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Variance Reporting - Blood Bank

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

This document will provide the Blood Bank (BB) staff with procedure and policies for identifying and timely reporting of variances, which occur within the Blood Bank and have the potential to affect the quality and safety of blood products and services.

II. DEFINITIONS/ACRONYMS:

A. **Variance**: Event detected that may be an error, accident, complaint, occurrence, unplanned deviation, exception, or incident that is documented for review, evaluation, investigation, and correction.

B. **Sentinel Event**: An unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof.

C. **Mistransfusion**: Any event involving the transfusion of a blood component to the wrong patient or the transfusion of the wrong component to the intended recipient.

D. **Misidentification of a Patient's Blood Sample**: Any incident involving a blood specimen label and/or a blood sample that does not represent the intended recipient, also referred to as Wrong Blood in Tube (WBIT) event.

E. **Critical Error**: Any unexpected occurrence for which a recurrence would carry a significant chance or risk of a serious adverse outcome. Examples: mistransfusion and WBIT events.

F. **"Near Miss" incident**: An unexpected occurrence that did not adversely affect the outcome but could have resulted in a serious adverse event.

G. **Authorized Deviation**: Departure from routine operating procedure that is approved prior to implementation, which may or may not affect the quality of the product or service.

H. **Complaint**: Any issue of concern or dissatisfaction reported by a customer. Transfusion Services customers include, but is not limited to, physicians, nurses, patients, and other healthcare personnel.

I. **Root Cause Analysis (RCA)**: A structured method used to analyze serious adverse events.

J. **Corrective Action**: Includes both immediate intervention and subsequent steps taken to correct the situation or to mitigate resulting adverse consequences.

K. **Preventative Action**: Long term solutions based on incident analysis intended to prevent recurrence of similar incident.

L. **Designee**: Lead Medical Technologist, Blood Bank Supervisor, Division Blood Bank Manager, Lab Quality Coordinators, Operations Director.

III. POLICIES:

A. Staff are responsible for reporting variances. Reporting may include communication of the variance to the supervisor/designee or Medical Director, communication to the corporate compliance line, and/or documenting as an internal variance or in the RL Solutions automated system.

B. Once a variance is discovered, all necessary steps should be taken to provide appropriate intervention as required for the safety, well-being or effective care of patient or other involved individuals. The scope of immediate corrective action is dependent on the scope of occurrence.

C. The supervisor/designee or Medical Director should be notified immediately or as soon as possible, when a “critical error” is discovered and has a potential for immediate harm or adverse patient outcome.

D. Staff are responsible for fully cooperating in efforts to improve patient safety, reduce risk and minimize occurrences.

1. Blood Bank Staff Responsibilities
    a. Participate in identification, detection, timely reporting, and investigation of variances.
    b. Participate in efforts aimed at preventing similar occurrences.
    c. Participate in submission of external reports to the hospital incident reporting system as mandated by policy/procedure.
2. Manager/Supervisor/Designee Responsibilities
    a. Encourages staff to identify and report variances.
    b. Reviews and categorizes variance reports.
    c. Assists with investigation and root cause analysis when indicated.
    d. Identifies, approves, and implements corrective action/preventive action as appropriate.
    e. Determines if occurrence is externally reportable.
    f. Notifies appropriate parties of the variance/occurrence, when indicated.

g. Submits reports externally, when indicated.

3. Medical Director Responsibilities
    a. Reviews monthly summary of variance reports.
    b. Involved with review and approval of corrective/preventive action plan for sentinel or high severity risk events.
    c. Determines if occurrence is externally reportable.

IV. PROCEDURE:

A. Indications for Variance Reporting

The table below identifies the most frequently seen problems, incident or situations that are reported as a variance by the Blood Bank. The list is NOT all inclusive and any other event/situation that affects the quality and safety of patients/ blood products or services should be reported.

