228**	**8**	**7**	**15**	**6**	**0**	**6**	**7**	**3**	**10**	**355**	**69**	**424**
Number (Number per 100 000 donations)				*62.09*	*0.63*	*7.13*	*74.34*	*2.22*	*9.85*	*3.27*	*0.34*	*0.65*	*2.45*	*0.00*	*0.26*	*2.86*	*0.14*	*0.43*	*145.00*	*3.33*	*18.31*
SA	**94 168**	**1 049 091**	**1 143 259**	**55**	**8**	**63**	**49**	**16**	**65**	**0**	**3**	**3**	**3**	**0**	**3**	**5**	**0**	**5**	**112**	**27**	**139**
Number (Number per 100 000 donations)				*58.41*	*0.76*	*5.51*	*52.03*	*1.53*	*5.69*	*0.00*	*0.29*	*0.26*	*3.19*	*0.00*	*0.26*	*5.31*	*0.00*	*0.44*	*118.94*	*2.57*	*12.16*
TAS	**30 395**	**333 394**	**363 789**	**6**	**1**	**7**	**19**	**4**	**23**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**1**	**25**	**6**	**31**
Number (Number per 100 000 donations)				*19.74*	*0.30*	*1.92*	*62.51*	*1.20*	*6.32*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.30*	*0.27*	*82.25*	*1.80*	*8.52*
VIC	**239 109**	**2 396 451**	**2 635 560**	**281**	**19**	**300**	**155**	**23**	**178**	**5**	**6**	**11**	**14**	**0**	**14**	**3**	**2**	**5**	**458**	**50**	**508**
Number (Number per 100 000 donations)				*117.52*	*0.79*	*11.38*	*64.82*	*0.96*	*6.75*	*2.09*	*0.25*	*0.42*	*5.86*	*0.00*	*0.53*	*1.25*	*0.08*	*0.19*	*191.54*	*2.09*	*19.27*
WA	**96 070**	**1 024 194**	**1 120 264**	**91**	**15**	**106**	**60**	**11**	**71**	**2**	**0**	**2**	**5**	**0**	**5**	**6**	**4**	**10**	**164**	**30**	**194**
Number (Number per 100 000 donations)				*94.72*	*1.46*	*9.46*	*62.45*	*1.07*	*6.34*	*2.08*	*0.00*	*0.18*	*5.20*	*0.00*	*0.45*	*6.25*	*0.39*	*0.89*	*170.71*	*2.93*	*17.32*
National	**1 127 758**	**10 180 237**	**11 307 995**	**946**	**91**	**1 037**	**802**	**138**	**940**	**22**	**22**	**44**	**36**	**1**	**37**	**25**	**19**	**44**	**1 831**	**271**	**2 102**
Number (Number per 100 000 donations)				*83.88*	*0.89*	*9.17*	*71.11*	*1.36*	*8.31*	*1.95*	*0.22*	*0.39*	*3.19*	*0.01*	*0.33*	*2.22*	*0.19*	*0.39*	*162.36*	*2.66*	*18.59*

Table 3 Number and prevalence[1] of HBV infection among first time donors, 2007-2013, by state/territory and year of donation

	2007			2008			2009			2010		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	51 427	38	73.89	48 607	45	92.58	51 821	45	86.84	48 130	40	83.11
NT	759	3	395.26	815	0	0.00	965	2	207.25	799	0	0.00
QLD	28 575	20	69.99	29 498	15	50.85	28 889	12	41.54	28 097	19	67.62
SA	10 886	9	82.67	15 908	8	50.29	11 400	9	78.95	9 284	3	32.31
TAS	2 650	0	0.00	3 936	1	25.41	3 736	0	0.00	3 222	1	31.04
VIC	23 172	43	185.57	30 286	40	132.07	34 133	34	99.61	25 820	35	135.55
WA	11 292	8	70.85	11 307	8	70.75	12 387	17	137.24	11 149	10	89.69
Total	**128 761**	**121**	**93.97**	**140 357**	**117**	**83.36**	**143 331**	**119**	**83.02**	**126 501**	**108**	**85.37**

	2011			2012			2013			Total 2007-2013		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	51 528	42	81.51	41 780	34	81.38	35 060	25	71.31	328 353	269	81.92
NT	772	3	388.60	937	1	106.72	853	1	117.23	5 900	10	169.49
QLD	28 839	13	45.08	24 881	16	64.31	21 181	17	80.26	189 960	112	58.96
SA	10 164	3	29.52	8 900	7	78.65	6 417	4	62.33	72 959	43	58.94
TAS	3 587	1	27.88	3 823	3	78.47	3 058	0	0.00	24 012	6	24.99
VIC	31 286	27	86.30	27 718	22	79.37	25 332	25	98.69	197 747	226	114.29
WA	10 992	10	90.98	9 925	15	151.13	8 815	10	113.44	75 867	78	102.81
Total	**137 168**	**99**	**72.17**	**117 964**	**98**	**83.08**	**100 716**	**82**	**81.42**	**894 798**	**744**	**83.15**

1 Rate per 100 000 first time donations

Table 4 Number and rate[1] of HBV infection among repeat donors, 2007-2013, by state/territory and year of donation

