Attachment 3

Investigating the Causes of Post Donation Information (PDI): Errors in the Donor Screening Process

For the National Heart, Lung, and Blood Institute
Retrovirus Epidemiology Donor Study-II

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INVESTIGATING THE CAUSES OF POST DONATION INFORMATION (PDI): ERRORS IN THE DONOR SCREENING PROCESS

SUMMARY

Obtaining an accurate health-history prior to blood donation is a key step in protecting the safety of the blood supply. However, the health history process is known to be error-prone and the reasons for those errors are largely unknown and untested. Frequently donors fail to report a risk that would have resulted in deferral, but at a subsequent point, information is learned that results in deferral, consignee notification and product recall. Post Donation Information (PDI) events are clear examples of the kind of errors that can occur during the donor health history screening process. PDI most often represents an occasion where information that should have been provided as part of the health history process is not disclosed during the index donation visit, but rather is provided by the donor, or other reliable source, subsequent to the donation. Most PDI is discovered at a subsequent donation event when a deferrable history is now disclosed by the donor. This may be at the next donation event, but many examples of PDI are not disclosed nor discovered until several intervening donation events have occurred. The reasons why donors fail to disclose a deferrable history at the time of one donation but subsequently disclose this information at a later time are unknown and unstudied.

This protocol is designed to ascertain why PDI error events occur. We will investigate PDI events by conducting in-depth individual telephone interviews with donors involved in PDI. These interviews will provide important information about why PDI occurs – a question that has never been addressed with any scientific rigor. The interviews will ask the identified donors to discuss the PDI in question including why they failed to disclose the deferrable information at the index donation, general understanding of the donor health history questionnaire, their views on the donor screening process in general, and their opinions about how they were treated at the blood center. For comparison purposes, representative telephone interviews will also be done with donors who were properly deferred from donating blood (and are not PDI donors) and donors who were accepted.

We propose this as an exploratory study that will allow us to better understand the problems and issues related to the health-history screening process and the roles that donors and

health-historians play. By gathering these initial data on PDI donors and the reasons for PDI events, we lay the ground work for a possible larger scale PDI donor survey to further examine these issues. This will also allow us to strategize potential interventions as a comprehensive part of a phase two study. Additionally, given the present dearth of information about why these errors occur, we believe this initial study with interviews of PDI and deferred donors will provide meaningful insight on this problem that may be useful in helping reduce the incidence of PDI while also providing publishable data regarding this problem.

A. BACKGROUND AND SIGNIFICANCE

Background

The donor health-history taking process is considered one of five levels of protection designed to safeguard the blood supply. Infectious disease testing, deferred donor registry, quarantine procedures, and error/accident reporting to the FDA with corrective action are the other four. Of concern in the health-history process is obtaining a complete and accurate history from the donor at the time of donation and the historians' ability to elicit this information and to make correct decisions regarding donor suitability, the most prevalent category and cause for FDA reportable Blood Product Deviations (BPD).

Data from the FDA's FY07 Annual Summary on Blood Product Deviation Reports[1] show that errors and accidents related to donor suitability account for the majority of BPD reports - 75.4% for a total of 32,380 reports (Table 1). The majority of the donor suitability BPD reports (30,033) are due to Post Donation Information (PDI). PDI is commonly defined as information that the donor should have provided at the time of donation. In FY07 most PDI information (90%) was known by the donor at the time of the index donation (the donation where the deferrable history was known by the donor and not disclosed) but, for unknown reasons, was not provided. Most of the remaining cases of PDI are things not known by the donor at the time of donation but later reported. This might include the subsequent diagnosis of a disease and the donor calls to inform the blood center of this new health information that may pose recipient risk. Most of the remaining BPDs (2,027) related to donor suitability were outright donor screening errors made by the health historians during the screening process and most frequently were related to accepting donors with an overt history that was deferrable.

There has been no change in these data since the FDA began publishing them in FY01. The donor suitability system and PDI account for the largest number of BPD reports, but there has been almost no research into why these PDI and donor screening errors occur or what could be done to prevent or reduce their occurrence.

