



**RECOMMENDATIONS FOR THE NOTIFICATION OF RECIPIENTS OF A BLOOD
COMPONENT RECALL:
A NAC and Canadian Blood Services Collaborative Initiative**



RECIPIENT NOTIFICATION SUBCOMMITTEE

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TABLE OF CONTENTS

RECIPIENT NOTIFICATION SUBCOMMITTEE	2
TABLE OF CONTENTS.....	3
ABBREVIATIONS	4
DEFINITIONS.....	5
ACKNOWLEDGEMENTS.....	5
SUMMARY OF REVISIONS	6
1.0 OVERVIEW AND GENERAL RECOMMENDATIONS	8
2.0 RECALL AND RECIPIENT NOTIFICATION PROCESS	9
3.0 POST-DONATION INFORMATION.....	11
4.0 TECHNICAL MANUFACTURING ISSUES	13
5.0 BACTERIAL CONTAMINATION.....	14
6.0 TRANSFUSION RELATED ACUTE LUNG INJURY	14
7.0 NATIONAL RECIPIENT ADVISORY COMMITTEE.....	14
7.1 MANDATE.....	15
7.2 MEMBERSHIP	15
7.3 MEETINGS	15
REFERENCES	16
APPENDIX A: SUPPLEMENTARY INFORMATION	20
POST-DONATION INFORMATION.....	20
TECHNICAL MANUFACTURING ISSUES	23
BACTERIAL CONTAMINATION.....	24
TRANSFUSION RELATED ACUTE LUNG INJURY	25



ABBREVIATIONS

CJD	Creutzfeldt-Jakob Disease
CMV	Cytomegalovirus
EBV	Epstein Barr Virus
NA	Not Applicable
NAC	National Advisory Committee on Blood and Blood Products
NAT	Nucleic Acid Testing
NRAC	National Recipient Advisory Committee
Mpox	Monkey Pox
P/T	Provinces/Territories
TRALI	Transfusion Related Acute Lung Injury
TT-malaria	Transfusion-Transmission of Malaria



DEFINITIONS

Associated Blood Component – A blood component that is directly associated in a recall (i.e. packed red blood cell unit).

Checkmark – Indicates affirmation for that column. Please see antithetical column for any exceptions.

Companion Blood Component – A blood component that has been produced from the same donation (i.e. pooled platelet unit from the same donation as the implicated red blood cell unit).

Large Scale Recall – A recall of 50 or more blood components OR a recall of a small number of blood components involving multiple provinces. This does not include reasons for common recalls outlined in this document.

NA – Indicates “Not Applicable” for that column. Please see notes in the antithetical column.

Notification Not Recommended – If this applies, then further investigation/action is not required.

Notification Recommended – If this applies, then an investigation is recommended which may include patient chart review, discussion with the patient’s clinician for additional information or testing recommendations, and/or patient notification.

Recall – The removal from further distribution, or use, of a product (blood component) that violates legislation administered by Health Canada (a regulatory requirement).

Unusual Recall – A recall due to an unanticipated event impacting a large or small number of blood components.

Withdrawal – The voluntary removal by the manufacturer (blood supplier) of a product (blood component) that does not violate legislation administered by Health Canada.

ACKNOWLEDGEMENTS

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SUMMARY OF REVISIONS

May 2026

General	Variant Creutzfeldt-Jakob Disease removed from document as Canadian Blood Services no longer has criteria for past donor travel to countries classified as at risk. Overall formatting and layout changes to improve readability and consistency with other NAC publications.
Table 1	Row added for Parvovirus B19. Row added for Hepatitis A Virus.
References	Updated.

2023

Acronyms	Removed acronyms that are no longer used and included those that were not listed.
Definitions	Updated definition of 'Large Scale Recall'. Included definitions listed before Section 3.0.
Section 1.0	Moved position regarding fresh blood components versus fractionated or recombinant plasma protein products for clarity.
Section 2.0	Added definitions for recipient notification.
Figure 1	Second box down, left side – removed 'CBS calls then faxes...' and changed to 'CBS notifies hospitals'. Updated.
Table 1	Updated 'High-Risk Behaviour' section. Updated 'Possible donor infection in donor with a travel history (not related to malaria risk)' section. Updated 'Viral' section. Updated 'Mononucleosis (Epstein-Barr Virus)' section. Updated 'Variant CJD Risk: Donor travel to an at risk country' section.
Table 2	Updated 'Documentation Errors' section.
Sections 7.1 & 7.2	Changed to a single committee with ad hoc guests as required.
Section 7.3	Removed reference to secondary NRAC.
References	Updated.
Appendix A	Updated 'Cancer' section. Updated 'Malaria Risk' section. Updated 'Tattoo, piercing, electrolysis' section. Added 'Mpox (Monkey pox)' section. Added 'COVID-19 (SARS-CoV-2)' section. Added 'Mpox' and 'SARS-CoV-2' sections to Appendix A Table. Updated 'Rh D or red cell antigen phenotyping errors or discrepancies' section under 'Technical Manufacturing Issues'.



