Fatalities Reported to FDA Following Blood Collection and Transfusion

Annual Summary for Fiscal Year 2013

I. Background

As mentioned in the previous annual summaries of fatalities reported to the FDA, the blood supply is safer today than at any time in history. Due to advances in donor screening, improved testing, automated data systems, and changes in transfusion medicine practices, the risks associated with blood transfusion continue to decrease. Overall, the number of transfusion related fatalities reported to the FDA remains small in comparison to the total number of transfusions. In 2011, for example, there were approximately 21 million blood components transfused.[1] During the proximate period of Fiscal Year (FY) 2011, there were 58 reported transfusion related and potentially[2] transfusion related fatalities, with subsequent reports of 65 in FY2012, and 59 in FY2013.

CBER is distributing this summary of transfusion fatality reports received by the FDA to make public the data received in FY2013, to provide the combined data received over the last five fiscal years, and to compare the FY2013 report to the fatality reports received in the previous four fiscal years.[3] We also include information on the infrequent reports of post-donation fatalities. Throughout this report we note changes over time, but the reader should interpret these changes cautiously, given the small numbers of reports and inherent variations in reporting accuracy. The significance of shifts in numbers derived from small populations may appear to be greater than they really are.

Refer to Sections 606.170(b) and 640.73 of Title 21, Code of Federal Regulations (21 CFR 606.170(b) and 21 CFR 640.73), for fatality reporting requirements. For information regarding the notification process, see our web page, Notification Process for Transfusion Related Fatalities and Donation Related Deaths, http://www.fda.gov/biologicsbloodvaccines/safetyavailability/reportaproblem/transfusiondonationfatalities/default.htm. For further information, see our *Guidance for Industry: Notifying FDA of Fatalities Related to Blood Collection or Transfusion*, September 2003.[4]

A team of CBER medical officers reviews the documentation submitted by the reporting facilities and obtained by FDA investigators, to assess the relationship, if any, between the blood donation or transfusion and the reported fatality.

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[1] Report of the US Department of Health and Human Services. The 2011 national blood collection and utilization survey report. Washington, DC: US Department of Health and Human Services, Office of the Assistant Secretary of Health, 2012.
[2] Transfusion could not be ruled out as the cause of the fatality.
[3] The FY2005 - FY2008 data are not discussed in this report, but are available at: http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/TransfusionDonationFatalities/default.htm
[4] Guidance for Industry: Notifying FDA of Fatalities Related to Blood Collection or Transfusion, September, 2003. http://www.fda.gov/biologicsbloodvaccines/guidancecomplianceregulatoryinformation/guidances/blood/ucm074947.htm.

If you have questions concerning this summary, you may contact us using any of the three following options:

1. Email us at fatalities2@fda.hhs.gov,
2. Call us at 301-827-6220, or
3. Write us at:
   FDA/Center for Biologics Evaluation and Research
   Office of Compliance and Biologics Quality
   Division of Inspections and Surveillance (HFM-650)
   1401 Rockville Pike, Suite 200 North
   Rockville, Maryland 20852-1448

II. Results

During FY2013 (October 1, 2012, through September 30, 2013), we received a total of 72 fatality reports. Of these reports, 65 were transfusion recipient fatalities and 7 were post-donation fatalities.

Of the 65 transfusion recipient fatality reports, we concluded:

a) 38 (58%) of the fatalities were transfusion-related,
b) 21 (32%) of the fatalities were cases in which transfusion could not be ruled out as the cause of the fatality,
c) 6 (9%) of the fatalities were unrelated to the transfusion.

Of the 7 post-donation fatality reports, we concluded:

a) 5 of the fatalities were cases in which donation could not be ruled out as the cause of the fatality,
b) 2 of the fatalities were unrelated to the donation.

We summarize the results of our review in the following sections. Sections A through D of this document present the transfusion-related fatalities. Sections E and F present, respectively, the reported fatalities which were unrelated to the transfusion, and those in which we could not rule out the transfusion as the cause of death. Section G presents the post-donation fatality reports.

A. Overall Comparison of Transfusion-Related Fatalities Reported from FY2009 through FY2013

In combined Fiscal Years 2009 through 2013, Transfusion Related Acute Lung Injury (TRALI) caused the highest number of reported fatalities (38%), followed by Transfusion Associated Circulatory Overload (TACO) (24%) and hemolytic transfusion reactions (total of 22%) due to non-ABO (15%) and ABO (7%) incompatibilities. Microbial infections (10%) and anaphylactic reactions (5%) each accounted for a relatively small number of reported fatalities (Table 1 and Figure 1).

While the number of fatalities attributed to TACO has varied, TACO was the second leading cause of transfusion-related fatalities over the 5-year reporting period. There is increasing interest in TACO, as exhibited by recent articles. [5, 6, 7, 8, 9] The National Heart Lung and Blood Institute (NHLBI) Recipient Epidemiology and Donor Evaluation Study-III (REDS-III) focuses on transfusion and reducing its risks. Among their commitments for completion in Phase 1 (in the first two years) is *A Retrospective Cohort Study of Plasma Use, Transfusion Related Circulatory Overload (TACO), and Risk Associated with Use of ABO compatible, non-identical Plasma.*.[5]

The number of reported transfusion related deaths attributable to anaphylaxis[6,7,8] has remained small over the last five fiscal years. With the exception of one FY2010 case, in which IgA levels were not measured, patient IgA deficiency was ruled out in 8 of the 9 cumulatively reported cases. In another FY2010 case, a haptoglobin deficiency was possibly implicated in the patient's anaphylactic reaction.

