Supporting information for transfusion-transmissible infections surveillance report

Blood donation: from volunteer to recipient

In Australia, blood donations from each state and territory are processed and tested at one of the four Blood Services' processing centres. Each of the States (excepting Tasmania and South Australia) has a processing centre in their capital city. Blood donations collected during the period of the report in South Australia and Tasmania were sent to Melbourne for testing while those collected in the Australian Capital Territory and Northern Territory were sent to Sydney for testing and further processing.

Australian volunteer blood donors may be aged 16 to 80 years of age. Each donor is required to self-complete a comprehensive donor questionnaire every time they donate. The questionnaire is reviewed at a private and confidential interview with the donor and a legally binding Declaration Form is signed in the presence of the interviewer prior to donation. There are penalties including fines and imprisonment for anyone providing false or misleading information. The questionnaire asks about various medical conditions, travel history and behaviours related to increased risk of a blood-borne infection. The Blood Service is highly reliant on the donor's complete and truthful answers to all interview questions (i.e. 'compliance'). This is particularly important for questions relating to risk behaviour for transfusion-transmissible infection given the existence of the testing window period (see below). Should a donor in the window period fail to answer truthfully a question that would normally result in their deferral from donation, they will place recipients at risk because a potentially infectious unit of blood will be collected that testing will not identify.

Subsequent to satisfactorily completing the above assessment process the donor proceeds to donate. Every donation is processed and undergoes mandatory tests for specific transfusion-transmissible infections (TTIs). Additional testing for other transfusion-transmissible infections (e.g. malaria) as well as testing for bacteria is performed on selected donations. Donations positive for mandatory screening tests are quarantined and subsequently discarded. Confirmatory testing is conducted to determine the infectious status of the donor and if positive, they are recalled for follow-up testing and counselling.

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

The 'tiered' safety approach

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

1. Through pre-donation public education using the www.donateblood.com.au website, Blood Service Community Relations staff, the media and the Blood Service National Contact Centre as well as brochures and handouts in collection facilities, donors are informed of eligibility criteria for blood donation and the reasons for deferral from donation.
2. Individuals whose behaviours or actions result in them having an increased risk of transmitting blood-borne infection are excluded by specific responses to questions asked prior to donation.
3. State-of-the-art tests are undertaken on donated blood to identify prospective donors with pre-existing infection and newly acquired infections in repeat donors.
4. Where available, physical and/or chemical measures are applied to inactivate viruses and other infectious agents (pathogen reduction technologies or PRT). Presently PRT are used for manufactured plasma products but are not routinely available in Australia for fresh blood components.

Each donation is tested for hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus (HIV), human T- lymphotropic virus (HTLV) and *T. pallidum* (syphilis). Testing for selected donors at risk for malaria (e.g. travelers to /residents of endemic countries) has also been performed since 2005. Despite incremental improvements, testing is not 100% effective in identifying infected donors. The primary limitation relates to the existence of a 'window period' (WP), defined as the period immediately after infection but before the agent is first detectable in the bloodstream. The window period varies in duration from several days (for HIV) to several weeks (for HBV) depending on the transfusion-transmissible infectious agent and the specific test used.

The addition of nucleic acid tests (NAT) to existing serological assays for HIV and HCV in June 2000 substantially reduced the WP from approximately 22 days and 66 days to approximately 9 days for HIV-1 and 5 days for HCV[1]. During 2010, the Blood Service implemented NAT for HBV DNA as a mandatory screen for all blood donations in addition to existing HBV test (HBsAg), which reduced the HBV window period from approximately 38 to 24 days[2]. An updated NAT triplex (HIV-1/HCV/HBV) test was implemented during 2013 reducing the HBV window period to approximately 15 days. These advances incrementally lower risk of not detecting a recently infected donor but importantly the WP is not eliminated. Thus, despite state-of-the-art donation testing there remains a small, but non-zero risk of transmission from donors with very recently acquired infection, who may test negative if they donate during the window period.

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

The Blood Service has collected and periodically presented data about detected infections in Australian blood donors since its establishment in 1996. In 2011, a review of available data pertaining to TTIs in Australia was jointly produced by the Australian Red Cross Blood Service and the Surveillance and Evaluation Program for Public Health at the Kirby Institute. This was the first, of what have now been established as annual reports that summarise data and trends for detected infections among Australian blood donors. The 2011 report included data for the period of 2005-2010 and demonstrated an overall reduction in prevalence of TTIs by almost 30% over the six years. Subsequently three annual surveillance reports have now been published focusing on data from 2011 (published in 2012), 2012 (published in 2013), and 2013 (the current report). While these focus on data from the current year they also assess for trends against the previously published data. Data on malaria testing and surveillance activity for emerging infections were also included from the 2011 report. Consistent with previous years, both the prevalence and incidence of TTIs in Australian blood donors generally remained low in 2013, with a steady or declining trend for most infections except active syphilis. Notably though, both the numbers and rates of incidence for HBV, HCV and HIV has slightly increased in 2013 compared to 2012. 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.

This is the fourth annual surveillance report that analyses data from the national surveillance system for blood donors maintained electronically by the Blood Service. The analysis of the previous report is extended to accommodate the most recent available data pertaining to the presence of TTIs among Australian blood donors. The report aims to inform further revision and evaluation of donor education/selection guidelines and donation testing algorithms in Australia. Finally, the residual risk estimates provide an important tool particularly for clinical stakeholders involved in patient consent for transfusion.

1 Busch MP, Glynn SA, Stramer SL, Strong DM, Caglioti S, Wright DJ, et al. A new strategy for estimating risks of transfusion-transmitted viral infections based on rates of detection of recently infected donors. Transfusion. 2005; 45(2):254-64.

2 Kleinman SH, Busch MP. Assessing the impact of HBV NAT on window period reduction and residual risk. Journal of Clinical Virology. 2006;36, Supplement 1(0):S23-S9.

Objective

The main objectives of the report are to:

1. Monitor trends over time in TTIs in blood donors in Australia, in particular, for HCV, HBV, HIV, HTLV and syphilis and to compare the findings from the most recent analysis with that reported in the previous year.
2. Compare the level of TTIs in first-time and in previously negative repeat blood donors with the general population.
3. Identify and analyse the risk factors that are associated with TTIs in blood donors and compare them to the risk factors in the general population.
4. Provide estimates of the residual risk of infection in the blood supply for HCV, HBV, HIV and HTLV.
5. Summarise the data from bacterial testing of platelets and assess the risk of transfusion-associated sepsis.
6. Estimate the rate of 'non-compliance' with TTI specific deferral questions.
7. Summarise major surveillance activity for emerging infectious disease and the Blood Service response.

Data

This report incorporates national donation testing data on Australian blood donors for the period 2005 to 2013. Anonymous donor data for all donors who donated blood between January 2005 and December 2013 were extracted from the Blood Service national donor database.

Trends in TTIs among first-time and previously negative repeat donors were analysed for donations in the years from 2005-2013. Demographic factors associated with TTIs in blood donors were analysed for donations made in 2013 and were compared with the findings from 2008-2012. Likely routes of exposure (termed 'infective risk factors') for each TTI in blood donors were also identified and analysed. Data from the 2012 and 2013 calendar years was combined and risk modelling conducted to derive estimates of the risk of transmission for HIV, HCV, HBV and HTLV in Australia. Additional modeling was performed to account for the risk associated with blood components from donors with occult HBV infection (OBI). This modeling used data from January 2013 to March 2014.