A Drive for Change: Reforming U.S. Blood Donation Policies

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HHS Advisory Committee on Blood Safety and Availability Meeting
June 10–11, 2010

GMHC
FIGHT AIDS. LOVE LIFE.
We all want to increase the number of blood donors

Maintaining the safety of the blood supply is a critical concern of ours

We acknowledge gay men are more likely to be HIV-positive than the greater population, but most gay men are not HIV-positive

We are not advocating for all gay men to donate blood

We recognize the complicated history of blood contamination and its impact on people with hemophilia; we understand their concerns for any change to the blood donor policy

We do not think those in favor of maintaining the current policy are motivated by homophobia
The FDA Blood Ban

- The lifetime MSM blood donation ban, which dates to the early 1980s, is obsolete as it does not take account of significant technological advances which minimize threat to blood supply.

- The two most commonly used HIV tests, the Antibody Test and the Nucleic Acid Test (NAT), can detect the presence of an HIV infection several days to several weeks after the date of infection.

- “Prior to AIDS, gay people used to go in together to donate blood, as a community effort” – Supplies of Blood Fall as Demand Increases, New York Times (10/29/2000)

- Inconsistencies in blood donation guidelines: heterosexual person who knowingly has had sex with a HIV-positive person can donate after 1 year
Media

**Washington Times:**
“Senators ask FDA to lift gay blood donor ban”  
*(March 5, 2010)*

**Kansas City Star:**
“Blood donation ban for gay men facing new scrutiny”  
*(March 5, 2010)*

**Los Angeles Times:**
“Government revisiting restrictions on blood donations by gay men”  
*(March 13, 2010)*

**St. Louis Dispatch:**
“Gay men may get to donate blood”  
*(March 25, 2010)*

**USA Today:**
“Senators: Lift ban on gay men donating blood”  
*(May 3, 2010)*

**New York Times:**
Letter to the Editor: “Turning away blood donors”  
*(May 18, 2010)*

**CNN:**
“Blood, sex, and the FDA”  
*(May 31, 2010)*
Recent Developments

In recent years, leaders within the public health and blood bank communities have voiced support for reforming this policy:

- AABB
- American Red Cross
- America’s Blood Centers

Senator John Kerry in March spearheaded a letter signed by 17 other U.S. Senators calling on the FDA to revisit the policy.

33 members of the U.S. House of Representatives and 9 Senators have issued a joint letter to the HHS ACSBA committee calling for a revision to the policy.

New York City Council passed a resolution calling upon the FDA to reverse the policy.

District of Columbia Council unanimously passed a resolution urging the FDA to review the policy.

47 organizations have signed a letter supporting revision of the FDA’s policy.

Several prominent LGBT and hemophilia groups issued a joint statement articulating their commitment to the safety of the nation’s blood supply and a willingness to carefully revisit the current policy.
Not All Gay Men are at High-Risk

- Between 60% and 70% of gay men used condoms when having sex, compared with a third or less of heterosexual men and women.¹

- Gay men have safer sex at twice the rate of the general population.², ³, ⁴

- 91% of a sample of HIV-negative and untested MSM had not intentionally set out to have unprotected anal sex with someone other than a primary partner.⁵

- 90% of HIV-negative MSM had not had unprotected anal sex with another man in the past 2 years (San Francisco) ⁶ or 1 year (Seattle), ⁷ respectively.

- 90% of gay and bisexual men are HIV-negative (based on a meta analysis conducted by the CDC in 2010 which estimates that 2% of the adult population are MSM).

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Consequences of the Current Policy

- Provides false perception of low risk for HIV infection among heterosexual people

- Missed opportunity to promote public health and safer sex practices—a more rigorous behavior-based exclusion involving a questionnaire that asks all prospective donors about high-risk behavior would better accomplish this.

- Potential lifetime donors may be alienated by a policy that is perceived as discriminatory

- Poses complex issues of disclosure, lack of team spirit for gay men in schools and corporations

- Opposition to blood drives on university campuses, in most instances boycotts:
  - Keene State College, NH (2010)
  - University of Kansas (2010)
  - University of Pennsylvania (2008)
  - Oregon State University (2008)
  - University of Maine (2005)

- San Jose State University in California does not allow blood drives on campus because the ban violates non discrimination policies
Advancement in HIV Testing vs. Policy

**Testing**
- **1983**: FDA broadens the exclusion to defer "any man who has had sex with another man since 1977."
- **1986**: First Western Blot test kit
- **1987**: First rapid HIV test
- **1988**: First oral fluid test
- **1991**: First home and urine test
- **1994**: First rapid test using finger prick
- **1996**: Nucleic Acid Testing: detection of HIV in blood within several days of infection
- **2002**: First rapid oral fluid test

**Policy**
- **1983**: FDA broadens the exclusion to defer "any man who has had sex with another man since 1977."
- **1989**: The Public Health Service recommends deferrals for "all males who have had sex with more than one male since 1979, and males whose male partner has had sex with more than one male since 1979."
- **1990**: The CDC holds first public meeting on the AIDS virus and the blood supply, at which a ban on "sexually active homosexual and bisexual men with multiple partners" is first considered.
Policy Recommendations


- Decreased risk to recipients
- Objective risk factors,
- Non-discriminatory impact,
- Awareness raising,
- Technology-driven procedures,
- Expansion of donor pool.
5 Year Deferral

**Pros:**

- Would allow abstinent gay and bisexual men, and heterosexual-identified men with past same-sex experiences to donate blood

- Would be consistent with donating guidelines for tissue and semen donation among MSM

**Cons:**

- Would not significantly increase the number of newly eligible donors to the blood pool

- Five years is far longer than the window period for detecting HIV through post-donation tests under any presently used technology
1 Year Deferral

**Pros:**

- Would be consistent with current deferral periods for other high-risk groups, and would therefore be sustainably less discriminatory against gay and bisexual men as a group.

