



2009 National Blood Collection and Utilization Survey

Your help is critical to assess the adequacy of our blood resources.

This biennial survey is the single best means of determining detailed accurate information about collection and utilization of blood and blood components in the United States. The data you contribute and the time you take to ensure its accuracy are critical to the success of the survey and the interpretation of findings. In the past, we have asked questions about blood, blood components, and cell therapy collection and utilization. This year, due to the needs of the blood banking and hospital blood resource providers, there are questions regarding detailed utilization, biovigilance, human tissue collection and utilization, and the practices related to these products and services. We look forward to seeing what unfolds and to sharing that report with you. Thank you in advance for your participation in this important national survey.

If you have any questions regarding the survey, while you are compiling the data or afterwards, please call our toll-free number: 800-793-9376.

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0990-0313. The time required to complete this information collection is estimated to average 1 hour per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: U.S. Department of Health & Human Services, OS/OCIO/PRA, 200 Independence Ave., S.W., Suite 531-H, Washington D.C. 20201, Attention: HHS PRA Reports Clearance Officer OMB No. 0990-0313.

Statement on Data Release

The completed questionnaires will be processed and data compiled for analysis and used for statistical purposes only. No institutional data provided in response to this survey will be reported that may allow a blood center or hospital to be identified. Results will be released only in aggregate form. Public use data from this survey may be used by researchers throughout the blood community. The public use data sets will be in a format that will adhere to HIPAA standards and will minimize the risk of identification of the responding institution.



2009 National Blood Collection and Utilization Survey

Instructions: Please read carefully!

- This survey can be submitted either online (www.bloodsurvey.org) or by mailing it in the enclosed postage paid envelope to AABB Survey Processing Center, C/o Images to Data, 212 Decatur Street, Suite 102, Doylestown, PA 18901. This will be on the only paper copy of the survey that you receive.
- We encourage you to complete the survey online for data accuracy. Check the cover memo for details about an incentive to show our thanks for your participation.
- Report all data for the 2008 calendar year, 1/1/08 through 12/31/08, unless otherwise specified (some questions are about current practices only). If your institution cannot provide calendar year data, please report data for the most recent 12-month period that your institution has available.
- Answer all questions—DO NOT LEAVE ANY ITEMS BLANK, unless instructed to skip an item.
- If your answer is zero, it is important that you enter “0” rather than leaving a blank.
- Be sure your responses are printed clearly and legibly.
- Consult your records whenever possible to provide the most accurate information available. If records are not available, please provide your best estimate, or that of your most qualified co-worker. It may be necessary for you to forward this questionnaire to another department for completion of some items.
- Before you begin, read the glossary on the inside back cover of this booklet. Terms included in the glossary are underlined when first used in the survey.
- If you have any questions, please call the toll-free survey helpline at 800-793-9376 or send an e-mail to dataprograms@aabb.org.
- Be sure to make and keep a copy of your completed questionnaire before returning it.
- Thank you in advance for your assistance with this important survey!

Section A. General Information

A1. Provide the name, title, telephone number, and e-mail address of each person completing this survey:

| Prefix | First Name | Last Name | Title/Position | Telephone | E-mail |
|--------|------------|-----------|----------------|-----------|--------|
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

A2. Is your institution [Choose one]:

- 1 A local or regional blood center (non-hospital) that collects blood from donors and supplies blood and components to other facilities?
- 2 A hospital-based blood bank and transfusion service that collects blood from donors (may be only autologous or directed) and provides blood and components for transfusion primarily to your own facility?
- 3 A transfusion service that provides blood and components for transfusion, but does not collect blood from donors?
- 4 A local or regional blood center that collects blood from donors and supplies blood, components, and crossmatched blood products to participating facilities (such as a centralized transfusion service)? In this category, the service is not limited to reference laboratory work, but includes routine transfusion service work.

A3. Does your institution collect, process, manufacture, store, distribute, issue and/or infuse hematopoietic progenitor cells (HPCs) or other cell therapy products? [If you perform only infectious disease testing, please check "No."]

Yes

No

A4. Does your institution maintain an inventory of, or use human tissue for transplantation? [If you perform only infectious disease testing, please check "No".]

