Blood donor deferrals: biting the hand that feeds us!

In this issue of TRANSFUSION, the article by Zou and colleagues 1 details trends in donor deferral and retention using the American Red Cross database. The power of the study is the enormous experience culled from almost half the nation’s blood supply. Prominent among the observations are the increasing deferrals for failing to achieve minimum hemoglobin (Hb)/hematocrit (Hct) criteria and for donor travel, especially to areas considered to pose a potential risk for malaria. Travel deferrals for residing in countries with variant Creutzfeldt-Jakob disease (vCJD) risk showed a gradual fall, perhaps reflecting prior culling followed by self-deferral and general awareness of these criteria among repeat donors and the public in general.

More worrisome is the far higher rate of nonreturn among younger donors who receive a temporary deferral (2.1 times higher among 16- to 19-year-olds than those 50-59 years). Although this phenomenon has been previously observed, this study serves to quantitate the enormous lifetime loss of donors that results from these early deferrals. Whether it is because the donors have yet to bond with the center or whether they have not yet incorporated “donorness” into their self-concept is being explored in various donor motivational studies, but the simple empirical observation is that temporary deferrals play greatest havoc with the donors who represent the future of volunteer blood donation. 2,3

The magnitude of the deferrals should give pause, especially in light of their disproportionate effect on younger donors. Since any new donor infectious disease screening test requires extensive validation, so too should our current or new donor screening questions. For example, the authors cite the apparent illogic that although there is empirical evidence to support the transfusion transmissibility of vCJD, no case of transfusion transmission from donors subsequently deferred for a family history of CJD has ever been observed, despite extensive lookback efforts. Hence, the cost (in terms of donor loss) for continuing to defer donors when even a distant family member is identified with CJD clearly exceeds any benefit. Fortunately, the number of these deferrals is relatively small. Conversely, malarial travel represents the single greatest reason for deferral with an estimated more than 90,000 donors deferred annually (Dr Roger Dodd, American Red Cross testimony before Blood Products Advisory Committee, Sept 11, 2008). Even more potential donors are likely self-deferring, knowing that others who went on similar trips are deferred. Since many of these donors have traveled to Mexico, primarily to areas with minimal risk, such as the “Mexican Riviera” region south of Cancun, there is an unintended emphasis on deferring the majority of donors for having traveled to an area unassociated with prior transfusion transmissions. Specifically, in the retrospective study by the CDC of the last 91 cases of transfusion-transmitted malaria, none in the past 45 years was associated with casual travel to Mexico and only 3 of 64 were from civilian travelers. 4

The authors further observed an increasing rate of deferrals due to failure to meet Hct/Hb criteria. Since their screening technology was largely static during the time of data collection, they ascribe the high rates of donor loss either to moving the assay earlier in the donation process (generally, for logistic reasons the donor interview stops at time of first deferral) or to more aggressive recruiting of repeat donors. Since the timing of the Hb test is a one-time change, if the trend persists, one might safely conclude that donor erythropoiesis has become the major limiting factor as blood centers engaging in donor iron studies have observed. 5

Finally, they observed that because our current donor base is already so pedigreed and so safe relative to the total population, any further modifications of the donor health history are unlikely to have measurable effects on diseases we already screen for, since the questions have likely already reached the limit of their effectiveness. Of note, requiring donors to answer the high-risk questions on computer results in elicitation of more high-risk behavior than face-to-face interviews, which should result in greater use of computer-assisted self-interview (CASI) strategies. 6

Food and Drug Administration (FDA) requirements for clearance of new blood donor screening tests or software systems emphasize extensive validation. Yet historically, this same rigor has not been applied to implementing new donor screening questions. Indeed, the operating standard seems to have been if adding the question might reasonably be expected to defer a donor at risk of transmitting a transfusion borne pathogen, then the question was implemented, regardless of the query’s positive or negative predictive value. Indeed, this application of the precautionary principle was raised in advocacy for a question about xenotransplantation, which fewer than 100 US citizens have undergone and, most recently, the implementation of a simian foamy virus screening question in Canada. 7 The role of the AABB Uniform Donor

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History Questionnaire (UDHQ) committee working in concert with FDA officials to review and come to agreement on a set of uniform questions with tested validity is much appreciated. Attempts have been made to simplify, reword, and remove compound questions to prevent donor confusion. Furthermore, where possible, questions have been validated with focus groups or by their ability to correlate with donor infectious disease screening results.8

As documented by the current and other studies, the highest yield opportunities for donor retention are likely reconsideration of malarial travel, especially with reference to casual travel to Mexico and new approaches to Hb/Hct deferral for female donors.9 Additional opportunities for preventing loss of young donors have been implemented by donor centers whose states license tattoo parlors and mitigate the risk of hepatitis transmission by requiring single client use of needles and inks. The recent loss of a second supplier of the required human T-lymphotropic virus (HTLV) test also raises the opportunity to reconsider whether there are measurable benefits from maintaining this relatively nonspecific test. Furthermore, data were submitted questioning the utility of syphilis testing in light of the paucity of polymerase chain reaction–positive samples among serologically deferred donors.10 Donors and donations can be saved by eliminating the requirement for this test.