Table 1 – FY07 Blood Product Deviation Data Reported to the FDA from all blood and plasma manufacturers*

Total Blood Product Deviation Reports (BPD)	42,830 (100%)		
Total BPD Reports related to donor suitability	32,280 (75.4%)	Post Donation Information (PDI) a. Licensed Blood Establishments b. Other centers	30,033 (70.1%) 22,856 7,177
		Donor Screening Errors	2027 (4.7%)
		Donor Deferral Errors	220 (0. 5%)
Total BPD Reports due to other reasons**	10,550 (24.6%)		

* licensed and unlicensed blood establishments, plasma centers and transfusion services

**QC, distribution, labeling, laboratory testing, collections and component preparation

The types of deferrals behind PDI vary but all the reasons for PDI deferral clearly pose potential recipient safety issues. Nationwide in FY07 the majority of PDI were due to a history of travel to a malaria area/history of malaria (32.9%) that put the donor (and thus the recipient) at theoretical risk for malaria followed by a history of travel related to a theoretical risk for variant Creutzfeldt-Jakob Disease (vCJD) (17.4%). Other less common but still significant reasons for PDI include a history of disease or surgery; tattoo or piercings in the past 12 months; receiving Proscar, Tegison or Accutane; taking antibiotics or other medication; male to male sex; IV drug use; and having had a bone graft or transplant and these occur in significant numbers every year. Appendix A contains a table that shows the specific breakdown of PDI for licensed establishments by type in FY07.

PDI is usually provided by the donor subsequent to the index donation, but it may also be provided by a third party. Eighty-eight percent of deferrable PDI histories reported to the

FDA in FY07 were disclosed at a subsequent donation by the donor but not necessarily at the next immediate donation. Thus, blood components manufactured from the index donation and any intervening donations prior to disclosure of a deferrable history would most likely have been transfused by the time a PDI is identified. While increased testing and new test methodologies have done much to make the blood supply the safest it has ever been, testing has not yet been implemented for vCJD or malaria and the most numerous PDIs are due to a history of travel that puts the donor and recipient at theoretical risk for these two diseases. Furthermore, even for the infectious agents for which tests exist, there is always the chance that an infectious donor may give in the window period before detection is possible.[2] Many of the behavioral PDI reasons involve donors who could have window period risk.

In previous REDS studies, two anonymous mail surveys sent to 50,162 and 92,581 US blood donors retrospectively captured the levels of unreported deferrable risks (UDRs) that ranged from 1.7% in 1993[3] to 2.45% and 3.01% for whole blood and apheresis donors respectively in 1998.[4] UDRs were defined as behaviors that would have resulted in donor deferral had they been reported (such as being a man who had sex with another man (MSM) since 1977, injection drug users, etc.). These UDRs are also reasons for PDI and are clearly associated with the safety of the blood supply. Both PDI and UDR may relate to a failure of the health history screening process to capture risk factor information.

While there is detailed information available on the breakdown of PDI types and when they are identified, there is a clear absence of research on why this health history information is not obtained, nor volunteered, at the index donation, but is disclosed subsequently. Blood establishments generally believe a PDI event is "caused" by the donor, but that is unlikely to be the whole story. We suspect that the reasons behind PDI are likely to be many and varied based on what little information is available in the literature.

One of the first things that might influence the occurrence of PDI is that the donor does not read or fails to understand the educational materials accompanying the questionnaire. Rugege-Hakiza and colleagues[5] reported that among respondents to an anonymous mail survey, those donors who were less educated, had a reactive screening test or UDR, or donated to receive an HIV test (HIV test seekers), were more likely to find the educational materials difficult to understand. Difficulties in comprehension may greatly influence a donor's ability to answer questions completely and accurately. Lack of comprehension may also be due to not using a

donor's preferred language during the health-history taking process. Demographic profiles of first-time donors at five US blood centers over a 5-year period noted an increase in the number of non-US-born donors with a concomitant decrease in the number of US-born donors.[6] Lack of comprehension may also occur when a donor has less education. As noted in the study above, 33.5% of donors evaluated had some college education, but 12.1% of first-time donors from these five centers had less than a high school education.

