



Australian Red Cross  
**BLOOD SERVICE**

# Inquiry into the growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients: The Australian Red Cross Blood Service Submission.

March 2016

## **About the Australian Red Cross Blood Service**

Australian governments fully fund Red Cross for the provision of blood products and services to the Australian community. This is possible through the support of more than half a million voluntary blood donors. For more information or to make an appointment to give blood call **13 14 95** or visit [www.donateblood.com.au](http://www.donateblood.com.au)

## Background

The Australian Red Cross Blood Service (the Blood Service) was established as a national blood service in 1996. The Blood Service is governed by a board that is accountable to donors, the Australian community, Australian Red Cross and state and federal governments. The National Blood Authority is a statutory agency within the Australian Government health portfolio that manages and coordinates arrangements for the supply of blood and blood products and services on behalf of the Australian Government and state and territory governments. Australian governments fully fund the Blood Service for the provision of blood products and services to the Australian community. Consequently, we have specific financial and other reporting obligations to the National Blood Authority. The primary policy objective for the Australian blood sector described in the National Blood Agreement is to provide an adequate, safe, secure and affordable supply of blood products, blood-related products and blood-related services in Australia. Australia has one of the safest blood supplies in the world with respect to infectious disease risk. Protecting recipients of blood and blood components from the potential threat of infectious disease pathogens is a Blood Service imperative.

Each year the Blood Service collects approximately 1.25 million blood donations from approximately half a million voluntary blood donors. Blood donations are processed by the Blood Service into fresh components (packed red blood cells, platelets and clinical plasma) for transfusion. Plasma is also sent to CSL Behring as a starting material for the manufacture of plasma-derived blood products (e.g. albumin, clotting factors and immunoglobulins). The plasma is pooled at CSL Behring, and the manufacturing processes undertaken are capable of inactivating most infectious agents. Thus, plasma-derived blood products are not usually associated with the transmission of infectious diseases. The preparation of fresh blood components at the Blood Service involves splitting whole blood donations into the relevant blood components and storage under strict conditions. However, if any infectious agent can survive modern blood storage conditions, it is possible that the infection could be transfusion-transmitted.

## Aim of submission

The Blood Service has received various enquiries from community members with concerns about Lyme disease or a Lyme-like illness in Australia and the potential spread by transfusion. Although this is not one of the key terms of reference listed in the Senate Inquiry, because of persistent enquiries from the community, the Blood Service believes it is appropriate to take the opportunity to provide the Inquiry with information on how the Blood Service manages the potential risks from both known (such as Lyme disease caused by the bacterium *Borrelia burgdorferi sensu lato*) and unknown (a Lyme-like illness that may be caused by an unknown infectious agent) infectious diseases.

This submission also provides details to the Senate Inquiry on frequently asked questions about Lyme disease and blood transfusion from community members. The frequently asked questions and responses are in Appendix 1.

In the case of illnesses where a causative agent has not been identified, such as a potential Lyme-like illness in Australia that may be caused by an unidentified local causative agent, the Blood Service relies on its comprehensive risk management framework to prevent unwell people from donating blood and the recall of donations if a donor becomes unwell after donating. These strategies are described below and in detail in Appendix 2.

## Risks and mitigation strategies to prevent the transfusion of infectious agents via blood transfusions

The international blood transfusion community recognises that it is not possible to completely remove the risk of patients contracting an infectious disease from a blood transfusion. However, the Blood Service has a system to reduce the risk of both known and as yet unknown transfusion-transmissible infections to *as low as reasonably achievable* (known as the ALARA principle). The ALARA principle balances safety, supply and affordability. For example, it is not possible to screen for every single known infectious agent, as it would not be feasible or cost-effective, taking into account limited availability of licensed tests, limited resources and the level of risk posed by the agent. The Blood Service ensures the safety of the blood supply through a combination of methods:

