Status **Active** PolicyStat ID **12922196**

Beaumont

Origination	3/10/2023
Last Approved	2/10/2023
Effective	3/10/2023
Last Revised	2/10/2023
Next Review	2/9/2025

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Area	Laboratory-Blood Bank
Applicability	All Beaumont Hospitals

Notification Process for Transfusion Related Fatalities

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

The purpose of this document is to provide the Blood Bank staff with guidance and policies for a timely reporting of a blood product transfusion related fatality (death) to the Food and Drug Administration (FDA).

II. CLINICAL SIGNIFICANCE:

A. Title 21, CFR, Section 606.170(b) states: When a complication of blood transfusion is confirmed to be fatal, the Director, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, shall be notified by: telephone, facsimile, express mail, or electronically transmitted mail as soon as possible; a written report of the investigation shall be submitted to the Director, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, within 7 days after the fatality by the facility that performed the compatibility tests.

III. PROCEDURE:

A. Initial FDA Notification

1. Submit the initial notification if possible by e-mail to the FDA at: E-mail: fatalities2@fda.hhs.gov. An e-mail confirmation receipt will be sent to the notifying facility.
    a. If e-mail is not feasible, notification should be done by telephone or facsimile.
        i. Telephone/voice-mail number: 240-402-9160
        ii. Fax number: 301-827-0333, Attn: CBER Fatality Program Manager

2. Provide the following information if available with the notification:
    a. Date and time of the notification.
    b. Reporting individual name, title, telephone number with area code, and fax number (if available).
    c. Facility's name, mailing address, and FDA registration number.
    d. Age and sex of the deceased. **Do not include personal identification of patient, donor or involved employees or any other confidential information when submitting the report.**
    e. Date, time, and cause or suspected cause of death (briefly describe what happened).
    f. If an autopsy was or will be performed.
    g. Transfusion date(s).
    h. Blood/blood component(s) and unit number(s) of product(s) that may be implicated.
    i. Name and address of facility(ies) providing the blood.
    j. Brief description of events that led to the fatality - include underlying medical condition or disease and circumstances necessitating this hospitalization, reason for transfusion, how the patient initially responded to the transfusion, any medical intervention taken or response to the reaction, and time from initiating the transfusion to patient's death.

B. Follow Up - 7 Day Report

1. Submit a 7-day follow up report after the initial notification which will include any new findings or information relevant to the fatality and include the following:s are send by e-mail, facsimile, or express mail.
2. The report may include the following:
    a. Discharge summary and/or death certificate.
    b. Autopsy report (if performed).
    c. Conclusions and follow-up actions (a corrective action plan), if appropriate/ indicated.
    d. Complete transfusion reaction report, including the manufacturer and lot number of the blood collection system and results of the clerical, serological, and visual re-checks performed.
    e. Additional relevant documents, include hematology reports; clinical chemistry reports for cardiac and/or liver enzymes, albumin, and bilirubin; viral marker tests; microbiology reports; reports of anti-HLA and/or anti-neutrophil antibody testing; tryptase levels; radiology reports; and physicians' consults/opinions.
    f. If replacement fluid(s) was given during the transfusion, indicate which fluid(s) and the unit or lot number(s), and include any other relevant information, manufacturer's notices, contamination warnings, or replacement fluid recalls.
    g. If responsibility for the fatality appears to be outside the Blood Bank, the nurses' and/or physicians' notes on the patient, radiology reports, and physicians' consults/

opinions.

h. Results of lookback investigation, including follow-up testing on implicated donor(s) when the fatality was the result of transfusion transmitted infectious disease such as hepatitis or HIV.

i. Meeting minutes or report from your transfusion committee when the fatality was reviewed and discussed. If this incident was reviewed by any other hospital oversight group(s) such as risk management or quality practices, include the report or summary of their findings.

3. The report may be sent by e-mail, facsimile, or express mail.
    a. E-mail: fatalities2@fda.hhs.gov
    b. Fax number: 301-827-0333, Attn: CBER Fatality Program Manager
    c. Express mail address:
    U.S. Food and Drug Administration
    Center for Biologics Evaluation and Research Document Control Center
    10903 New Hampshire Avenue
    WO71, G112
    Silver Spring, MD 20993-0002

IV. NOTES:

A. Document and maintain appropriate files for all investigative activities/information. Supporting documents should be included in the written FDA report.

B. Due to the complexity of some fatality investigations, some of the information may not be available when the 7-day report is submitted. In that event, the 7-day report may be amended by filing additional information as it becomes available.

C. Consult the FDA website for additional assistance and applicable information available for the **notification process for transfusion related fatalities.**

D. A variance report should also be filed in accordance with the Transfusion Medicine policy, *Variance Reporting*.

V. REFERENCES:

1. AABB, *Standards for Blood Banks and Transfusion Services*, current edition.
2. College of American Pathologists (CAP), *Transfusion Medicine Checklist*, current edition.
3. FDA: 21 Code of Federal Regulations (CFR) Section 606.170(a and b).

Approval Signatures

Step Description	Approver	Date

	Vaishali Pansare: Chief, Pathology	2/10/2023
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	Kristen Lafond: Mgr Laboratory	1/24/2023
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