Government of Newfoundland and Labrador

Department of Health and Community Services
Provincial Blood Coordinating Program

RECIPIENT NOTIFICATION OF A BLOOD COMPONENT OR BLOOD PRODUCT RECALL	NLBCP-048

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Overview

This document addresses notification associated with the transfusion of fresh blood components that have been distributed by Canadian Blood Services (CBS) and blood components that have been transformed by the facility, but may also apply to plasma protein products 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. Each facility shall have policies, procedures and processes to permit the recall at any time of any released blood components and blood products when the safety or efficacy is questionable.
2. These policies shall identify the responsible position to manage recall activities.
3. Recipients shall be informed of recalled blood components or blood products as required. Recipient safety shall not be compromised.
4. Each Regional Health Authority (RHA) shall have a policy to address disclosure to recipients as required.
5. The Transfusion Medicine (TM) Laboratory shall acknowledge receipt of retrieval notification.
6. Recalled blood components or blood products shall be quarantined until final disposition is determined.

Guidelines

1. The National Advisory Committee on Blood and Blood Products (NAC) Recommendations for the Notification of Recipients of Blood Component Recall (2015) should be referenced when determining whether recipient notification is recommended. The final responsibility for recipient notification rests with the most responsible healthcare provider.
2. In the event that an unusual situation triggers a recall of blood components/products, or a large number of blood components/products are involved in a recall, it is recommended that the National Recipient Advisory Committee (NRAC) be convened to make recommendations regarding recipient notification.
3. The NRAC may be convened to provide recommendation regarding recipient notification for recall situations that are not currently addressed in the NAC recommendations.

Procedure

1. CBS shall initiate a recall or withdrawal of blood components and/or blood products from inventory according to its standard operating procedures.

   1.1. A recall may also be initiated by a TM Laboratory if it is suspected that a blood component (or product) has the potential to cause harm to a patient.

2. CBS shall fax notification of the recall to hospitals who have received the suspected blood component(s) or product(s).
3. The receiving hospital shall review the disposition of component(s) received.
4. CBS shall be informed of the disposition of the component identified in the recall.
5. The receiving hospital shall identify whether the suspected component(s) have been transfused.
6. If the suspected component has been transfused, consultation with the TM Medical Director or designate shall occur to discuss the recipient notification process.

   NOTE: Refer to the NAC Recommendations for the Notification of Recipients of Blood Component Recall link here.

7. If recipient notification is required:

   7.1. The recipient shall be informed (where practical) in person by the most responsible healthcare provider, according to RHA policy.

   7.2. The recipient shall be notified by phone if notification in person is not practical.

   7.3. Notification in writing shall occur if the recipient cannot be informed in person or by phone. If recall notification is required via mail, the notification shall be sent by registered mail.

8. A note shall be placed on the recipient's health record indicating that notification was provided.
9. Recipient notification may occur through a Substitute Decision Maker where circumstances are warranted.
10. In the event that more than one recipient is involved with the recall of blood components or blood products, the RHA will establish a mechanism to address notification of all impacted recipients that complies with the multi-client disclosure as described in the provincial disclosure policy.

Key Words

Recall, notification

References

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