Table 1: Transfusion-Related Fatalities by Complication, FY2009 through FY2013

Complication	FY09	FY09	FY10	FY10	FY11	FY11	FY12	FY12	FY13	FY13	Total	Total
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
TRALI*	13	30%	18	45%	10	33%	17	45%	14	37%	72	38%
HTR (non-ABO)	8	18%	5	13%	6	20%	5	13%	5	13%	29	15%
HTR (ABO)	4	9%	2	5%	3	10%	3	8%	1	3%	13	7%
Microbial Infection	5	11%	2	5%	4	13%	3	8%	5	13%	19	10%
TACO	12	27%	8	20%	4	13%	8	21%	13	34%	45	24%
Anaphylaxis	1	2%	4	10%	2	7%	2	5%	0	0%	9	5%
Other	1**	2%	1**	3%	1**	3%	0	0%	0	0%	3	2%
Totals	44	100%	40	100%	30	100%	38	100%	38	100%	190	100%

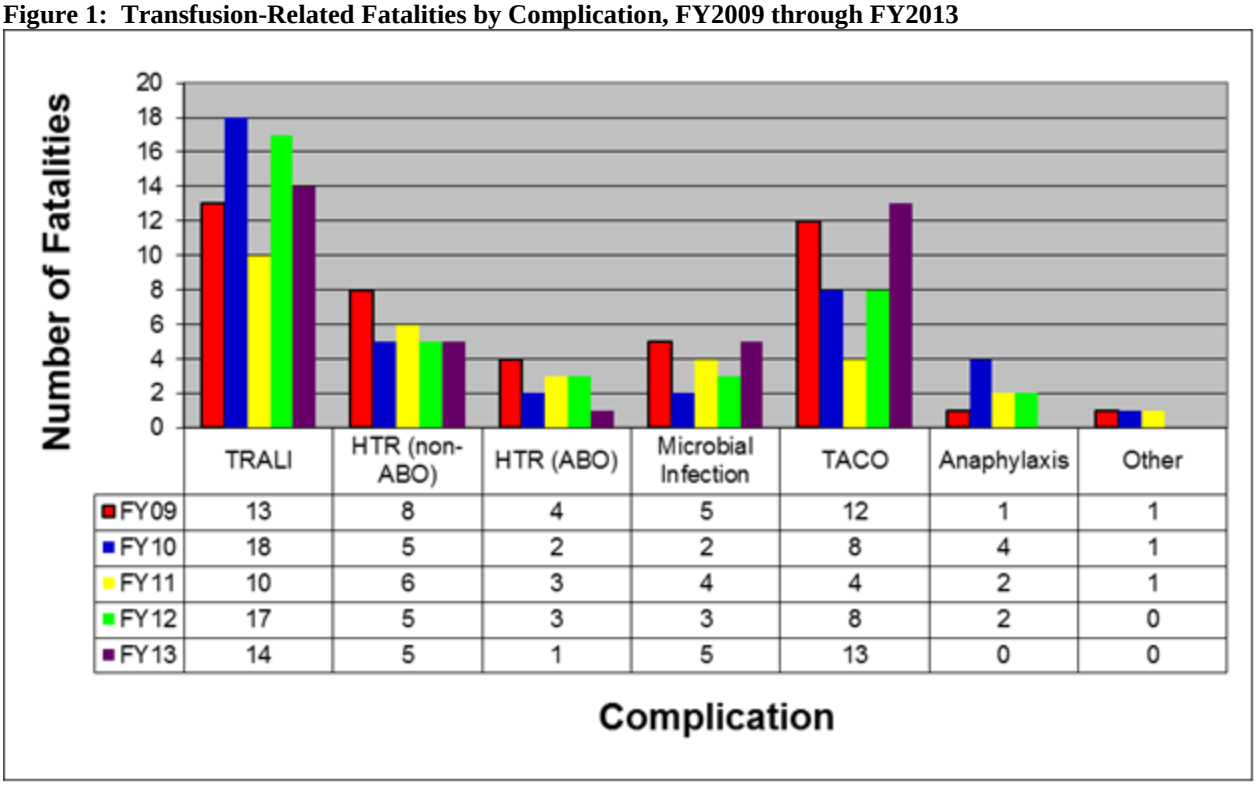
*These numbers include both "TRALI" and "possible TRALI" cases[9,10]

**Other:

FY2009: Hypotensive Reaction[11]
FY2010: Graft vs. Host Disease (GVHD)
FY2011: GVHD

[5] https://reds-iii.rti.org/REDSProgram.aspx.
[6] Lindsted G, Larsen R, Kriegaard M, et al. Transfusion-Associated Anaphylaxis during anaesthesia and surgery – a retrospective study. Vox Sanguinis (2014). doi: 10.1111/vox.12133.
[7] Hirayama F. Current Understanding of allergic transfusion reactions: incidence, pathogenesis, laboratory tests, prevention and treatment. British Journal of Haematology 2013;160:434-444.
[8] Savage W, Tobian A, Savage J, et al. Scratching the surface of allergic transfusion reactions. Transfusion 2013;53:1361-1371.
[9] Goldman M, Webert KE, Arnold DM, et al. Proceedings of a consensus conference: towards an understanding of TRALI. Transfus Med Rev 2005;19:2-31.
[10] Kleinman S, Caulfield T, Chan P, et al. Toward an understanding of transfusion-related acute lung injury: statement of a consensus panel. Transfusion 2004;44:1774-1789.
[11] Centers for Disease Control and Prevention. The National Healthcare Safety Network (NHSN) Biovigilance Component protocol. 2009:17.