2018

Section 3.8	Removed recommendation for consultation regarding donor re-testing as this step is not likely to be helpful.
Table 1	<p>Title clarified.</p> <p>Added ‘Possible donor infection in donor with a travel history (not related to malaria risk)’ section.</p> <p>Added ‘Zika virus infection, lab confirmed’ section.</p> <p>Updated ‘Medication, unacceptable’ section.</p> <p>Edited notification criteria in ‘Mononucleosis’ section.</p> <p>Updated relative risk of recalls due to variant CJD versus classic CJD.</p> <p>Removed ‘Miscellaneous – Vaccinations’ category owing to very low frequency of recalls.</p> <p>Updated the percent of total recalls captured within the reason list.</p>
Table 2	<p>Title clarified.</p> <p>Updated ‘BacT/ALERT testing /Quality Control’ section to reflect new platelet testing process and edited the notification criteria.</p> <p>Updated ‘Screening Errors’ section.</p> <p>Removed ‘Appearance’ category owing to very low frequency of recalls.</p> <p>Edited the notification criteria in ‘Sterility Breach’ section.</p> <p>Edited the notification criteria in ‘Unacceptable QC WBC Results’ section.</p> <p>Updated the % of total recalls captured within the reason list.</p>
Section 8	Acknowledgements updated.
References	Updated.
Appendix A	<p>Added information on ‘Possible donor infection in donor with a travel history (not related to malaria risk)’ section.</p> <p>Updated deferral period in ‘Tattoo, piercing and electrolysis’ section.</p> <p>Updated information on variant CJD and classic CJD.</p> <p>Removed ‘Miscellaneous – Vaccinations’ category owing to low frequency of recalls.</p> <p>Added information on ‘Zika virus infection, lab confirmed’.</p> <p>Updated ‘Invalid BacT/Alert Testing’ section to reflect new platelet testing process.</p> <p>Removed “Appearance” category owing to low frequency of recalls.</p>



1.0 OVERVIEW AND GENERAL RECOMMENDATIONS

The National Advisory Committee on Blood and Blood Products (NAC) is an interprovincial medical and technical advisory body to the Provincial and Territorial (P/T) Health Ministries and the blood supplier Canadian Blood Services. Its mandate is to provide professional leadership and advice in matters directly affecting the practice of transfusion medicine in hospitals. In 2010, NAC was asked by Canadian Blood Services and the P/T Ministries of Health to:

- Develop national recommendations ensuring consistent recipient notification when a recall or a withdrawal of a blood component has occurred;
- Identify who is responsible for each stage of the notification process; and,
- Recommend a group of resource experts that would be convened in the event of an unusual or large scale recall/withdrawal to provide direction regarding recipient notification for a situation that is not specifically addressed in the national recommendation document.

NAC collaborated with Canadian Blood Services in the development of this recommendation document. It is recommended that this document be used as a reference by hospital transfusion services, the blood supplier, and P/T representatives.

Although the definitions for a recall and a withdrawal of blood components differ (refer to the list of definitions), from a practical perspective the consequences for the blood component is the same. The blood supplier removes the blood component from inventory and hospital transfusion services supplied by Canadian Blood Services are notified if they have received associated or companion blood components. This document does not distinguish between the two terms. The term ‘recall’ is used as a comprehensive term throughout the remainder of the document.

The recommendations for recipient notification outlined in this document are the suggested actions required in terms of notification. The general recommendations presented are applicable to causes of blood component recalls that are known to occur and initiated by the blood supplier; the blood supplier being Canadian Blood Services in all P/Ts with the exception of Québec. This document does not prevent P/Ts or individual hospitals from implementing notification processes above and beyond what has been recommended, or modifying processes as determined locally.

It is recommended that all hospitals have their own policies and procedures for the process of notification in accordance with applicable P/T regulations. Throughout this document when notification is recommended every hospital should have an internal procedure outlining who is responsible for notification and the process by which it should occur. It is recommended that local risk management be consulted in the development of this process.

This document does not address recalls initiated due to a donor testing positive for a transmissible disease test such as Hepatitis B, Hepatitis C, human immunodeficiency virus, human T-lymphotropic virus 1, Syphilis, West Nile Virus or *T. cruzi* (Chagas disease). In these instances, Canadian Blood Services indicates to the hospital the required actions via standard lookback procedures.

This document currently only addresses recipient notification in terms of recalls associated with the transfusion of fresh blood components collected, produced and/or distributed by Canadian Blood Services (i.e., red blood cell, platelet and frozen plasma components). However, there



may be applicability to a recall of fractionated or recombinant plasma protein products (i.e. an unusual or large scale recall) that may result in the National Recipient Advisory Committee (NRAC) being convened which is discussed further in [Section 7.0](#).

These recommendations for notification have been made in consideration of the available literature. There are clinical situations that the treating physician should consider when further evaluating the recommendations for notification contained in this document. These conditions 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 (relevant if patient is immunocompromised and donor developed Epstein Barr Virus infection);
- The age of the patient; and,
- Relevant prognosis.

