

THE GIFT OF LIFE: Gay Men and US Blood Donation Policy

Understanding existing discrimination and how it might be changed

By Bob Roehr

INTRODUCTION

The US Food and Drug Administration (FDA) establishes and administers policy with regard to all blood products used within the United States. The purpose is to ensure availability and uniformly high standards that guarantee safety and minimize the possibility of transmission of blood-bourn infectious diseases in those blood products. About 14 million units of blood will be donated in the US in 2001.

Most people who have not yet gone through the screening process to donate blood are surprised to learn that there are pages of exclusionary factors that may keep one from making a donation. Writing in the November/December 2000 edition of *GMHC Treatment Issues*, published by the Gay Men's Health Crisis in New York City, Derek Link listed some of the top 52 reasons for not being able to donate blood. And at least one more has been added since that date. The net result of these exclusionary screening procedures is that an estimated 30-40 percent of the American public is prohibited from donating blood for one reason or another.

The system relies on screening at three different levels in order to minimize the possibility of disease transmission through blood products. It encourages certain individuals, such as gay men, to self-select and not even show up to donate; it administers an elaborate questionnaire and on paper rejects those who may be at risk of carrying a blood-bourn disease; finally, it submits every unit of blood that is drawn to an elaborate series of chemical tests for HIV, hepatitis B and C, syphilis, and other infections. That process takes about three days to perform.

Blood found to carry any of these infectious agents is removed from the system and destroyed. Donors are notified that their blood tested positive for specific infections, counseled as to what that means, and are encouraged to see their physician.

None of these efforts are failsafe, but the redundancy of overlapping systems has proven remarkably effective. So much so that the America Red Cross states in one of its "Frequently Asked Questions" prepared for consumers: "The risk of not getting a blood transfusion when it's needed is infinitely greater than the risk of infection from receiving one."

Most of the blood that is donated comes from a loyal 5% of the population that donates repeatedly throughout the year. But that group of repeat donors has been slowly shrinking, while the development of new medical procedures has increased the need for blood. The need has outpaced supply so that seasonal shortages and emergency appeals have become annual rituals in most major American cities.

HISTORY & SCIENCE

The current blood donation policy excludes all men who have had sex with another man since 1977. It is important to understand the context within which the ban was adopted, and how that context has changed over the ensuing years.

What came to be known as AIDS was identified in the United States in the early 1980s, first as a disease that affected gay men. As early as 1983 they were asked to refrain from donating blood. The FDA adopted the current policy in 1985, soon after HIV was identified as the virus that causes AIDS, and a test was developed to identify the antibody to that virus in blood. It was thought that HIV was not present or at least not widely prevalent in the United States prior to 1977, which explains why that date was chosen.

No one challenges the fact that people who know that they are HIV-positive should refrain from donating blood. And most people, including gays, believed that the draconian policy made sense in light of the devastating nature of HIV infection; the then limited epidemiological data and knowledge of how HIV is transmitted; and the relatively crude tools available to detect the virus in blood. Those conditions have changed substantially since 1985, but the policy has not.

The most recent research concludes that there is virtually no risk of transmission of HIV through oral sex, regardless of which end of the transaction one is on. Data from heterosexual couples in Uganda indicates that those with a sufficiently low viral load only rarely transmit HIV through vaginal sex. And proper, consistent use of condoms and lubricant is highly effective in preventing transmission of the virus when engaging in either vaginal or anal sex.

What policy makers have been most worried about is the window of time between the point of infection with HIV and when screening tests can detect that infection in a blood donation of that person. The early laboratory tests that screened blood for HIV looked for antibodies to the virus, which take several weeks, and in some individuals several months to develop. Blood policymakers worried that during this window HIV-tainted blood might slip through the screening mechanism.

This is where conditions have changed most dramatically since 1985—the window has closed to the point where it is barely open. The nucleic acid test (NAT) has become the standard by which all blood donations are screened in the US. It amplifies and looks for small fragments of HIV RNA in pooled samples from 512 units of donated blood at a time. It is virtually foolproof, able to detect HIV in pooled blood within 12 days of infection, says the FDA. If the technology is used on individual rather than large pooled samples, NAT can detect HIV within 4-5 days, according to testimony before the FDA by Michael Busch, MD, with the Blood Centers of the Pacific.

Another simple screening technique already in place is likely to catch many of these very early infections even before donors roll up their sleeves. Standard procedure calls for taking the temperature of every donor and turning away those with a fever as an indication of some sort of infection, even a common cold. Primary HIV infection often will result in such a fever. There also is some evidence supporting the view that the form of virus during this very early stage of infection may not be very capable of transmission to a third party.

The gay ban differs from every other blood policy exclusion in two significant ways. First, it is based on a person's status rather than acts that put them at risk for infection. Second, it reflects a double standard where the same risky acts performed by heterosexuals brings a temporal restriction that generally is limited to 12 months, while a gay man is banned for life.

