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BLOOD BULLETIN

Consignee Notification

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KEY POINTS

- This *Blood Bulletin* aims to elucidate how the hospital transfusion service receives blood component notifications from blood suppliers, defines key terminology, clarifies the regulatory and accreditation requirements, and suggests a standardized process control, notification, and documentation process when handling real-time containment and retrospective transfusion reporting.
- The hospital transfusion lab should communicate with the blood center upon receiving consignee notifications to be certain appropriate responses occur.
- This collaborative approach is essential to facilitate process control and ensure compliance with regulatory requirements and address patient safety concerns.

CONSIGNEE NOTIFICATION

A consignee is the individual or entity designated to receive consigned goods. Within the U.S. Food and Drug Administration (FDA), a consignee is broadly defined as anyone who has received, purchased, or utilized blood products.

Consignee notifications, as defined within the Code of Federal Regulations (CFR), involve instances where a hospital receives communication from a blood supplier concerning the recall, market withdrawal, or lookback notification of blood products. These notifications serve as alerts to the consignee regarding specific actions or precautions necessary in response to the specified events.

Blood collection necessitates strict adherence to regulations and quality systems to ensure the product's integrity, potency, and safety. Despite the stringent regulatory environment, instances of non-conforming products may occur due to factors such as laboratory errors, issues in storage, labeling discrepancies, deviations from local standard operating procedures (SOP), or the acquisition of information after donation that would have disqualified the donor or product. When these events occur and blood products are issued and later found unsuitable, the blood center will initiate a blood product removal and corrective action. Although this process is resource-intensive, consignee notifications only account annually for 0.39 percent of blood components associated with post-issue notifications.

Effective communication in response to consignee notifications is crucial and should occur promptly through a method agreed upon by the collection facility and transfusion service to ensure immediate awareness. While some notifications, like the discovery of positive bacterial platelet results, demand urgent action with implications for patient care, others may not require an emergent response but necessitate thorough communication and documentation within specified time frames.

The consignee notification form should include essential details: the unit number, product type, date of shipment, reason for market withdrawal, and guidance on unit management (e.g., quarantine, return to supplier, or discard). The blood supplier typically requests the hospital consignee to provide the current unit status and acknowledge receipt of the notification.

When follow-up information, e.g., a test result affecting the final recommendation for the implicated unit, becomes available, the blood center should provide it promptly.

Effective communication between the hospital and the blood center is paramount irrespective of the notification's content. Seeking additional clarification and engaging in further discussion may be essential for an understanding of the situation and how to address the regulatory elements.

A lookback investigation, a subset of consignee notification responses, is initiated by the blood supplier when the consignee notification suggests a potential risk of transmitting infection from a donor to a recipient. In such instances, the blood center must locate blood components for a defined period from previous collections assuming they may have been collected during the "window period" before donor testing becomes positive. These investigations typically require the identification and testing of recipients, retesting of archived samples if available, and recall of unused components from the donations in question.

There are three categories of lookback notifications, ranging from those mandating specific legally bound actions to those allowing the medical director's discretion in determining subsequent courses of action. CFR-compliant lookbacks necessitate adherence to federal regulations, are legally binding, and violations may result in legal actions or penalties. Conversely, notifications may follow FDA or the Association for the Advancement of Blood & Biotherapies (AABB) guidance, involving the voluntary adoption of

recommendations and best practices (See Table 1). While not legally enforceable, failure to follow may lead to increased scrutiny or regulatory reviews. Finally, some notifications lack industry guidance, relying on the medical director to determine the appropriate follow-up.

Determining when to notify prior transfusion recipients when there is no industry guidance, is not always straightforward, particularly with inconclusive test results or infections without effective treatment or for post-donation information that has no clinical consequences (i.e., donor high pulse). There may be no medical benefit to recipient notification when there is no effective treatment or diagnostic test (i.e., variant Creutzfeldt-Jakob disease) and no recognized risk to the recipient's contacts. Public health benefits, including surveillance and behavior modification to prevent secondary transmissions, may guide notification decisions.

RECOMMENDATIONS TO TRANSFUSION SERVICES FOR MANAGING CONSIGNEE NOTIFICATIONS

Below are recommendations to manage consignee notifications:

- Develop a SOP for consignee notification management.
- Take immediate action to quarantine, return, or discard blood components following supplier instructions.
- Discuss any elements of the consignee notification with the blood center that require further regulatory or process clarification.
- Assess and determine the medical and regulatory implications of already transfused components.
- Maintain records of all notices and corresponding actions as mandated.
- Report events during the transfusion committee meetings.
- Seek input from additional resources, including the infectious disease service, ethics committee, public relations, risk management, or legal office, as necessary.

TABLE 1. LOOKBACK PATIENT/RECIPIENT NOTIFICATION GUIDANCE

CODE OF FEDERAL REGULATIONS COMPLIANT		
Infectious Disease	**Lookback Period**	**Recipient/Patient Notification**
Hepatitis C virus (HCV)[3] or HIV[4]	12 months prior to the donor's most recent nonreactive licensed multiantigen screening test or NAT-reactive	Notify recipients or their physician of record of the increased risk of HCV or HIV infection from prior blood collections, and the need for recipient HIV or HCV testing and counseling. Notify the recipient's legal representative or relative for minors, those adjudged incompetent, deceased, or competent individuals under state law allowing representation. Make reasonable attempts to notify within 12 weeks of receiving HIV or HCV test results or donor's reactive screening, as per FDA guidelines

FDA/AABB GUIDANCE		
Infectious Disease	**Lookback Period**	**Recipient/Patient Notification**
Babesiosis[5]	12 months prior to the date of the reactive index donation	Encourage consignees to have a discussion with the recipient's physician of record about a possible risk of transfusion-transmitted babesiosis, particularly if the involved component(s) had not been tested or pathogen reduced.
Trypanosoma cruzi (Chagas Disease)[6]	10 years or 12 months prior to the most recent negative test result (whichever is the lesser time period).	Encourage consignees to notify the recipient's physician of record of a possible increased risk of *T. cruzi* infection. Notification should be done within 12 weeks.
West Nile Virus (WNV)[7]	For donors with a medical diagnosis of WNV, recipients of donations from -14 to +120 days from illness onset For donors as the likely source of transfusion transmitted WNV infection, recipients of units donated from -120 days to +120 days from the infectious donation should be notified.	May consider notifying treating physicians of prior recipients of blood and blood components collected from that donor.

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