	2007			2008			2009			2010		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	338 173	3	0.89	339 062	1	0.29	372 806	1	0.27	380 014	4	1.05
NT	10 214	0	0.00	11 166	0	0.00	11 158	0	0.00	10 470	1	9.55
QLD	209 556	0	0.00	226 726	1	0.44	242 001	1	0.41	243 837	3	1.23
SA	114 618	0	0.00	118 476	1	0.84	126 855	0	0.00	123 587	3	2.43
TAS	28 019	0	0.00	33 321	0	0.00	37 274	0	0.00	41 484	0	0.00
VIC	252 340	0	0.00	259 052	4	1.54	276 835	1	0.36	278 897	3	1.08
WA	109 425	0	0.00	113 274	0	0.00	118 327	3	2.54	120 646	1	0.83
Total	**1 062 345**	**3**	**0.28**	**1 101 077**	**7**	**0.64**	**1 185 256**	**6**	**0.51**	**1 198 935**	**15[2]**	**1.25**

	2011			2012			2013			Total 2007-2013		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	390 455	5	1.28	377 220	6	1.59	373 670	4	1.07	2 571 400	24	0.93
NT	10 782	0	0.00	9 673	0	0.00	9 493	0	0.00	72 956	1	1.37
QLD	245 975	3	1.22	237 599	4	1.68	243 042	1	0.41	1 648 736	13	0.79
SA	124 199	2	1.61	120 720	0	0.00	119 530	1	0.84	847 985	7	0.83
TAS	44 661	0	0.00	46 379	0	0.00	48 953	1	2.04	280 091	1	0.36
VIC	288 085	4	1.39	285 168	2	0.70	292 058	2	0.68	1 932 435	16	0.83
WA	121 057	5	4.13	117 728	3	2.55	123 298	3	2.43	823 755	15	1.82
Total	**1 225 214**	**19**	**1.55**	**1 194 487**	**15**	**1.26**	**1 210 044**	**12**	**0.99**	**8 177 358**	**77**	**0.94**

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

Table 5 Number and percentage of donors with HBV infection, 2010-2013, by year of donation, sex and age group

	Year of donation											
	2010		2011		2012		2013		2010-2013			
Donor status	**M**	**F**	**M**	**F**	**M**	**F**	**M**	**F**	**M**	**F**	**Total**	**%**
First time donors												
<20 years	5	4	6	7	3	6	9	7	23	24	47	10.3
20-29 years	23	17	17	12	28	7	18	7	86	43	129	28.2
30-39 years	16	6	17	5	18	6	16	4	67	21	88	19.3
40-49 years	15	4	16	4	10	5	9	0	50	13	63	13.8
50-59 years	7	5	5	5	11	2	8	3	31	15	46	10.1
60 years and above	3	3	4	1	0	1	3	1	10	6	16	3.5
Repeat donors												
<20 years	0	0	0	0	0	0	0	0	0	0	0	0.0
20-29 years	0	2	0	0	0	0	0	2	0	4	4	0.9
30-39 years	1	0	3	0	2	0	1	1	7	1	8	1.8
40-49 years	6	0	2	0	1	0	0	0	9	0	9	2.0
50-59 years	6	1	6	2	7	0	4	0	23	3	26	5.7
60 years and above	2	1	3	3	4	2	4	2	13	8	21	4.6
Total	**84**	**43**	**79**	**39**	**84**	**29**	**72**	**27**	**319**	**138**	**457**	**100.0**

Table 6 Number and percentage of donors with HBV infection, 2010-2013, by year of donation and region of birth[1]

	2010		2011		2012		2013		2010-2013	
Region of birth	**Number**	**%**	**Number**	**%**	**Number**	**%**	**Number**	**%**	**Number**	**%**
Australia	17	13	15	13	19	17	14	14	65	14
Overseas born										
Other Oceania	*14*	*11*	*15*	*13*	*10*	*9*	*14*	*14*	*53*	*12*
United Kingdom and Ireland	*0*	*0*	*2*	*2*	*1*	*1*	*1*	*1*	*4*	*1*
Other Europe	*8*	*6*	*5*	*4*	*9*	*8*	*10*	*10*	*32*	*7*
Middle East/North Africa	*3*	*2*	*10*	*8*	*4*	*4*	*2*	*2*	*19*	*4*
Sub-Saharan Africa	*4*	*3*	*4*	*3*	*4*	*4*	*3*	*3*	*15*	*3*
South East Asia	*67*	*53*	*45*	*38*	*51*	*45*	*43*	*43*	*206*	*45*
Southern and Central Asia	*9*	*7*	*14*	*12*	*14*	*12*	*10*	*10*	*47*	*10*
North America	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*
South/Central America and the Caribbean	*0*	*0*	*0*	*0*	*1*	*1*	*0*	*0*	*1*	*0*
Total with a reported country of birth	**122**	**96**	**110**	**93**	**113**	**100**	**97**	**98**	**442**	**97**
Not reported	**5**	**4**	**8**	**7**	**0**	**0**	**2**	**2**	**15**	**3**
Total	**127**	**100**	**118**	**100**	**113**	**100**	**99**	**100**	**457**	**100**