- 1) A framework to effectively manage the risk from emerging, re-emerging and emerged infectious diseases (EREEIDs). The criteria the Blood Service considers when assessing the risk from known infectious agents are presented in Appendix 3. The EREEID framework includes risk management options for specific infectious diseases, which may result in changes to donor assessment and blood donor selection and eligibility. Current risk management options for potential infectious disease risks include:
  - Donor education.
  - Identification and deferral from blood donation of at-risk donors. Deferral is a temporary or permanent exclusion from blood donation or certain types of blood donation.
  - Quarantine of fresh components may occur as a precaution if a donor is considered at risk of an infectious disease. However, such donors could be subsequently confirmed as not having the infectious disease and therefore potentially eligible to donate again.
  - Restriction of fresh components for transfusion. Many infectious diseases pose no risk to plasma-derived blood products because the manufacturing procedures undertaken at CSL Behring are capable of inactivating infectious agents in pooled plasma, e.g. the malarial agent, dengue virus. Therefore, donors potentially at risk for these infections may be restricted to donating plasma for manufactured plasma products only.
  - Introduction of new/additional screening tests.
- 2) The Donor Questionnaire (DQ).

The DQ is the primary screening tool that identifies potentially unwell individuals and those who have higher risk of acquiring a transfusion-transmissible infection. The DQ contains a number of searching questions about a person's health, medical condition(s), travel history and behaviour/lifestyles. It must be completed by the blood donor at each donation, and donors are required to sign a legally binding declaration in the presence of a Blood Service staff member at the end of a private and confidential interview.
- 3) The Blood Service's donor selection criteria and deferral policies.

The Guidelines for the Selection of Blood Donors (GSBD) document contains the donor selection and deferral policies. This reference document is used by Blood Service staff to determine the eligibility of individuals to donate blood. The GSBD is revised annually. Urgent changes to donor criteria and/or deferral can also be made. All donor-interfaced staff are trained in the use of the GSBD and they can also refer any issues to Blood Service medical officers.
- 4) Recall of donations  

For donors who donate and subsequently become unwell, the Blood Service has a donation recall system. In the event of a post-donation notification of illness or potential exposure to an infectious agent, a risk assessment is performed prior to

making a decision about as to whether it is necessary to quarantine any blood components on the premises, recall any blood components which have been issued to hospitals/pathology services or discard blood components which have not been transfused. If the implicated blood component has been transfused, this process may involve notification of the treating clinician, depending on the nature of the risk.

## The EREEID framework

The threat from emerging, re-emerged and emerged infectious diseases (EREEIDs) is constantly monitored at the Blood Service, with a dedicated unit assigned to this function. This includes continued surveillance, risk assessment, risk management by dedicated staff.

The Blood Service continues to actively monitor and engage with both national and international stakeholders and researchers regarding infectious disease developments, taking into account the Australian context, to ensure we maintain one of the safest blood supplies in the world. The Blood Service liaises closely with government departments with communicable disease expertise and is a member of various international groups involved in horizon scanning for EREEIDs, including blood safety infectious disease working parties capable of global surveillance. The Blood Service has infectious disease agent templates (factsheets) for specific infectious disease agents that assess the blood safety threat and facilitate risk management. All potential transfusion-related infectious disease risks are formally reviewed at a minimum of every 6 weeks and forwarded to our regulator, the Therapeutic Goods Administration.

In relation to Lyme disease and Lyme-like illness in Australia, the Blood Service continues to monitor and assess research and developments both nationally and internationally, including tick-related research. In addition, the Blood Service actively monitors and assesses research and developments in other tick-borne infections such as ehrlichiosis, anaplasmosis, babesiosis and other forms of borreliosis. New discoveries, such as the newly identified novel pathogenic *Borrelia* species with high levels of bacteria and different symptoms to usual Lyme disease [1], highlight the importance of continued vigilance from the threat of emerging infectious diseases. Data from other countries and information from international blood services are very important in the Blood Service's continual monitoring of infectious disease risks internationally. If an infectious disease agent is transmissible by blood, it is most likely to be determined in a country with a high rate of infection. Examples of agents shown to be transfusion-transmissible include West Nile virus, dengue virus and *babesia*.

