AMERICAN ASSOCIATION OF BLOOD BANKS

ASSOCIATION BULLETIN #04-06

Date: August 31, 2004
UPDATED JULY 2022

To: AABB Members

From: Kathleen Sazama, MD, JD - President
Karen Shoos Lipton, JD - Chief Executive Officer

Re: Reporting Donor Fatalities

Summary
The Code of Federal Regulations, in Title 21 CFR 606.170(b), requires a facility to notify the Food and Drug Administration (FDA) Center for Biologics Evaluation and Research when a complication of blood collection or transfusion is confirmed to be fatal. Deaths resulting from blood donation are extremely rare and their evaluation is made even more difficult by the lack of uniform reporting. Currently, no forms or standardized criteria are used for reporting donor fatalities, making it very difficult to obtain, review, and analyze the significant information. The purpose of this Association Bulletin is to identify the critical data relating to a donor fatality. It is anticipated that the use of these forms will allow FDA and the blood banking community to collect consistent types of data in a manner that will permit meaningful analysis.

Background
In December 2003, FDA presented data relating to donor fatalities to its Blood Products Advisory Committee. The data were derived from 52 reports received by FDA from November 1, 1983 through October 2003. Of these possible 52 donor fatality reports, 29 involved source plasma donors, 20 involved whole blood donors, and three involved plateletpheresis donors. Several of the whole blood donations were preoperative autologous donations. FDA noted that over the past 20 years, reports of donation-related deaths have increased. It is not known if this is the result of an increase in deaths or if it is the result of increased reporting activity. FDA also concluded that the majority of the deaths were probably caused by coronary heart disease, a feature that remained fairly consistent over time.

Following this meeting, AABB filed a Freedom of Information Act request for copies of these reports. The reports were primarily in a narrative form, making them very difficult to analyze. As a result of concerns about interpreting data from diverse reporting formats, AABB formed an interorganizational task force to address the issue. The AABB Interorganizational Task Force includes representatives of America's Blood Centers (ABC), American Red Cross (ARC), AABB, and the Plasma Protein Therapeutics Association (PPTA) and liaisons from FDA. This Association Bulletin expands the information covered in the August 2003 FDA "Guidance for Industry: Notifying FDA of Fatalities Related to Blood Collection or Transfusion," and is intended to assist facilities in investigating and reporting potential donor fatalities.

Standardized Forms

The Task Force prepared this guidance and accompanying forms to facilitate standardized reporting of donor fatalities. It is hoped that use of these forms will result in the collection of more meaningful data. The standardized forms should be used by all facilities that collect blood, including both allogeneic and autologous blood, or source plasma. Any death occurring as the result of a therapeutic collection should be reported as a patient, not a donor, death. Two report forms are attached.

The *Initial Report of Fatality Related to Donation* form is used in the following circumstances:

~~**1. If the donor death, or the first symptom reasonably related to the death, occurs within 36 hours of completion of the donation.**~~

1. If the death or the first symptom occurs more than 36 hours after the donation, and there is a reasonable chance that the death might be donation-related.
2. If there is any doubt about whether to report a case.

Due to the potential change in email address, phone number and fax number, AABB suggests individuals refer to the FDA website to determine what the most up to date contact information is.

This first form, *Initial Report of Fatality Related to Donation*, should be completed and sent to FDA **as soon as possible** ~~**(within 24 hours of receiving information, if possible)**~~ by email. ~~**attachment to fatalaties2@fdh.hhs.gov fatalities2@cber.fda.gov or Fax to 301-827-0333 301-827-6748, ATTN: CBER Fatality Program Manager. If these methods are not available, contact FDA at 240-402-9160 301-827-6220 and leave a message and/or send the completed form by express mail to:**~~

~~**US Food and Drug Administration**~~
~~**Office of Compliance and Biologics Quality/CBER**~~
~~**Attention: Fatality Program Manager**~~
~~**10903 New Hampshire Ave.**~~
~~**Bldg. 71, Rm. 3128**~~
~~**Silber Spring, MD 20993-0002**~~

~~**Office of Compliance and Biologics Quality/CBER ATTN: Fatality Program Manager (HFM-650)**~~
~~**1401 Rockville Pike, Suite 200N Rockville, MD 20852-1448**~~

The second form, *Follow-up Reporting of Fatality Due to Donation*, lists all of the additional or follow-up information that should be reported within seven days of filing the initial report. This may be sent by email, fax, or express mail.