Figure 1: Transfusion-Related Fatalities by Complication, FY2009 through FY2013



	TRALI	HTR (non-ABO)	HTR (ABO)	Microbial Infection	TACO	Anaphylaxis	Other
FY09	13	8	4	5	12	1	1
FY10	18	5	2	2	8	4	1
FY11	10	6	3	4	4	2	1
FY12	17	5	3	3	8	2	0
FY13	14	5	1	5	13	0	0

B. Transfusion Related Acute Lung Injury (TRALI)

TRALI represented 38% of confirmed transfusion-related fatalities reported to CBER over the last five fiscal years. There was a decrease in TRALI fatalities, from 17 (45% of confirmed transfusion-related fatalities) in FY2012, to 14 (37%) in FY2013 (Table 1 and Figure 1). Figure 2 shows the overall decrease in the number of TRALI fatalities since FY2007, when the number of TRALI fatalities represented 65% (34/52) of transfusion-related fatalities. Following this decrease, the total number of TRALI fatalities, as well as the number of TRALI fatalities associated with plasma products, have remained relatively unchanged over the reporting period FY2009 - FY2013 (Figure 2 and Figure 3).

In FY2013, the 14 TRALI cases were temporally associated with products collected from 51 donors. Genders were identified for 49 of the donors, which included 22 males and 27 females. HLA/HNA antibody test results were available for 38 of these donors.

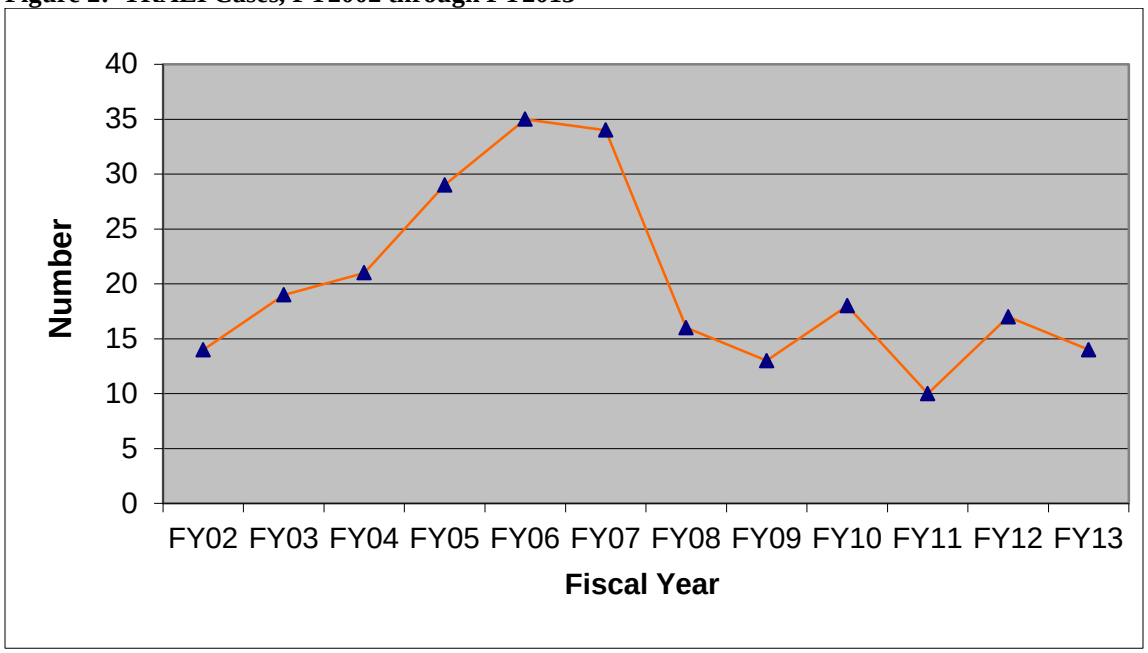
In 10 of the 14 FY2013 TRALI cases, reporters who included patient testing data were able to match donor antibodies with recipient cognate antigens.

Our limited data do not elucidate the role of particular donor antibodies or donor gender in the etiology of the TRALI reactions.

Although this complication of transfusion continues to be one of the leading causes of transfusion-related fatalities reported to the FDA, the voluntary measures taken by the transfusion community to reduce the risk of TRALI have coincided with a reduction in the number of TRALI deaths. Current literature describes the results