Feedback from the community regarding blood donor infectious disease screening has queried why the Blood Service can't screen donations for specific infectious diseases such as Lyme disease. The criteria required of a screening test for well people are different from those of diagnostic tests for unwell people. Because blood donor screening targets a population with a very low prevalence of infection (i.e. the vast majority are not expected to be infected), a screening test needs to be both highly sensitive (the probability of a positive test among those with the disease) and specific (the probability of a negative test among those without the disease). As a result, any blood donation screening test needs to be specifically evaluated and validated for blood donor screening. There is no licensed blood donor screening test in Australia for the causative agent of Lyme disease. Therefore, the Blood Service manages the potential risk of transfusion-transmission by infectious agents that are not subject to screening tests as described briefly below and in detail in Appendix 2.

## **Donor eligibility guidelines and their role in minimising risks from known and unknown infectious diseases**

The first step in ensuring blood safety is that donating blood must be voluntary and non-remunerated. In an effort to ensure the blood supply is as safe as possible, all donors must meet specific blood donation eligibility criteria that are regulated and approved by the Therapeutic Goods Administration (TGA). To donate, individuals must be at least 16 years old, healthy and feeling well on the day of donation. In addition, donors must meet weight and haemoglobin level requirements. Donors are also screened for disease risk factors using a confidential Donor Questionnaire. Donors are asked specific and direct questions regarding behaviour, lifestyle, health, medical history and travel to ensure their own health will not be compromised by a blood donation and the blood supply is as safe as possible for recipients.

Information on the Donor Questionnaire in relation to risks from a tick-borne or Lyme-like illness and how they are managed is provided in Appendix 2.

## **Conclusion**

While transfusion-transmitted Lyme disease or the transfusion-transmission of a Lyme-like illness has not been confirmed to date, the Blood Service remains vigilant in maintaining the safety of the blood supply. In the absence of a specific licensed screening test for the causative agent of Lyme disease and the absence of an identifiable causative agent in Lyme-like illness, the strict donor questionnaire and selection guidelines that the Blood Service has in place effectively minimises the risk from infectious agents to as low as reasonably achievable. Finally, the current principles of patient blood management acknowledge that there are risks associated with transfusion and apply an evidence-based approach to patient management and potential treatment with blood components. Therefore, all clinicians are aware that while blood transfusion is a lifesaving treatment, it should only be considered when the benefits outweigh the risks.

## **Appendix 1: Frequently Asked Questions**

### **Is it possible for Lyme disease to be transmitted by blood products?**

Transfusion-transmission of Lyme disease is only considered theoretical, as the bacteria that cause Lyme disease have not been reported to be transmissible by blood transfusion, even in endemic areas where the bacteria is present such as areas of the US and Europe. In addition, studies that have looked back at blood donations where the bacteria are detected have not found any evidence of infection in the recipients. The conclusion is that Lyme disease is a very low risk to blood safety in Australia.

### **Could donors have infection present in their blood?**

The Blood Service has measures in place that prevents unwell blood donors from donating blood (see below). In addition, in people with Lyme disease the bacteria are only present in the bloodstream for a very short time. There is only a very low likelihood that a donor could have acquired the infection overseas, have no symptoms and have the bacteria present in their blood at the time of donation.

### **Is there a test which could be used to test blood donors for Lyme disease?**

No, there is no available Lyme disease screening test that is suitable to screen blood donors.

### **What does the Blood Service do to decrease the risk then?**

As a precaution, the Blood Service requires all blood donors to be healthy and well prior to blood donation and requires all donors to declare whether they have seen a doctor or had any tests or investigations in the last year, to ensure we are only accepting healthy donors. Donors who have had a tick bite are also not permitted to donate blood until they have recovered. Donors with a history of current or past infection of Lyme disease are also permanently deferred from donating blood. Donors with other chronic illnesses such as chronic fatigue syndrome are indefinitely deferred from donating blood.

### **What would happen if someone thinks they have acquired Lyme disease from a blood transfusion?**

Given the extremely low risk of Lyme disease being transmitted by blood transfusion, this would be unlikely. For any investigation to be considered, the Blood Service would first establish that the diagnosis is confirmed.