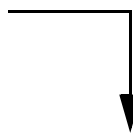
Yes

No

A5. List the official name, city, state, and zip code of every institution for which data are reported on this questionnaire. [If necessary, continue on the opposite page.]

| | | | |
|----------------------------|-------------|--------------|------------|
| a. Institution Name | | | |
| | | | |
| Street Address | City | State | Zip |
| | | | |
| b. Institution Name | | | |
| | | | |
| Street Address | City | State | Zip |
| | | | |
| c. Institution Name | | | |
| | | | |
| Street Address | City | State | Zip |
| | | | |

A6. Does your institution serve as a transfusion service for other institutions?

- Yes
 - No
- 

Which other institutions are served? [Please provide the official name, city, and state of every such facility, if different from your institution. Attach a separate sheet if needed.]

| | | | |
|----------------------------|-------------|--------------|------------|
| a. Institution Name | | | |
| | | | |
| Street Address | City | State | Zip |
| | | | |
| b. Institution Name | | | |
| | | | |
| Street Address | City | State | Zip |
| | | | |
| c. Institution Name | | | |
| | | | |
| Street Address | City | State | Zip |
| | | | |

PLEASE GO TO SECTION B

Section B. Blood Collection, Processing, and Testing

This section includes questions about blood donors, blood collection and testing. **All facilities should answer question B1.** Any facility collecting blood should complete the rest of the section.

B1. Does your institution collect blood from donors? [If you collect autologous units only, check "Yes" and complete this section.]

Yes —————> COMPLETE THIS SECTION

No —————> SKIP TO SECTION C

B2. How many collection procedures (and for automated collections, how many products?) were successfully completed by your institution in each of the following categories in 2008? [If a breakdown is not available, put the total under "Allogeneic Whole Blood." Do not count low-volume or incomplete procedures.]

Manual Whole Blood Collections

No. of Procedures

1) Community (non-directed allogeneic donations)

2) Autologous

3) Directed

Automated Collections

No. of Procedures

No. of Products

1) Apheresis red cells [Count double units resulting from double collections as two units.]

a. Allogeneic red cells

b. Autologous red cells

c. Directed red cells

d. Concurrent plasma

e. Concurrent plasma – jumbo

2) Apheresis platelets

a. Single-donor platelets

b. Directed single-donor platelets

c. Concurrent plasma

d. Concurrent plasma – jumbo

e. Concurrent red cells

Automated Collections (Continued)

| | No. of Procedures | No. of Products |
|-------------------------------------|----------------------|--------------------|
| 3) Plasmapheresis | _____ | |
| a. <u>Jumbo FFP (>400 mL)</u> | | _____ |
| b. <u>FFP/24-hour plasma (FP24)</u> | | _____ |

B3. How many units were collected by your institution at mobile blood drive sites:

_____ units

B4. How many units were processed by your institution in each of the following categories in 2008?

a. Number of whole blood units processed for distribution as whole blood:

_____ units

b. Number of red cell units processed:
[Count double units resulting from double collections as two units. Exclude pediatric units. Include packed red cells plus units from red cell apheresis.]

_____ units

B5. How many whole blood and red cells units (combined) were released for initial distribution? [Count double units resulting from double collections as two units. Units returned and released for distribution multiple times should be counted only once.]

| |
|--------------|
| TOTAL |
| |

B6. How many units of the following were produced from whole blood?

- | | | |
|----|--------------------------------|-------------|
| a. | FFP | _____ units |
| b. | Plasma frozen within 24 hours | _____ units |
| c. | Plasma cryoprecipitate reduced | _____ units |

B7. Of the following components, how many units were produced by your institution in 2008? [Count double or triple units resulting from double or triple collections or splits as two or three units. Count pools of whole-blood-derived platelets or cryoprecipitate in terms of individual unit equivalents.]

- a. Plasma for further manufacture _____ units
- b. Whole-blood-derived platelets _____ units
- c. Apheresis platelets from single collections
[do not include autologous or therapeutic units] _____ units
- d. Apheresis platelets produced from double collections _____ units
- e. Apheresis platelets produced from triple collections _____ units
- f. Cryoprecipitate _____ units
- g. Granulocytes _____ units

B8. For each of the following categories, how many units did your institution collect/prepare/modify to achieve prestorage leukoreduction in 2008?

- a. Red cells/whole blood _____ units
- b. Whole-blood-derived platelets _____ units
- c. Apheresis platelets _____ units
- d. Other component units, including pediatric units _____ units

B9. From how many of the following types of donors did you successfully collect blood products in 2008?