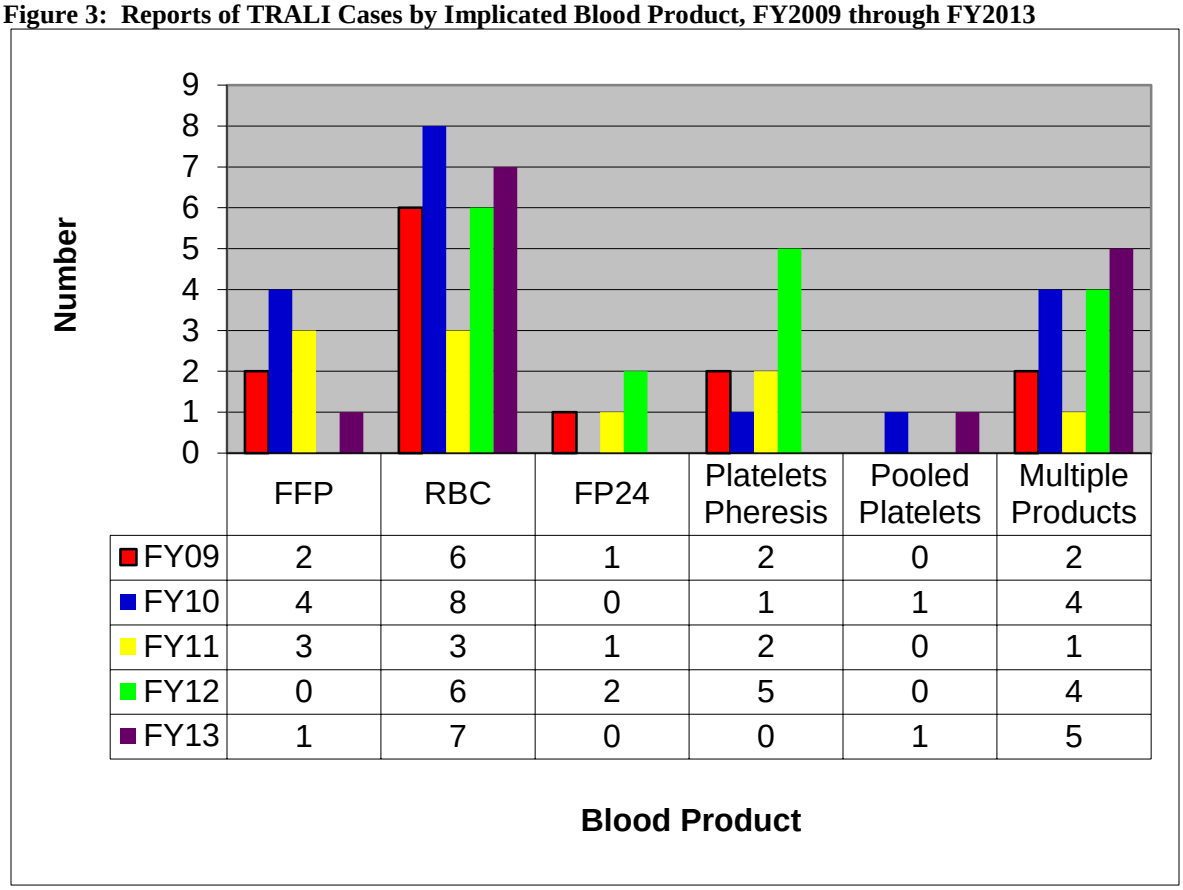
of continued international efforts to reduce the use of plasma for transfusion prepared from female donors, and other strategies to reduce the incidence of TRALI.[12,13,14,15,16,17,18,19,20,21]

Figure 2: TRALI Cases, FY2002 through FY2013



[12] Muller MCA, Juffermans NP. Transfusion-related acute lung injury: a preventable syndrome? Expert Rev. Hematol. 2012;5(1):97-106.
[13] Wiersum-Osselton JC, Middleburg RA, Beckers EAM, et al. Male-only fresh frozen plasma for transfusion-related acute lung injury prevention: before-and-after comparative cohort study. Transfusion 2011;51:1278-1283.
[14] Schmidt AE, Adamski J. Pathology Consultation on Transfusion-Related Acute Lung Injury (TRALI). Am J Clin Pathol 2012;138:498-503..
[15] Saidenberg E, Petraszko T, et al. Transfusion-Related Acute Lung Injury (TRALI): A Canadian Blood Services Research and Development Symposium. Transfusion Medicine Reviews 2010;24:305-324.
[16] Arinsburg SA, Skerrett DL, Karp JK, et al. Conversion to low transfusion-related acute lung injury (TRALI)-risk plasma significantly reduces TRALI. Transfusion 2012;52:946-952.
[17] Reesink HW, Lee J, Keller A, et al. Measures to prevent transfusion-related acute lung injury (TRALI). Vox Sanguinis 2012;103:231-259.
[18] Toy P, Ognjen G, Bacchetti P, et al. Transfusion-related lung injury: incidence and risk factors. Blood 2012;119:1757-1767.
[19] Eder A, Herron Jr R, Strupp A, et al. Effective reduction of transfusion-related lung injury risk with male-predominant plasma strategy in the American Red Cross (2006-2008). Transfusion 2010;50:1732-1742.
[20] Clifford L, Singh A, Wilson G, et al. Electronic health record surveillance algorithms facilitate the detection of transfusion-related pulmonary complications. Transfusion 2013;53:1205-1216.
[21] Association Bulletin #14-02 – TRALI Risk Mitigation for Plasma and Whole Blood for Allogeneic Transfusion. http://www.aabb.org/resources/publications/bulletins/Pages/abwhatsnew.aspx.

Figure 3: Reports of TRALI Cases by Implicated Blood Product, FY2009 through FY2013



	FFP	RBC	FP24	Platelets Pheresis	Pooled Platelets	Multiple Products
FY09	2	6	1	2	0	2
FY10	4	8	0	1	1	4
FY11	3	3	1	2	0	1
FY12	0	6	2	5	0	4
FY13	1	7	0	0	1	5

C. Hemolytic Transfusion Reactions

In FY2013, there was one reported ABO hemolytic transfusion (3% of confirmed transfusion- related fatalities) that was confirmed to be fatal, compared to three (8%) in FY2012. The total number of reported fatal hemolytic transfusion reactions in FY2013 remained relatively unchanged in comparison to the number reported in FY2012, with five non-ABO hemolytic transfusion reactions reported in both Fiscal Years (Tables 1 and 2, and Figure 1). The downward trend in the total number of reported fatalities due to hemolytic transfusion reactions has continued since FY2001 (Figure 4).