Donors may simply not understand the questions being asked. In a study that evaluated the content and clarity of seven health-history questions from the American Red Cross blood donor questionnaire that were prone to result in PDI, a focus group of donors provided simplified language that became helpful in formulating the AABB Uniform Donor History Questionnaire.[7] Further, the mode of questioning may also influence the donor's likelihood to provide accurate and complete responses. While studies have suggested that oral questioning of high-risk behaviors by health historians may result in more responses that are truthful, other data suggest that self-administered questionnaires about sensitive information are more likely to result in truthful responses about behaviors of a personal nature.[8-11] Computer-assisted self-interviewing may also result in the disclosure of risk factors associated with personal behaviors.[12] Katz and colleagues[13] reported increased admissions of high-risk behaviors using computer-assisted self-interviewing when compared to paper-and-pencil self-administered questionnaire, but the number of PDI events did not differ between the two donor screening methodologies.

It is also highly likely that the health historian contributes to PDI events either through failure to use resource materials available to them or failure to use appropriate follow-up or probing questions to elicit a more accurate health history. The latter was demonstrated by Lee et al. who showed in their study that donors should have been deferred based on their answers to travel and disease history questions.[14] Historians may also be providing an environment that makes it hard for donors to respond correctly. We know that donors are reluctant to stop the health historian to ask clarifying questions, particularly if the health historian is going quickly.[15]

In addition to these reasons, we hypothesize that there are many other places where potential error can occur in the health history screening process that have not been investigated. For example, does the donor understand why specific questions are asked? Further, how comfortable are donors in disclosing personal health history information that may not be acceptable by all segments of society? Are donors fearful of being denied the ability to

donate if they admit to certain health histories? Until a systematic study of PDI errors is done, all we have are speculations or educated guesses as to why these events occur.

Significance

This study is important for many reasons. It will be the first study of any kind to address the issue of PDI errors in any systematic fashion. By conducting interviews with donors involved in PDI errors, we will gain important qualitative knowledge about this problem. Information gathered from these interviews will not only elucidate the issue of PDI but will provide insight into donor understanding of the screening process and their feelings about the process and blood donation in general.

Although a critical step in safe-guarding the blood supply, the health history screening process is known to be error prone. This is evidenced by the volume of donor suitability errors that are reported to the FDA as Blood Product Deviations. The majority of these deviations are due to the non-disclosure of information known by the donor at the time of donation. These post-donation information errors are typically discovered at a subsequent donation, after products from the index donation are likely transfused. While blood centers may attribute these types of events to the donor, it is unknown what causes the donor to fail at one time to disclose certain international travel destinations, personal health history information, or high risk behaviors like MSM, but subsequently reveals this information. Donor behaviors related to the health history process and the reasons for failure to give an accurate health history have not been studied.

If we can more fully understand how and why PDI errors occur in donors, we will have made an important contribution to the literature using a methodology of data collection that is extremely informative and relatively low cost. At this point, all we have is theories on why PDI occurs but no systematically collected empirical data with which to substantiate them. Depending on the outcome of this study, there are several possible avenues we can pursue. If the interviews reveal clear domains of concern, plans can be made to collect information from larger groups of PDI donors using a structured survey that could also address problems related to comprehension or interpretation of the questions. If the interviews elucidate the reasons for PDI occurrences from the donors' perspective but present no further research questions to address, we

can report this in the literature, but also consider designing interventions to help reduce PDI occurrences.

Finally, learning about PDI adds importantly to our knowledge of donor behavior by shedding light on the donor screening process as a whole and the interaction of the donor with the blood center staff. We know that temporarily deferred donors are less likely to return to donate, and some PDI donors are temporarily deferred as they attempt to donate. Therefore, it would also be of interest to evaluate the relationship between these donors' responses and their plans to donate in the future, which could impact blood availability.

B. OBJECTIVES

B.1 Primary Objectives

1. To explore reasons behind errors in the donor screening process when donors initially fail to disclose an accurate and complete health history.
2. To explore PDI donors' knowledge, attitudes, behaviors and beliefs (KABB) about the health history questionnaire and their experience with the screening process and the center.
3. To compare KABB in PDI donors to deferred (but not PDI) donors and accepted donors.

