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Donor Return Following Temporary Deferral

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Abstract

Background—The consequences of temporary pre-donation donor deferrals are unsatisfactorily understood. Previous studies have found that deferral negatively impacts future return for donation in both first time and repeat donors. However, the applicability of these findings across centers has not been established.

Methods—Using a cohort design, presenting donors with a temporary deferral in the years 2006 – 2008 in 1 of 6 categories (low hematocrit, blood pressure or pulse, feeling unwell, malaria travel, tattoos/piercing and related exposures, or couldn't wait/second thoughts) were passively followed for up to a 3-year period for the time to first return after the expiration of the deferral at 6 US blood centers. Time-to-event methods were used to assess return following the receipt of each deferral. We also analyzed which donor characteristics are associated with return following temporary deferral using multivariable logistic regression.

Results—Of 3.9 million donor presentations, 505,623 resulted in deferral in 1 of the 6 categories. Low hematocrit was the most common deferral, had the shortest median time to return, and largest cumulative number of donors returning. Deferrals of shorter duration had better return. Longer term deferrals (up to 1-year in length) had the lowest cumulative return which did not exceed 50% during the study period for malaria travel or tattoo/piercing and related exposures. In multivariable logistic regression modeling, return following deferral was associated with previously identified factors such as repeat donor status, older age, and higher educational attainment regardless of the type of deferral. In addition, return was associated with having been born in the USA, Asian race/ethnicity, and donation at fixed sites regardless of the type of deferral.

Conclusion—The category of temporary deferral influences the likelihood of future return, but the demographic and donation factors associated with return are consistent regardless of the deferral.

Introduction

Potential blood donors may be classified as ineligible to donate for a variety of reasons related to behavior and medical conditions.¹ Temporary donor deferral is used to protect recipients of blood from possible infectious disease exposure or is used to protect donors if

health status measures such as hematocrit or blood pressure are outside acceptable values. Temporary deferral is known to be non-specific; the majority of donors who receive temporary deferrals are unlikely to pose a threat to the safety of transfusion. Several previous studies have investigated the impact of donor selection on blood donation.¹⁻¹⁰ At least 6 of these studies provided quantitative estimates of donor return following deferral.^{1,3,4,7,9,10} These previous studies have consistently demonstrated that temporary deferral, no matter how short in duration, represents a virtually indefinite deferral for a sizable percentage of both first time and repeat donors because donors often never attempt to donate again.

One previous study that examined different categories of temporary deferral found the type of deferral had a large influence on future return for donation in both first time and repeat donors.¹ However the generalizability of these findings to other centers is in doubt as the study was conducted at a single blood center and could be influenced by that center's practices. A study from a nationally-representative sample reflecting donors who present at different blood collection agencies has yet to be reported. In this analysis, we investigated pre-donation temporary deferral by analyzing deferred donor return following the expiration of these deferrals at the 6 Retrovirus Epidemiology Donor Study-II (REDS-II) blood centers.

Materials and Methods

The REDS-II centers represent geographically and demographically diverse populations and collectively represent over 8% of annual blood collections in the USA. The REDS-II blood centers are: the Blood Centers of the Pacific, in San Francisco, CA; Blood Centers of Wisconsin, in Milwaukee, WI; Hoxworth Blood Center, in Cincinnati, OH; the Institute for Transfusion Medicine, in Pittsburgh, PA; the American Red Cross, New England Region, in Boston, MA; and the American Red Cross, Southern Region, in Atlanta, GA. These centers provide donation and deferral data that is processed into a common research database by the REDS-II Coordinating Center, Westat, Inc, Rockville, MD.

In this analysis we focused on a limited set of temporary deferrals. These include deferral for travel to malaria endemic areas, recent tattoos or piercing, feeling unwell, low hematocrit/hemoglobin, blood pressure or pulse, and donors who had second thoughts or couldn't wait. Some deferrals were combined to create the 6 deferral categories for this analysis. For example blood pressure or pulse outside of acceptable ranges was grouped into a single category. Likewise the category of feeling unwell includes any transient illness such as elevated temperature, colds, or flu. Similarly, the category of tattoo and piercing also includes electrolysis and other non-surgical cosmetic procedures. The category of second thoughts/couldn't wait is defined in different ways at the blood centers and includes donors who decided they did not want to donate or indicated they didn't have time to donate following registration. Instead of being a blood center initiated deferral, this is type of deferral is initiated by the donor. It was included in this analysis to see if differences exist between blood center and donor initiated deferrals.