Category	Method of Variance Reporting	Event Description
Blood Sample	Blood Bank Specimen Rejection Log	Misidentification of a patient's blood sample, including WBIT events
		Specimen labeling error or sample collection which causes a significant delay in patient care and results in emergency issue of product
		Missing, incomplete, incorrect, or misrepresented ID band identifier
		No collector ID on sample label nor in computer
		No collection date on sample nor in computer
		Sample collected into incorrect tube
Product	Internal Variance/ Downtime Variance Report Form or RL Incident Reporting System	Mistransfusion
		Transfusion Related Fatality
		Incorrect/incomplete labeling of blood or tissue products (from suppliers, within the Blood Bank and/or dispensed from the Blood Bank)
		Issue of an incorrect unit or non-requested component
		Incorrect blood/tissue product expiration date and/or time
		Leaking or broken containers (except broken FFP during thaw)
		Abnormal blood/tissue product appearance
		A blood/tissue product damaged after issue*
		Mishandled blood/tissue product (returned out of

		temperature)*
		Issue of a blood/tissue product having a reactive infectious disease test
Equipment	Internal Variance or Downtime Variance Report Form	Equipment failure which may have jeopardized product or personnel safety, or test accuracy
		Problems with equipment
Testing	Internal Variance or Downtime Variance Report Form	Error in determining ABO Group or Rh Type
		Editing a patient's blood type (with MD approval)
		Error in resulting or reporting
		Problems with reagents
Quality Control	Internal Variance or Downtime Variance Report Form	QC failures, occurrence/event
Other	Internal Variance or Downtime Variance Report Form	Any deviation from approved procedures, policies or standards practice.
		Physician notification of **approved** blood product deviation
		Failure to follow or perform approved procedures
		Problems with supplies or labels
		Service concerns

B. Methods for Variance Reporting

There are multiple methods for reporting a variance. The method used will depend on the site/situation in which the variance occurred. These methods are listed below:

1. **Blood Bank Internal Variance:** This is the most commonly used method for reporting internal variances within the Blood Bank.The preferred method for documenting and submitting this type of variance at Dearborn, Farmington Hills, Grosse Pointe, Royal Oak and Troy is to access the electronic variance form located on the Blood Bank SharePoint site. Alternatively, the attached paper copy form used routinely at Taylor, Trenton and Wayne can be used during downtime for those sites unable to utilize SharePoint.
    a. Document each field of the variance as indicated.
    b. Supporting documents can be attached to the variance if available.
    c. The SharePoint site will automatically route the submitted variance to the email inbox of the supervisor/designee when the variance is marked "forward for review" in the variance form Status of Report field.
    Note: If a downtime variance form is used, then place the completed form in the designated area for follow up.
    d. The supervisor/designee will process the variance and add a follow-up response to the variance, as necessary.

e. If the occurrence involves equipment/instrument problems and/or failure, remove it from service, tag it with attached *Equipment Out of Service Form* and follow up appropriately with Beaumont Biomedical/Facilities or the equipment vendor as applicable.

2. **Blood Bank Rejected Specimen Log**: This method is used for reporting deviations in the specimen collection process. If it is determined that a Blood Bank specimen is improperly collected in accordance with Transfusion Medicine policy, Triaging And Identifying Acceptable Samples For Testing this form will be documented and the following steps will be followed:
    a. Cancel current tests. Refer to Transfusion Medicine policy, Triaging and Identifying Acceptable Blood Samples for Testing, and Laboratory Procedure for Canceling Orders on Unacceptable Inpatient Specimens.
    b. Notify the patient caregiver. If needed re-order the test for recollection in Epic.
    c. Complete attached *Blood Bank Rejected Specimen Log.*
    d. DB, FH, GP, TR, TTW: Report the specimen collection error in the hospital incident reporting system for follow up by the employee manager (phlebotomy or nursing). Refer to RL Solutions Quality/Safety Report Instructions.
    e. RO: QA Lead/Designee will save a scan of the Blood Bank Rejected Specimen Log on the S: Drive along with a color scan of the rejected specimen's label. The error in the specimen collection will be reported to the corresponding manager via email for follow up.
3. Quality Safety Reports (QSR): This method of variance reporting is used to submit hospital variances, rather than internal Blood Bank variances. QSRs should be generated for a **critical error** or a near miss event and any other occurrence/incident that is inconsistent with the routine operation of the hospital or the routine care of patients.
    a. For most events, the Blood Bank Manager/Supervisor designee will initiate a QSR that involves Blood Bank related events.
    b. QSRs are submitted online through the Beaumont Health Intranet using the RL Solutions application using RL Solutions Quality/Safety Report Instructions.