- a. First-time allogeneic donors _____ donors
- b. Repeat allogeneic donors _____ donors
- c. Directed donors _____ donors

B10. In 2008, how many people presented to donate?

_____ people

B11. How many people were deferred for the following reasons:

- Low hemoglobin _____ people
- Other medical reasons _____ people
- High-risk behavior _____ people
- Travel _____ people

B12. How many donations were from repeat allogeneic donors?

_____ donations

B13. How many units were collected from 16- to 24-year-old donors?

_____ units

B14. How many units were collected from all minority populations (ie, including African, Asian, and/or Hispanic origin, combined)

_____ units

B15. How many severe related donor adverse events did you have in 2008?

From whole blood collections: _____ events

From automated collections: _____ events

B16. What was the total number of allogeneic units (non-directed and directed combined) discarded in 2008 for abnormal disease marker test results?

_____ units

B17. What was the total number of allogeneic units (non-directed and directed combined) discarded in 2008 for all other reasons?

_____ units

B18. For all tested donations collected by your facility in 2008, indicate the number of repeat reactive and confirmed positive allogeneic donors by infectious disease marker below:

| Infectious Disease Marker | No. of Repeat Reactive Allogeneic Donors | No. of Confirmed Positive Allogeneic Donors | Test Not Performed |
|--|--|---|--------------------|
| a. Anti-HIV-1/HIV-2 | | | |
| b. Anti-HTLV-I/II | | | |
| c. Anti-HCV | | | |
| d. Anti-HBc | | | |
| e. HBsAg | | | |
| f. Serologic test for syphilis | | | |
| g. HIV-1 NAT (antibody negative) | | | |
| h. HCV NAT (antibody negative) | | | |
| i. Undifferentiated NAT (if HIV-1 and HCV discriminatory negative when applicable) | | | |
| j. WNV NAT | | | |
| k. Anti- <i>Trypanosoma cruzi</i> (Chagas disease) | | | |
| l. HBV NAT | | | |

PLEASE GO TO SECTION C

Section C. Blood Transfusion

This section should be completed by transfusion services and includes questions about transfusion, utilization, availability, and hemovigilance. **All facilities should complete question C1.** Any facility transfusing blood or serving as a centralized transfusion service for others should complete this section.

C1. Is your institution directly involved in the transfusion of blood to patients or does it serve as a transfusion service for another institution that transfuses blood?

Yes —————> COMPLETE THIS SECTION

No —————> SKIP TO SECTION D

C2. In 2008, how many units of allogeneic whole blood and red cells (WB/RBCs) did your institution transfuse either directly or as a transfusion service for another institution?

[Exclude directed units transfused to the intended patients.]

| | Total No. of Units Transfused | Total No. of Recipients |
|----------------------------|-------------------------------|-------------------------|
| Allogeneic Whole Blood | | |
| Allogeneic Red Blood Cells | | |

C3. Indicate below the total number of units transfused in each of the following categories and report the number of recipients of these units.

| | Total No. of Units Transfused | Total No. of Recipients |
|---|-------------------------------|-------------------------|
| a. Directed WB/RBC units transfused to the intended patient | | |
| b. Autologous WB/RBC units transfused to the autologous donor | | |

C4. Indicate below the total number of units transfused to the pediatric population (as defined by your institution).

| | No. of Adult Equivalent Units Used in Whole or in Part for Pediatric Patients | No. of Pediatric Recipients |
|--------------|---|-----------------------------|
| a. WB/RBCs | | |
| b. Plasma | | |
| c. Platelets | | |

C5. In 2008, how many units of each of the following components did your institution transfuse, either directly or as a transfusion service for another institution?

