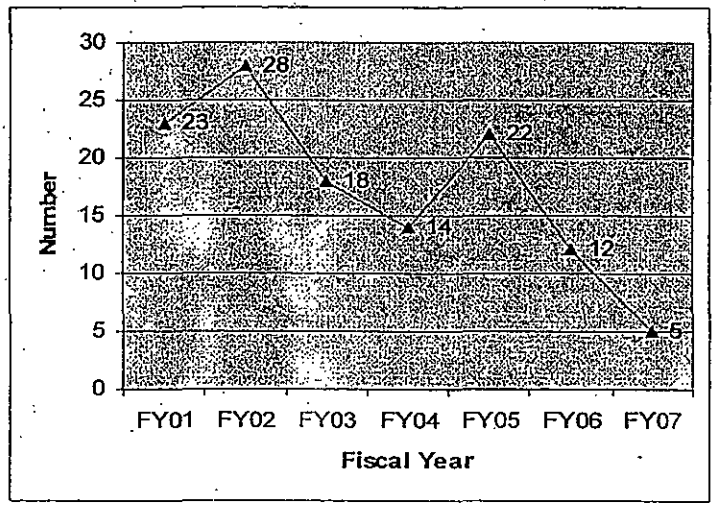
Table 3: Hemolytic Transfusion Reactions by Implicated Antibody, FY2005 through FY2007

	FY05		FY06		FY07		Total (FY05+06+07)	
Antibody	No.	%	No.	%	No.	%	No.	%
ABO	6	27%	3	25%	3	60%	12	31%
Multiple Antibodies*	6	27%	4	33%	1	20%	11	28%
Other**	3	14%	0	0%	0	0%	3	8%
Jk^b	3	14%	0	0%	0	0%	3	8%
Jk^a	1	5%	1	8%	1	20%	3	8%
K	1	5%	1	8%	0	0%	2	5%
Fy^a	0	0%	1	8%	0	0%	1	3%
Fy^b	0	0%	1	8%	0	0%	1	3%
E	1	5%	0	0%	0	0%	1	3%
I	1	5%	0	0%	0	0%	1	3%
Js^a	0	0%	1	8%	0	0%	1	3%
Totals	22	100%	12	100%	5	100%	39	100%

*FY2005 antibody combinations included E+c, Fy^a+K, Fy^a+Jk^b, E+I+A_1, possible C+E+K, Wr^a+warm autoantibody.
*FY2006 antibody combinations included E+c, S+K, Jk^b+cold agglutinin, unidentified auto- and alloantibodies.
*FY2007: anti-M+C
**Includes one report of non-immune hemolysis, one report of an unidentified antibody to a low incidence antigen, and one report of Cold Agglutinin Syndrome due to *Mycoplasma pneumonia* or Lymphoma.

Figure 3: Hemolytic Transfusion Reactions, FY2001 through FY2007



In FY2007, there were three reports of fatal hemolytic transfusion reactions due to ABO-incompatible blood transfusions:

- 1 case: recipient identification error at the time of transfusion
- 1 case: blood bank clerical error (incorrect sample used for testing)
- 1 case: initial recipient ABO/Rh typing results switched with another patient; ABO incompatible FFP issued prior to completion of required second typing

D. Microbial Infection

In FY2007, there were 6 reported fatalities attributed to microbial infection compared with 7 reported in FY2006 and 8 reported in FY2005. Three different bacteria were implicated in three fatalities, and three other fatalities resulted from Babesia transmission following Red Blood Cell transfusions from donors who subsequently tested positive for *Babesia microti*. The babesiosis cases accounted for 50% (3/6) of the microbial infections associated with transfusion fatalities in FY2007. Babesia accounted for 24% (5/21) of reported cases over the last three fiscal years, followed by Staphylococcus aureus, which accounted for 19% (4/21) (Table 4).