Thus monogamous gay couples in stable long-term relationships, who have little risk of recent HIV infection, are barred from donating blood. However, a single heterosexual female who is dating around may be allowed to donate blood, or at worst will be deferred from doing so for a year after her sexual pattern stabilizes.

The discriminatory character of this policy has long been noted both outside the FDA and within it. Justification for the policy became increasingly difficult as blood screening technology improved and the chance of a tainted unit slipping through declined. Most experts in the field understand these changes since 1985 and have been willing to modify the de facto lifetime ban on gay men donating blood.

RECONSIDERATION

The FDA professional staff administers policy, but that policy is set through public comment, the most visible portion of which is the consultation mechanism of an advisory committees meeting in public session. It is an opportunity for professional experts and the interested public to participate in the rulemaking process. The FDA uses it to solicit input, educate the general and targeted publics, and often to take some of the heat on controversial policy issues. A solid consensus recommendation from an advisory committee inevitably is embraced by the agency, while a divided committee sometimes is overruled. Regardless, the final decision on all policy rests with the FDA.

The September 14, 2000 meeting of the FDA Blood Products Advisory Committee (BPAC) was a watershed event in reconsidering the policy of blood donations by gay men. For purposes of discussion, the FDA proposed changing the ban on donation by men who have had sex with another man from 1977 to a more flexible standard of having had sex with another man within the last five years.

By posing the question, and through its presentation in suggesting such a relaxation, the FDA professional staff indicated that it was predisposed to loosening the policy. There also was a strong suggestion that the FDA was willing to go farther in changing restrictions, but that their proposal was a compromise made with the hope of gaining support from those most opposed to any change.

FDA medical officer Andrew Dayton, MD, presented a worse case scenario model of how many additional units of HIV contaminated blood might slip through by relaxing the standard to a five-year deferral of donations. He estimated the risk at "around 1 in 750,000" units.

In reviewing data from hospitals in New York that process their own blood, Dayton found that even though they process just 10 percent of the volume of blood drawn, they produced 80 percent of the errors in the region. "He concluded, inappropriate release [of tainted blood] primarily due to non-automated blood handling systems, remains the biggest problem," far exceeding any risk from letting gay men donate blood.

At the BPAC meeting, the American Association of Blood Banks (AABB) went farther than the FDA and called for "modifying the deferral time period for male to male sexual contact to 12 months" to make it "consistent with those for other high risk sexual exposures." It has held that position since 1997.

By changing the policy, "The potential donor will be directed to focus on recent rather than remote risk behaviors and should have better recall for answers to the screening questions," said Louis Katz, MD, in speaking for the AABB. The organization represents professionals and facilities responsible for virtually all of the collection and more than 80 percent of the transfusion of the nation's blood supply.

America's Blood Centers (ABC) reinforced that same message. The association of 75 not-for-profit, community based blood centers collects nearly half of the nation's blood each year. Executive vice president Celso Bianco, MD, said, "I believe that we would not see a real difference between the five year and the one year" deferral standard.

He called the current policy counterproductive because "the question focuses attention on events that occurred more than twenty years ago instead of events that occurred within the currently known window period of days or weeks" when the technology may not detect early HIV infection.

"Like risks should be treated alike," said Adrienne Smith, MD, in testifying on behalf of the Gay and Lesbian Medical Association and other gay organizations. "This maxim exposes the central flaw in the current donor deferral policy which tolerates a wide range of risks associated with heterosexual sex while imposing a zero tolerance attitude toward MSMs [men having sex with men], regardless of the risk associated with individual behavior."

"By focusing on the source of the risk rather than the size of the risk, the current policy stigmatizes gay men." Smith urged a revised policy and screening questionnaire that focuses on recent behaviors and risks.

Only the American Red Cross (ARC) opposed changing the policy. It collects nearly half of the nation's blood. Rebecca Haley, MD, called changing the deferral question "a public health issue, not a social policy issue... Modifying the MSM deferral criterion to five years would result in a small but measurable increase in the possibility that infectious blood might be released."

"Until data are available to show that changing the MSM deferral criterion will not elevate the risk to the nation's blood supply, we cannot support this change," said Haley. Her statement was a Catch-22 because it would be impossible to collect such data until the policy is changed, as Dr. Busch did not hesitate to point out to the committee.

The BPAC voted 7-6 not to change the policy, with five members of the committee absent. It is not clear if or how the outcome might have changed had those members been present.

MOTIVATIONS

A recounting of events over the last few years clearly indicates that opposition to changing the policy on blood donation by gay men does not come from the FDA staff, the association representing professionals in the field, or the association representing agencies that collect about half of the blood in the United States. Opposition to changing the policy comes primarily, one is tempted to say solely, from the American

Red Cross, which wields a de facto veto over the process.