- a. Whole-blood-derived platelets
[Individual concentrates and pools expressed as individual concentrate equivalents] _____ units
- b. Apheresis platelet units – full dose ($\geq 3 \times 10^{11}$) _____ units
- c. Directed platelets to intended recipients _____ units
- d. FFP _____ units
- e. Pediatric size (100 mL) FFP _____ units
- f. Plasma, frozen within 24 hours _____ units
- g. Jumbo plasma (>400 mL) _____ units
- h. Plasma cryoprecipitate reduced _____ units
- i. Cryoprecipitate (all uses)
[Include individual units and pools expressed as unit equivalents] _____ units
- j. Granulocyte units _____ units

C6. Indicate below how many irradiated, leukoreduced, and leukofiltered units of each of the following components your institution transfused, either directly or as a transfusion service for another institution in 2008 (for pediatrics use the number of adult equivalent units used in whole or part). Components that are both irradiated and leukoreduced should be included in the count for both columns.

| | Components Irradiated | Components Leukoreduced Before or After Storage (Not at the Bedside) | Components Leukofiltered at the Bedside |
|---|------------------------------|---|--|
| a. WB/RBCs | | | |
| b. Whole-blood-derived platelets | | | |
| c. Apheresis platelets | | | |
| d. Other blood component units, including pediatric units | | | |

C7. How many units of blood in your facility went to the following departments in 2008? [this can be determined by location or by physician use.]

| Department | | No. of RBC Units | No. of Platelet Units |
|------------|--------------------------|------------------|-----------------------|
| a. | Surgery – general | | |
| b. | Orthopedic surgery | | |
| c. | Cardiac surgery | | |
| d. | Trauma/ER | | |
| e. | Hematology/Oncology | | |
| f. | Transplantation services | | |
| g. | Obstetrics/Gynecology | | |
| h. | Pediatrics/Neonatology | | |
| i. | Nephrology/Dialysis | | |
| j. | ICU | | |
| k. | General medicine | | |
| l. | Other | | |

C8. What is the average age of a unit transfused at your institution?

| Component | Days | Calculated Average | Estimate | Don't Know |
|----------------------------------|------|--------------------------|--------------------------|--------------------------|
| a. Red Blood Cells | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| b. Whole-blood-derived platelets | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| c. 5-Day apheresis platelets... | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| d. 7-Day apheresis platelets... | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

C9. In 2008, how many therapeutic platelet doses were transfused?

a. As plateletpheresis products _____ doses

b. As whole-blood-derived platelets _____ doses

↓

If you indicated a quantity above, what is the usual (most common) dosage at your institution of whole blood units from which the dose was derived? [Check one.]

- <3 3 4 5 6 7 8 9 10 >10

C10. What volume of plasma is most commonly transfused during a single transfusion episode at your institution? _____ mL

C10a. Do you routinely transfuse plasma (to non-pediatric patients) based on: (Choose one)
 Patient size
 Unit volume

C11. How many grams of IVIG (not RhIG) were purchased by your institution? _____ grams

C12. What was the average whole dollar amount your institution paid per unit in 2008 for the following components? [Include discounts in your calculations. A response of \$0 should be entered as "NA" rather than 0.]

| | Average Amount Paid |
|--|---------------------|
| a. Plasma, frozen within 8 hours of phlebotomy | \$ |
| b. Plasma, frozen within 24 hours of phlebotomy | \$ |
| c. Red cells, leukofiltered | \$ |
| d. Whole-blood-derived platelets, not leukoreduced, not irradiated | \$ |
| e. Apheresis platelets, leukoreduced | \$ |
| f. Cryoprecipitate | \$ |

C13. Does your institution have an established "bloodless" surgery program?
 Yes
 No
 Don't know

C14. Does your hospital use intraoperative autologous blood recovery therapies?
 Yes
 No
 Don't know

C15. How many days in 2008 was elective surgery postponed due to actual blood inventory shortages?

_____ days

If any, how many surgeries were postponed? ←

[Do not count any single patient's surgery more than once.]

_____ surgeries

C16. On how many days in 2008 was your order incomplete?

- a. For red cells _____ days
- b. For plasma _____ days
- c. For apheresis platelets _____ days
- d. For whole-blood-derived platelets _____ days

C17. On how many days in 2008 were you unable to meet other non-surgical blood requests (eg, red cells, platelets)?

_____ days

C18. At your facility, how many units of group O red cells are on your shelf on an average weekday?

_____ units

C19. At your facility, what is the maximum number of units of group O positive and group O negative red cells in uncrossmatched inventory considered to be "critically low"?

_____ units

C20. How many WB/RBC crossmatch procedures were performed at your facility in 2008 by any method?

_____ procedures

C21. How many samples (patient specimens submitted for testing) did your facility receive at the blood bank in 2008?

_____ samples

C22. Does your facility currently collect data on sample collection errors (eg, wrong blood in tube)?