Depending on the age and prognosis of the recipient, the treating physician may consider notifying next of kin or family members as an alternative to notifying the recipient directly about a blood component recall. This should be done in accordance with applicable provincial or territorial regulations.

For instances where recipient notification is not recommended and a review of recipient records are required to confirm this, it is recommended that hospitals maintain a record of their activities related to the review of information as appropriate. Recipient notification and any follow-up testing should occur as soon as possible in relation to the relative risk that is associated with the cause of the blood component recall.

It is recommended that consultation with a Canadian Blood Services Medical Officer occur as necessary should further information or clarification be required with respect to any notification received regarding a blood component recall.

2.0 RECALL AND RECIPIENT NOTIFICATION PROCESS

Recalls and withdrawals of blood products are initiated by Canadian Blood Services in accordance with Health Canada regulations and standard operating procedures.

Once Canadian Blood Services makes the decision to recall or withdraw blood components from inventory, the required notification to hospitals is conducted as per standard procedure. If upon notification the hospital concludes that the identified blood component was transfused, a decision with regard to recipient notification must be made.

For recalls associated with infectious disease markers, Canadian Blood Services will provide direction to hospitals regarding recipient notification in accordance with lookback procedures. As per Figure 1, found below, if the reason to recall a blood component is unusual or if the recall involves a large amount of blood components, a recommendation for recipient notification may be made by the NRAC. The recommendation made by the NRAC will be communicated to hospitals by Canadian Blood Services through regular communication methods. In these instances, hospital reference to the *NAC Recommendations for Recipient*



Notification of a Blood Component Recall is not required unless information with respect to the functionality and scope of the NRAC is needed.

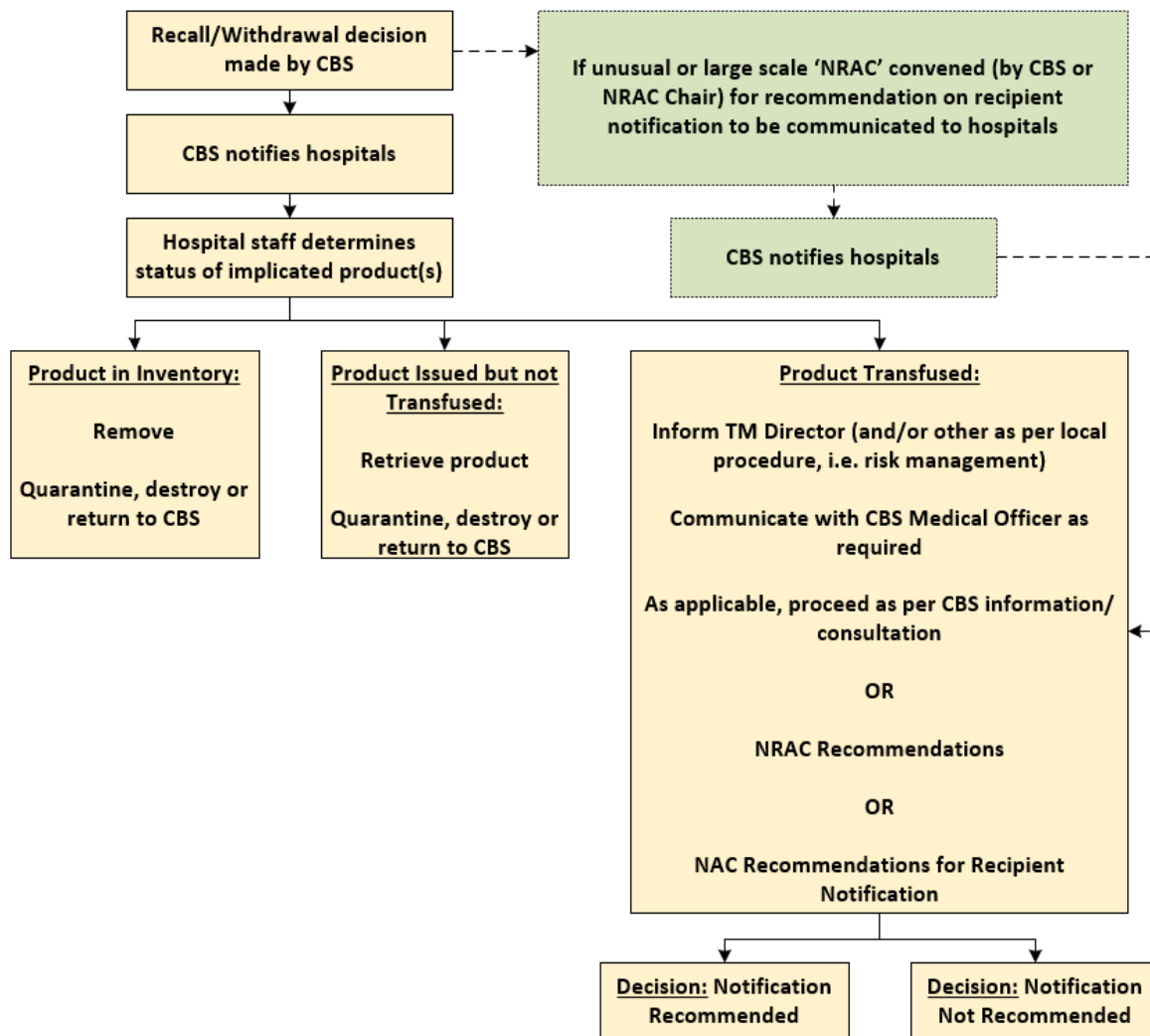


Figure 1: Flow chart indicating the process prior to recipient notification being conducted.

