# Recommendations for the Notification of Recipients of a Recalled Blood Component.



## Overview

This document gives recommendations for when recipients of a recalled blood component should be notified of the recall. It also discusses the factors that influence a decision to notify recipients. It is limited to notifications related to recalls of fresh blood components only (i.e. red cells, platelets, frozen plasma components) and not to recalls of fractionated plasma products.

Notifications as a result of positive tests for infectious agents that Lifeblood screens for on a mandatory basis (i.e. hepatitis B. hepatitis C, HIV, HTLV, syphilis) are excluded from this document as notification in these cases is carried out as part of lookback investigations.

## Contents

## 1. Background

Lifeblood receives post-donation information with relevance to recipient safety including:

- The diagnosis of a potentially transfusion-transmissible infection (TTI) in a donor via internal or external testing
- A clinical history suggestive of a potential TTI in a donor
- A donor reporting a previously undisclosed risk factor for a TTI that occurred prior to donation
- A donor reporting a previously undisclosed teratogenic medication or vaccination that was administered prior to donation

When fresh blood components that carry a significantly increased risk of harm to a recipient have already been transfused, Lifeblood has a duty of care to notify transfusing clinicians. This document provides recommendations and rationale for clinicians to decide under what circumstances it would be appropriate to notify the transfused recipients and what actions, if any, to perform for their patients.

## 2. Purpose

To assist clinicians in evaluating whether recipient notification of potential transmission of infectious disease is required.

## 3. Scope

The scope of this document is limited to clinician notification to patients regarding recalls of fresh blood components (i.e. red cells, platelets, frozen plasma components).

## 4. Out of scope

- Notifications as a result of positive tests for infectious agents that Lifeblood screens for on a mandatory basis (i.e. hepatitis B, hepatitis C, HIV, HTLV, syphilis) are excluded from this document. Notification in these cases is mandatory and communications to clinicians provide specific advice regarding testing of recipients.
- Recalls initiated as a result of the failure of Lifeblood processes or failure of materials used in the collection process (referred to as process recalls).
- Recalls of fractionated plasma products.
- This document is not intended for internal use by Lifeblood staff in the assessment of blood component recalls.

## 5. General recommendations

- The recommendations for recipient notification outlined in this document are suggested actions, and **the decision to notify a recipient remains at the discretion of the treating clinician.**
- The clinical situation of the recipient is an important factor when considering notification of a blood component recall. The clinical factors that may be considered by the treating clinician in evaluating the value of notification in individual cases include, but are not limited to:
  - presence or absence of symptoms during or after transfusion (relevant for possible bacterial contamination, malaria risk)
  - pregnancy (relevant for teratogenic drugs)
  - underlying condition (e.g. if patient is immunocompromised and the donor developed EBV infection shortly after donation)
  - the age of the patient
  - the prognosis of the patient
- It is recommended that all hospitals have their own policies and procedures for the process of notification in accordance with applicable regulations. These should specify who is responsible for notification and the process by which it should occur. For instances where a review of recipient records are required to inform a notification decision, it is recommended that hospitals maintain a record of their activities related to the review of information as appropriate. It is recommended that a local risk management expert be consulted in the development of this process and procedures.
- Recipient notification, follow-up testing and post exposure prophylaxis where indicated should occur as soon as possible after the risk that is associated with the cause of the blood component recall becomes known.
- It is recommended that consultation with a Lifeblood Transfusion Medicine Specialist and/Lifeblood Medical Microbiologist occur as necessary should further information or clarification be required with respect to any recall notification received.
- If post exposure prophylaxis (PEP) is potentially indicated, immediate consultation should occur with the hospital's Infection Control Specialist or local Public Health Unit to determine the appropriateness of use.
- In addition, isolation of non-immune recipients in hospital settings would be necessary for contacts of diseases such as measles and varicella. Discuss with the hospital's Infection Control Specialist or local Public Health Unit.
- This document does not address recalls initiated due to a donor testing positive for a mandatory infectious disease test, i.e. hepatitis B, hepatitis C, HIV, HTLV and syphilis. In these instances, Lifeblood will notify the hospital via standard lookback procedures.

