



ABC Talking Points

Blood Donor Deferrals: Males who have had Sex with Males

Background

In 1983, the Food and Drug Administration (FDA) issued a guidance that permanently prohibits from donating blood men who have had sex with men (MSM) even once since 1977 and anyone who had sex with a gay man in the past 12 months. The stated reason was that gay men and their sexual partners have a much higher prevalence and incidence of HIV than the general population and their donations increase the risk of transmission of HIV, the virus that causes AIDS, to recipients of blood and blood products.

The exclusion of potential donors based on sexual behavior has been discussed by the FDA's Blood Products Advisory Committee (BPAC) at several meetings. This FDA advisory panel of independent experts continues to recommend the MSM prohibition, known in the blood industry as a "deferral." As a result, the agency has never rescinded the guideline.

At a December 1997 BPAC meeting, the committee voted to reconsider the MSM deferral. Data on the incidence and prevalence of HIV and other viruses in men who have had sex with other men and data on HIV positive blood donors were also presented at a November 1998 FDA Workshop on Blood Donor Suitability. A transcript from this workshop can be obtained from CBER's Web site at:

www.fda.gov/cber/minutes/bld112398trans.pdf

ABC's Position

During the 2000 BPAC hearing, America's Blood Centers (ABC) proposed changing the MSM deferral from the current lifetime deferral to one year, saying it would not increase the risk of HIV infection in the blood supply. Celso Bianco, MD, executive vice president of ABC, said that "when the lifetime deferral of MSM was introduced in the early 1980s, little was known about the epidemiology of HIV, and screening assays required further refinement."

"Since the height of the AIDS epidemic, donors have received clear information about risk behavior, HIV transmission and why they should not donate to obtain an HIV test," he said. "Moreover, individuals with one positive HIV test in their lifetime are already permanently deferred, he said. Similarly, medical history procedures are more rigorous, with direct questions about risk behavior, venereal diseases, contact with individuals with infectious diseases, and use of IV drugs, etc."

Most importantly, new testing methods have reduced the window period for HIV assays from an average of 56 days (at the beginning of HIV testing) to an average of 11 days

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(with the introduction of nucleic acid amplification testing). Dr. Bianco also indicated that, based on evidence from animal models, this window may even be shorter. ABC tried unsuccessfully to convince the committee that, because of the shortened window period, donor questions should focus on recent behavior, instead of behavior that took place decades before.

MSM Deferral Q&A

Q: If testing for HIV in blood is so advanced, why are male donors who've had sex with other males still excluded from donating blood?

A: While HIV testing is better than ever, there is still a remote chance that HIV and other diseases may be transmitted via blood transfusions because of donations made during the window period of infection and potential for errors. The Blood Products Advisory Committee, which advises the FDA on matters of blood safety, has approved the continuation of these policies.

Q: Why are gay men and not gay women deferred from donating blood?

A: The FDA, based on research from the Centers for Disease Control, has determined that gay men are at the highest risk for HIV infection. After infection rates declined in the late 1980s and 90s, recent data indicate an unfortunate increase in HIV and other sexually transmitted diseases among gay men. Other groups excluded from giving blood under the HIV deferral criteria include those born in sub-Saharan Africa and those who have ever used intravenous drugs, along with individuals who have exchanged money for sex.

Q: But isn't this discrimination?

A: The FDA states that its policies are based on sound epidemiological data. They are preventative measures, based on scientific data, whose intent is to protect public health. According to the FDA, the policy is similar to the one that excludes people who've traveled to certain countries because of the risk of malaria and the one that excludes those who've had a recent tattoo because of the risk of hepatitis. These measures are extremely conservative, but the FDA does revisit the data every few years to determine if the policies should be changed.

Q: What is ABC's Position on the MSM Deferral question?

A: ABC has proposed changing the MSM deferral from lifetime to the same as most other risk deferrals (the period of one year far exceeds the window period of viral diseases transmitted by transfusion). The reason is three-fold: First, much more is known about the epidemiology and risk of HIV/AIDS than when FDA issued its original guidance. Second, donor history questionnaires are more rigorous today and are more likely to screen out people with a risk of a blood-borne disease. Third, the introduction of nucleic acid amplification testing has dramatically reduced the "window" period of infectivity – basically how long it takes to detect the presence of the virus in a person who has been infected – from 56 days to 11 days.

Q: Where can I learn more about the FDA's blood donation policies and how can I voice my opinion about these policies?