~~**Please refer to the most recent FDA Guidance concerning notification of fatalities to the FDA updated in August of 2021. FDA Guidance: Notifying FDA of Fatalities Related to Blood Collection or Transfusion, September 2003, Updated August 2021.**~~

~~**https://www.fda.gov/regulatory-information/search-fda-guidance-documents/notifying-fda-fatalities-related-blood-collection-or-transfusion**~~

INITIAL REPORT OF FATALITY RELATED TO DONATION

(Please fill in all blanks. If the information is unknown, enter "unknown.")

When reported to FDA: _____ Date _____ Time AM/PM

Person reporting fatality: _____ Name _____ Title

Contact numbers: _____ Telephone No. _____ Fax No.

_____ Pager No. _____ Email address

Facility Name: _____

Facility Address: _____ Street City/State Zip code

Facility License/Registration Nos.: _____ License No. _____ Registration No.

How did you first learn of the donor's death?

□ Direct observation (Attach a description of the medical interventions taken or other response to the situation.)

□ Notified by other health-care entity □ Read death notice in the newspaper

□ Contacted by third party (specify) _____

□ Other (specify) _____

Type of collection:

□ Allogeneic — whole blood donation

□ Allogeneic — automated collection (check ALL that apply)

○ Platelets ○ Plasma ○ Red cells ○ Granulocytes ○ Other _____

__ Double __ Jumbo __Double

__ Triple __ Source

□ Autologous—whole blood donation (specify)_____

□ # Autologous—automated collection (specify)_____

Donation frequency: □ First time □ Repeat ____ times/past year □ Unknown

Demographic Data

Unique Identifier: _____

NOTE: This can be any institutionally defined code, EXCEPT it cannot be the person's name. For example, it could be a unit number, donor number, or medical record number. This identifier should be used for all attachments and follow-up information.

Age: _____ years **Gender:** □ Female □ Male **Weight:** _____ lb/____kg

Name and address of facility (if known) where fatality occurred (if different from your own):

_____

_____

Time relationships between donation and death (if known or best estimate):

Date of donation _____ Date of death _____

Interval (actual or best estimate in hours) between donation and onset of symptoms _____hours

Interval (actual or best estimate in hours) between donation and death _____hours

Predonation Vital Signs:

Temperature ____°F/___°C Pulse ____ bpm □ Regular □ Irregular

Blood pressure: Systolic _____ /Diastolic _____

Any problems during collection? (Attach completed report.)

□ Device related □ Disposables □ Donor reaction

Will an autopsy be performed? □ Yes □ No □ Unknown

For Automated Collections:

Name of collection device _____Model _____

Manufacturer _____ Manufacturer notified? □ Yes □ No

Name of disposable collection sets used _____

Lot No._____ Expiration date _____

Duration of collection _____hours Collection volume _____ mL

Replacement fluids used during collection (check all that apply):

□ ACD ____ mL □ 0.9% NaCl ____ mL □ Other (specify) _____ ____mL

Disposition of collection: □ Quarantined □ Distributed □ Destroyed

□ Other (specify) _____

FOLLOW-UP REPORTING OF FATALITY RELATED TO DONATION

(Please check all appropriate items and attach relevant documents)

1. Blood and plasma collection facilities should provide the following additional documents within seven days (if possible) * of filing the initial report, including:

□ Written report of the complete fatality investigation, including date of initial notification, conclusions, and follow-up actions (corrective action report), on institutional letterhead

□ Copies or report of all donations for two years preceding death, including reports of reactions and reports of physical examinations to qualify donor for frequent plasma donations

□ Additional information related to disposables and fluids used, such as manufacturer's notices, contamination warnings, or fluid recalls.

□ Performance log for the implicated device; maintenance records, manufacturer's notices, or recalls related to the device during the past two years.

2. FDA will also be interested in obtaining additional information that may not be readily available from the blood collection facility. Blood collection facilities should contact hospitals or medical examiners requesting that they provide the following additional information of interest to the FDA, if available and releasable.

□ If the donor was hospitalized before death, all relevant documents, such as laboratory reports, progress notes, etc, that may help determine the cause of death

□ Copy of discharge summary, if applicable

□ Copy of death certificate

□ Autopsy report, if performed

3. From these reports, FDA can capture information such as donor height and weight (to calculate body surface area), any known current or past serious medical diagnoses or conditions, the names and doses of medications being taken by the donor, known allergies, predonation immunization or cellular mobilization, and whether organs/tissues were donated for transplantation.

*This report may be amended with additional data as it becomes available.