This study will address the following primary hypothesis:

B.2 Primary Hypotheses:

1. PDI donors will express that they had more difficulties understanding the donor health history questionnaire than donors who were appropriately deferred or accepted donors.
2. PDI donors will report more dissatisfaction with the screening process including concerns that it is too lengthy, that questions are redundant or unnecessary given that all donations are tested for disease.
3. PDI donors will be more likely to express having issues with the blood center staff than deferred or accepted donors.

C. STUDY POPULATIONS

C.1 Inclusion Criteria:

C.1.1 Donors with a PDI: Donors with a PDI **(PDI-donors)** will be defined as identified donors with an FDA reportable donor suitability BPD classified as PDI and a temporary or permanent deferral at the REDS-II centers. Donors who did not know about their PDI at the time of donation such as donors who were diagnosed with a disease subsequent to their donation that presents recipient risk will not be included. PDI donors identified from hearsay or third-party sources will likewise be excluded.

C.1.2 Deferred donors: Donors who attempted to donate but were appropriately deferred at the REDS-II centers. These donors will not be deferred PDI donors.

C.1.3 Accepted Donors: Donors appropriately accepted for donation at the REDS-II centers

C.2 Exclusion Criteria:

Donor who are 18 years and older will be approached to participate in the study. 17 year old donor will not be eligible to participate.

D. STUDY ENROLLMENT AND DESIGN

D.1 Questionnaire and Screening Process

D.1.1 Responsibilities of Blood Center Research Staff – Recruitment of Subjects for Study

Telephone interviews will be conducted with enrolled donors to collect information regarding their knowledge, attitudes, behaviors and beliefs about the donor health history process. We plan to interview a total of 60 PDI donors, 30 properly deferred donors and 12 accepted donors (Table 2). Overall, each centers' research staff will be responsible for recruiting 10 PDI, 5 deferred and 2 accepted donors. Even though the interviews with the donors

will be individual, we would like to form groups of similar PDI and deferred donors for analysis purposes.

The five groups of interest include PDI occurrences or deferrals that are due to

- Travel (malaria, vCJD)
- Medical (history of diseases including jaundice/hepatitis, surgery and medications needed to treat disease including Tegison, Proscar and Accutane)
- Blood/Disease Exposure – (tattoo, piercings, accidental needle stick)
- High Risk Behavior – Sexual (MSM, sex with IV drug-user or test-positive individual)
- High Risk Behavior – Non-Sexual (IV drug use, non-sexual exposure to Hepatitis C or Hepatitis B.

Each center will recruit sufficient donors to assure two PDI donors and one deferred donors within each category and two accepted donors. Blood center staff will contact the identified donor and if the donor agrees, will mail study packet to him/her. The study packet will include information material and the consent form for study participation and for the coordinating center to call and schedule an interview. The donor will be instructed to return the signed consent to the blood center. The interviewer from the coordinating center will then contact the donor to schedule an interview. We believe each center should project needing to contact approximately 68 donors. We are assuming that 50% of all approached donors will consent to participate in the study. The number of donors approached at each center will provide margin for further attrition incase some of the consented donors change their mind and opt to discontinue when contacted by the coordinating center to schedule the interview. Because enrollment will be prospective, the overall number of donors to contact could potentially be less if consent rates are higher than expected. In other words, if the first PDI Malaria Travel deferral consents to contact and successfully completes the interview, the blood center would not need to recruit for this category again. They would, however, still need to recruit a vCJD donor from this category. Table 2 lists the PDI/deferral reasons of interest within the 5 broad categories.

Table2: List of PDI/Deferral Reasons of Interest

Broad Categories	PDI/Deferral Reasons of Interest
Travel	Variant Creutzfeldt-Jakob Disease (vCJD)--Travel
	Travel to malaria area/history of malaria
Medical	History of surgery
	History of disease
	Received Proscar, Tegison or Accutane
	Received tissue allograft or transplanted organ
	Received medication, antibiotics, vaccine or immune globulin
	History of hepatitis (type not specified), HBV, HCV or jaundice
	Risk factors associated with CJD
	Donor received transfusion or clotting factors
Blood/Disease Exposure – not drug related	Accidental exposure to blood or body fluids
	Donor received body/ear piercing or tattoo or both
High Risk Behavior – Not sex	IV drug use
	Incarcerated/Multiple risks
	Non-sexual exposure to HIV, hepatitis (type not specified), HBV, HCV
High Risk Behavior - Sex	Male to male sex or female to male who had sex with male
	Exchanged sex for drugs or money/Sex with high risk behavior partner
	Had STD or Sex partner was positive for STD, HIV, HTLV, HBV, HCV, Hep
	Donor/sex partner lived in or immigrated from HIV group O area