The analysis was restricted to presenting blood donors in years 2006 through 2008. The donors in the study received a deferral during donation eligibility assessment. The length of the deferral period for the 6 deferral categories varies from as little as 1 day at most of the REDS-II centers for the majority of deferrals included in the analysis to as long as 1 year for travel to malaria-endemic areas or recent tattoo or piercing. However, these longer-term deferrals are based on the date the deferrable behavior or exposure happened as opposed to the date the donor presented to donate, so that in most cases these longer-term deferrals are less than 1 year's duration. An individual ineligibility period was calculated for each donor based on the date of the deferral and the date when the deferral lapses. Donors were

passively followed for the date of return to the blood center up until December 31, 2008. All donors who did not return were censored on this date. In addition for tattoo/piercing deferral is managed in different ways based on State regulations and blood center medical policy so that deferral at 1 center might not have lead to deferral at another center.

James and Matthews have described how time-to-event methods can be used to quantify donor return behavior.^{11,12} Conceptually, a temporary deferral resets the clock meaning the expiration of the required deferral period represents a new time zero after which the time to return to the blood center can be determined. Kaplan-Meier (KM) curves were generated to determine the time to first return and cumulative pattern of first return based on the category of deferral. Overall KM and stratified curves by key factors were generated. For time to return we included all returning donors regardless of whether they were determined to be eligible or ineligible at the return. In addition, we estimated the percentage of donors out of the initial cohort who successfully donated at least once following the deferral according to the category of deferral and donor characteristics. A comparison group of eligible whole blood donors who were not deferred during an index presentation in 2006 – 2008 were included so that we could compare time to first return and cumulative total returning during the same time frame.

The demographic and donation factors associated with return following deferral were identified using multivariable logistic regression. For each deferral a separate multivariable logistic regression model was estimated with the outcome defined as returning or not within a 400-day period following the expiration of the deferral. Each multivariable model included the following explanatory variables: age in groups, gender, race/ethnicity, location of birth (USA or elsewhere), donation history (first time or repeat), educational attainment, and collection site (fixed or mobile) at the time of deferral. The explanatory variables included in each model were the same across the deferral categories in order to assess whether donor characteristics associated with returning are different for the different deferral categories. Odds ratios (OR) for the likelihood of returning were estimated for each level of explanatory relative to a reference group. Ninety-five percent confidence intervals (95% CI) that did not include a value of 1.0 for each OR were considered evidence of statistically significant differences between the levels of each explanatory variable. Statistical analyses were conducted using SAS version ??, Cary, North Carolina.

Results

Between 2006 – 2008 there were over 3.9 million donor presentations to the REDS-II centers. There were 655,308 presentations that resulted in deferral with 505,623 (77%) in the 6 temporary deferral categories included in this analysis. The most common deferral was for low hematocrit/hemoglobin, representing over 76% of the 6 deferrals in this analysis followed by blood pressure or pulse, feeling unwell, travel to a malaria-endemic area, second thoughts, and tattoo, piercing or electrolysis (Table 1). Low hematocrit/hemoglobin had the shortest median time to return of 155 days (95% CI 154 – 158). For all other deferrals the median return time was >300 days. In comparison, the median return time in accepted whole blood donors was 399 days (95% CI 398 – 403). The type of temporary deferral is important in predicting the time of return and cumulative number of returning donors (Figure 1). Tattoo, piercing and electrolysis had the smallest proportion of returning donors with less than 30% returning during the follow-up period. Note that at approximately 1-year following deferral each deferral category shows a small up-tick in the number of returns.