The power of the Red Cross comes from the fact that it is a centralized behemoth that carries out a multitude of activities with an annual budget of about three billion dollars. It has a massive public relations machine that maintains its iconic image before the American public. The other organizations may represent equal or greater interests in the field of blood donation and use, but their resources are diffused and they are no match for the ARC.

What motivates the American Red Cross to maintain its opposition to changing the policy? Their rhetoric focuses on maintaining minimal risk within the blood supply, but that is at odds with the policy of the AABB to which many of their professional members belong.

Some past board members and lower level officials resigned from the Red Cross in past years, charging that the ARC was homophobic. ARC spokesmen have denied the charge, but the legacy of suspicion remains.

It seems likely that money, marketing, and sheer arrogance are factors contributing to ARC's maintenance of the policy.

The FDA is not allowed to consider financial matters when it evaluates policy issues, however, from time to time they do creep into the public debate. Those with a vested financial interest in such policy outcomes have no such restrictions.

Allowing gay men to donate blood is likely to result in some increase in the number of units of infected blood that enter into the physical screening process to detect the presence of those infections. When an occasional batch turns up positive for one of the pathogens, the samples are retested in increasingly smaller batches until the individual contaminated unit is identified and destroyed. The donor of that unit is notified and counseled on the often life-threatening infection that he or she carries and is advised to see their doctor. All of this costs additional money.

The decentralized, autonomous members of America's Blood Centers have accepted this relatively small incremental cost as a normal cost of business. But when that cost is aggregated in the centralized accounting system of the Red Cross, it becomes a temptingly larger target that one may seek to contain by administrative fiat. Prohibit higher risk donations and you reduce associated costs.

That type of cost containment is common in the for-profit sector. But it is legitimate to ask if a nonprofit entity that receives certain benefits of tax exemption from government should be held to a different standard. It may well be justified to ask such an entity to also consider public costs, such as the discrimination suffered by gay men under such a policy, in carrying out its nonprofit mission. Other organizations within the blood community have been willing to include that factor in their calculations.

The Red Cross may also be seeking a marketing edge in being able to claim the "safest" blood, by using standards that are more stringent than what the FDA demands. Recently they unilaterally implemented stricter screening guidelines than what the FDA requires for "mad cow" disease, much to the consternation of that agency, other blood providers, and the Department of Defense, which has allowed civilian organizations to conduct blood drives on military bases. Many view the ARC

as arrogant in dealing with their colleagues in the industry.

POST SEPTEMBER 11

One of the immediate effects of the September 11 terrorist attack on New York and Washington was a surge of people wanting to donate blood. Many were first time donors who were surprised to find that the honest answers they gave to the screening questionnaire had them quickly shown the door. Others only later received notice that testing had found evidence of HIV or hepatitis in their blood and were advised to consult a physician.

This surge of donations has put at least a temporary end to the national problem of blood shortages. Estimates are that the bulge in donations will last ease shortages for about a year. Some among this influx of new donors will become sustaining donors who will give on a continual basis, but it is too early to know what percentage will choose to do so. And it is too early to say if the long-term problem of blood scarcity has been resolved.

CHANGING POLICY

Attempts to modify the current policy that bans donation of blood by gay men should start by proposing to amend the policy to a 12 month deferral, the same policy as with other risky behavior. It is the policy advocated by the American Association of Blood Banks and America's Blood Centers.

But the community should not stop there, it should seek parity with heterosexuals at all levels based upon the element of risky behavior.

Couples in monogamous, long-term relationships where both are HIV-negative should be held to the same standards, whether heterosexual or homosexual.

Consideration should be given to removing oral sex as a category of risky behavior.

The consistent use of condoms in anal sex, and whether the donor is exclusively insertive or receptive (top or bottom) are also factors worthy of consideration in reexamining the policy.

Alternative handling of a blood donation also should be explored. It may make sense, and be cost effective, to segregate blood from higher risk donors and screen them individually or in smaller pools.

Gay organizations may want to organize recruitment drives for first time donors, perhaps where donors are prescreened for pathogens weeks before being allowed to donate, or where the initial donation receives special handling. After that initial donation has cleared screening, the donor will be entered into the standard registry and mainstreamed, as it were into the donor network.

Regardless the course taken, it seems likely that internal and external pressure will have to be brought to bear on the American Red Cross for it to abandon its lone opposition to changing the policy. Even if the FDA decides to modify the policy, the ARC can always undercut it by maintaining its own, stricter policy. The most effective

public argument in moving the ARC is likely to be one of identifying their position as one adopted for strictly for financial reasons, to save processing costs, while discriminating against a segment of American society when there is no valid scientific reason to do so.

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