1 Region of birth from the Australian Bureau of Statistics.

Table 7 Number and percentage of HBV infection among first time donors, 2010-2013, by exposure category and sex

	2010		2011		2012		2013		Total (2010-2013)			
Exposure categories	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Total**	**%**
Ethnicity/Country of birth	62	34	56	32	66	24	59	22	243	112	355	91.3
Intravenous drug user	0	0	0	0	0	0	0	0	0	0	0	0.0
Tattoo/Piercing	0	0	1	1	0	2	0	0	1	3	4	1.3
Partners with any risks or known to be positive	1	0	1	0	1	1	0	0	3	1	4	1.3
Male-to-male sexual contact	0	0	0	0	0	0	0	0	0	0	0	0.0
Exposure in health care setting	0	0	0	0	0	0	0	0	0	0	0	0.0
Engaged in sex work	0	0	0	0	0	0	0	0	0	0	0	0.0
Blood or tissue recipient	2	1	0	0	0	0	0	0	2	1	3	1.0
Household contact	0	0	0	0	3	0	1	0	4	0	4	1.3
Other blood to blood contact	0	1	0	0	0	0	0	0	0	1	1	0.3
Other	0	0	1	0	0	0	2	0	3	0	3	1.0
No risk factors identified	1	1	0	0	0	0	0	0	1	1	2	0.7
Not reported	3	2	6	1	0	0	1	0	10	3	13	4.3
Total	**69**	**39**	**65**	**34**	**70**	**27**	**63**	**22**	**267**	**122**	**389**	**128**

Table 8 Number and percentage of HBV infection among repeat donors, 2010-2013 by exposure category and sex

	2010		2011		2012		2013		Total (2010-2013)			
Exposure categories	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Total**	**%**
Ethnicity/Country of birth	9	1	10	2	8	2	6	2	33	7	40	58.8
Intravenous drug user	1	0	0	0	0	0	0	1	1	1	2	3.7
Tattoo/Piercing	1	0	0	1	1	0	1	0	3	1	4	7.4
Partners with any risks or known to be positive	3	1	1	1	2	0	1	0	7	2	9	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	1	1	1	0	2	0	0	1	4	2	6	11.1
Engaged in sex work	0	0	0	0	1	0	0	0	1	0	1	1.9
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	1	0	0	0	0	0	0	0	1	1	1.9
Other	0	0	2	0	0	0	0	0	2	0	2	3.7
No risk factors identified	0	0	0	1	0	0	1	1	1	2	3	5.6
Not reported	0	0	0	0	0	0	0	0	0	0	0	0.0
Total	**15**	**4**	**14**	**5**	**14**	**2**	**9**	**5**	**52**	**16**	**68**	**126**

Table 9 Number and prevalence[1] of HCV infection among first time donors, 2007-2013, by state/territory and year of donation

	2007			2008			2009			2010		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	51 427	34	66.11	48 607	50	102.87	51 821	46	88.77	48 130	37	76.88
NT	759	0	0.00	815	0	0.00	965	1	103.63	799	1	125.16
QLD	28 575	31	108.49	29 498	23	77.97	28 889	13	45.00	28 097	12	42.71
SA	10 886	7	64.30	15 908	7	44.00	11 400	10	87.72	9 284	7	75.40
TAS	2 650	1	37.74	3 936	4	101.63	3 736	4	107.07	3 222	1	31.04
VIC	23 172	25	107.89	30 286	18	59.43	34 133	17	49.81	25 820	14	54.22
WA	11 292	7	61.99	11 307	4	35.38	12 387	10	80.73	11 149	3	26.91
Total	**128 761**	**105**	**81.55**	**140 357**	**106**	**75.52**	**143 331**	**101**	**70.47**	**126 501**	**75**	**59.29**

	2011			2012			2013			Total 2007-2013		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	772	0	0.00	937	1	106.72	853	1	117.23	5 900	4	67.80
NT	28 839	13	45.08	24 881	21	84.40	21 181	12	56.65	189 960	125	65.80
QLD	10 164	4	39.35	8 900	3	33.71	6 417	3	46.75	72 959	41	56.20
SA	3 587	1	27.88	3 823	1	26.16	3 058	2	65.40	24 012	14	58.30
TAS	31 286	12	38.36	27 718	16	57.72	25 332	15	59.21	197 747	117	59.17
VIC	10 992	8	72.78	9 925	6	60.45	8 815	2	22.69	75 867	40	52.72
WA	11 149	3	26.91	10 992	8	72.78	9 925	6	60.45	78 168	44	56.29
Total	**137 168**	**68**	**49.57**	**117 964**	**78**	**66.12**	**100 716**	**56**	**55.60**	**894 798**	**589**	**65.82**

1 Rate per 100 000 first time donations

Table 10 Number and rate[1] of HCV infection among repeat donors, 2007-2013, by state/territory and year of donation