Table 2: Hemolytic Transfusion Reactions by Implicated Antibody, FY2009 through FY2013

	FY09	FY09	FY10	FY10	FY11	FY11	FY12	FY12	FY13	FY13	Total	Total
Antibody	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
ABO	4	33%	2	29%	3	33%	3	38%	1	17%	13	31%
Multiple Antibodies*	2	17%	3	43%	1	11%	2	25%	1	17%	9	21%
Other**	2	17%	0	0%	2	22%	0	0%	0	0%	4	9%
Fy^a	1	8%	0	0%	1	11%	0	0%	0	0%	2	5%
Jk^b	0	0%	1	14%	0	0%	1	13%	1	17%	3	7%
Kell	0	0%	0	0%	1	11%	1	13%	2	33%	4	9%
Jk^a	2	17%	0	0%	0	0%	0	0%	1	17%	3	7%
c	0	0%	0	0%	1	11%	0	0%	0	0%	1	2%
Js^b	1	8%	0	0%	0	0%	1	13%	0	0%	2	5%
Co^a	0	0%	1	14%	0	0%	0	0%	0	0%	1	2%
Totals	12	100%	7	100%	9	100%	8	100%	6	100%	42	100%

*Multiple Antibodies:

FY2009: antibody combinations included $E+Jk^b$, $S+Jk^a+Jk^b+K+Fy^a+Fy^b+V+C+N+HTLA$.

FY2010: antibody combinations included $D+C+K+S$, $Jk^b+FY^a+C+E+K+Le^a+Le^b$, $c+E+Jk^b+K+Le^a$+panagglutinin+cold agglutinin.

FY2011: anti-Jk^a+c+E+M (warm reacting).

FY2012: antibody combinations included S+E, C+K.

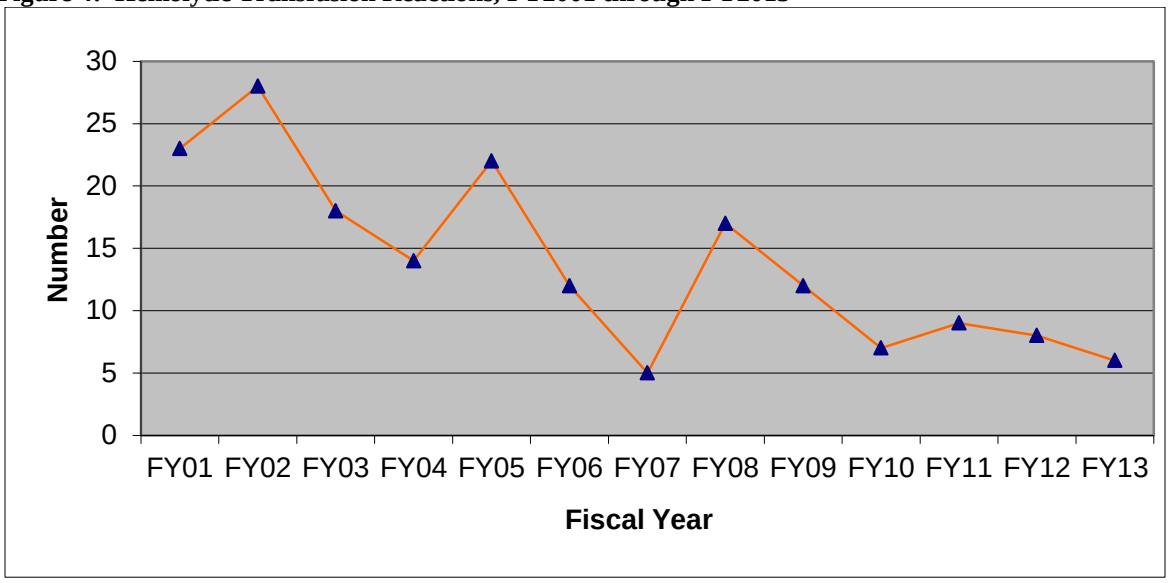
FY2013: anti-c+E

**Other:

FY2009: Includes one report of an unidentified warm autoantibody, and one report of Hyperhemolysis Syndrome. Information about this syndrome has been published.[22]

FY2011: Includes one report of Hyperhemolysis Syndrome, and one report of an unidentified antibody.

Figure 4: Hemolytic Transfusion Reactions, FY2001 through FY2013



The single ABO-incompatible transfusion fatality resulted when blood intended for one patient (group A) was transfused to another patient (group O) in the operating room (OR). Two procedural errors were identified. The first error occurred when patient information for another OR patient was used to retrieve the properly-

[22]Win N, New H, et al. Hyperhemolysis Syndrome in sickle cell disease: case report (recurrent episode) and literature review. Transfusion 2008;48:1231-1238.

labelled product from the storage device in the OR. The second error was a failure to properly identify the patient prior to starting the transfusion.

There were five reports of non-ABO fatal hemolytic transfusion reactions in FY2013, as follows:

Two of the five cases were attributed to laboratory errors:

- In the first case, the patient's transfusion and antibody history were unknown. After initial testing, the lab reported the antibody screen as negative, and the full crossmatch as compatible. Following the reported reaction, repeat testing demonstrated a positive antibody screen and incompatible crossmatch, using both the pre-transfusion and post-transfusion samples. An anti-K was identified.
- In the second case, the patient had a known history of anti-K, and the crossmatch was performed using an RBC unit labeled as K negative. Although the phenotyping of the unit was properly performed and determined to be K positive, the unit was labeled incorrectly as K negative. The employee who performed the crossmatch reported the unit as compatible. Following the reported reaction, repeat testing demonstrated an incompatible crossmatch, using both the pre-transfusion and post-transfusion samples.