The following sections (3.0 to 6.0) provide recommendations for notification depending on the reason for recall. The following definitions apply to all 4 sections:

Notification Recommended – If this applies, then an investigation is recommended which may include patient chart review, discussion with the patient’s clinician for additional information or testing recommendations, and/or patient notification.

Notification Not Recommended – If this applies, then further investigation/action is not required.

NA – Indicates “Not Applicable” for that column. Please see notes in the antithetical column.

Checkmark (✓) – Indicates affirmation for that column. Please see antithetical column for any exceptions.



3.0 POST-DONATION INFORMATION

Table 1: Recalls initiated as a result of post donation information received by the blood supplier.

Reason	Description/Rationale	Notification Recommended	Notification NOT Recommended
Parvovirus B19	Common community acquired virus that is screened for via nucleic acid testing by plasma fractionators, with individual results of viral titers >10 ⁴ IU/mL reported back to Canadian Blood Services.	Chart review and consider notification if recipients are pregnant or of child bearing potential, immunocompromised, have underlying anemia or hematologic disorder, or display evidence of infection.	If chart review identifies no patient high risk factors.
Hepatitis A Virus	Uncommon, vaccine-preventable, community acquired infection, but most commonly travel related in Canada. May also be acquired from contaminated/imported food products. Screened for via nucleic acid testing by plasma fractionators with reactive results reported back to Canadian Blood Services.	Notification recommended in all cases to assess recipient hepatitis A immune status (history of prior infection or prior vaccination), assess clinical status, and to offer post-exposure prophylaxis (vaccine and/or immunoglobulin as appropriate).	Notification recommended.
Cancer	There are no documented cases of transfusion-transmitted cancer. See Appendix A.	NA	✓
Malaria Risk	History of, Travel to, or Residence in an endemic area. Vast majority of malaria-risk recalls, (94%), are travel related and pose a low risk of transfusion-transmission. Most previously described cases of transfusion-transmitted malaria cases in North America involve donors born or having lived in endemic countries. See Appendix A.	Confirmed case with history of blood donation. Note: in event of a recall due to a reported <i>suspect</i> case of transfusion-transmitted malaria (TT-malaria), Canadian Blood Services will provide recommendations for recipient notification, based on Canadian Blood Services medical assessment of donor malaria status	Donor traveled to a malaria risk zone.
High-Risk Behaviour	Includes donors who had anal sex with a new partner or multiple partners, in the last 3 months, IV drug use, household contact with HCV and susceptible household contact with HBV. See Appendix A.	✓	Contact Canadian Blood Services to determine if the donor is available for repeat testing, or the donor has screened negative (via subsequent donation or follow up testing) for the marker.
Tattoo/Piercing/ Electrolysis	These activities pose low risk of transmission of blood-borne viral disease provided they are performed under good conditions, disinfection techniques and with the use of single use needles. See Appendix A.	NA	✓
Possible donor infection, including cold, flu-like illness, COVID-19, diarrhea, fever	Immunocompromised patients may be at risk. See Appendix A.	NA	✓



Possible donor infection in donor with a travel history (not related to malaria risk)	Immunocompromised patients may be at risk. Other pathogens (such as Dengue fever) should be considered. See Appendix A.	Contact attending physician to assess immune status (including vaccination history as applicable) of recipient and potential risk.	Notification usually not required if immune competent recipient.
Viral	Mumps, rubella, rubeola (measles) rash, chicken pox, primary Herpes Simplex I or II, disseminated herpes zoster, or shingles (68% in this category were shingles) COVID-19, Mpox. There are no known reported cases of transfusion transmission. See Appendix A.	Consider contacting the attending physician to assess immune status (including vaccination history as applicable) and clinical status of recipient and potential risk. See Appendix A for information on specific viruses.	✓
Zika virus infection, lab confirmed	Rare transfusion-transmitted cases have been reported. See Appendix A.	Contact attending physician if recipient may be pregnant.	Majority do not require notification.
Medication, unacceptable	Most common - Finasteride, Dutasteride. See Appendix A.	1. If teratogenic and recipient is of childbearing age. 2. Anti-platelet therapy received by an apheresis platelet donor and patient did not have an adequate hemostatic response post transfusion.	Majority do not require notification.
Mononucleosis (Epstein-Barr Virus)	See Appendix A.	Contact attending physician to assess immune status of recipient and potential risk.	Notification usually not required if immune competent recipient.
Miscellaneous – Medical Conditions	Hematological, positive external testing for WNV, Lyme disease/ tick bites, tuberculosis.	NA	Majority do not require notification. Consult Canadian Blood Services Medical Officer as required.