	2007			2008			2009			2010		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	338 173	7	2.07	339 062	11	3.24	372 806	6	1.61	380 014	3	0.79
NT	10 214	0	0.00	11 166	0	0.00	11 158	0	0.00	10 470	0	0.00
QLD	209 556	3	1.43	226 726	8	3.53	242 001	9	3.72	243 837	4	1.64
SA	114 618	0	0.00	118 476	2	1.69	126 855	4	3.15	123 587	0	0.00
TAS	28 019	1	3.57	33 321	0	0.00	37 274	1	2.68	41 484	0	0.00
VIC	252 340	3	1.19	259 052	2	0.77	276 835	7	2.53	278 897	2	0.72
WA	109 425	2	1.83	113 274	1	0.88	118 327	0	0.00	120 646	1	0.83
Total	**1 062 345**	**16**	**1.51**	**1 101 077**	**24**	**2.18**	**1 185 256**	**27**	**2.28**	**1 198 935**	**10**	**0.83**

	2011			2012			2013			Total 2007-2013		
State/Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	390 455	3	0.77	377 220	1	0.27	373 670	2	0.54	2 571 400	33	1.28
NT	10 782	1	9.27	9 673	0	0.00	9 493	0	0.00	72 956	1	1.37
QLD	245 975	3	1.22	237 599	5	2.10	243 042	7	2.88	1 648 736	39	2.37
SA	124 199	1	0.81	120 720	2	1.66	119 530	3	2.51	847 985	12	1.42
TAS	44 661	0	0.00	46 379	1	2.16	48 953	0	0.00	280 091	3	1.07
VIC	288 085	2	0.69	285 168	3	1.05	292 058	1	0.34	1 932 435	20	1.03
WA	121 057	3	2.48	117 728	1	0.85	123 298	1	0.81	823 755	9	1.09
Total	**1 225 214**	**13**	**1.06**	**1 194 487**	**13**	**1.09**	**1 210 044**	**14**	**1.16**	**8 177 358**	**117**	**1.43**

1 Rate per 100 000 repeat donations

Table 11 Number and percentage of donors with HCV infection, 2010-2013, by year of donation, sex and age group

	Year of donation											
	2010		2011		2012		2013		2010-2013			
Donor status	M	F	M	F	M	F	M	F	M	F	Total	%
First time donors												
<20 years	6	0	2	1	1	2	0	0	9	3	12	3.7
20-29 years	6	3	8	6	7	4	5	2	26	15	41	12.5
30-39 years	9	5	11	2	9	6	9	2	38	15	53	16.2
40-49 years	12	7	12	4	9	4	7	6	40	21	61	18.6
50-59 years	9	8	6	5	12	11	10	7	37	31	68	20.7
60 years and above	0	2	1	1	1	1	1	3	3	7	10	3.0
Repeat donors												
<20 years	1	0	0	0	0	0	0	0	1	0	1	0.3
20-29 years	1	1	1	0	0	0	2	0	4	1	5	1.5
30-39 years	1	2	0	0	2	0	1	1	4	3	7	2.1
40-49 years	3	1	5	2	8	3	4	4	20	10	30	9.1
50-59 years	5	2	8	5	4	3	3	2	20	12	32	9.8
60 years and above	1	1	1	0	3	1	1	0	6	2	8	2.4
Total	**54**	**32**	**55**	**26**	**56**	**35**	**43**	**27**	**208**	**120**	**328**	**100.0**

Table 12 Number and percentage of donors with HCV infection, 2010-2013, by year of donation and region of birth[1]

	2010		2011		2012		2013		2010-2013	
Region of birth	Number	%	Number	%	Number	%	Number	%	Number	%
Australia	61	71	51	63	62	68	41	59	215	66
Overseas born										
Other Oceania	2	2	4	5	6	7	4	6	16	5
United Kingdom and Ireland	2	2	3	4	6	7	6	9	17	5
Other Europe	5	6	2	2	3	3	7	10	17	5
Middle East/North Africa	1	1	0	0	1	1	0	0	2	1
Sub-Saharan Africa	1	1	0	0	1	1	1	1	3	1
South East Asia	2	2	11	14	4	4	4	6	21	6
Southern and Central Asia	4	5	3	4	2	2	4	6	13	4
North America	1	1	1	1	3	3	1	1	6	2
South/Central America and the Caribbean	2	2	0	0	0	0	0	0	2	1
Total with a reported country of birth	**81**	**94**	**75**	**93**	**88**	**97**	**68**	**97**	**312**	**95**
Not reported	**5**	**6**	**6**	**7**	**3**	**3**	**2**	**3**	**16**	**5**
Total	**86**	**100**	**81**	**100**	**91**	**100**	**70**	**100**	**328**	**100**

1 Region of birth from the Australian Bureau of Statistics.

Table 13 Number and percentage of HCV infection among first time donors, 2010-2013, by exposure category and sex