Yes No

If yes, How many were reported in 2008? _____ errors

C23. How many transfusion-related adverse reactions were reported to the transfusion service in 2008? [Count the number of reactions that required any diagnostic or therapeutic intervention.]

_____ reactions

If any reactions reported, complete the table below indicating how many types of each reaction occurred:

| Event Description | No. of Reactions |
|---|------------------|
| a. Life-threatening, requiring major medical intervention following the transfusion, eg, vasopressors, blood pressure support, intubation, or transfer to the intensive care unit | |
| b. Transfusion-related acute lung injury (TRALI) | |
| c. Transfusion-associated circulatory overload (TACO) | |
| d. Acute hemolytic transfusion reaction (ABO) | |
| e. Acute hemolytic transfusion reaction (other antibodies) | |
| f. Delayed hemolytic transfusion reaction | |
| g. Delayed serologic transfusion reaction | |
| h. Febrile, nonhemolytic transfusion reaction | |
| i. Hypotensive transfusion reaction | |
| j. Posttransfusion purpura | |
| k. Transfusion-associated dyspnea | |
| l. Transfusion-associated graft-vs-host disease | |
| m. Posttransfusion sepsis | |
| n. Severe allergic reactions | |

C24. Do you have an electronic system for tracking events (ie, unplanned, unexpected, and undesired occurrences)?

Yes No

PLEASE GO TO SECTION D

Section D. Bacterial Testing

This section pertains to methods used for testing for bacteria in platelets. Question D1 should be completed by all facilities.

D1. Does your institution perform bacterial testing?

Yes —————> COMPLETE THIS SECTION

No —————> SKIP TO SECTION E

D2. Indicate what methods are used by your institution to limit/detect bacterial contamination? [Check the applicable boxes.]

| | Culture-Based Testing | Swirling | pH | Glucose | Other | None |
|---|-----------------------|----------|----|---------|-------|------|
| a. Apheresis platelets? | | | | | | |
| b. Whole-blood-derived platelets, singly? | | | | | | |
| c. Whole-blood-derived platelets, pooled? | | | | | | |

D3. How many confirmed positives and false positives were detected by method in 2008?

| Method | No. Tested | No. of Confirmed Positives | No. of False Positives |
|--------------------------|------------|----------------------------|------------------------|
| a. Culture-based methods | | | |
| b. Rapid immunoassay | | | |
| c. Alternative methods | | | |

PLEASE GO TO SECTION E

Section E. Product Disposition

*This section contains questions about products disposition performed by both collection and treatment facilities **and should be completed by all facilities.***

- E1. In 2008, how many autologous and directed units of red cells and whole blood were crossed over to the community supply?**
- a. Autologous _____ units
- b. Directed _____ units
- E2. How many total units of red cells, group O positive red cells, and group O negative red cells (allogeneic, non-directed) were outdated in 2008?** [Include only those units that were outdated while on your shelf. If you transfuse blood, include units outdated at your institution, as well as any other institutions for which you serve as a transfusion service.]
- a. All Red Cell Units outdated _____ units
- b. Group O positive red cells outdated _____ units
- c. Group O negative red cells outdated _____ units
- E3. How many units in each of the following categories were outdated in 2008?** [Include only those units that were outdated while on your shelf. If you transfuse blood, include units outdated at your institution, as well as any other institutions for which you serve as a transfusion service.]
- a. Whole blood _____ units
- b. FFP or FP24 (including whole-blood-derived and apheresis plasma) _____ units
- c. Whole-blood-derived platelets (express pools as individual unit equivalents) _____ units
- d. Apheresis platelets _____ units
- e. Cryoprecipitate (express pools as individual unit equivalents) _____ units
- f. Directed WB/RBC units _____ units
- g. Autologous WB/RBC units _____ units

PLEASE GO TO SECTION F

Section F. Human Tissue

*This section contains questions regarding the use of human tissue for transplantation. **Please give this section to the appropriate laboratory or other specialized personnel to complete!***