### **Why don't you ask all donors about tick bites and stop them from donating blood?**

The vast majority of tick bites do not transmit any infectious diseases, and likewise most people infected with a tick-borne disease do not recall an associated tick bite. In addition, donors reporting tick bites may be less likely to be infected given they may be more likely to remove the tick before any infectious agent is transmitted. Most Lyme disease is transmitted by the smaller immature ticks and these are difficult to see.

## Appendix 2: The Donor Questionnaire and the Guidelines for Selection of Blood Donors

### *The Donor Questionnaire (DQ)*

The Donor Questionnaire is the preliminary screening tool the Blood Service uses to identify potentially at-risk donors. All donors must answer the following questions at **each donation** that are relevant to potential infectious disease risks from a tick-borne or Lyme-like illness in Australia:

1. Are you feeling healthy and well today?
2. In the last week have you had any cuts, abrasions, sores or rashes?
3. Since your last donation, have you – or if you are a new donor, have you in the last 12 months:
  - a) Been unwell, or seen a doctor or any other health care practitioner, had an operation or any tests/investigations?
  - b) Taken any other medication including regular or clinical trial medication?

If the donor answers yes to any of the above questions, they are asked further questions about their history of illness, including any condition that caused them to be unwell recently along with any diagnoses and related treatment. If they have seen a doctor or other health practitioner they are asked why. If they have had any tests or investigations they are asked what they were for and why. If they have had any sores they are asked about the nature of the lesion, whether it relates to an underlying condition and whether it has healed.

To capture any potential infectious disease risks from overseas, new donors are asked if they have ever been outside Australia. Repeat donors are asked if they have been outside Australia since their last donation.

A specific question on tick exposures or tick bites has been evaluated, with the conclusion that this is not a suitable screening question for blood donors. Published studies have described the ability of blood donors to recall recent tick exposure. However, a clear correlation between a donor's ability to recall a tick exposure and demonstrable infection could not be made, largely because the sensitivity of such questions is low [2]. Most people infected with a tick-borne disease do not recall an associated tick bite. In addition, donors reporting tick bites may be less likely to be infected given they may be more likely to remove the tick before any infectious agent is transmitted. .

### *The Guidelines for the Selection of Blood Donors (GSBD)*

For any donors who answer yes on any of the above infectious disease screening questions that are potentially related to a tick bite, an illness or feeling unwell, then the GSBD guides Blood Service staff on the appropriate action, with input from an internal medical officer or specialist where required. The list below is not a comprehensive list but illustrates situations where conditions may be potentially related to a known or unknown infectious agent that could be associated with Lyme-like illness in Australia.

- **Donor under investigation for illness:** If a donor is under investigation by a health practitioner for any illness or potential illness, or the Blood Service requires further information from the treating doctor to decide on blood donation eligibility, the donor will be referred to a Blood Service medical officer. The blood donor is indefinitely deferred from donating blood whilst under investigation or if there is insufficient information relating to the illness.
- **Non-specific illnesses:** If a donor has an infection with an unknown cause, or a non-specific illness where infection cannot be ruled out, the donor is deferred for 2 weeks from the date of **recovery**. If the illness is known, then the Blood Service has specific

deferrals for infectious diseases that are conservative in nature in relation to the known infectious period, and are generally set at a minimum of double the **longest** known infectious period.