Two additional cases, in which no errors in pre-transfusion serologic testing were identified, involved delayed hemolytic transfusion reactions:

- In one case, the patient had 3 previously identified antibodies. The transfused units were appropriately phenotyped for the corresponding antigens, and were crossmatch compatible. Following the reported reaction, the lab identified a new anti-Jk^a in the post-transfusion sample.
- The other case involved a patient with a prior history of transfusion, and a negative pre-transfusion antibody screen. The transfused units were compatible by electronic crossmatch. Following the reported reaction, the lab identified a new anti-Jk^b in the post-transfusion sample.

The remaining case involved an emergency transfusion of two uncrossmatched RBC units to a patient with an anti-c and E, whose prior history was unavailable. In this case, there was insufficient time to complete the antibody screen and crossmatches prior to transfusion. The transfusion service followed all procedures for emergency release of blood products in accordance with their Standard Operating Procedures.

D. Microbial Infection

In FY2013, there were five reported fatalities attributed to microbial infection, compared to three in FY2012. Red Blood Cell transfusions were associated with the fatal infections due to *Babesia microti and Pseudomonas fluorescens.* Transfusions of Apheresis Platelets were implicated in the fatalities due to West Nile Virus, *Staphylococcus epidermidis,* and an unidentified species of *Acinetobacter* (Figure 5).

Babesia microti and *Staphylococcus aureus* each accounted for 21% of the reported deaths due to microbial infection over the previous five fiscal years. During the reporting period, 4 of the 5 infections associated with RBC transfusions were due to *Babesia microti*, and 3 of the four *Staphylococcus aureus* infections were associated with transfusion of Apheresis Platelets (Table 3 and Figure 5).

Recent articles provide additional information about transfusion transmitted *Babesia,*[23,24,25] and reflect continuing interest in bacterial contamination of platelet products.[26,27,28,29]

During the five-year reporting period, 17 of the implicated bacteria associated with fatal microbial infections were facultative anaerobes, and two - *Acinetobacter* and *Pseudomonas fluorescens* - were obligate aerobes.

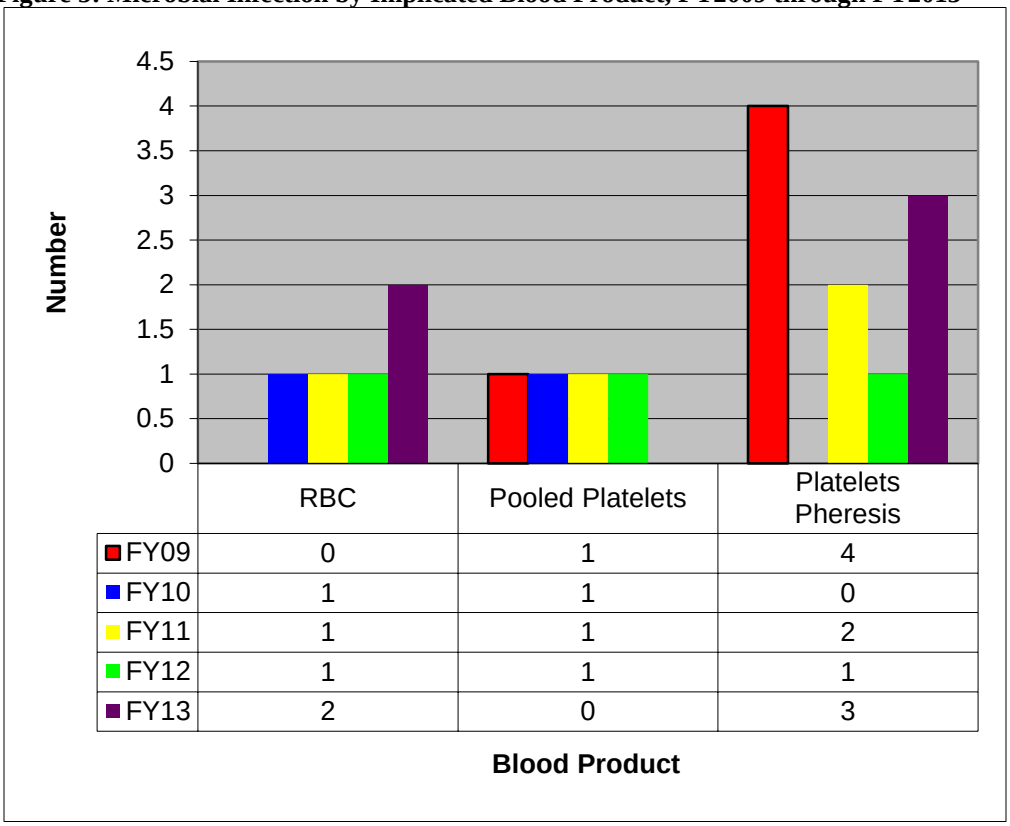
Figure 6 shows the overall downward trend in the number of bacterial infections associated with Apheresis Platelets since FY2001.

[23] Johnson ST, Van Tassell ER, et al. Babesia microti real-time polymerase chain reaction testing of Connecticut blood donors: potential implications for screening algorithms. Transfusion 2013;53:2644-2649.
[24] Young C, Chawla A, et al. Preventing transfusion-transmitted babesiosis: preliminary experience of the first laboratory-based blood donor screening program. Transfusion 2012;52:1523-1529..
[25] Simon M, Leff J, Pandya A, et al. Cost-effectiveness of blood donor screening for *Babesia microti* in endemic regions of the United States. Transfusion 2014;54:889-899.
[26] Rollins MD, Molofsky AB, Nambiar A, et al. Two Septic transfusion reactions presenting as transfusion-related acute lung injury from a split plateletpheresis unit. Crit Care Med 2012;40:2488-2491.
[27] Palavecino EL, Yomtovian RA, Jacobs MR. Bacterial contamination of platelets. Transfus Apher Sci 2010;42:71-82.
[28] Eder AF, Kennedy JM, Dy BA, et al. American Red Cross Regional Blood Centers: Limiting and detecting bacterial contamination of apheresis platelets: inlet-line diversion and increased culture volume improve safety. Transfusion 2009;49:1554-1563.
[29] Slichter S, Corson, J, Jones, MK, et al. Exploratory studies of extended storage of apheresis platelets in a platelet additive solution (PAS). Blood 2014;123:271-280.