	2010		2011		2012		2013		Total (2010-2013)			
Exposure categories	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Total**	**%**
Ethnicity/Country of birth	8	2	10	1	3	2	3	2	24	7	31	14.8
Intravenous drug user	10	4	7	2	10	4	9	2	36	12	48	22.9
Tattoo/Piercing	8	7	8	3	0	0	10	6	26	16	42	20.0
Partners with any risks or known to be positive	1	2	1	1	0	0	1	6	3	9	12	5.7
Male-to-male sexual contact	0	0	0	0	0	0	0	0	0	0	0	0.0
Exposure in health care setting	1	1	0	2	2	0	4	1	7	4	11	5.2
Engaged in sex work	0	0	0	0	0	0	0	0	0	0	0	0.0
Blood or tissue recipient	2	5	5	2	4	1	0	1	11	9	20	9.5
Household contact	5	2	1	4	2	2	0	1	8	9	17	8.1
Other blood to blood contact	2	0	3	2	0	0	1	0	6	2	8	3.8
Other	2	0			1	0	0	1	3	1	4	1.9
No risk factors identified	1	0	2	0	0	1	1	0	4	1	5	2.4
Not reported	2	2	3	2	0	0	3	0	8	4	12	5.7
Total	**42**	**25**	**40**	**19**	**22**	**10**	**32**	**20**	**136**	**74**	**210**	**100**

Table 14 Number and percentage of HCV infection among repeat donors, 2010-2013, by exposure category and sex

	2010		2011		2012		2013		Total (2010-2013)			
Exposure categories	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Total**	**%**
Ethnicity/Country of birth	0	0	0	0	0	0	0	0	0	0	0	0.0
Intravenous drug user	1	1	7	1	0	1	2	0	10	3	13	17.1
Tattoo/Piercing	2	1	3	2	5	3	3	4	13	10	23	30.3
Partners with any risks or known to be positive	1	2	0	0	1	0	2	0	4	2	6	7.9
Male-to-male sexual contact	0	0	0	0	0	0	0	0	0	0	0	0.0
Exposure in health care setting	1	1	0	2	2	1	1	2	4	6	10	13.2
Engaged in sex work	0	0	0	0	0	0	0	0	0	0	0	0.0
Blood or tissue recipient	2	1	0	2	0	0	1	0	3	3	6	7.9
Household contact	1	0	2	0	0	1	0	0	3	1	4	5.3
Other blood to blood contact	0	0	0	0	1	0	1	0	2	0	2	2.6
Other	1	0	0	0	0	0	1	0	2	0	2	2.6
No risk factors identified	1	1	0	0	0	1	0	1	1	3	4	5.3
Not reported	0	1	3	0	2	0	0	0	5	1	6	7.9
Total	**10**	**8**	**15**	**7**	**11**	**7**	**11**	**7**	**47**	**29**	**76**	**100**

Table 15 Number and prevalence[1] of HIV infection among first time donors, 2007-2013, by state/territory and year of donation

	2007			2008			2009			2010		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	51 427	1	1.94	48 607	1	2.06	51 821	0	0.00	48 130	1	2.08
NT	759	0	0.00	815	0	0.00	965	0	0.00	799	0	0.00
QLD	28 575	0	0.00	29 498	3	10.17	28 889	0	0.00	28 097	2	7.12
SA	10 886	0	0.00	15 908	0	0.00	11 400	0	0.00	9 284	0	0.00
TAS	2 650	0	0.00	3 936	0	0.00	3 736	0	0.00	3 222	0	0.00
VIC	23 172	1	4.32	30 286	1	3.30	34 133	1	2.93	25 820	0	0.00
WA	11 292	1	8.86	11 307	0	0.00	12 387	0	0.00	11 149	0	0.00
Total	**128 761**	**3**	**2.33**	**140 357**	**5**	**3.56**	**143 331**	**1**	**0.70**	**126 501**	**3**	**2.37**

	2011			2012			2013			Total 2007-2013		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	51 528	1	1.94	41 780	0	0.00	35 060	2	5.70	328 353	6	1.83
NT	772	0	0.00	937	0	0.00	853	0	0.00	5 900	0	0.00
QLD	28 839	2	6.94	24 881	0	0.00	21 181	0	0.00	189 960	7	3.68
SA	10 164	0	0.00	8 900	0	0.00	6 417	0	0.00	72 959	0	0.00
TAS	3 587	0	0.00	3 823	0	0.00	3 058	0	0.00	24 012	0	0.00
VIC	31 286	0	0.00	27 718	2	7.22	25 332	0	0.00	197 747	5	2.53
WA	10 992	1	9.10	9 925	0	0.00	8 815	0	0.00	75 867	2	2.64
Total	**137 168**	**4**	**2.92**	**117 964**	**2**	**1.70**	**100 716**	**2**	**1.99**	**894 798**	**20**	**2.24**

1 Rate per 100 000 first time donations

Table 16 Number and rate[1] of HIV infection among repeat donors, 2007-2013, by state/territory and year of donation

	2007			2008			2009			2010		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	338 173	0	0.00	339 062	1	0.29	372 806	0	0.00	380 014	1	0.26
NT	10 214	0	0.00	11 166	0	0.00	11 158	0	0.00	10 470	0	0.00
QLD	209 556	1	0.48	226 726	1	0.44	242 001	2	0.83	243 837	2	0.82
SA	114 618	1	0.87	118 476	0	0.00	126 855	0	0.00	123 587	0	0.00
TAS	28 019	0	0.00	33 321	0	0.00	37 274	0	0.00	41 484	0	0.00
VIC	252 340	0	0.00	259 052	3	1.16	276 835	0	0.00	278 897	1	0.36
WA	109 425	0	0.00	113 274	0	0.00	118 327	0	0.00	120 646	0	0.00
Total	**1 062 345**	**2**	**0.19**	**1 101 077**	**5**	**0.45**	**1 185 256**	**2**	**0.17**	**1 198 935**	**4**	**0.33**