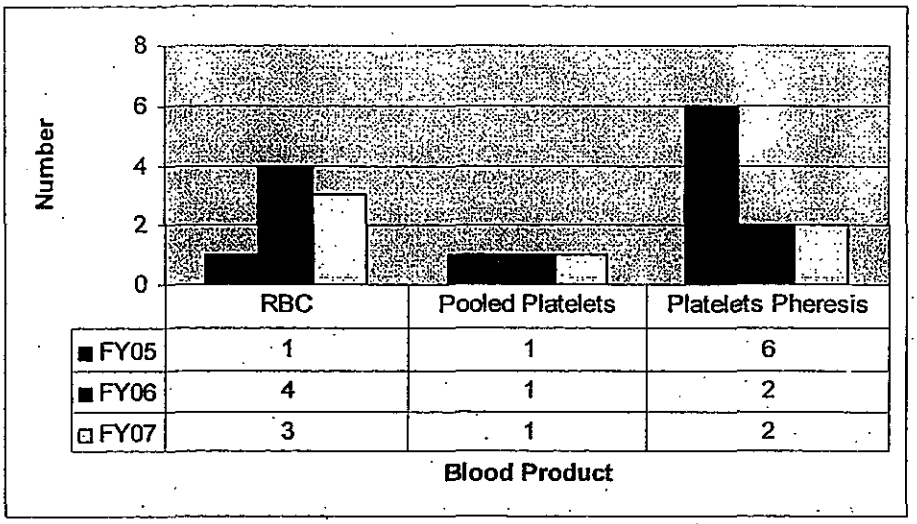
There was one strict anaerobe, *Eubacterium limosum,* implicated in a fatal bacterial infection during the 3-year reporting period; this fatality occurred in FY2005. The remaining bacteria are facultative anaerobes.

In FY2007, the decrease in reports of fatal microbial infections associated with apheresis platelets seen between FY2005 and FY2006 persisted (Figure 4). This finding is consistent with an overall decrease in the number of bacterial infections associated with apheresis platelets since FY2001 (Figure 5).

Table 4: Microbial Infection by Implicated Organism, FY2005 through FY2007

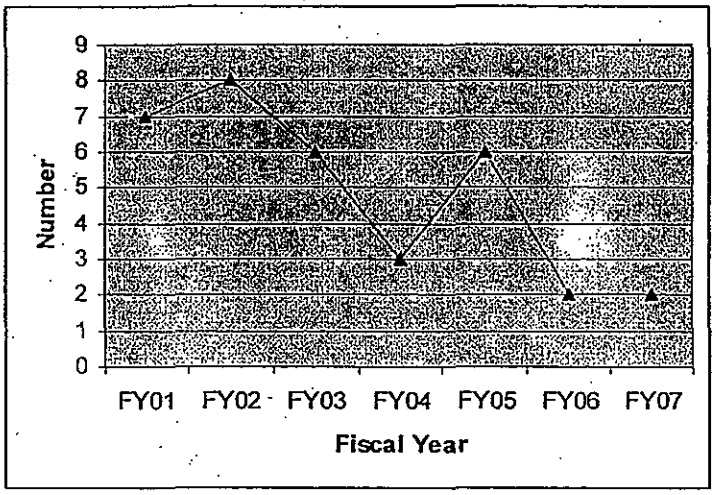
	FY05		FY06		FY07		Total (FY05+06+07)	
Organism	No.	%	No.	%	No.	%	No.	%
Babesia microti	0	0%	2	29%	3	50%	5	24%
Staphylococcus aureus	3	37%	0	0%	1	17%	4	19%
Escherichia coli	0	0%	3	43%	0	0%	3	14%
Serratia marcescens	2	24%	0	0%	0	0%	2	10%
Staphylococcus lugdunensis	1	13%	0	0%	0	0%	1	5%
Staphylococcus epidermidis	1	13%	0	0%	0	0%	1	5%
Eubacterium limosum	1	13%	0	0%	0	0%	1	5%
Morganella morganii	0	0%	1	14%	0	0%	1	5%
Yersinia enterocolitica	0	0%	1	14%	0	0%	1	5%
Streptococcus dysgalactiae	0	0%	0	0%	1	17%	1	5%
Klebsiella oxytoca	0	0%	0	0%	1	17%	1	5%
Total	8	100%	7	100%	6	100%	21	100%

Figure 4: Microbial Infection by Implicated Blood Product, FY2005 through FY2007



Red Blood Cells microorganisms: *S. marcescens (1), E. coli (1), Y. enterocolitica (1), B. microti (5)*
Pooled Platelets microorganisms: *S. aureus (1), E. coli (1), Streptococcus dysgalactiae (1)*
Platelets Pheresis microorganisms: *S. aureus (3), S. marcescens (1), S. lugdunensis (1), S. epidermidis (1), E. limosum (1), E. coli (1), M. morganii (1), K. oxytoca (1)*

Figure 5: Bacterial Infection by Apheresis Platelets, FY2001 through FY2007



E. Transfusion Not Ruled Out as Cause of 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 5). We did not include these reported fatalities in the analysis in Sections II.A through II.D (transfusion-related fatalities), above.