Table 3: Estimated number of donors needed for interviews

Donors	Travel	Medical	Blood/Disease Exposure (not drug related)	High Risk Behavior (Sex)	High Risk Behavior (Not Sex)	Total
PDI	12	12	12	12	12	60
Deferred	6	6	6	6	6	30
Accepted						12

Within a week of their PDI identification, appropriate deferral or accepted donation, research staff will call the identified donor and obtain permission to mail a study

packet and consent form. This packet will explain the study to the donor and will request him/her to return the signed consent form. By signing the consent form, the donor will agree to participate in this study and to be contacted by the coordinating center for scheduling an interview. Donors who do not respond to the letter within 7 business days will need to be called by the blood center research staff to confirm receipt of the letter and ascertain their willingness to participate in the study. In the letter and over the phone, donors will be asked to consent to having their contact information sent to the coordinating center so that the Westat interviewers can contact them to set up an interview. If the donor subsequently refuses to participate when contacted by the coordinating center, this information will be relayed back to the blood center and the research staff will then have to find a replacement donor of the same type to interview. It should be stressed to the donors that the central coordinating center is conducting the study to ensure the anonymity of their responses and none of the individual donor responses will be sent back to the blood center. Detailed information on how to recruit for each type of donor is detailed in the following three sections.

D.1.2 Recruitment of Donors into the PDI sample

Each center will be responsible for recruiting 10 PDI donors for interviews. Data obtained from the six REDS-II centers indicate that the vast majority of PDI events are discovered at the time of a subsequent donation visit, usually because of new histories that result in a deferral. Less often, PDIs are discovered when donors contact the centers to inform them of changes in their health histories and through communication with donors during telerecruitment. For enrollment, the REDS-II centers' operations and/or quality assurance staff will notify the blood center research staff of any donor identified as having a PDI and a temporary or permanent deferral. This identification will occur on a real-time basis and potential PDI donors will be recruited prospectively to participate in the study. Centers will need to recruit several different types of PDI donors within each of the five groups to ensure a representative sample. For example, for the Travel category, it would be necessary to recruit both Malaria and vCJD PDI travel deferrals. Based on estimates from June 2006 – July 2007 for all 6 REDS-II centers, we anticipate that four months will provide sufficient time to allow for the identification and recruitment of donors for interviews. Table 4 details the total number of PDIs of interest in this study at the six REDS-II centers during June 2006 – July 2007. This table excludes donors who

contact the center after donation to report a new diagnosis of a disease or an illness like a cold or flu that developed after their donation as this represents knowledge that was not known by the donor at the time of donation. We will not be pursuing PDI donors for the interviews that came to the attention of the center from hearsay or third-party sources.

Table 4: PDI Events at the 6 REDS-II centers from June 2006-July 2007

Interview Group	Representative PDIs Included	Number from July 1, 2006 – June 30, 2007
Travel	Creutzfeldt-Jakob Disease (vCJD) – travel; Travel to malaria endemic area/history of malaria	1209
Medical	History of any kind of hepatitis or jaundice; Donor received transfusion, clotting factors, tissue allograft, transplanted organ; History of disease or surgery; History of Cancer; Hx or risk factors associated with Creutzfeldt-Jakob Disease; Received finasteride, Tegison, Accutane, or Avodart; Received medication or antibiotics	418*
Blood/Disease Exposure	Donor received tattoo, ear or body piercing; Donor received accidental needle stick, exposed to blood or body fluids; Exposure to a disease	128
High Risk Behavior – Sexual	Sexually transmitted disease; Sex partner has or had a sexually transmitted disease; Sex partner tested reactive for HIV, HBV, HCV; Male to male sex; Female had sex with MSM; Sex with IV drug user; Donor or donor's sex partner lived in or immigrated from an HIV Group O risk area; Donor or donor's sex partner exchanged sex for drugs or money	206
High Risk Behavior – Non Sexual	IV drug use; Non-sexual exposure to HIV or any kind of hepatitis; Incarcerated	98

*Note – 174 of these were because of a history of cancer which is now not considered a PDI by the Food and Drug Administration.