## 6. Specific recommendations

The following table provides a list of common reasons for blood component recalls which are initiated following receipt of post-donation information and that require notification to clinicians. Recommendations with respect to recipient notification are provided in each case

If a recipient has the specific infection confirmed as part of the evaluation, then Lifeblood should be notified as part of adverse transfusion reaction reporting. This will trigger further investigation and actions from Lifeblood.

| Reason | Recall Trigger | Risk assessment | Evaluation |
|---|---|---|---|
| **Chagas' disease** | A donor who is found to be infected with Trypanosoma cruzi. | Transfusion transmission has been documented but risk will depend on stage of disease in the individual case. | Consider discussion with a Lifeblood Transfusion Medicine Specialist or a Hospital or Lifeblood Medical Microbiologist. |
| **Chickenpox** | A donor who is diagnosed with chickenpox, after a donation within the known incubation period. | Transfusion transmission of varicella zoster virus (VZV) with chickenpox is possible though this has not been reported at the time of publication. The incubation period is 10-21 days with viraemia detectable 8-10 days prior to rash development and followed by a secondary viraemia 5 days before rash development and lasting about 10 days.<br>Leucodepletion of blood components likely decreases the risk as VZV is primarily white blood cell (WBC) associated. Clinical plasma has fewer leucocytes than leucodepleted products. | Recipient notification is recommended.<br>Depending on the recipient's immune status, consider:<br>• PEP with varicella vaccine (up to 5 days post transfusion), or<br>• Zoster Ig may be indicated (within 96 hours of transfusion) if immunocompromised.<br>Consider discussion with a Lifeblood Transfusion Medicine Specialist or a Hospital or Lifeblood Medical Microbiologist.<br>Testing of the recipient is recommended in the event of a clinically compatible illness and timing is consistent with transfusion-transmission. |

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| **Gonorrhoea** | A donor who has had gonorrhoea in the last 3 weeks where there is a risk of gonococcal bacteraemia. | Transfusion transmission has not been reported at the time of publication and the risk is thought to be negligible. | Recipient notification is recommended if the recipient was febrile post-transfusion or there are symptoms suggestive of disseminated gonococcal infection (skin lesions, arthralgia, acute arthritis and tenosynovitis).<br>Consider discussing with a Hospital or Lifeblood Medical Microbiologist. |
| **Hepatitis A/E** | A donor who is diagnosed with hepatitis A or E, after a donation within the known incubation period or infectious period. | Transfusion transmission of both hepatitis A and E has been reported. The individual risk in a particular case can be discussed with the Lifeblood Public Health Physician or Lifeblood Medical Microbiologist.<br>Testing the archived sample of the donation to aid risk management will be organised by Lifeblood. | Recipient notification is recommended.<br>Hepatitis A – if within 2 weeks of exposure, consider PEP (vaccination or Normal Immunoglobulin).<br>Hepatitis E – no PEP available.<br>Consider discussion with a Lifeblood Transfusion Medicine Specialist or a Hospital or Lifeblood Medical Microbiologist.<br>For hepatitis A, testing is recommended in the event of clinically compatible illness and timing is consistent with transfusion-transmission.<br>For hepatitis E, given infection can be asymptomatic, testing is recommended to determine whether transfusion-transmission occurred. For hepatitis E, there is a risk of chronic infection in immunosuppressed patients that may be asymptomatic yet cause progressive liver damage. |