- **Tick bites:** For a reaction to a bite that has symptoms beyond the bite site, the Blood Service will defer according to the specific infectious agent diagnosed. If the infectious agent is unknown, then this will be discussed with a Blood Service Medical Officer. The donor is not permitted to donate whilst unwell or under investigation for a potential infectious disease.  
For tick bites resulting in a local reaction, where there are no other symptoms the donor is not permitted to donate fresh products until the bite is healed and they otherwise meet eligibility criteria. It should be noted that fractionated plasma (i.e. plasma sent to CSL for further processing) is considered at no risk of bacterial contamination.
- **Lyme disease:** Donors who report a diagnosis of Lyme disease are permanently deferred from blood donation. By relying on donor report rather than laboratory criteria, this deferral covers potential Lyme-like illness in Australia, as donors who report a locally-acquired diagnosis are deferred. This deferral is based on the rationale that donors who report a Lyme disease diagnosis are generally unwell and it may adversely affect their health if they donate blood. Additionally, this deferral decreases the risk from any potentially unknown infectious agent associated with a Lyme-like illness.
- **Other tick-borne infectious agents:** Donors who have ever been diagnosed with babesiosis are permanently deferred from blood donation. Donors diagnosed with diseases caused by *Rickettsiae* bacteria are deferred from blood donation for 3 months following the date of recovery. Donors diagnosed with Q fever are permanently deferred from donation of fresh components.

Donors who meet eligibility requirements and donate are instructed to contact the Blood Service should they become unwell after donation to allow assessment of potentially at-risk donations that may have been donated during the incubation period of an illness. The Blood Service has a dedicated recall office that works closely with our medical team to assess post-donation events. Any post-donation illness is assessed for risk of infectivity. If there is a risk of potential infectivity, the blood donation and associated blood components are recalled and destroyed. The time period of recall prior to the donation is generally set conservatively as twice the **longest** known incubation period (the time from when someone is exposed to the illness to when they develop symptoms). If the blood components have been transfused, a process known as clinician notification will occur. Clinicians treating the recipient are notified by letter and, if urgent, by telephone to inform them of the potential infectious disease risk. If needed, Blood Service medical staff will advise the treating clinician of any risk, symptoms, management and follow-up issues.

The Blood Service has received enquiries from community members about people diagnosed with chronic fatigue syndrome and fibromyalgia, with the concern that these may be undiagnosed Lyme-like illness cases that could pose a risk of transfusion-transmission of Lyme disease or a Lyme-like illness. However, the Blood Service has donor deferrals for both of these conditions that prevent collection of a donation as below:

- **Chronic fatigue syndrome:** If a donor has ever been diagnosed with chronic fatigue syndrome a donation is not possible and the donor is indefinitely deferred.
- **Fibromyalgia:** Donors are only permitted to donate if they have not received any treatment (including over the counter pain relief) in the last 12 months.



The GSBD has travel deferrals for recent travel to many countries that relate to known and potential transfusion-transmitted infections such as malaria, dengue virus and West Nile virus. If a donor has visited a country that has a malarial risk they are deferred from donating fresh blood components for 120 days. Similarly there is a 4 week deferral from donating for area exposure to viruses such as dengue and West Nile viruses. For example, donors who travel to the United States of America are not permitted to donate fresh blood components until a 4 week deferral expires because of West Nile virus risk. These travel deferrals have also been shown to decrease the risk from other overseas-acquired infectious diseases, as donors would be prevented from donating fresh blood components during the incubation period of an illness.

### **Appendix 3: Blood Service criteria to assess known infectious disease risks**

For infectious disease risks, there are three criteria that the Blood Service uses to determine the risk an infectious disease poses to blood safety and guide risk mitigation strategies. Application of these criteria is illustrated by using the infectious agent that causes Lyme disease (*Borrelia burgdorferi sensu lato*).

#### ***The evidence of transfusion-transmission***

For the purpose of risk assessment, the transfusion-transmissibility of infectious disease agents is classified as either known to be transfusion-transmissible or potentially transfusion-transmissible. For an infectious agent to be transfusion-transmissible the agent must be present in the blood of donors who are asymptomatic/minimally symptomatic, the infectious agent must retain viability after routine blood processing and storage, the infectious agent must be in a state capable of causing infection via transfusion and present at a level higher than minimal infectious dose, and there needs to be a population of susceptible blood transfusion recipients [3].

Examples of agents known to be transfusion-transmissible include human immunodeficiency virus (HIV), hepatitis B virus, hepatitis C virus and other infectious agents including *Plasmodia* (malaria), dengue virus, West Nile virus and variant Creutzfeldt-Jakob disease.