Stratified KM plots for repeat versus first time donor status and fixed versus mobile collection location demonstrate important differences in return according to these factors

(Figure 2). The up-tick evident in the overall KM curve is clearly related to return to mobile collection sites and is attributable to annual blood drives. The patterns of return following deferral were not the same for first time and repeat donors. In repeat donors there was some evidence of differences in donor return according to the type of deferral because the return curves have different shapes and cumulative return proportions. For return in first time donors, deferral for feeling unwell, blood pressure or pulse, and low hematocrit/hemoglobin were closely grouped together with approximately 30% of donors returning. Likewise return to fixed sites was much higher than return to mobile sites. Less than 55% of donors deferred for hematocrit/hemoglobin who tried to donate at mobile sites tried to donate again during the follow-up period. For other deferral categories return was even lower at mobile sites. For comparison we also estimated return in donors who were deferred overall and according to first time and repeat donor status. Cumulatively, just over 60% of all eligible donors return, which is comprised of 65% return in repeat donors and 44% return in first time donors. The proportion of repeat donors who were deferred for low hemoglobin/hematocrit, feeling unwell, or blood pressure/pulse and who came back to try to donate again were higher than the for whole blood donors who were eligible at index presentation.

In single variable stratified analyses, different donor characteristics were related to the frequency of successful subsequent donation. The relationship with gender was not consistent across the 6 deferral categories with males more likely to donate following most deferrals, but females more likely to donate following travel to malaria-endemic areas. Over 52% of males deferred for low hematocrit/hemoglobin successfully donated at least once during the follow-up period whereas this was true for 36% of females. For other donor characteristics the patterns were unique with respect to the particular donor or donation characteristics but largely similar regardless of the category of deferral (Figure 3). For example, except for the oldest age category, younger age donors did not subsequently donate in as high of proportion as older donors. Not surprisingly, first time donors were far less likely to have subsequent donations than were repeat donors regardless of deferral category. Similarly, for each deferral the pattern for country of birth showed deferred donors born in the USA were two times more likely to donate.

The multivariable logistic regression modeling accounts for confounding factors simultaneously and provides the best indication of the donor characteristics associated with return following deferral. Many demographic characteristics were consistently associated with a higher or lower likelihood of returning to donate (Table 2), including expected factors such as repeat donor status, older age groups, and higher educational attainment. Compared to younger donors, donors who are older are increasingly more likely to return following deferral expiration. Likewise, first time donors were less likely to return compared to repeat donors. Higher educational attainment was associated with return. Being born outside of the USA resulted in a lower likelihood of returning than if the donor was born in the USA. Interestingly, while in stratified analyses white donors had had higher percentage of successful donations following deferral, in multivariable analyses that controlled for other factors, Asian donors were the most likely to return following deferral than any other race/ethnicity regardless of the reason for deferral. Donation at fixed sites was associated with returning.

In the second thoughts/couldn't wait category for most explanatory variables the results from multivariable modeling were similar to those observed in the other deferral categories. These include associations between returning and male gender, repeat donation history, USA country of birth, and fixed collection site. Age groups were associated with increased or decreased likelihood of return, but not in a consistent manner. African American race/ethnicity was associated with lower likelihood of return compared to white donors, but no

other association with race/ethnicity was evident. Educational attainment was not strongly associated with return.

Discussion

In this analysis we investigated the impact of temporary donor deferral on future presentation at 6 representative blood centers in the USA. The results of this analysis substantiate previous analyses conducted within individual blood collection programs, and show that the 6 most common deferrals lead to different likelihood of donors trying to donate following the expiration of a deferral. In addition, specific donor demographic characteristics were strongly associated with the both the likelihood of returning during the following up period and also the percent of donors who successfully donated when they returned.

The type and duration of deferral appears to be related to donor return. Shorter duration deferrals tended to have better return. However the cumulative proportion of donors returning following deferral for travel to malaria endemic areas was similar to that of donors who self-deferred because they couldn't wait to donate or they had second thoughts, suggesting that deferral duration alone is not a critical factor in predicting donor return.