	2011			2012			2013			Total 2007-2013		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	390 455	0	0.00	377 220	0	0.00	373 670	2	0.54	2 571 400	4	0.16
NT	10 782	1	9.27	9 673	0	0.00	9 493	0	0.00	72 956	1	1.37
QLD	245 975	1	0.41	237 599	0	0.00	243 042	0	0.00	1648 736	7	0.42
SA	124 199	0	0.00	120 720	1	0.83	119 530	0	0.00	847 985	2	0.24
TAS	44 661	0	0.00	46 379	0	0.00	48 953	0	0.00	280 091	0	0.00
VIC	288 085	1	0.35	285 168	0	0.00	292 058	0	0.00	1932 435	5	0.26
WA	121 057	0	0.00	117 728	0	0.00	123 298	0	0.00	823 755	0	0.00
Total	**1 225 214**	**3**	**0.24**	**1 194 487**	**1**	**0.08**	**1 210 044**	**2**	**0.17**	**8 177 358**	**19**	**0.23**

1 Rate per 100 000 repeat donations

Table 17 Number and percentage of donors with HIV infection, 2010-2013, by year of donation, sex and age group

	Year of donation											
	2010		2011		2012		2013		2010-2013			
Donor status	M	F	M	F	M	F	M	F	M	F	Total	%
First time donors												
<20 years	0	0	0	0	0	0	0	0	0	0	0	0.0
20-29 years	0	0	3	0	0	0	1	0	4	0	4	19.0
30-39 years	1	0	0	0	1	0	0	0	2	0	2	9.5
40-49 years	0	0	1	0	0	0	0	0	1	0	1	4.8
50-59 years	0	0	0	0	1	0	1	0	2	0	2	9.5
60 years and above	0	0	0	0	0	0	0	0	0	0	0	0.0
Repeat donors												
<20 years	0	0	0	0	1	0	0	0	1	0	1	4.8
20-29 years	1	1	0	1	0	0	0	0	1	2	3	14.3
30-39 years	2	0	0	0	0	0	1	0	3	0	3	14.3
40-49 years	0	0	0	1	0	0	0	0	0	1	1	4.8
50-59 years	1	1	0	0	0	0	0	0	1	1	2	9.5
60 years and above	0	0	1	0	0	0	1	0	2	0	2	9.5
Total	**5**	**2**	**5**	**2**	**3**	**0**	**4**	**0**	**17**	**4**	**21**	**100.0**

Table 18 Number and percentage of donors with HIV infection, 2010-2013, by year of donation and region of birth[1]

	2010		2011		2012		2013		2010-2013	
Region of birth	Number	%	Number	%	Number	%	Number	%	Number	%
Australia	6	86	2	29	2	67	3	75	13	62
Overseas born										
Other Oceania	1	14	0	0	0	0	0	0	1	5
United Kingdom and Ireland	0	0	1	14	0	0	0	0	1	5
Other Europe	0	0	1	14	0	0	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 Asia	0	0	1	14	0	0	1	25	2	10
Southern and Central Asia	0	0	0	0	1	33	0	0	1	5
North America	0	0	0	0	0	0	0	0	0	0
South/Central America and the Caribbean	0	0	1	14	0	0	0	0	1	5
Total with a reported country of birth	**7**	**100**	**6**	**86**	**3**	**100**	**4**	**100**	**20**	**95**
Not reported	**0**	**0**	**1**	**14**	**0**	**0**	**0**	**0**	**1**	**5**
Total	**7**	**100**	**7**	**100**	**3**	**100**	**4**	**100**	**21**	**100**

1 Region of birth from the Australian Bureau of Statistics

Table 19 Number and percentage of HIV infection among first time donors, 2010-2013, by exposure category and sex

	2010		2011		2012		2013		Total (2010-2013)			
Exposure categories	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Total**	**%**
Ethnicity/Country of birth	0	0	0	0	0	0	1	0	1	0	1	11.1
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	1	0	3	0	1	0	0	0	5	0	5	55.6
Male-to-male sexual contact	0	0	1	0	1	0	1	0	3	0	3	33.3
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	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**	**4**	**0**	**2**	**0**	**2**	**0**	**9**	**0**	**9**	**100**

Table 20 Number and percentage of HIV infection among repeat donors, 2010-2013, by exposure category and sex

	2010		2011		2012		2013		Total (2010-2013)			
Exposure categories	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Total**	**%**
Ethnicity/Country of birth	0	0	0	0	0	0	0	0	0	0	0	0.0
Intravenous drug user	0	0	0	0	0	0	0	0	0	0	0	0.0
Tattoo/Piercing	0	0	0	0	0	0	0	0	0	0	0	0.0
Partners with any risks or known to be positive	2	2	0	1	1	0	0	0	3	3	6	50.0
Male-to-male sexual contact	1	0	0	0	0	0	2	0	3	0	3	25.0
Exposure in health care setting	0	0	0	0	0	0	0	0	0	0	0	0.0
Engaged in sex work	0	0	0	0	0	0	0	0	0	0	0	0.0
Blood or tissue recipient	0	0	0	0	0	0	0	0	0	0	0	0.0
Household contact	0	0	0	0	0	0	0	0	0	0	0	0.0
Other blood to blood contact	1	0	1	0	0	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	0	0	0	0	0	0	0	0	0	0	0	0.0
Not reported	0	0	0	1	0	0	0	0	0	1	1	8.3
Total	**4**	**2**	**1**	**2**	**1**	**0**	**2**	**0**	**8**	**4**	**12**	**100**