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| **Infections, other:**<br>• **Glandular fever (Epstein Barr Virus), infection**<br>• **Barmah Forest virus**<br>• **Ross River virus**<br>• **Whooping cough** | A donor who has been diagnosed with any of these infections with onset within a specified period after donation for each, which includes the incubation period. | Transfusion transmission cannot be excluded; however the risk is considered negligible. | Recipient notification is recommended taking into account symptoms and timing of transfusion<br>If a clinically compatible illness occurs and the timing is consistent with possible transfusion-transmission, then recipient testing is strongly recommended. |
| **Malaria** | A donor who is diagnosed with malaria<br>or<br>A donor with a malaria risk exposure in the 4 month period prior to donation<br>or<br>A donor with a malaria risk exposure preceding donation when a negative antibody screening result taken after the 4 month window period is not available and a risk assessment demonstrates an increased risk of malaria in the donor. | Transfusion transmission has been documented. The risk needs to be assessed on a case by case basis and depends upon the level and duration of exposure, the time since the potential exposure, and the country where the donor was exposed. The individual risk in a particular case can be discussed with the Lifeblood Medical Microbiologist. | Recipient notification is recommended if<br>i. The donation was not tested for malaria, or<br>ii. Lifeblood testing shows the donor was antibody reactive or parasitaemic, or<br>iii. The donor reports a diagnosis of malaria post-dating the donation following an exposure which occurred before the donation, or<br>iv. The recipient was febrile post-transfusion. Other symptoms and signs of post-transfusion malaria include fatigue, anaemia and altered mental state.<br>Testing of the recipient is recommended in the event of a clinically compatible illness. |

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| **Measles** | A donor who has been diagnosed with measles after donation with onset within a specified period after donation, which includes the incubation period. | Transfusion transmission is possible but there is only one possible case report in 1924.<br>The incubation period is 10-14 days with viraemia potentially occurring from 2 to 7 days post-exposure.<br>Leucodepletion of blood components likely decreases the risk | Recipient notification is recommended.<br>Depending on the recipient's immune status, consider:<br>• PEP with Measles Mumps Rubella vaccine (up to 72 hours post transfusion), or<br>• Normal Human Ig may be indicated (within 6 days of transfusion).<br>Consider discussion with a Lifeblood Transfusion Medicine Specialist or a Hospital or Lifeblood Medical Microbiologist.<br>If a clinically compatible illness occurs and the timing is consistent with possible transfusion-transmission, then recipient testing and appropriate infection control precautions are strongly recommended |
| **Mumps** | A donor who has been diagnosed with mumps after donation with onset within a specified period after donation, which includes the incubation period | Transfusion transmission has not been reported at the time of publication and the possibility of this is thought to be remote due to a short period of viraemia.<br>The incubation period is 16-18 days but can be up to four weeks with transient viraemia during the first 2 days of illness. | Recipient notification is recommended.<br>Consider testing the recipient's immunity.<br>If the recipient is not immune, consider discussion with a Lifeblood Transfusion Medicine Specialist or a Hospital or Lifeblood Medical Microbiologist.<br>If a clinically compatible illness occurs and the timing is consistent with possible transfusion-transmission, then recipient testing and appropriate infection control precautions are strongly recommended. |

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| **Rubella** | A donor who has been diagnosed with rubella after donation with onset within a specified period after donation, which includes the incubation period. | Transfusion transmission is possible though this has not been reported at the time of publication.<br>The incubation period is 14-21 days with viraemia as early as 9 days before onset of rash and until 2 days after the rash appears. | Recipient notification is recommended.<br>If the recipient is pregnant, consider Normal Human Ig.<br>Consider discussion with a Lifeblood Transfusion Medicine Specialist or a Hospital or Lifeblood Medical Microbiologist.<br>If a clinically compatible illness occurs and the timing is consistent with possible transfusion-transmission, then recipient testing and appropriate infection control precautions are strongly recommended. |
| **Parvovirus B19 infection** | A donor who has been diagnosed with Parvovirus B19 and donated either before symptoms develop or within 2 months post recovery | Parvovirus B19 is a known transfusion transmissible agent. Although viraemia is known to occur for over a year, transmission generally occurs with high level viraemia in the first weeks after initial infection. Lifeblood will perform a risk assessment including testing the archived sample of the donation for DNA and viral load if positive. | Recipient notification is recommended.<br>Consider testing the recipient's immunity and/or testing for parvovirus DNA if there is a clinically compatible illness.<br>If positive, seek treatment advice from Lifeblood Transfusion Medicine Specialist or a Hospital or Lifeblood Medical Microbiologist. |
| **Potential bacterial transmission risk:**<br>• **Pneumonia**<br>• **Abscess**<br>• **Septicaemia**<br>• **Endocarditis, Infective**<br>• **Diverticulitis** | A donor who has developed symptoms after a donation and subsequently been diagnosed with an infection that could have been present at the time of donation.<br>See also Positive BCS result below. | Transfusion transmission risk depends on the pathogenic potential of any organism involved and requires individual case assessment.<br>The risk is relatively greater following transfusion of platelet components due to higher storage temperature. | Recipient notification is recommended if the recipient was febrile post-transfusion. |