Recent tattoos, piercing or electrolysis had the lowest return probability. This low return may have two explanations. Some donors may misinterpret the deferral as a permanent. Alternately donors may be self-deferring based on ongoing risk exposure if they have had a newly applied tattoo. The approach to managing donors who present with recent tattoos has shifted in recent years such that at some blood centers recent tattoos are not deferrable if the tattoo was applied in a licensed facility. Donors with tattoos are managed this way in at least 1 of the 6 REDS-II centers. At this center donors with recent tattoos from licensed facilities were not be included in this analysis because they were not deferred as a result of the tattoo. However, for the other centers it is unclear whether donors misunderstand the deferral for tattoos or are at continued risk based of having newly or re-applied tattoos and self-deferring as result. Survey studies of deferred donors would likely be necessary to distinguish between these possible explanations.

Our analysis of donor return has limitations. This analysis focused on the first return following deferral. We did not assess the cumulative number of future donations during the study period. Some donors may have gone on to successfully donate multiple times after expiration of the deferral, or alternately been deferred multiple times. Analyses of these types of repeated events represent an important next step in analyses of the impact of deferral. The frequency with which deferred donors become long-term repeat donors would be expected to be lower than for similar donors who were never deferred, but was not assessed in this study.

Another potential limitation for the multivariable logistic regression analysis is that we focused on return within 400 days following the expiration of the deferral. The reason for doing this was to standardize follow-up time so that all donors had the same time under follow-up. Donors who returned outside of this interval were not included in the analysis of factors associated with return. The inclusion of a longer follow-up time could modify some of the observed associations.

The patterns of low return for several deferrals and particularly for first time deferred donors are consistent with previous studies, but analytical methods used are not identical so direct comparison of results is difficult. Another notable consistent finding is that for repeat donors a larger or similar proportions of donors deferred for specific short duration deferrals (hematocrit, feeling unwell, or blood pressure or pulse) returned than was observed for

eligible whole blood donors.¹ The results of this study substantiate that the type of deferral is related to the probability of donor return. Temporary deferrals intended to protect donors appeared to have better return than deferrals intended to protect blood recipients, although overall return was no greater than 60% for donors who were deferred for reasons other than low hematocrit/hemoglobin. Restricted to repeat donors, return was higher with 80% of donors deferred for hematocrit/hemoglobin returning at least once. However, only 40% of these repeat donors actually donated on this return visit. We did not evaluate what percentage of donors returned were deferred again, but the difference between the percent returning and percent successfully donating suggests that a substantial proportion of these donors are deferred again.

This study did not seek to assess the predictive value of deferrals that are intended to reduce recipient risk (travel to malaria endemic area, recent tattoo or piercing, feeling unwell or having a cold). For the USA the safety that these deferrals provide remains undefined. The American Red Cross has sought to evaluate the safety that some deferrals provide. However the deferrals that were associated with confirmed infectious marker positive results were directly related to a history of hepatitis exposure, including signs or symptoms, or to higher risk behaviors such as injected drug use.¹³

Donor characteristics that are either positively or negatively associated with returning were largely consistent across categories of temporary deferral. In other studies many of the same factors we report here (younger age, some minority race/ethnicity categories, and first time status) have been associated with lower return for eligible donors who have not been deferred.¹⁴⁻¹⁶ The implications of these findings is that deferral is an additional aspect that further reduces the likelihood of donor return. Thus re-recruitment strategies for deferred donors can parallel those for eligible donors, but may require special emphasis to overcome the impact of deferral on donors' willingness to return.

Our study further substantiates that the experience of receiving a temporary deferral is in effect an indefinite deferral for many donors. While presenting donors may or may not understand the reasons for deferral, large proportions of these donors do not present again regardless of the reason for the deferral. This remains an important area to better understand because these presenting donors have overcome the first barrier to donating by presenting. In particular the experience of deferral in first time donors may create a perception about the way blood centers treat potential donors that cannot be overcome. This may continue to be a burden blood centers are willing to bear because blood shortages are not currently evident,¹⁷ but could be far more problematic as the current donor base ages and is not replenished with new donors.

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Figure 1.

Time to return after the expiration of the each type of temporary deferral. The horizontal line indicates a 50% return proportion and the median return time for each deferral is indicated where each curve crosses this line. The vertical line represents a one year elapsed time period from the date of deferral expiration.

