

**Central Blood Bank
Pittsburgh, PA**

Evaluation of Donor Platelet Counts in Relation to Donation Frequency

In response to the draft guidance issued by the FDA in September 2005, titled 'Collection of Platelets by Automated methods' the Central Blood Bank conducted a study to evaluate the relationship, if any, between the frequency of donation and donor platelet count.

We looked at our entire apheresis donor population during the time frame of 10/01/2004 through 9/30/2005. In that time period, the average donation frequency was 3.7 donations per year. Platelet counts of a subset of 227 donors (Group A) who donated 4 times/year were investigated. The mean initial platelet count for that group was $262 \pm 53 \times 10^3/\text{ul}$. The mean final platelet count for that same group was $258 \pm 57 \times 10^3/\text{ul}$.

We then looked at our most frequent donors (Group B) during the time frame of 10/1/2003 through 9/30/2005, who donated at a frequency greater than 12 times per year. In that time frame the average donation frequency of 64 donors was 14.65 per year. The mean initial platelet count for Group B was $267 \pm 53 \times 10^3/\text{ul}$. The mean final platelet count for the same group was $267 \pm 52 \times 10^3/\text{ul}$.

We also looked at those donations associated with a platelet yield less than 150,000/ul. Within Group A there were 2 such donors or .88% of the donors involved in this study and .22% of the donations. A 45 year old male (Donor A1) during the time frame of the study donated 4 times with a total of 5 platelet products. His initial count on 12/23/2004 was 205, on 4/15/2005 the count was 148, on 7/24/2005 the count was 197, and on 8/21/2005, the count was 197. The donation on 8/21/2005 was the donation that yielded two platelet products. A 35 year old male (Donor A2) during the time frame of the study has a history of 4 donations with 4 products as a result of those donations. His initial count on 12/1/2004 was 155, on 6/7/2005, the count was 170, on 7/26/2005, the count was 160, and on 8/30/2005, his last donation in the time frame of the study, was 146.

Within Group B there were a total of 2 donors with a platelet count that fell below 150,000/ul. This is 3.1% of the donors from Group B involved in this study and .67% of the donations. A 47 year old male (Donor B1) donated a total of 16 times during the time interval involved in this study. These 16 donations yielded a total of 24 products. His initial platelet count was 244 on 10/9/2004. On his 8th donation on 2/26/2005, during the time frame of the study, his platelet count was 100. His following donation took place on 3/19/2005, and at that time his platelet count was 214. Eight donations later on 8/27/2005 or his 16th donation during the time frame of the study, his platelet count was 239. At no other donation interval did this donor's platelet count fall below the acceptable range. The second donor in group B whose platelet count fell below 150,000 is a 47 year old male (Donor B2) who donated a total of 12 times, in the time frame of the study. These 12 donations yielded a total of 23 products. During his first donation on 10/11/2004, his platelet count was 226, 10 donations later on 6/27/2005 his count was 62. On his next

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donation which occurred 7/25/2005, his platelet count was 243, and his final count on 9/8/2005, for the time frame of the study was 229. At no other time in the time frame of the study did this donor's platelet count fall below the acceptable limits.

We next looked at the product yield for those donations in which the donor platelet count fell below the acceptable limits and found the yield of the products to be of satisfactory content (TABLE 1). This leads us to conclude, that with the possible exception of Donor A2, the donor platelet counts that fell below the acceptable limits were most likely a result of inaccurate test results.

TABLE 1

DONOR	DONOR PLATELET COUNT	PRODUCT YIELD
A1	148	5.25 x 10e11
A2	146	3.2 x 10e11
B1	100	5.5 x 10e11
B2	62	7.12 x 10e11

In Group B there are a total of 1461 platelet products during the time frame of the study and a total of 937 donations or an average of 1.6 platelet products per donation. The mean number of products per donor for Group B is 23.

We then looked at a subset of Group B, (Group C). The population of Group C is the donors with a donation frequency greater than 12 donations per year and yielding a total of 25 or more products per donor, during the time frame of the study. The population of Group C consists of 25 donors with a mean average of 30 products per year. The mean initial donor platelet count in Group C is 276 ± 49 , and the mean final donor platelet count for the same group is 275 ± 52 . Group C donated a total of 487 donations for a total of 751 platelet products or an average of 1.5 platelet products per donation. In Group C there are no donors that experienced a decrease in their donor platelet count below 150,000/uL.

In summary, this study shows that donors who donate 12-24 times per year adequately maintain their platelet levels. We believe these data support the current standard of donation frequency allowing a maximum of 24 per year without restrictions on the number of products donated.