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| **Positive BCS culture result** | A unit has flagged positive on the automated BacT/ALERT culture system; all fresh components associated with the donation are recalled and clinicians are notified if products have already been transfused.<br>Subsequent investigations may identify a contaminating organism, or the initial positive reaction is not confirmed (false positive) and this information is made available to the clinicians. | Transfusion transmission risk depends on the pathogenic potential of any organism involved.<br>The risk is relatively greater following transfusion of platelet components due to higher storage temperature | Recipient notification is recommended.<br>If the recipient was febrile post-transfusion, blood cultures from the patient and unit are recommended.<br>If the recipient was asymptomatic post transfusion, consider observation alone or treatment on spec.<br>Consider discussion with a Lifeblood Transfusion Medicine Specialist or a Hospital or Lifeblood Medical Microbiologist. |
| **Suspected transfusion-transmitted bacterial infection** | A recipient who has developed signs and symptoms of post-transfusion sepsis during or in the four hours post-transfusion.<br>A recall is triggered for all other fresh components from that donation. If those other fresh components have been transfused, the transfusing clinicians are notified irrespective of the interval since transfusion.<br>Subsequent investigations may identify or rule out a contaminating organism, and this information is made available to the clinicians | Transfusion transmission risk depends on the pathogenic potential of any organism involved.<br>The risk is relatively greater following transfusion of platelet components due to higher storage temperature | Recipient notification is recommended.<br>If the recipient was febrile post-transfusion, blood cultures from the patient and unit are recommended.<br>If the recipient was asymptomatic post transfusion, consider observation alone or treatment on spec.<br>Consider discussion with a Lifeblood Transfusion Medicine Specialist or a Hospital or Lifeblood Medical Microbiologist. |
| **Tuberculosis (TB), current infection** | A donor who has had tuberculosis infection diagnosed with positive culture and/or microscopy and/or molecular test. | Transfusion transmission has not been reported at the time of publication and the possibility of this is thought to be remote. However transmission by solid organ transplantation has been reported. | Recipient notification is recommended if the recipient was febrile post-transfusion. Note if transfusion-transmitted TB was to occur, it would most likely manifest as extra-pulmonary TB, which may be difficult to diagnose. |

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| **High Risk Exposures, including:**<br>• **Blood or body fluid splash**<br>• **Injecting drug use**<br>• **Needle stick injury**<br>• **Male to male sex**<br>• **Multi-use acupuncture**<br>• **Multi-use piercings**<br>• **Multi-use electrolysis**<br>• **Tattoos**<br>• **Use of illegal steroids** | A donor who discloses retrospectively an exposure known to carry an increased risk of TTI within 6 to 12 months prior to donation.<br>While all donations issued by Lifeblood have tested non-reactive for infection with hepatitis B, hepatitis C, HIV, HTLV and syphilis, a theoretical risk of window period infection remains.<br>If consent is obtained, Lifeblood subsequently screens the donor for hepatitis B & C, HIV, HTLV and syphilis. | In this situation, there is usually insufficient information to accurately assess the risk, but in most cases it is likely to be low given that all mandatory tests at the time of donation were negative.<br>More information about the residual risk estimates for transfusion transmissible infections is available at http://www.transfusion.com.au | If the donor subsequently tests reactive for a TTI (for hepatitis B, hepatitis C, HIV, HTLV and syphilis) notification is by standard lookback procedures.<br>In selected cases, even if the donor has not attended for follow-up testing, Lifeblood may notify the clinician. In these cases, it is recommended that notification of recipients be discussed with a Lifeblood Transfusion Medicine Specialist or a Hospital or Lifeblood Medical Microbiologist.<br>Lifeblood will not notify clinicians if the donor tests non-reactive for the related TTI after an appropriate window period. |
| **Contact with:**<br>• **hepatitis A**<br>• **hepatitis E** | A donor who, in the 4 months prior to donation, has had high risk exposure to hepatitis A or hepatitis E infections. | Negligible risk. Lifeblood will perform a risk assessment including testing the archived sample of the donation by direct viral detection and serology. | Recipient notification is recommended. If the recipient was febrile post-transfusion or develops jaundice or altered liver function, consider hepatitis A or hepatitis E infection.<br>Note hepatitis E can cause chronic asymptomatic infection and therefore a low threshold for testing is recommended. |
| **Contact with:**<br>• **Cytomegalovirus**<br>• **Chicken pox/shingles**<br>• **Glandular fever (Epstein Barr virus)** | A donor who has had contact with a potentially infectious individual and donated within the incubation period. | Negligible risk. Lifeblood will perform a risk assessment including the contacts immunity status +/- testing of the donation for potential viral infectivity | Assess immune competence and existing immunity of the recipient. |