Note: The reasons listed above account for over 90% of the total annual recalls in this category (based on Canadian Blood Services 2021/2022 data).



4.0 TECHNICAL MANUFACTURING ISSUES

Table 2: Recalls initiated by the blood supplier owing to technical manufacturing issues.

Reason	Description/Rationale (including but not limited to)	Notification Recommended	Notification NOT Recommended
BacT/ALERT testing/Quality Control	Includes errors that lead to invalid results (e.g. taking sample prior to 36 hours from collection; incomplete, incorrect, missing documentation; incorrect incubation and failure to hold following inoculation). See Appendix A.	If the recipient experienced symptoms (i.e., developed fever, chills, or other signs of sepsis during or in the hours post-transfusion); recipient blood cultures are recommended.	If the recipient was asymptomatic at the time of transfusion.
Screening Error	Incorrect assessment or documentation by RN/screener, donor registered incorrectly (wrong gender). Includes errors from Registration to Collection. See Appendix A.	If specifically requested by the manufacturer or Canadian Blood Services for the given situation.	✓
Documentation Errors	See Appendix A.	If specifically requested by the manufacturer or Canadian Blood Services for the given situation.	✓
Labelling Error	See Appendix A.	If specifically recommended by the manufacturer or Canadian Blood Services for the given situation	✓
Component production	Extraction errors, in process storage or processing times or conditions incorrect, unacceptable volume, inadequate SAGM added to RBCs.	Canadian Blood Services will provide hospitals with information on the reason for recall and the possible clinical risks to recipients.	
Retrieval/Release Related	Majority are issues with improper storage or documentation of storage; units not quarantined after improper site transfer conditions.	Canadian Blood Services will provide hospitals with information on the reason for recall and the possible clinical risks to recipients.	
Sterility breach	Incomplete seals, leaks found in companion components; incomplete arm prep or clamping errors during collections. See Appendix A.	If the recipient experienced symptoms (i.e., developed fever, chills, or other signs of sepsis during or in the hours post-transfusion); recipient blood cultures are recommended.	If the recipient was asymptomatic at the time of transfusion.
Rh D or red cell antigen phenotyping errors or discordant results	Errors/discrepancies with phenotyping testing. See Appendix A.	Alloimmunized patients should be observed for hemolysis. Patients receiving antigen negative units to prevent alloimmunization may be retested to determine if they have developed an antibody.	✓
Unacceptable (elevated) QC WBC results	See Appendix A.	Contact attending physician to assess immune status of recipient and potential risk of serious Cytomegalovirus (CMV) infection. Notification is required only if there is a concern of possible recipient illness due to underlying clinical/immune status.	✓

Note: The reasons listed above account for over 90% of the total annual recalls in this category (based on Canadian Blood Services 2021/2022 data).



5.0 BACTERIAL CONTAMINATION

Table 3: Recalls initiated as a result of the possibility of bacterial contamination in a blood component.

Reason	Description/ Rationale	Notification Recommended	Notification NOT Recommended
Positive Bac T/ALERT culture	See Appendix A.	Recipient notification and testing (blood cultures) is recommended in a recipient who developed fever or other signs of sepsis during or in the hours following transfusion. Clinical judgment is necessary to assess if blood cultures are necessary in a patient who is already on antibiotic therapy and has not experienced any symptoms post- transfusion.	NA
Contamination or possible contamination of companion component	See Appendix A.	Inspection, Gram stain, and culture of any residual transfused component may be performed if the bag is still available. Notification and blood cultures are recommended if the recipient was recently transfused and developed fever or other signs of sepsis during or in the hours post-transfusion. Since the likelihood of actual bacterial contamination is low, clinical judgment is required to determine the need and urgency of blood cultures and other possible actions.	NA

6.0 TRANSFUSION RELATED ACUTE LUNG INJURY

Table 4: Recalls initiated as a result of a reported transfusion reaction - TRALI.

Reason	Description/Rationale	Notification Recommended	Notification NOT Recommended
A companion blood component has been associated with a TRALI reaction	Note: Canadian Blood Services is not aware of any cases where 2 recipients of components from the same donation developed TRALI (i.e. recipients with the same target antigen(s) and exposure to similar plasma volume in transfused component(s)). See Appendix A.	Assess recipient health record for transfusion reaction occurring within 12 hours of transfusion and notify attending physician if TRALI is suspected.	NA

7.0 NATIONAL RECIPIENT ADVISORY COMMITTEE

In the event that an unusual situation triggers a recall of blood components, or a large number of blood components are involved in a recall, it is recommended that the National Recipient Advisory Committee (NRAC) be convened to make recommendations regarding recipient notification. This group of resource experts may also be convened to provide recommendations regarding recipient notification for recall situations that are not currently addressed in the preceding sections of this document.

Canadian Blood Services will accept the NRAC recommendation as the principal consideration in rendering a decision regarding recipient notification.