Combining the transfusion related fatalities with those that our medical officers could not rule out, there was a decrease in total reported fatalities from 73 in FY2006 to 63 in FY2007.

F. Not Transfusion Related

After reviewing the initial fatality reports and the investigation documentation, we categorized a number of reported 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 5). Thus, we did not include these reported fatalities in the analysis in Sections II.A through II.D (transfusion-related fatalities), above.

Table 5: Fatalities Not Related to Transfusion or Transfusion Not Ruled Out, FY2005 through FY2007

	FY05	FY06	FY07
Not Transfusion Related	21	8	13
Not Ruled Out	14	10	11
Totals	35	18	24

G. Post-Donation Fatalities

There was a small increase in the number of fatalities following Source Plasma donation, and two fatalities following donation of Apheresis Platelets (Table 6). In two cases (both Source Plasma donors), our medical reviewers determined that clear medical evidence supported a cause of death that was not donation related. For the remaining 13 of the 15 FY2007 fatalities following Source Plasma and Apheresis Platelet donations, 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 Source Plasma or Apheresis Platelet donations and subsequent death of the donors. This was also the case for the 12 fatalities following Source Plasma donation in FY2005 and FY2006.

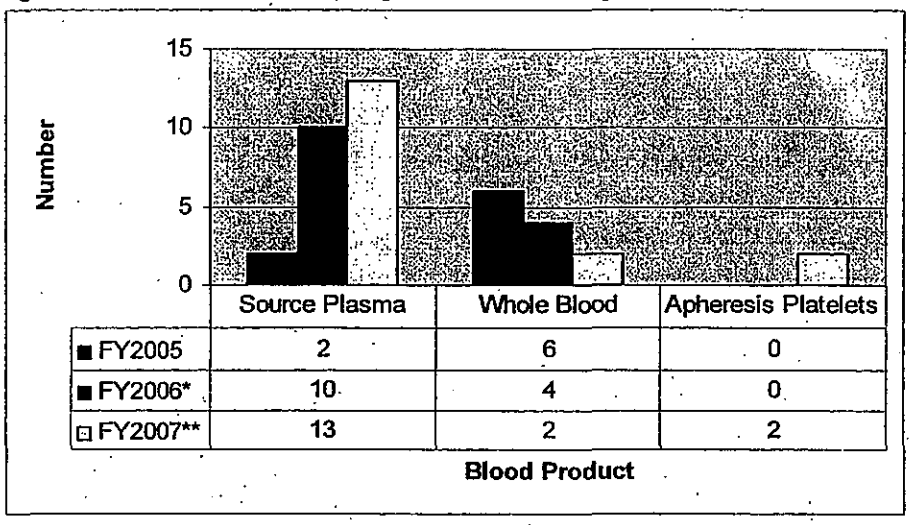
In FY2007, we received reports of two fatalities following Whole Blood donation, both autologous, collected by manual methods. In both cases, our medical reviewers found no evidence to support a causal relationship between the donation and subsequent death of the donor. For eight of the nine Whole Blood donations (includes two autologous donations) reported in FY2005 and FY2006, our medical reviewers found no evidence to support a causal relationship between the donation and subsequent death of the donor. In one FY2006 case, an autologous donation, our medical reviewers could neither confirm nor rule out the donation as contributing to the donor's death.

Table 6: Post-Donation Fatality Reports by Donated Product, FY2005 through FY2007

Donated Product	FY05	FY06	FY07
Source Plasma	2	10	13
Whole Blood	6	4*	2**
Apheresis Platelets	0	0	2
Total	8	14	17

*Includes 2 autologous donations
**Autologous donations

Figure 6: Post-Donation Fatality Reports, FY2005 through FY2007



*Includes 2 autologous Whole Blood donations
**Both Whole Blood donations in FY07 were autologous