

## Duties to donors

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THE NATIONAL BLOOD POLICY,<sup>1</sup> which was promulgated in 1973, set a number of goals including a safe, adequate blood supply. Nearly 20 years later, the safety of the blood supply is under relentless scrutiny, and its adequacy is challenged by the substantial transfusion needs of patients undergoing many of the newer medical and surgical protocols.

In discussions about the pursuit of safety and adequacy, there are indications that the nation's blood supply is being described in the same dispassionate fashion as other measures of industrial productivity, such as the annual steel output or the numbers of automobiles sold. This indifference glosses over the very personal contribution that provides the raw materials for the transfusion components that patients depend on. Voluntary whole blood donation has no counterpart in industry. Yet every time blood programs and blood donors are referred to as "part of the blood industry," distinctions are blurred and the opportunity to spotlight the dissimilarities between the donor room and the production line is lost. Whereas manufacturing principles such as quality assurance are as applicable at the blood center as they are at the factory producing therapeutic drugs, we must not lose sight of the fact that blood transfusion is a treatment made possible not so much by the cold mechanics of a pharmaceutical process as by the compassion and altruism of donors.

Blood bankers have inescapable responsibilities to these donors. The responsibilities include ensuring that donors understand not only the criteria for their candidacy, but also the reasons for deferral when those criteria are not met. It might be helpful for donors to be told that the criteria fall into two broad groups, those for their own protection and those for the protection of the recipient. In recent years, the donor protection criteria have changed little. A would-be donor still must be old enough, must weigh enough, and must have an acceptable hematocrit. Some of the criteria have, however, been relaxed; for example, upper age limits no longer apply.

Most of the changes that have been made in donor standards are for the protection of the transfusion recip-

ient—especially, against the risk of infection. The breadth of these changes and the earnestness of their application have influenced every aspect of the relationship between blood donors and blood programs. Amplifications in the donor history procedure have come tumbling into everyday practice at such a dramatic pace that there has hardly been time to pause and take stock of the new circumstances that confront potential donors.

These circumstances provoke a number of questions. Has the donor history interview been converted into a donor interrogation? Just how intimate, or how direct, can questions about sexual practices be before, in the legitimate interests of uncovering a few unacceptable donors, we offend a significant number of donors? A recent study<sup>2</sup> suggesting that repeat donors in a metropolitan area are, in general, not embarrassed is encouraging. However, we do not know if the same response could be predicted of other donors, such as those from rural areas or those who have not donated before.

How can the confusion that confidential unit exclusion policies occasionally provoke be avoided? For some donors, there is a dismaying ambiguity in a strategy that allows a few individuals to ignore the acquired immune deficiency syndrome information and be deceptive in giving their history, but insists on absolute integrity in everyone else.

How can directed donations be embraced without impugning the anonymous volunteer? What sort of encouragement is contained in the implicit message that volunteer donations are appropriate for emergency transfusion, but the family and friends of elective surgery patients are safer donors?

What can be done about the "nonspecificity trap"? In this context, heavy reliance is placed on laboratory testing in pursuit of the risk-free blood transfusion. This emphasis is not surprising, if one bears in mind the extent to which our society has enshrined technology. Though there is a beguiling simplicity in the idea that a test that could even slightly enhance transfusion safety should be implemented, technology-driven donor screening carries a price.

As 100-percent specificity does not exist, at least not side-by-side with 100-percent sensitivity, some donors have had to contend with false-positive results. As more screening tests are introduced, so will their ranks be increased. This does not bode well for anxious donors or for blood bankers trying to explain<sup>3</sup> why, if some test

Abbreviations: anti-HCV = hepatitis C virus antibody; anti-HIV-1 = antibodies to human immunodeficiency virus type 1; CCBC = Council of Community Blood Centers.

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results really are false, donation is still forbidden. Concepts such as test sensitivity, test specificity, and indeterminate results are difficult to translate into lay terms. There is scant enlightenment, let alone consolation, for the donor deferred with a "false-positive" result and given the explanation that the predictive value of the screening tests for antibodies to human immunodeficiency virus type 1 (anti-HIV-1) is only 10 to 30 percent when the seroprevalence of the antibodies is 0.04 percent.

The numbers of donors who have already been consigned to some type of nonspecificity limbo are not small. For example, during the year leading up to the first reentry program for selected donors who were repeatedly reactive for anti-HIV-1,<sup>3</sup> the records of the Council of Community Blood Centers (CCBC) on 2,308,405 donations showed that 3337 (0.15%) were repeatedly reactive on screening test, but were negative on confirmatory test (Starkey J, written communication, October 1989). If these figures represent national experience, then, in 12 months, some 20,000 donors were penalized by nonspecificity in testing for anti-HIV-1 alone.

For a marker with a higher prevalence in the donor community, such as hepatitis C virus antibody (anti-HCV), the predictions are more alarming. CCBC's experience with 1,543,074 donations in the first 8 months of screening for anti-HCV showed a repeatedly reactive rate of 0.78 percent (Starkey J, written communication, May 1991). Taking into account the fact that some 40 percent of individuals in low-risk populations are negative by recombinant immunoblot assay,<sup>4</sup> then about 50,000 donors, nationally, have already been penalized by nonspecificity in the anti-HCV screening test.

Whereas donor education can go a long way toward repairing misunderstandings about such relatively recent innovations as confidential unit exclusion, questions about sexual activities, or the role of directed donations, the nonspecificity issue, which has an important part to play in shaping our duties to donors, has to be dealt with more broadly. The indications for new screening tests must be well established and the tests introduced must

be of high specificity. Manufacturers must be encouraged to develop confirmatory tests that can be licensed, if not at the same time as the corresponding screening tests, then certainly sooner than has been our experience with both anti-HIV-1 and anti-HCV testing. The Food and Drug Administration must be urged to incorporate these confirmatory tests into reentry algorithms as soon as feasible, so that donors in whom false-positive results are confidently identified can continue donating.

If these requirements are not met, then the quality of information donors are given is defective and they are rendered a disservice in return for their participation in our programs. We must not make donation a discouraging experience by giving some donors confusing test result information that they correctly appreciate is inconsistent with their good health. In essence, we cannot afford to make blood donation so cumbersome, or the donation deferral process so arbitrary, that we alienate the very people whose commitment is essential for the transfusion support of our patients.

Continued dedication to an adequate and safe blood supply is essential, but a promise of absolute safety in transfusion is as hollow as a promise of complete recovery from the diseases that justify transfusion in the first place. We cannot hold donors hostage to an illusory goal.

#### References

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