Potential transfusion-transmission is based on whether there is evidence of an asymptomatic blood phase and its duration. Lyme disease is considered a potentially transfusion-transmissible agent and therefore a theoretical risk, as there is a known blood phase. Although there is a known blood phase, the evidence [4] suggests that this is short-lived and occurs early on in the disease.

In addition to an asymptomatic blood phase, the infectious agent must be able to survive blood storage conditions and remain infectious. There is some evidence that suggests *Borrelia burgdorferi* organisms can survive blood storage conditions. Badon et al [5] were able to recover organisms in their study using inoculation concentrations of 3,000/mL (for RBC and plasma) and 200/mL (for platelets). Nadelman et al [6] were also able to recover viable *Borrelia burgdorferi* from red cell samples when high concentrations of organisms were inoculated – when low concentration of organisms were used, they were not able to recover any organisms. In contrast, Johnson SE et al [7] were able to recover organisms at low concentration. However, it should be noted that these studies were published approximately 25 years ago and the methods used to prepare red cells and platelets at that time were different from contemporary Australian practice. Furthermore, during the subsequent 25 years of surveillance, transfusion-transmission of Lyme disease has not been reported. Two animal studies have suggested that the organism is infectious during the blood phase [8, 9]. However, in both studies fresh blood not stored according to contemporary blood banking standards was transfused. There have not been any studies that have demonstrated infectivity of *Borrelia burgdorferi* in blood components stored according to contemporary standards.

The vast majority of Lyme disease infections are symptomatic [10], which prevents blood donation because infected individuals will either be too sick to attend to donate or, if they do, will be identified by the screening questions in the DQ. No transfusion cases have been documented, even in countries where Lyme disease is endemic. In Lookback (the process of identifying and investigating people who may have received potentially infected blood) studies of recipients of blood components from DNA-positive (i.e. having *Borrelia burgdorferi* genetic material) donors in endemic countries, no evidence of infection was found. [4].

However, given the theoretical risk, the Blood Service takes a conservative approach to agents with the potential for transfusion-transmission, with the aim of preventing potentially at-risk donations entering the blood supply – especially when impact on sufficiency of the blood supply is not critical.

### ***The prevalence of the disease among donors***

The Blood Service has measures in place that prevent unwell donors from donating blood (see Appendix 1). In order for an infectious agent to be a threat to blood safety, it must be present in the blood without symptoms in the donor. In the case of Lyme disease, it is likely that the prevalence among blood donors is very low due to:

- a) the short-lived blood phase of the illness and
- b) the very low likelihood of a donor acquiring Lyme disease, being asymptomatic and having the bacteria present in the blood during a donation.

### ***The severity of infection in transfusion recipients***

Given transfusion-transmission of Lyme disease has not been described, the clinical presentation of transfusion-transmitted Lyme disease is unknown and may be difficult to identify with traditional reporting methods.

The importance of these criteria can be illustrated by comparing *Babesia microti* to Lyme disease. *Babesia* is a known transfusion-transmissible agent which, similar to Lyme disease, is a tick-borne infectious disease. Transfusion-transmission of *Babesia* has resulted in more than 160 cases in the United States but despite the significantly higher incidence of Lyme disease in the United States compared with *Babesia*, there has never been a reported transfusion-transmitted case of Lyme disease. In healthy individuals, such as blood donors, *Babesia* is capable of asymptomatic infection, whereas in transfusion recipients it is more likely to result in severe or complicated disease [11]. This may be related to the fact that many transfusion recipients are immunosuppressed (have weakened immune systems). *Babesia* is capable of causing severe infection in recipients, with 12 deaths reported due to transfusion-transmission. Fortunately, in Australia there has only ever been one case [12] of locally acquired babesiosis described in the literature, which was not transfusion-transmitted. This indicates the extremely low, but not zero, likelihood of transfusion-transmission of *Babesia* in Australia despite it being a known transfusion-transmissible agent. This adds to the evidence base that Lyme disease transfusion-transmission, if it occurs at all, must be exceptionally rare.

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