CRS INSIGHT

Orlando Shooting Revives Debate over Restricting Blood Donations by Gay Men

August 1, 2016 (IN10535)

Related Author

• <u>C. Stephen Redhead</u>

C. Stephen Redhead, Specialist in Health Policy (credhead@crs.loc.gov, 7-2261)

Within hours of the <u>shooting</u> at Pulse, a gay nightclub in Orlando, hundreds of people responded to the call for blood donations to help the injured. Gay men were among those who lined up outside local donation centers. They were motivated by rumors that the regional blood bank <u>OneBlood</u>, which serves the Orlando area, had lifted the decades-old ban on donations from sexually active gay men.

The rumors turned out to be untrue, and most of the gay men who showed up were turned away. OneBlood released a <u>statement</u> on social media that the ban had not been suspended.



Since the 1980s, the Food and Drug Administration (FDA) has recommended that men who have sex with men (MSM) be indefinitely deferred (i.e., permanently banned) from donating blood. This action was taken to help control the spread of the human immunodeficiency virus (HIV) through the blood supply.

Last December, after years of advocacy and debate, FDA issued new industry guidance with revised donor deferral recommendations. The agency recommended reducing the MSM permanent ban to a 12-month deferral. Under the new MSM deferral policy, gay men may not donate if they have had sex with another man within the past year. While the recommendations are nonbinding, all blood banks are implementing them.

Gay rights advocates say that while the change is a step in the right

direction, it will have limited impact. Sexually active gay men will still be excluded. Advocates also contend that the new deferral policy is no less discriminatory than the one it replaces, because it is still based on sexual orientation and fails to take into account differences in individual behavior that affect risk. They note, for example, that a married gay man who always uses a condom is at far lower risk of HIV infection than a single gay man who is sexually promiscuous and never uses a condom. But the policy makes no distinction between these two types of individuals.

Donor Screening and Testing Has Reduced Risk

In 1983, FDA <u>recommended</u> that blood banks screen potential donors at increased risk for HIV infection. The donorscreening procedures adopted prior to the introduction of the first HIV antibody test in 1985 significantly reduced the number of HIV-infected donations and, therefore, the risk of viral transmission via blood transfusions.

Today's <u>blood tests</u> are extremely sensitive and able to detect HIV and other blood-borne viruses soon after an individual becomes infected. Donations that test positive are destroyed.

Prior to donation, individuals are asked a series of personal <u>questions</u> to screen out those engaged in behaviors that place them at risk for HIV and other blood-borne viral infections. The screening questions help identify individuals who are in the "window period" at the beginning of an infection when the virus is present in the blood at levels too low to detect. The HIV window period typically lasts between 9 and 11 days.

One question asks potential male donors if they have had sex, even once, with another male at any time since 1977. Answering yes results in a permanent ban. Under the new MSM deferral policy, males will instead be asked whether they have had sex with another male in the past 12 months.

Together, the screening questions and the blood tests (along with other <u>blood safety procedures</u>) have reduced the HIV infection rate to <u>one in every 1.47 million blood donations</u>, down from one in every 2,500 donations prior to HIV testing.

Some sexually active gay men lie on the screening questions and donate despite the deferral policy. But it appears that lower-risk individuals are more likely to engage in this type of behavior. A <u>survey</u> of sexually active gay men found an HIV prevalence rate of 0.25% among those who reported donating blood, compared to a rate of 11%-12% for the entire group.

FDA Takes an Evidence-Based Approach

FDA examined several alternative options and concluded that the 12-month deferral, which matches the policies of other advanced countries, had the most scientific support. The experience in <u>Australia</u> was particularly important in the agency's decisionmaking. An analysis of data from Australia's national blood surveillance system found no change in risk to the blood supply after the country switched from an indefinite deferral policy to a 12-month policy.

Following the Orlando shooting, <u>116 Representatives</u> and <u>24 Senators</u> wrote to FDA urging it to eliminate the 12-month policy and assess risk on an individual basis. That approach has been implemented in a handful of countries. In Italy, for example, potential donors are asked about sexual promiscuity, irrespective of sexual orientation. Individuals who report they are in a monogamous relationship are allowed to donate. FDA maintains that self-reports of monogamy are too unreliable because of the high rate of infidelity between sexual partners.

FDA says that time-based MSM deferral remains necessary and that there is insufficient evidence to remove it. It points out that gay men still comprise a large proportion of adults with HIV infection. In 2010, the majority of <u>new HIV</u> <u>infections</u> were attributed to MSM. FDA estimates that eliminating the MSM deferral would increase the rate of infected donations <u>fourfold</u> to about one in every 375,000 donations.

Last week, FDA requested <u>public comment</u>, supported by scientific evidence, on the feasibility of moving from a timebased deferral to individual risk assessment. The agency says it will continue to reevaluate and update blood donor deferral policies as new scientific information becomes available.

In the meantime, FDA plans to study the impact of the switch to a 12-month deferral. In partnership with the National Institutes of Health (NIH), it is implementing a <u>Transfusion Transmissible Infections Monitoring System</u> to monitor the safety of the blood supply. It may take multiple years to see if there is any increase in the number of infected donations and transfusions.

Blood banks are busy implementing the 12-month MSM deferral policy. This entails updating deferral codes in

computer systems, revising (and having FDA approve) donor educational materials and donor screening questionnaires, updating standard operating procedures, and training staff.