The Terms of Reference for this committee are as follows:

7.1 Mandate

The NRAC will develop recommendations and provide advice to Canadian Blood Services with respect to recipient notification in the event of a blood component recall situation that involves a large number of blood components or if the situation is not currently addressed in available national recommendations.

To this end the NRAC will:

- Discuss if recipient notification is required;
- Develop a recommendation for consistent recipient notification across the country with respect to specific recall scenarios;
- Indicate if follow-up testing should be considered for recipients that were transfused impacted blood components; and,
- Provide recommendations regarding the communications issued to hospitals via Canadian Blood Services.

7.2 Membership

The Chair of the NRAC will be the current chair of the National Advisory Committee on Blood and Blood Products (NAC). The Vice Chair of NAC shall act as chair in the absence of the NAC Chair.

Membership of the NRAC includes the following:

- Canadian Blood Services Chief Supply Chain Officer;
- NAC Chair and Vice Chair (or designates);
- Canadian Blood Services Vice President, Medical Affairs and Innovation;
- Blood Portfolio Lead Province Representative; and,
- Depending on the size and nature of the recall, further experts may be engaged on an ad hoc basis including but not limited to:
 - National Emergency Blood Management Committee members;
 - Ethicist;
 - A blood transfusion recipient representative; either an actual recipient or a 'representative' of an appropriate patient society; and,
 - Public Health Agency of Canada representative.

7.3 Meetings

Meetings will be convened at the request of Canadian Blood Services or the Chair as required. Decisions of the NRAC will be made by consensus. Consensus is defined as 80% (or greater) agreement of the voting members present.

In the event that consensus cannot be reached, Canadian Blood Services will make decisions considering the advice received from the NRAC.

The National Emergency Blood Management Committee Secretariat will arrange teleconferences/meetings, record and distribute meeting minutes and the record of decisions and maintain the membership list and respective contact information for the NRAC.



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BACTERIAL CONTAMINATION

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INFECTION

Possible donor infection, including cold, flu, diarrhea, fever

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Possible Viral Infection

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Includes fact sheets for: Herpes simplex viruses 1 and 2, varicella zoster (chicken pox, shingles), Influenza A or B viruses, Mumps virus, Mononucleosis (Epstein-Barr Virus), Zika virus, and many other pathogens



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MPOX (MONKEYPOX)

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APPENDIX A: SUPPLEMENTARY INFORMATION

POST-DONATION INFORMATION

Cancer

Donors who have had most forms of cancer are temporarily deferred from donation until recurrence-free for a specified time period. Donors reporting a diagnosis of recent cancer post-donation are a frequent cause of post-donation information. In-date components at the time the information is obtained (up to 12 months from donation for plasma or cryoprecipitate) are recalled.

A large Scandinavian cohort study of cancer incidence in recipients of blood from donors who had subclinical cancer at the time of donation demonstrated no excess risk of cancer compared to recipients who had received blood from donors who did not develop cancer post-donation. The FDA found no evidence that development of cancer in donors affected the safety, purity, or potency of blood components, and does not require recall of components after a diagnosis of cancer is made in donors. There is no evidence of transfusion-transmission of solid-organ cancer.

Malaria Risk

Recalls are usually due to unreported malaria risk travel. Cellular components are recalled if the donor left an at risk area 6 months or less prior to donation. The overall risk of transfusion-transmission of malaria (TT-malaria) in the US and Canada is less than 1 per million cellular components transfused. From 1997 to 2021, there were no cases of TT-malaria reported in Canada, and approximately 1 to 2 cases of TT-malaria reported annually in the US. A probable TT-malaria case was described in Canada in 2022. Cases are most commonly associated with partially immune donors who are immigrants from malaria-risk areas. Short-term travel to malaria-endemic areas poses a very low risk of TT-malaria. In addition, a 21-day post-travel donor deferral for travel outside Canada, continental US, or Europe further reduces risk of travel-associated infections like malaria and other arbovirus infections such as Dengue, Chikungunya or Zika. Symptoms and signs of post-transfusion malaria include fever, fatigue, anemia, and altered mental status, usually developing from 2 to 3 weeks post-transfusion for *falciparum* malaria. The incubation period may be longer after other species, and up to 73 days for *P. malariae*.

High Risk Behaviour

Occasionally, donors report high risk behaviour, such as illicit intravenous drug use that would have led to indefinite deferral. Components are recalled if such behaviour occurred recently. Since infectious disease testing at the time of donation was negative, risk of disease transmission is likely extremely low. At the present time, Canadian Blood Services analytic detection window periods for HIV, HCV, and HBV are estimated at 6.1, 2.9, and 18.8 days, respectively. However, recipient infection with any of these viruses may be asymptomatic at the time of transfusion but have major health consequences both for the individual and their household and sexual contacts.

Possible donor infection, including cold, flu-like illness, COVID-19, diarrhea, fever

Donors who develop symptoms such as fever, chills, and diarrhea in the days post-donation may have been bacteremic at the time of donation. Culture of all platelet components has



provided more information about possible sources of asymptomatic bacteremia in donors. Donors in the incubation phase of a gastrointestinal or upper respiratory tract bacterial infection are extremely rarely associated with positive bacterial cultures. Generally, common, often seasonal, community-acquired respiratory viruses are not considered transfusion-transmissible.