D.1.3 Recruitment of Deferred Donors

Each center will be responsible for recruiting 5 deferred donors for interviews, one from each group of interest. Deferred donors will be recruited during the same period that the PDI donors are and in the same categories as the PDI donors. We suggest that when a PDI donor is identified, the research staff identify a deferral of the same type (as the PDI) from that week to

try to recruit them into the study. Center research staff should double check that these deferred donors did not also have a PDI.

D.1.4 Recruitment of Accepted Donors

For comparison purposes, a smaller number of telephone interviews will be conducted with 12 accepted donors. Research staff at each center will need to recruit 2 accepted donors. However, since these donors have no particular risk factor to investigate, these interviews will only include the general portion of the interview and will have mostly closed ended questions.

D.2 Consenting donors to participate in the study

Upon notification by the blood centers' operations/quality assurance staff, the research staff will call the eligible donor and if donor agrees, will mail a study packet. This study packet will include study information sheet, request/invitation to participate, the study consent form and a postage paid envelope. A week after the packet is mailed, research staff will follow up via phone call to ensure receipt of the study packet and answer any questions or concerns that a donor may have regarding the study material. If the donor is interested in participating in the PDI study, he will be reminded to sign and mail the consent form back to the blood center using a postage paid envelope. By signing the consent form, the donor will allow the blood center to forward his/her contact information along with the blood donation history to the coordinating center and will also agree to be contacted for a telephone interview. No further follow-up will be made with donors who decline to participate in the study.

D.3 Telephone Interviews Conducted by the Coordinating Center

After contact information is released to Westat, one of the interviewers with the study will try to make contact to conduct the interview or set up a time for the interview. All interviews will be conducted by telephone using senior level staff experienced in telephone interviews. Quality assurance procedures will also be applied to ensure consistency in the way that the questions are asked and establish that the interviewers are probing appropriately. In addition, throughout the course of the study, senior researchers will provide ongoing feedback to interviewers based on listening to selected recordings of their interviews. All interviews will be digitally-recorded and the recordings uploaded onto computers as dss files; these files will be

transcribed and then coupled to the interviewer notes to form an analytic package for the data analysts.

D.4 Incentive for Participation

Once the interview is conducted successfully, each study donor will be mailed a check of $25 as an incentive for participating in the study.

E. STUDY TIMELINE

Task	Date of completion
Finalize protocol	August, 2009
OSMB review	September-October 2009
OMB packet development	June – August 2009
OMB approval	December 2009
IRB reviews	October 2009
MOP development	September- December 2009
Donor enrollment	January - April 2010
Data compilation and QC	April – May 2010
Analysis and interpretation	June – August 2010

F. DATA COLLECTION

F.1. Semi-structured interviews with PDI, Deferred and Accepted Donors

Individual semi-structured interviews will be done with PDI donors, deferred but non-PDI donors and accepted donors. By semi-structured, we mean that the sets of common questions asked of all three group of donors will be largely close-ended, while the more probing, in-depth questions exploring the reasons for the PDI occurrences will be more open-ended. For example, if the donor's PDI was related to travel to a malarial area, these questions would explore what had prompted the donor to recall and/or report their travel accurately at a later point but not at the time of their donation when the information should have been shared. We would also explore their knowledge about malaria endemic areas and the risks malaria might pose to the blood supply.

F.1.1 Domains for the PDI Donor Interviews

1. Their personal interpretation and understanding of the question that was the cause for their PDI and deferral
2. Their beliefs about why the question is asked and its value in enhancing the safety of the blood supply.
3. Reasons given by donors as to why they failed to remember or disclose the information
4. Reasons for PDI related to perceptions of the blood donation process in general and at the index donation, including their views of their interactions with the centers. This will include their views of and experiences with the health history taking process, including the role of the health historian, reactions to the mode of questioning used to evaluate donor suitability and how all this may have figured into their initial failure to recall or disclose deferrable information.
5. Awareness prior to presenting for donation that they may be deferred from donation for some reason.
6. Awareness of the insufficient health history given previously, the PDI, how it was addressed by the center and feelings as to how the process was managed.