Table 21 Number and prevalence[1] of HTLV infection among first time donors, 2007-2013, by state/territory and year of donation

	2007			2008			2009			2010		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	51 427	1	1.94	48 607	0	0.00	51 821	2	3.86	48 130	0	0.00
NT	759	0	0.00	815	0	0.00	965	0	0.00	799	0	0.00
QLD	28 575	0	0.00	29 498	0	0.00	28 889	2	6.92	28 097	1	3.56
SA	10 886	0	0.00	15 908	1	6.29	11 400	1	8.77	9 284	0	0.00
TAS	2 650	0	0.00	3 936	0	0.00	3 736	0	0.00	3 222	0	0.00
VIC	23 172	0	0.00	30 286	4	13.21	34 133	2	5.86	25 820	0	0.00
WA	11 292	0	0.00	11 307	2	17.69	12 387	2	16.15	11 149	0	0.00
Total	**128 761**	**1**	**0.78**	**140 357**	**7**	**4.99**	**143 331**	**9**	**6.28**	**126 501**	**1**	**0.79**

	2011			2012			2013			Total 2007-2013		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Prevalence**	**Donations**	**Positive**	**Prevalence**
NSW/ACT	51 528	1	1.94	41 780	0	0.00	35 060	3	8.56	328 353	7	2.13
NT	772	0	0.00	937	0	0.00	853	0	0.00	5 900	0	0.00
QLD	28 839	0	0.00	24 881	0	0.00	21 181	1	4.72	189 960	4	2.11
SA	10 164	1	9.84	8 900	0	0.00	6 417	0	0.00	72 959	3	4.11
TAS	3 587	0	0.00	3 823	0	0.00	3 058	0	0.00	24 012	0	0.00
VIC	31 286	0	0.00	27 718	2	7.22	25 332	5	19.74	197 747	13	6.57
WA	10 992	1	9.10	9 925	0	0.00	8 815	0	0.00	75 867	5	6.59
Total	**137 168**	**3**	**2.19**	**117 964**	**2**	**1.70**	**100 716**	**9**	**8.94**	**894 798**	**32**	**3.58**

1 Rate per 100 000 first time donations

Table 22 Number and percentage of donors with HTLV infection, 2010-2013, by year of donation, sex and age group

	Year of donation											
	2010[1]		2011		2012		2013		2010-2013			
Donor status	**M**	**F**	**M**	**F**	**M**	**F**	**M**	**F**	**M**	**F**	**Total**	**%**
First time donors												
<20 years	0	0	0	0	0	0	0	0	0	0	0	0.0
20-29 years	0	0	0	1	1	0	0	0	1	1	2	13.3
30-39 years	0	0	0	0	1	0	1	1	2	1	3	20.0
40-49 years	0	0	1	1	0	0	3	1	4	2	6	40.0
50-59 years	0	0	0	0	0	0	1	2	1	2	3	20.0
60 years and above	0	1	0	0	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	0	0	0	0	0	0	0	0	0	0	0.0
60 years and above	0	0	0	0	0	0	0	0	0	0	0	0.0
Total	**0**	**1**	**1**	**2**	**2**	**0**	**5**	**4**	**8**	**7**	**15**	**100.0**

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

Table 23 Number and percentage of donors with HTLV infection, 2010-2013, by year of donation and region of birth[1]

	2010		2011		2012		2013		2010-2013	
Region of birth	**Number**	**%**	**Number**	**%**	**Number**	**%**	**Number**	**%**	**Number**	**%**
Australia	0	0	0	0	0	0	2	22	2	13
Overseas born										
Other Oceania	0	0	0	0	0	0	0	0	0	0
United Kingdom and Ireland	0	0	0	0	0	0	0	0	0	0
Other Europe	0	0	0	0	0	0	0	0	0	0
Middle East/North Africa	0	0	1	33	0	0	5	56	6	38
Sub-Saharan Africa	0	0	0	0	0	0	0	0	0	0
South East Asia	0	0	0	0	0	0	1	11	1	6
Southern and Central Asia	0	0	0	0	2	100	1	11	3	19
North America	0	0	0	0	0	0	0	0	0	0
South/Central America and the Caribbean	1	50	0	0	0	0	0	0	1	6
Total with a reported country of birth	**1**	**50**	**1**	**33**	**2**	**100**	**9**	**100**	**13**	**81**
Not reported	**1**	**50**	**2**	**67**	**0**	**0**	**0**	**0**	**3**	**19**
Total	**2**	**100**	**3**	**100**	**2**	**100**	**9**	**100**	**16**	**100**