The broader issue is adequacy of blood inventory. The AABB works with the Department of Health and Human Services to perform routine surveys of blood collection and utilization. While collections have continued to grow, total usage appears to be growing faster and the margin of collections over distributions is narrowing. As a blood center recently charged by the AABB disaster task force to help ensure adequate supplies for the recent political convention in our city, the clear message is that our role is to ensure adequate supplies for an array of contingencies. Therefore, it is implicit that we address the root causes of this dwindling margin before significant shortages occur. Hence attention must be given to rigorous assessment of appropriateness of usage as well as ensuring adequate supplies.

The erosion of the total size of the blood donor base was discussed in the study by Riley and coworkers11 that observed only 37 percent of individuals over age 18 were likely to be eligible given the myriad strictures on donation and the stringent health requirements. While the donor base is currently being expanded one more notch by many states dropping the donor eligibility age to 16 with parental permission, this one-time compensatory adjustment will not suffice. If these young donors are to be successfully integrated into the committed donor base, it is imperative that adverse reactions be kept to a minimum as it is well documented that a syncopal reaction at the time of the first donation provides a marked disincentive to return. Indeed the September 2008 TRANSFUSION has several articles and an editorial12–14 addressing the higher rates of donor reactions and interventions that may play a role in mitigating that risk among younger donors.

Donor satisfaction also plays a key role in donor return. Prolonged waiting times and frustrating systems are cited by some donors for waning interest in returning. Those centers that were able to implement an abbreviated donor history have reported that it substantially reduces the perception of how long it takes to get through the donation process. We need the FDA to approve the abbreviated version of the donor history questionnaire (ADHQ), a shorter form for loyal, safer, repeat donors in a timely fashion. We also caution the agency to consider the inevitable mathematical implications of new test introduction. A test with 99 percent specificity performed each donation will defer 50 percent of donors after approximately 69 donations (less than 3 years for the most frequent platelet [PLT] donors). We therefore suggest that the FDA consider alternative screening requirements for tests with low likelihood of yield, such as screening a donor only once for HTLV-I and/or -II, as is done in some European countries, or for Trypanosoma cruzi (Chagas disease) both to minimize donor loss and to improve affordability.

The move toward harmonization of transfusion policies across international boundaries has had some unfortunate unintended consequences. For example, the United Kingdom had one of the more physiologically sensible approaches to donor eligibility. Specifically, recognizing that approximately 1 in 7 (15%) of women who are not iron deficient normally have Hct levels between 36 and 38 percent, they allowed female blood donors to donate down to a Hct level of 36 percent but only allowed three whole-blood donations annually. Since it is the rare donor that actually donates every 2 months, this served to both protect the donor by preventing iatrogenic anemia yet made many more units available for the public health supply. Alas this option disappeared with European Union harmonization. In a recent editorial, Newman9 suggested that the FDA consider a gender-specific cutoff. At the very least dropping the Hct requirement to 36 percent for PLT donors (whose only red blood cell loss is the volume in the sample bag) would make more product available at no measurable donor risk.

The FDA workshop on donor screening tests for malaria (Summer 2006) gave hope that alternatives to the 1-year deferral for travel might follow. In anticipation of the revised FDA malarial guidance, donor centers are collating data on the percentage of malarial deferrals that result from Mexican travel. One clear mantra emanating from the meeting was best phrased by Dr Louis Katz, who summed up the needs of blood donor centers as “Just give me Mexico!” (see for example, comments by Dr Alan Williams at this same workshop documenting numbers of donors deferred http://www.fda.gov/cber/blood/
malaria071206aw.pdf). This suggestion is consistent with the paucity of risk from casual travelers to Mexico previously discussed. A more rational malaria policy would accept donors traveling casually to Mexico, but perhaps permanently defer prospective donors who have had malaria or lived in malaria-endemic countries—those who have actually been implicated in recent transfusion-transmitted malaria in the United States.

Part of prudent disaster planning is ensuring adequacy of supplies in bad times as well as good. This process requires periodic reassessment of the efficacy and necessity of rules or regulations that result in deferral or otherwise dissuade potential blood donors. In short, regulators must ensure that blood donor questions and deferrals be subjected to reviews using the same rigor and criteria applied to blood donor screening (such as sensitivity, specificity, and positive predictive value) as tests and blood establishment computer systems and only be implemented when the benefit to recipient safety outweighs the risk to recipients from inadequate supply. In addition, we must collaborate to create blood establishment computer systems robust enough to maintain safety but flexible enough to allow alternative screening algorithms such as one-time donor screening. Finally, we must remain committed to donor safety including prevention of donor iron deficiency as opposed to simply deferring donors once we have induced it.

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REFERENCES