- F1. Does your institution maintain an inventory of, or use, human tissue for transplantation?** Refer to the definition of tissue in the Glossary – this differs from the definition of “tissue” used by The Joint Commission in their Standards)
- Yes
- No —————> SKIP TO END
- F2. In 2008, what was the total number of human tissue implants/grafts that your facility:** [Include acellular dermal matrix products (eg, alloderm, repleform, etc) and consult with specialty departments, if necessary (eg, Orthopedics/ Dermatology/ Ophthalmology).]
- a. Used/implanted? _____ implants/grafts
- b. Discarded? _____ implants/grafts
- c. Returned? _____ implants/grafts
- d. Removed/explanted? _____ implants/grafts
- F3. Do you maintain an inventory of human skin?** Product used for burn application, traumatic wound, and integument problems.
- Yes
- No
- F4. In 2008 how many proven tissue-related adverse events have you reported from human tissue implants/grafts?** _____ events
- F5. If available:** [Please direct to the appropriate department eg, risk management, quality assurance, etc.]
- a. **How many reported adverse events were related to viral transmission?** _____ events
- b. **How many reported adverse events were related to bacterial infection?** _____ events
- c. **How many reported adverse events were related to fungal infection?** _____ events
- d. **How many adverse events were related to graft failure?** _____ events

Please return the questionnaire in the enclosed postage-paid envelope or go to www.bloodsurvey.org and enter your responses directly at our confidential web site.

Thank you very much for your help!

**National Blood Collection and Utilization Survey
AABB Survey Processing Center
c/o Images to Data
212 Decatur Street, Suite 102
Doylestown, PA 18901**

Survey Glossary

Autologous: self-directed donations.

Collected: successful whole blood or apheresis collections placed into production (not QNS, or other removals).

Community: in this survey refers to those allogeneic donations not directed to a specific patient.

Deferrals: The number of donors deferred for specific reasons:

- A) Donors deferred for low hemoglobin do not meet the current FDA blood hemoglobin level requirements for blood donation.
- B) Deferrals for other medical reasons may include the use of medications on the medication deferral list, growth hormone from human pituitary glands, insulin from cows (bovine, or beef, insulin), Hepatitis B Immune Globulin (HBIG), unlicensed vaccines, or presenting with physical conditions or symptoms that do not qualify a person to be a blood donor.
- C) High-risk behavior deferrals include deferrals intended to reduce the risk of transmission of infectious diseases including HIV and hepatitis viruses. Examples of questions intended to identify these risks are sexual contact and needle use questions.
- D) Travel deferrals are deferrals for travel to a specific region of the world.

Directed: allogeneic donations intended for a specific patient.

Dose/Dosage: a quantity administered at one time, such as a specified volume of platelet concentrates.

FFP: fresh frozen plasma.

First-time donor: first time at your center

Modify: used in this survey to refer to procedures applied by a blood center, hospital blood bank, or transfusion service that may affect the quality or quantity of the final product (eg, irradiation, leukofiltration, or production of aliquots of lesser volume).

Plasma, frozen within 24 hours of phlebotomy: plasma separated from the blood of an individual donor and placed at -18 C or colder within 24 hours of collection from the donor. Sometimes also referred to as **FP24**.

Plasma, Jumbo: for the purposes of this survey, FFP having a volume greater than 400 mL.

Present to Donate: A person presents to donate when he or she initiates the donation process through appearance and registration at a donation site.

Processed: subjected, after collection, to any manipulation or storage procedure. One cellular therapy product can be divided and processed in more than one way and would be counted as one collection but as two or more products processed.

Recipient: A unique individual patient receiving a transfusion one or more times in a calendar year.

Released for Distribution: units that have fulfilled all processing requirements and have been made available for transfer to customers.

Severe Donor-Related Adverse Events: adverse events occurring in donors attributed to the donation process that include, for example, major allergic reaction, arterial puncture, loss of consciousness of a minute or more, loss of consciousness with injury, nerve irritation, etc.

Transfusion Related Adverse Reactions: www.cdc.gov/nhsn/PDFs/HemovigModuleProtocol_current.pdf

Transfusion Service: a facility that performs, or is responsible for the performance of, the storage, selection, and issuance of blood and blood components to intended recipients.

Tissue: Articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer to a human recipient, to include musculoskeletal tissue, skin, ocular tissue, human heart valves, dura mater, reproductive tissues, tissue/device, and other combination therapies. Not included: vascularized human organs, minimally manipulated marrow, xenografts, blood products, hematopoietic stem/progenitor cells, other cellular therapies, human milk, collagen, cell factors, in-vitro diagnostic products, and blood vessels ("conduits") recovered with organs for use in organ transplantation.