1 Region of birth from the Australian Bureau of Statistics

Table 24 Number and percentage of HTLV infection among first time donors, 2010-2013, by exposure category and sex

	2010		2011		2012		2013		Total (2010-2013)			
Exposure categories	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Total**	**%**
Ethnicity/Country of birth	0	1	1	1	2	0	5	2	8	4	12	80.0
Intravenous drug user	0	0	0	0	0	0	0	0	0	0	0	0.0
Tattoo/Piercing	0	0	0	1	0	0	0	0	0	1	1	6.7
Partners with any risks or known to be positive	0	0	0	0	0	0	0	2	0	2	2	13.3
Male-to-male sexual contact	0	0	0	0	0	0	0	0	0	0	0	0.0
Exposure in health care setting	0	0	0	0	0	0	0	0	0	0	0	0.0
Engaged in sex work	0	0	0	0	0	0	0	0	0	0	0	0.0
Blood or tissue recipient	0	0	0	0	0	0	0	0	0	0	0	0.0
Household contact	0	0	0	0	0	0	0	0	0	0	0	0.0
Other blood to blood contact	0	0	0	0	0	0	0	0	0	0	0	0.0
Other	0	0	0	0	0	0	0	0	0	0	0	0.0
No risk factors identified	0	0	0	0	0	0	0	0	0	0	0	0.0
Not reported	0	0	0	0	0	0	0	0	0	0	0	0.0
Total	**0**	**1**	**1**	**2**	**2**	**0**	**5**	**4**	**8**	**7**	**15**	**100**

Table 25 Number and prevalence[1] of active syphilis among first time donors, 2007-2013, by state/territory and year of donation

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

	2011			2012			2013			Total 2007-2013		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Prevalence**	**Donations**	**Positive**	**Prevalence**
NSW/ACT	51 528	0	0.00	41 780	0	0.00	35 060	0	0.00	328 353	0	0.00
NT	772	2	259.07	937	0	0.00	853	0	0.00	5 900	4	67.80
QLD	28 839	1	3.47	24 881	0	0.00	21 181	1	4.72	189 960	6	3.16
SA	10 164	1	9.84	8 900	1	11.24	6 417	0	0.00	72 959	4	5.48
TAS	3 587	0	0.00	3 823	0	0.00	3 058	0	0.00	24 012	0	0.00
VIC	31 286	1	3.20	27 718	0	0.00	25 332	0	0.00	197 747	3	1.52
WA	10 992	2	18.20	9 925	0	0.00	8 815	1	11.34	75 867	6	7.91
Total	**137 168**	**7**	**5.10**	**117 964**	**1**	**0.85**	**100 716**	**2**	**1.99**	**894 798**	**23**	**2.57**

1 Rate per 100 000 first time donations

Table 26 Number and rate[1] of active syphilis among repeat donors, 2007-2013, by state/territory and year of donation

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

	2011			2012			2013			Total 2007-2013		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	390 455	1	0.26	377 220	2	0.53	373 670	2	0.54	2 571 400	7	0.27
NT	10 782	0	0.00	9 673	0	0.00	9 493	0	0.00	72 956	2	2.74
QLD	245 975	0	0.00	237 599	0	0.00	243 042	1	0.41	1 648 736	3	0.18
SA	124 199	0	0.00	120 720	0	0.00	119 530	0	0.00	847 985	0	0.00
TAS	44 661	0	0.00	46 379	0	0.00	48 953	0	0.00	280 091	1	0.36
VIC	288 085	0	0.00	285 168	1	0.35	292 058	0	0.00	1 932 435	2	0.10
WA	121 057	0	0.00	117 728	2	1.70	123 298	0	0.00	823 755	4	0.49
Total	**1 225 214**	**1**	**0.08**	**1 194 487**	**5**	**0.42**	**1 210 044**	**3**	**0.25**	**8 177 358**	**19**	**0.23**

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:

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

Donor-years of observation

Data on interval between each donation by all donors who donated at least twice in 2011-2013 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 TTIs.

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

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

Newly acquired infection

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

Newly diagnosed infection

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

Prevalence

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

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

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

Residual risk estimates

Estimates were derived based on minor refinement to the method described in earlier studies.[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 incident donors (i.e., positive donors who have previously tested negative at the Blood Service for the same viral marker) in the repeat donor (RD) population as a measure of viral incidence (i.e. the rate of newly acquired infection).

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

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

The fourth model, applied only to HBV, estimates the risk specifically for OBI. The method is based on assessing the probability of 'non-detection' by HBV NAT and the average probability of HBV transmission from NAT non-reactive donations. NAT non detection is derived by examining HBV NAT data and assessing the frequency of prior NAT non-detectable donations from donors identified as OBI by NAT. The transmission function is based on investigation of the outcome of transfusions from blood components (termed lookback) sourced from donors with OBI. The HBV residual risk is the sum of the risk estimated from the WP-based and OBI models. Further information is available at http://www.transfusion.com.au/adverse_events/risks/estimates.

Statistical tests to analyse trends in transfusion-transmissible infections

Trends in prevalence and incidence of TTIs were examined for the year 2013. 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 2013. The association between demographic factors and presence of any TTIs (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;105:290-298

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