Possible donor infection in donor with a travel history (not related to malaria risk)

Donors with a travel history who develop symptoms such as fever, joint pain with or without rash and conjunctivitis necessarily have a broader differential diagnosis than donors who have not traveled abroad. Discussion with the Canadian Blood Services Medical Officer is recommended, as further information/testing may narrow the etiology, as is correlation with clinical signs/symptoms in the recipient. For donors with a travel history to areas of malaria risk, refer to Malaria Risk above.

Tattoo, piercing, electrolysis

A precautionary 3 month temporary donor deferral is applied after tattooing, any piercing, and after electrolysis with non-single use needles. Donors who return after temporary deferral have not been found to have an increased risk of positive HBV or HCV infectious markers compared to other donors. There appears to be little increased risk associated with these activities occurring in these time frames prior to donation.

Medication, unacceptable

Blood is recalled if donors are identified to be taking highly teratogenic medications that have been associated with birth defects when taken by pregnant women. However, there is limited data on the risk of a one-time exposure through blood transfusion. The one published study did not show any adverse outcomes such as malformations in infants of women taking one of these medications, acitretin, before or during pregnancy. Therapeutic efficacy of platelets may be decreased if a donor was taking medication with anti-platelet effects, such as ASA, at the time of donation. Depending on the medication, some of the platelet function defect may be reversible after transfusion.

Classical CJD risk

Donors are deferred for use of human pituitary derived growth factor and gonadotrophin hormones, and for a history of Creutzfeldt-Jakob Disease (CJD) in family members. Donors may report that they or a family member have developed CJD or did not report risk at the time of donation.

Two large cohort studies, one in the UK and one in the US, followed recipients who received blood components from donors who developed CJD. To date, after more than a decade of follow up in over 100 recipients, there has been no evidence of CJD transmission. The FDA Guidance document referenced above specifically mentions that the FDA does not believe it is appropriate to notify recipients of components from donors who develop CJD themselves or whose family members develop CJD.



Mononucleosis (Epstein-Barr Virus)

As a precautionary measure, all components donated in the 30 days prior to development of mononucleosis are recalled. Transmission of EBV has been documented in immunosuppressed recipients, especially following transplantation. Since EBV is a B lymphocyte associated virus, risk of transmission is substantially decreased by universal leukoreduction. Additionally, life-time chronic carriage of the virus occurs in over 90% of the adult population. Therefore, most recipients would be expected to be already infected.

Viral

As a precautionary measure, all components are recalled when donors are diagnosed with symptoms of these infections developing up to 7 days post-donation. Theoretically, the donor may have been viremic at the time of donation. In practice, transmission of these agents has rarely, if ever, been documented.

Recipient Follow up for Viral Infections Reported by Donor				
Viral Infection Reported by Donor	Incubation Period (from community acquisition)	Length of Viremia	Reported Cases of Transfusion-Transmission	Recipient Health Risk
Measles	10 – 14 days	From 2 days post-exposure to 5 – 7 days post exposure	None	Possible
Mumps	16 – 18 days (Range 2 – 4 weeks)	Transient - first 2 days of illness	None	Remote
Rubella	14 – 21 days	As early as 9 days before rash onset to 2 days after rash appears	None	Possible
Varicella (Chicken pox)	10 – 21 days	From rash onset up to 14 days	None	Possible
Varicella zoster (Shingles)	Reactivation of latent virus	Transient, at onset of symptoms	None	Remote
Herpes simplex I/II	2 – 12 days	Transient, at onset of symptoms, primary infection only	None	Remote
Mpox	7 – 17 days (mean 12 days)	Poorly described. Asymptomatic viremia not well studied; In a Cynomolgus Macaque model viremia occurred 1 – 2 days prior to symptom onset in an intrabronchial infection model and 1 day prior, on the day of or after intravenous inoculation.	None	Remote
SARS-CoV-2	2 – 14 days (but rarely as long as 27 days)	Poorly described; a small number of studies demonstrated that ≤ 1% blood donor specimens may be positive for a low level of SARS-CoV-2 RNA. No evidence of infectious virions in blood donor specimens.	None	Remote

Mpox

Monkey pox (Mpox) disease emerged from Africa in winter-spring of 2022. There have been no reported cases of transfusion-transmitted Mpox, although transmission by this route is considered theoretically possible. Canadian Blood Services added eligibility questions about Mpox in Aug 2022. Mpox infection requires a 42 day deferral from symptom onset. Close contact with a Mpox case in the previous 6 weeks requires a 42 day deferral from last contact.



Close contact is defined as contact with skin, body fluids, or a contaminated object such as clothing, as well as face-to-face contact without a mask for more than three hours. A medical review will be undertaken for each case in a donor in the post-donation period.

