Government of Newfoundland and Labrador

Department of Health and Community Services
Provincial Blood Coordinating Program

RECIPIENT NOTIFICATION OF A BLOOD COMPONENT OR PLASMA PROTEIN AND RELATED PRODUCTS RECALL	NLBCP-048

Office of Administrative Responsibility	Issuing Authority
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Overview

This document addresses recipient notification associated with the recall of a transfused blood component that had been distributed by Canadian Blood Services (CBS) or a Transfusion Medicine Laboratory (TML) but may also apply to plasma protein and related products (PPRP) in the event of a large scale or unusual recall. This document does not address recalls associated with positive donor testing for transmissible diseases. This is addressed through CBS lookback procedures.

Policy

1. NL Health Services (NLHS) facilities shall have policies, procedures, and processes to permit the recall at any given time of any released blood components or PPRP when the safety or efficacy is questionable and could cause harm to a recipient.
2. These policies shall identify the responsible position to manage the initiation and coordination of recall activities and the documentation.
3. CBS or the TML shall initiate a recall or removal of blood component(s) and/or PPRP according to its standard operating procedures.
4. CBS or the TML shall fax notification of the recall to the location that received the suspected blood component(s) or PPRP.
5. Personnel at the receiving location shall immediately review the disposition of blood component(s) or PPRP and shall acknowledge receipt of retrieval notification.
6. CBS or the TML shall be informed of the disposition of the blood component(s) or PPRP identified in the recall.
7. The receiving location shall identify whether the suspected blood component(s) or PPRP has been transfused. If not transfused the recalled blood component or PPRP shall be quarantined in a secure area until final disposition is determined.

   Note: If the blood component/ PPRP was sent to a hospital ward for transfusion the personnel on the ward shall return the blood component/PPRP to the TML even if the transfusion was started.

8. If the suspected blood component(s) or PPRP has been transfused, consultation with the TM Medical Advisor or designate shall occur to determine if recipient notification and follow up testing is required based on the reason for the recall.

   Note: Refer to the National Advisory Committee on Blood and Blood Products (NAC) Recommendations for the Notification of Recipients of Blood Component Recall found here.

9. NLHS facilities shall have a policy for recipient notification to be followed as soon as possible, identifying who is responsible for each stage of the notification process. Recipient safety shall not be compromised.
10. If the recall is the result of an error or accident refer to provincial/territorial and federal regulations for reporting requirements and see also Reporting Adverse Transfusion Events.
11. The notification shall be documented in the recipient's health record.
12. Recall documentation shall be retained. See Records Retention for Transfusion Medicine Documents.

Guidelines

1. The final responsibility for recipient notification rests with the most responsible healthcare provider who should consider evaluating the patient's presence or absence of symptoms, pregnancy, underlying condition, age and relevant prognosis when further evaluating recipient notification.
2. Recipient notification may occur through a Substitute Decision Maker or to next of kin where circumstances are warranted.
3. If an unusual situation triggers a recall of blood component(s)/PPRP, or many blood components/PPRP are involved in a recall, it is recommended that the National Recipient Advisory Committee (NRAC) be convened to make recommendations regarding recipient notification.
4. The NRAC may be convened to provide recommendation regarding recipient notification for recall situations that are not currently addressed in the NAC recommendations.
5. The CBS Medical Officer can be contacted about a recall if clarification is required.
6. It is recommended that facilities have their own policies and processes in consultation with local risk management to address recipient notification in accordance with applicable provincial/territorial and federal regulations.
7. If more than one recipient is involved with a recall of blood components or PPRP the facility will establish a mechanism to address notification to all impacted recipients that complies with the multi-client disclosure as described in the provincial disclosure policy.

Key Words

Recall, notification, recipient

References

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