Table 3: Microbial Infection by Implicated Organism, FY2009 through FY2013

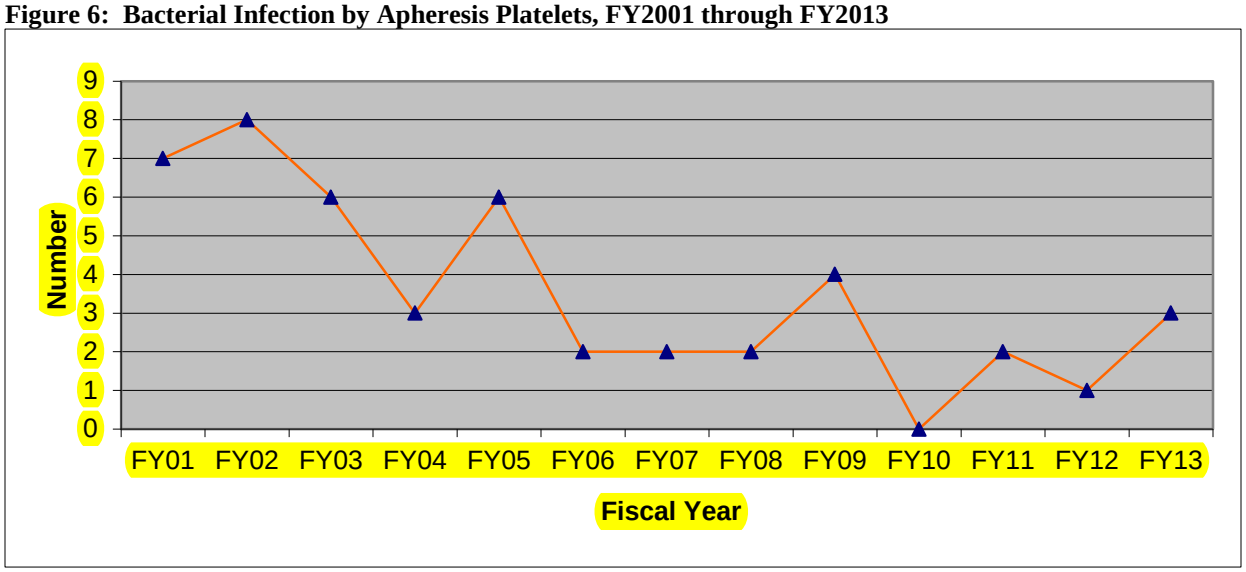
Organism	FY09	FY09	FY10	FY10	FY11	FY11	FY12	FY12	FY13	FY13	Total	Total
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Babesia microti	0	0%	1	50%	1	25%	1	33%	1	20%	4	21%
Staphylococcus aureus	2	40%	0	0%	1	25%	1	33%	0	0%	4	21%
Escherichia coli	0	0%	1	50%	0	0%	0	0%	0	0%	1	5%
Staphylococcus epidermidis	0	0%	0	0%	0	0%	0	0%	1	20%	1	5%
Morganella morganii	0	0%	0	0%	1	25%	0	0%	0	0%	1	5%
Streptococcus viridans	1	20%	0	0%	0	0%	0	0%	0	0%	1	5%
Streptococcus pneumoniae	1	20%	0	0%	0	0%	0	0%	0	0%	1	5%
Staphylococcus warneri	1	20%	0	0%	0	0%	0	0%	0	0%	1	5%
Klebsiella pneumoniae	0	0%	0	0%	1	25%	0	0%	0	0%	1	5%
Serratia marcescens	0	0%	0	0%	0	0%	1	33%	0	0%	1	5%
Pseudomonas fluorescens	0	0%	0	0%	0	0%	0	0%	1	20%	1	5%
Acinetobacter sp.	0	0%	0	0%	0	0%	0	0%	1	20%	1	5%
West Nile Virus	0	0%	0	0%	0	0%	0	0%	1	20%	1	5%
Total	5	100%	2	100%	4	100%	3	100%	5	100%	19	100%

Figure 5: Microbial Infection by Implicated Blood Product, FY2009 through FY2013



Red Blood Cells microorganisms: *B. microti (4), P. fluorescens (1)*
Pooled Platelets microorganisms: *S. aureus (1), E. coli (1), S. pneumoniae (1), S. Marcescens (1)*
Platelets Pheresis microorganisms: *S. aureus (3), S. epidermidis (1), M. morganii (1), S. viridans (1), S. warneri (1), K. pneumoniae (1),* West Nile Virus *(1), Acinetobacter sp. (1)*

Figure 6: Bacterial Infection by Apheresis Platelets, FY2001 through FY2013



E. Transfusion Not Ruled Out

As noted above, 21 (32%) of the 65 reported transfusion fatalities in FY2013 were cases in which the transfusion could not be ruled out as the cause of the fatality. In these reported fatalities, the reporting facilities were unable to identify a specific complication of transfusion as the cause of death. Often, these patients had multiple co-morbidities, and after review of the investigation documentation, our medical reviewers could neither confirm nor rule out the transfusion as the cause of the fatality (Table 4). Therefore, we did not include these reported fatalities in the analysis in Sections II.A through II.D (transfusion-related fatalities).