COVID-19 (SARS-CoV-2)

In spite of millions of COVID-19 cases world-wide, transfusion-transmission of the SARS-CoV-2 virus has not been demonstrated, and several studies suggest that transfusion-transmission does not occur or is so exceedingly rare that it has not been detected. By the fall of 2022 over 95% of Canadian Blood Services donors were vaccinated, and over 60% have already had a SARS-CoV-2 natural infection. In the instance that Canadian Blood Services receives post-donation information from donors about the development of recent COVID-19 post-donation (i.e. symptom onset within 10 days of donation), components will be withdrawn from inventory. No additional recipient follow up is recommended.

Zika virus infection, lab confirmed

Probable cases of transfusion-transmitted Zika virus infection have been rarely reported, and in these instances recipients were asymptomatic. Correlation with the patient's pregnancy status is important, as Zika virus is unlikely to be a significant risk to non-pregnant individuals. For pregnant recipients, follow up including testing for Zika virus is recommended.

TECHNICAL MANUFACTURING ISSUES

Invalid BacT/Alert Testing

Testing may not have been properly performed (for example, sample taken less than 36 hours post collection), or machine malfunction may have invalidated the results of BacT/ALERT culture. Since the platelet component did not have adequate testing performed, there is an increased risk of bacterial contamination of approximately 1 in 10,000 (rate of true positive bacterial cultures of platelets at Canadian Blood Services).

Documentation errors - donor screening and production

Documentation errors on the Canadian Blood Services Record of Donation or during component manufacturing are most often due to incomplete information, such as lack of a signature or missing documentation of storage time. These are errors of Good Manufacturing Process (GMP) therefore the product is recalled. However, it is extremely unlikely that there is any additional risk associated with transfusion of the component.

Labeling Errors

Errors may occur in the product code listed on the label, the volume of the component, or any other product attribute listed on the label. These are errors of GMP, therefore the product is recalled. However, in most cases, there is no additional risk associated with transfusion of the component. Exceptionally, there may be recipient risk; an example would be an incorrect ABO group.



Sterility Breach

Incidents such as incomplete seals may lead to a slightly increased risk of bacterial contamination of the component. The risk will vary depending on the component involved and the exact problem that occurred.

Rh D or red cell antigen phenotyping errors or discrepancies

These errors may be of importance if the recipient is alloimmunized against the mistyped antigen (for example, unit now known to be Kell positive transfused to recipient with anti-K); a delayed hemolytic transfusion reaction may occur. A recipient receiving units erroneously typed as antigen negative to prevent alloimmunization may actually develop an antibody. Discrepancies may be related to weak subgroups of A or B, or weak or partial D antigens.

Unacceptable Quality Control, WBC Counts

Products with elevated white blood cell counts over the maximum permitted in the Canadian Blood Services Circular of Information may have an increased risk of transmission of Cytomegalovirus (CMV). Transmission of CMV may be of major clinical significance in CMV seronegative recipients receiving a CMV seropositive product. Patients at risk for significant transfusion-transmitted CMV disease include recipients of allogeneic stem cell transplants from CMV seronegative donors.

BACTERIAL CONTAMINATION

Positive BacT/ALERT culture

Donation components will be recalled if the BacT/ALERT automated culture system indicates a positive reaction. Further information may follow the initial report. Subsequent investigation may show actual bacterial contamination (true positive), as well as identification of the organism. In other cases, further investigation may indicate a false positive reaction. Bacterial proliferation is most common in platelet units, however septic reactions have been reported with red cell and frozen components as well. Signs and symptoms of post-transfusion sepsis include fever, chills, and hypotension usually developing during or in the four hours post-transfusion. Investigation of a suspected reaction may include inspection, Gram stain, and culture of any residual component, if available. In addition, patient blood cultures may be indicated, particularly if recall notification is obtained shortly after transfusion, or the recipient has developed fever and chills post-transfusion.

Contamination or possible contamination of companion component

All components of a donation are recalled if a positive BacT/ALERT culture is found on an individual component, or if Canadian Blood Services is informed of a possible septic reaction in a patient having received a transfusion with one component from the donation. Further clarifying information may follow, such as repeat culture results or organism identification. In the case of positive bacterial cultures on a buffy coat platelet pool, all red cell and plasma components associated with the pool will be recalled. A small minority of these companion products will actually be bacterially contaminated.



TRANSFUSION RELATED ACUTE LUNG INJURY

TRALI, increased risk

Components may be recalled for increased Transfusion Related Acute Lung Injury (TRALI) risk if a companion blood component from the same donation or a component from a later donation from the same donor has been associated with a TRALI reaction.

The pathogenesis of TRALI is poorly understood. The presence of an anti-HLA or anti-granulocyte antibody in the donor directed against the cognate antigen in the recipient, plasma content of the component, and underlying disease in the recipient all play a role in the development of a TRALI reaction. In lookback studies performed on recipients of components from donors who have been clearly implicated in an antibody mediated TRALI reaction, the frequency of pulmonary complications and TRALI is slightly higher than in transfusion recipients in general. However, the majority of recipients did not develop TRALI reactions.