F.1.2 Domains for the Deferred Donor Interviews

1. Their personal interpretation and understanding of the question that resulted in their deferral.
2. Their beliefs about why the question is asked and its value in enhancing the safety of the blood supply.
3. Assistance that the health historian might have given them at the time to help them understand, interpret or answer the questions.
4. Their degree of comfort with mode of questioning used to evaluate donor suitability.

5. Awareness prior to presenting for donation that they may be deferred from donation for some reason.
6. Awareness during health history screening of risk for deferral versus such knowledge only acquired through health historian and their feelings regarding the management of the deferral process.

F.1.3 Domains for all donors:

General knowledge, beliefs, behaviors and attitudes about the health history screening process and about the specific health history questions that account for the highest number of PDI events along with views about the donor screening process in general will be asked. These questions will be standardized with close-ended response categories and presented to all participants.

1. Knowledge and understanding about the rationale for the health history questions that most often cause PDI
    a. What is the question asking?
    b. Are all the terms and the question format clear?
    c. If not, would you ask for more information? Is there a better way of asking the question?
    d. If additional information should be given, where and how should it be provided?
2. Basic knowledge about the question's intent in assuring a safe blood supply.
3. Fear of rejection as a blood donor because of behavior or disease (either because of personal investment, social pressure, or their desire for an incentive)
4. Attitudes and beliefs about the need for and value of these questions and the health history screening in general
5. Their opinion on whether certain questions are unnecessary because of their denial of the existence of the disease related to the question, their beliefs that a disease is curable and/or cured or their belief that blood testing makes the question unnecessary
6. Comfort with the mode of questioning that was used at that center (oral vs. self-administered)

7. Time to express opinions about blood donation in general and their interactions with health historians, the phlebotomist and the center staff

The National Center for Health Statistics (NCHS) conducted cognitive testing to four focus groups in 2002 to evaluate some of the proposed HHQ questions for the AABB Task Force to Redesign the Blood Donor Screening Questionnaire.[16] This work will be consulted for possible wording for specific study questions. The PIs of the study will work with Westat staff experienced in qualitative research to develop the interview questions.

F.2. Cognitive Testing of the Discussion Guide

The cognitive testing of the discussion guide will be conducted at the Hoxworth Blood Center. For this purpose, the blood center staff will identify 2 PDI and 2 deferred donors from the five broad categories of interest. They will also contact 2 accepted donors for study consent and interview. These donors will be approached and consented by following the same procedures that will be used for the actual study. After obtaining donor consent, telephone interviews will be conducted by trained interviewers at Westat. At the end of the interview, these donors will be queried about the questions asked during the interview and the interview process. Comments and feedback received will be used to refine the content and interview procedure that will be used for the actual study. These donors will also receive a compensation of $25.

G. DATA ANALYSIS

The data from the semi-structured interviews will be analyzed in two ways. The close-ended responses will be analyzed quantitatively, with an eye to differences and similarities across the three groups in their responses to the common set of questions. This will likely take the form of 3-way cross-tabulations of frequency distributions in responses to key questions. For example, we might compare the responses of PDI donors, deferred donors, and non-deferred donors with respect to their attitudes towards the health history-taking process.

The open-ended responses will be analyzed as qualitative data. Qualitative data analysis is a systematic process of finding meaningful recurrent themes and patterns in qualitative or word-based data. [17] Meaningfulness is defined in terms of the particular study

questions being addressed. So in this study, as just one example, we will be looking for systematic patterns in the reasons respondents give for not having initially reported the PDI, as well as any meaningful variations in this regard across the PDI group (by age, gender, center, reason for PDI). It should also be emphasized that qualitative data analysis is not a linear process, but involves making multiple iterations "back and forth" through the data. The description presented below simplifies the analytic process for purposes of illustration.