Figure 2.

Stratified time to return after the expiration of the each type of temporary deferral for repeat and first time donors (upper panels) and fixed and mobile collection site donors (lower panels). The horizontal line indicates a 50% return proportion and the median return time for each deferral is indicated where each curve crosses this line. The vertical line represents a one year elapsed time period from the date of deferral expiration.

Figure 3.
Panels A – G. Percent of temporarily deferred donors who return after deferral and successfully donate by deferral category and indicated demographic and donation characteristics.

Table 1

Proportion of donors returning following deferral at the REDS-II blood centers in 2006 for the six most common categories of temporary deferral.

Deferral category	Number at index	Number of donors returning	Time in days when 25% had returned (95% CI)	Time in days when 50% had returned (median return time) (95% CI)
Low hematocrit	385,439	240,704	53 (52 – 54)	155 (154 – 158)
Blood pressure/pulse	34,401	16,834	75 (72 – 77)	364 (357 – 364)
Feeling unwell/colds/temperature	32,106	16,483	73 (71 – 77)	313 (298 – 336)
Couldn't wait/second thoughts	16,684	7,333	78 (74 – 83)	818 (728 – 1013)
Malaria travel deferral	27,006	9,396	143 (136 – 151)	* (LB ** 1043)
Tattoo/piercing/related exposures	10,058	1,708	816 (LB ** 691)	* (LB ** 1156)
Eligible whole blood donors (non-deferred donors)	1,265,091	642,319	92 (92 – 93)	399 (398 – 403)

* Less than this percent returned during the up to 3-year follow-up period.

** Lower bound (LB) of 95% CI.

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Table 2

Odds ratios for returning from multivariable logistic regression modeling by deferral category and donor characteristics. Separate models were fit for each deferral category. Grey cells represent factors that were associated with significantly decreased donor return compared to the corresponding reference category, and cells with numbers in italics and marked with asterisks represent factors that were associated with a significantly increased donor return compared to the reference category.

Donor Characteristic	Deferral Category				
	Low hematocrit/hemoglobin	Blood pressure or pulse	Feeling unwell	Malaria travel	Tattoo/piercing/electrolysis
Gender					
	Male	1.0	1.0	1.0	1.0
	Female	0.83	0.95	1.06	1.06
Age group					
	16-20	1.0	1.0	1.0	1.0
	21-30	0.91	0.86	0.79	0.86
	31-40	1.15*	1.05	1.17*	1.31*
	41-50	1.37*	1.20*	1.45*	1.78*
	51-60	1.59*	1.38*	1.54*	1.64*
	61-70	1.54*	1.43*	1.61*	2.06*
	70+	1.43*	1.58*	1.69*	0.94
Country of Birth					
	Outside of USA	0.37	0.27	0.33	0.09
	In USA	1.0	1.0	1.0	1.0
Race/ethnicity					
	Asian	1.29*	1.71*	1.57*	1.59*
	Black	0.64	0.85	0.71	0.71
	Hispanic	0.99	0.94	1.03	1.15
	Other	0.86	0.84	1.01	0.99
	White	1.0	1.0	1.0	1.0
Donation history					
	First Time	0.25	0.32	0.48	0.65

Donor Characteristic	Deferral Category					
	Low hematocrit/hemoglobin	Blood pressure or pulse	Feeling unwell	Malaria travel	Tattoo/piercing/electrolysis	Second thoughts
Repeat	1.0	1.0	1.0	1.0	1.0	1.0
Education						
High school or less	0.92	0.96	0.98	1.11	0.78	0.86
High school diploma/GED	0.92	0.84	0.80	0.89	0.72	0.84
Some college	0.94	0.86	0.88	0.90	0.88	0.92
College degree or higher	1.0	1.0	1.0	1.0	1.0	1.0
Collection Site						
Fixed	1.0	1.0	1.0	1.0	1.0	1.0
Mobile	0.38	0.40	0.32	0.39	0.44	0.26
Key	x	Significantly lower return odds compared to the reference group				
	x*	Significantly higher return odds compared to the reference group				