F. Not Transfusion Related

After reviewing the initial fatality reports and the investigation documentation, we categorized 6 (9%) of the 65 reported transfusion fatalities as "Not Transfusion Related." Our medical reviewers concluded that, while there was a temporal relationship between transfusion and subsequent death of the recipient, there was no evidence to support a causal relationship (Table 4). Thus, we did not include these reported fatalities in the analysis in Sections II.A through II.D (transfusion-related fatalities).

Table 4: Fatalities Not Related to Transfusion or Transfusion Not Ruled Out, FY2009 through FY2013

	FY09	FY10	FY11	FY12	FY13
Transfusion Not Ruled Out	22	24	28	27	21
Not Transfusion Related	8	7	11	9	6
Totals	30	31	39	36	27

G. Post-Donation Fatalities

In FY2013, the number of fatalities following Source Plasma donation decreased to five, from 12 reports in FY2012. There were two reports of fatalities following Whole Blood donation. In 4 of the 5 Source Plasma donor deaths, and one of the two Whole Blood donor deaths, although the donations could not be definitively

ruled out as being implicated in the donors' deaths, our medical reviewers found no evidence to support a causal relationship between the donations and subsequent death of the donors.

In one of the 5 reports of fatalities following Source Plasma donation, and one of fatalities following Whole Blood donation in FY2013, the donations were definitively ruled out as being implicated in the death of the donors. In these cases, there was clear evidence showing the cause of death was unrelated to the donation.

Over the five-year reporting period there were five Source Plasma donations (one FY2013 report, three FY2012 reports and one FY2011 report), and two Whole Blood donations (one in FY2013 and one in FY2011), in which the donations were definitively ruled out as the cause of death. For the remaining cases, our medical reviewers concluded that, while there was a temporal link between the donations and the fatalities, there was no evidence to support a causal relationship between the donations and subsequent death of the donors (Tables 5 and 6 and Figure7).

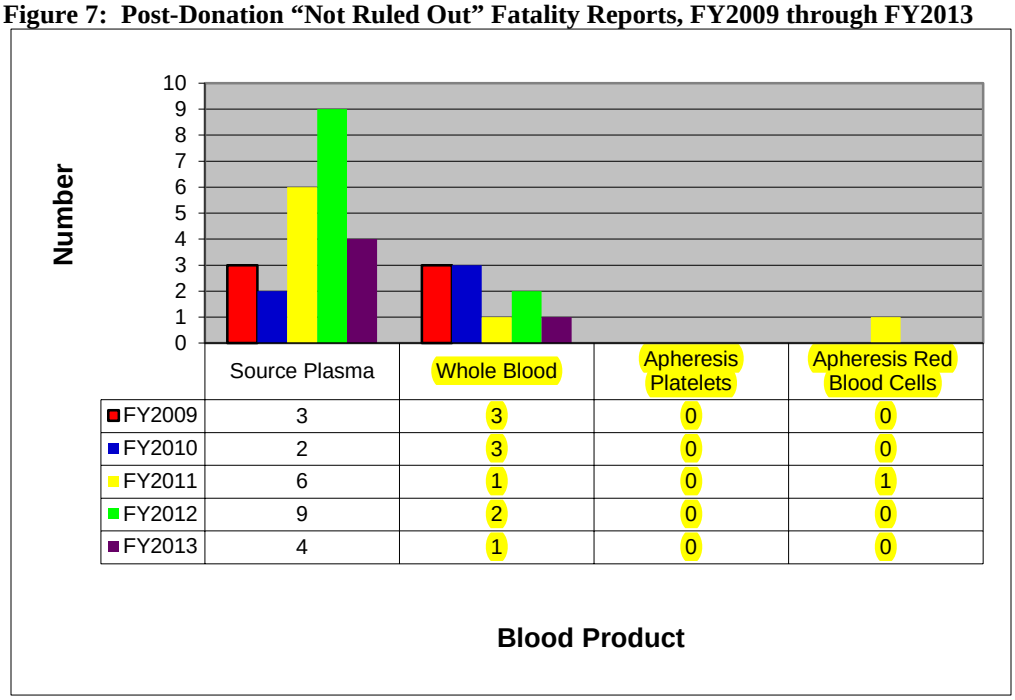
Table 5: Post-Donation "Not Ruled Out" Fatality Reports by Donated Product, FY2009 through FY2013

Donated Product	FY09	FY10	FY11	FY12	FY13
Source Plasma	3	2	6	9	4
Whole Blood	3	3	1	2	1
Apheresis Platelets	0	0	0	0	0
Apheresis Red Blood Cells	0	0	1	0	0
Total	6	5	8	11	5

Table 6: Post Donation "Ruled Out" Fatality Reports by Donated Product, FY2009 through FY2013

Donated Product	FY09	FY10	FY11	FY12	FY13
Source Plasma	0	0	1	3	1
Whole Blood	0	0	1	0	1
Apheresis Platelets	0	0	0	0	0
Apheresis Red Blood Cells	0	0	0	0	0
Total	0	0	2	3	2

Figure 7: Post-Donation "Not Ruled Out" Fatality Reports, FY2009 through FY2013



	Source Plasma	Whole Blood	Apheresis Platelets	Apheresis Red Blood Cells
FY2009	3	3	0	0
FY2010	2	3	0	0
FY2011	6	1	0	1
FY2012	9	2	0	0
FY2013	4	1	0	0