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|---|---|---|---|
| **Other medical risks** | | | |
| **Denosumab (Prolia)** | A donor who has taken Denosumab in the 6 months prior to donation, leading to a theoretical risk of a therapeutic dose being delivered via transfusion and hypocalcaemia in the recipient. | Individual case assessment dependent on the timing and dose the drug in relation to the donation, and the plasma content of the donation.<br>Signs and symptoms of hypocalcaemia include:<br>• perioral paraesthesia<br>• paraesthesia of extremities<br>• a metallic taste<br>• muscle fasciculation & spasm<br>• myoclonic jerks<br>• cardiac arrhythmias. | Recipient notification is recommended if the recipient develops clinical hypocalcaemia post-transfusion. |
| **Trial medications or vaccinations** | A donor who has taken part in a clinical trial of a medication or immunisation / vaccine. | Individual case assessment | Recipient notification is recommended if a potentially teratogenic substance is involved and the recipient was pregnant at the time of transfusion. |

## 7. Definitions and frequently used abbreviations

| Term | Definition |
|---|---|
| BCS | Bacterial contamination screening of fresh blood components performed by Lifeblood. BCS is routinely performed on all platelet components that are supplied by Lifeblood. |
| Clinician | For recall and donor-triggered lookback purposes, this is the recipient's doctor with responsibility for transfusing an implicated fresh blood component. |
| CSL | CSL Behring (Australia) Pty Ltd. From the plasma provided by Lifeblood, CSL uses a fractionation process to manufacture coagulation factor concentrates, immunoglobulin products and albumin solutions (fractionated plasma products). |
| Fresh blood component | Red cells, platelets, clinical fresh frozen plasma (FFP), cryo-depleted plasma, cryoprecipitate, granulocytes or serum eye drops |
| Ig | Immunoglobulin |
| Leucodepletion | Leucodepletion is the term for the process for the removal of leucocytes (white blood cells) from blood components using special filters |
| Lookback | The process of investigating transfusion transmission as a possible cause of infection which occurs post confirmation of a diagnosis of a potential transfusion-transmissible infection (TTI). |
| Donor triggered lookback | The investigation of donations collected from donors who are subsequently diagnosed with TTI. This includes identifying the recipient/s and, if possible, testing them for the specific TTI. |
| PEP | Post-exposure prophylaxis |
| Recall | A standard procedure for withdrawal of blood components and products following receipt of information that suggests the component/product presents a potential risk to a recipient. Recalls can be limited to fresh blood components but may also require recall of plasma provided to CSL for production of fractionated products. |
| Recipient | A person who has been transfused an implicated fresh blood component or fractionated plasma product. |
| Transfusion-transmissible infection (TTI) | A virus, bacteria, parasite, or other blood-borne infectious agent in donated blood that can be transmitted by transfusion to a recipient. |

## Change history

| Version number | Effective date | Reference | Summary of change |
|---|---|---|---|
| 1 | 01/09/2018 | N/A | First version |
| 2 | Refer to footer | N/A | Reference to CCR-19-000490<br>Transfer to Lifeblood template.<br>Reference to Blood Service replaced with Lifeblood. |

## Electronic signature

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