The analysts will work from verbatim transcripts of the open-ended portions of the interviews as well as summary notes taken by the interviewer immediately following the interview. The transcripts will be read and coded according to a scheme developed by the lead analysts on the basis of a close reading of an initial sample of the transcripts. Once a common coding scheme is agreed upon, each transcript will be read and coded by at least two analysts using that scheme, and any discrepancies between coders resolved through a consensus process.

After coding the data, the analysts will discuss the findings and create data displays, which may take the form of diagrams, matrices, tables, or "just plain text." [18] As a step in the process of qualitative data analysis, data display takes a step back from the coded data to reveal themes and patterns that might not be immediately apparent. For example, to follow the above example, we might find that clusters of reasons for the PDI vary according to the nature of the PDI, and can show that in a concise, summarized format. The final step in the analytic process, taken only after multiple rounds of revisiting the data to ensure that the patterns are well-founded, will involve drawing conclusions from the summarized and displayed data. All analytic steps and assumptions that led up to the conclusions, including competing interpretations of the data, will be fully discussed in the final report.

H. IRB CONSIDERATIONS AND OMB REQUIREMENTS

The donor interviews will require IRB and OMB approvals. A detailed packet including the protocol, consent form and the discussion guide will be submitted to the IRBs for the six blood centers and the coordinating center.

I. ESTIMATED BUDGET

The Coordinating Center budget includes the development of the telephone interview for PDI, appropriately deferred and accepted donors. This also includes the costs for the cognitive testing of these interview questions. In addition to the survey development, the Coordinating Center budget also includes the cost of conducting interviews over a 4 month period with approximately 102 donors (PDI, deferred and accepted) from the 6 centers and performing interim quality control assessments. The Coordinating center budget covers the cost of coding and transcribing the audiotapes, combining them with the interviewer notes and 6 months for data preparation and analysis.

The Centers' responsibilities include the costs for contacting and recruiting a selection of PDI, deferred and accepted donors for the individual interviews (17 completed donor interviews per center). For planning purposes, centers should plan to have to recruit 2 donors for each interview or 34 donors to allow for loss of subjects should a donor who agrees subsequently does not participate. For budgeting a 50% agreement rate should be planned. Thus, it is anticipated that 68 donors at each center will have to be contacted to yield the 34 who initially agree to the interview.

Budget for project:

	Direct and Indirect Costs
Centers	$12,000
Coordinating Center	$192,601
Central Laboratory	NA
Total	**$204,601**

J. REFERENCES

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Appendix A: FDA FY07 PDI and Reasons for Deferral

Table A– FDA FY07 PDI and Reasons for Deferral

	2007 Number of PDI FDA*	2007 Percentage PDI FDA*
Travel to malaria endemic area/history of malaria	7513	32.9%
Variant Creutzfeldt-Jakob Disease (vCJD) travel	3973	17.4%
History of cancer	1516	6.6%**
Tattoo within last 12 months	953	4.2%
Male to male sex	817	3.6%
History of disease or surgery	607	2.7%
Received finasteride (Proscar/Propecia), Tegison, Accutane or Avodart	576	2.5%
IV drug use	423	1.9%
Received tissue allograft/transplant	419	1.8%
Sex partner lived in or immigrated from an HIV Group O risk area	347	1.5%
Non-sexual exposure to Hepatitis C	266	1.2%
History of hepatitis, type not specified	223	1.0%
Received body piercing	213	0.9%
Sex partner tested reactive for HCV	193	0.8%
Received other medication or antibiotics	192	0.8%
Sex with IV drug user	185	0.8%
Non-sexual exposure to Hepatitis B	173	0.8%
Risk factors associated with CJD-- Family history	162	0.7%
Donor received transfusion or clotting factors	123	0.5%
History of Hepatitis A	120	0.5%
Incarcerated	110	0.5%
Received ear piercing	106	0.5%
Miscellaneous behavior/history	1646	8.0%

Total Behavior/History	20516	89.8%
Illness	2099	9.2%
Testing	152	0.7%
Not specific to high risk behavior	89	0.4 %
Total PDI	22856	100.0%

*These data represent licensed blood establishments only – 22, 856 of 29,356 total BPD reports due to donor suitability

**History of cancer is no longer considered PDI by the Food and Drug Administration