C. Variance Incident and Follow Up

Once a variance has been submitted:

1. The Blood Bank Manager/Supervisor/MT Lead or designee will review the variance report, recognize “critical error(s)” and follow up as indicated.
2. The Blood Bank Manager/Supervisor/MT Lead or designee will categorize the variance as per the attachment *Categorizing Blood Bank Variances.*
3. Investigation, including Root Cause Analysis (RCA) will be conducted, when and if indicated, by the supervisor or Medical Director to determine all possible contributing factors for the variance.
    a. Complete attached *Initial Information for Root Cause Analysis (RCA) Purposes*, when indicated.

4. The analysis summary and all contributing factors that apply will be documented in the variance. Any supportive documents will be attached to the variance report.
5. Based on the findings of the investigation or RCA, a corrective action may be indicated. All corrective and preventive action is determined by the Blood Bank Manager/Supervisor and/or Medical Director.
6. All follow-up action should be documented in the corresponding variance including contributing factor and severity level.
7. Document any steps taken to immediately prevent repeat occurrences. Include process and system improvement initiatives that were implemented for preventive measures. Attach all applicable documents to the original variance.

D. Additional Variance Reporting

1. Variance reports will be reviewed monthly by the Blood Bank Medical Director and/or designee.
2. If a QSR report has been generated that is related to an internal Blood Bank variance, add the QSR tracking number to the variance form.
3. If it is determined that an occurrence has affected the safety, purity or potency of a blood product issued for transfusion, it must be reported to the Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER), within 45 days of detection of variance. Refer to Transfusion Medicine policy, Biological Product Deviation (BPD) Reporting.
4. Document the FDA tracking number on the associated internal Blood Bank variance form.
5. When applicable, the Blood Bank Supervisor or Lead Medical Technologist will notify the supplier(s) of reagent(s) and/or product(s) and follow up appropriately. Document the notification and any follow up information, if indicated.
6. Fatality related to blood product transfusion or computer related event must be reported within 24 hours by phone or e-mail to FDA's CBER. For complete instructions refer to Transfusion Medicine policy, Biological Product Deviation Reporting (BPD) and Notification Process for Transfusion Related Fatalities.
7. When applicable, the variance event will be discussed during the Blood Bank huddles and Lab Quality and Blood Bank best practice meetings.

V. REFERENCES:

1. AABB, *Technical Manual*, current edition.
2. AABB, *Standards for Blood Banks and Transfusion Services*, current edition.
3. College Of American Pathologists, *Transfusion Medicine Checklist*, current edition.

Attachments

Blood Bank Internal Variance Category Summary

Blood Bank Rejected Specimen Log

Downtime Variance Reporting Form

Equipment Out of Service Form

Root Cause Analysis Form

Approval Signatures

Step Description	Approver	Date
	Kristina Davis: Staff Physician	3/30/2023
	Jeremy Powers: Chief, Pathology	3/21/2023
	Ann Marie Blenc: System Med Dir, Hematopath	3/17/2023
	Vaishali Pansare: Chief, Pathology	3/6/2023
	John Pui: Chief, Pathology	3/2/2023
	Ryan Johnson: OUWB Clinical Faculty	3/2/2023
	Muhammad Arshad: Physician	3/2/2023
Policy and Forms Steering Committe (if needed)	Kelly Sartor: Supv, Laboratory	3/2/2023
Policy and Forms Steering Committe (if needed)	Gail Juleff: Project Mgr Policy	3/2/2023
	Rebecca Thompson: Medical Technologist Lead	3/2/2023
	Kristen Lafond: Mgr Laboratory	3/1/2023
	Fatima Bazzi: Medical Technologist Lead	2/28/2023
	Ashley Beesley: Mgr Laboratory	2/28/2023
	Hilary Morey: Medical Technologist Lead	2/28/2023
	Michele Ferla: Medical Technologist Lead	2/27/2023

Abigail Swaney: Medical Technologist Lead	2/26/2023
Katherine Persinger: Mgr Laboratory	2/23/2023
Karrie Torgerson: Supv, Laboratory	2/23/2023
Teresa Lovins: Supv, Laboratory	2/23/2023
Kelly Sartor: Supv, Laboratory	2/23/2023
Brooke Klapatch: Medical Technologist Lead	2/22/2023
Kelly Sartor: Supv, Laboratory	2/22/2023