- Endorsed by Association of American Blood Banks, American Red Cross, and America’s Blood Centers.

**Cons:**

- It fails to distinguish between gay, bisexual, and other MSM at high or low risk of HIV infection.

- Would still bar many healthy, sexually active gay and bisexual men from donating blood, including men in long-term monogamous relationships.
Quantitative Risk Assessment:

- Estimated risk to U.K. blood supply:
  - 1-year deferral: risk of HIV-infected unit entering blood supply would increase from 0.45 per year to 0.75 per year
  - Complete end of ban: risk would increase from .45 per year to 2.5 per year
- Authors estimated .07% to .84% of MSM donors would be HIV-positive but unaware of their status

Challenges with the data:

- Study conducted prior to the introduction of NAT
- Meaningful confidence intervals are not available for many of the assumptions and estimates used to calculate risk estimates
Germain et al. (2003)
“The risks and benefits of accepting men who have had sex with men as blood donors.” Transfusion.

Quantitative Risk Assessment:
- 1-year MSM deferral would result in a risk increment of 1 HIV-positive unit escaping detection for every 11 million units of blood donated
- 0.6% estimated prevalence of undiagnosed HIV infection in MSM

Challenges with the data:
- Prevalence of undiagnosed HIV infection estimated from a cohort of men who had not abstained for 1 year and had not self-selected to donate
Anderson et al. (2009)
“Quantitative estimate of the risks and benefits of possible alternative blood donor deferral strategies for men who have had sex with men.” Transfusion.

Quantitative Risk Assessment:
- 1-year MSM deferral would correlate with 1 additional HIV-infectious unit released for transfusion every 5.55 years and decline four- to fivefold after the first year; 5-year MSM deferral would correlate with 1 additional HIV-infectious unit released every 33.3 years
- 2% estimated prevalence of undiagnosed HIV infection in MSM donors

Challenges with the data:
- Significant overestimate of the risk posed by MSM donors
- Not based on actual data re: prevalence of undiagnosed HIV infection in MSM
- Outdated 1996 data used to substantiate probability of erroneous release of HIV-positive units from quarantine; technology to protect against quarantine release errors has advanced significantly since then
Vamvakas argues that Anderson et al.’s estimate that 2% of MSM blood donors would be undiagnosed HIV-positive is much too high.

Omega study in Montreal of sexually active young gay men: 1.45% were HIV-positive.

MSM who abstain for 12 months and self-select to donate would have much lower HIV prevalence and undiagnosed HIV.

Vamvakas suggests using Germain et al.’s estimate of 0.6% undiagnosed HIV among MSM blood donors.

Using Germain’s 0.6% v. Anderson’s 2%, a 1 year MSM deferral would correlate with 1 additional HIV-infectious unit being released for transfusion every 18.5 years.

The continued use of pooled whole-blood derived platelets for 12.5% of U.S. patients’ transfusion needs represents a risk several times greater than would 1-year MSM deferral.
Wainberg et al. (2010)  
“Reconsidering the lifetime deferral of blood donation by men who have sex with men.” 
*Canadian Medical Association Journal.*

- Re: novel pathogen argument—“A future unknown agent could potentially be preferentially transmitted by heterosexual rather than homosexual relations.”
- MSM lifetime deferral “may suggest to the public that the blood of all such men is diseased.” (94% of Canadian MSM are HIV-negative)
- “MSM who are in a long-term relationship with the same partner, for a year or longer, would be likely to have a very low rate of HIV infection and would pose a correspondingly low risk to the blood supply.”
- “Men who have had sex with men but without risky behaviour for 5 years or longer are not at greater risk of transmitting HIV infection than members of the general population.”
- Recommends an end to the lifetime deferral for all MSM.
- “We believe that any potentially negative consequences of a change in deferral policy would be offset by benefits.”
Behavior-based Deferral

**Pros:**
- This policy would be more tailored to screen all donors based on actual risk, rather than over-inclusive group-based classifications
- Enable a greater pool of eligible MSM blood donors
- Potentially decrease risk of contaminated blood

**Challenges:**
- Data not currently available—requires quantitative risk assessment
- Exact language to defer high-risk persons needs to be developed
International Context

**Italy**

- January 26, 2001: The Italian Ministry of Health repealed a regulation which prevented blood donation by those engaged in “homosexual intercourse.” The current policy advises all prospective male and female donors to self-defer if they have a personal history of sex at high risk of transmission of infectious diseases (i.e. casual sex, promiscuous sex, sex for money, sex with someone with a personal history of STDs, HIV, hepatitis, drug use, or other high-risk situations).

- Since the policy has been in place, transfusion related HIV infections have dramatically decreased from 22 cases between 1999-2000 to 4 cases between 2007-2008.¹

**Spain**

- May 23, 2004: The policy defers for at least 6 months prospective male and female donors based on specific risky sexual behavior, such as sex with sex workers or sex with multiple partners. MSM who have not engaged in risky sexual behavior are eligible to donate blood.

- The Spanish Ministry for Health reports that the number of transfusion related HIV infections has steadily decreased, from 13 cases in 2001 to 4 cases in 2005.²

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¹ Notiziario dell’Istituto Superiore de Sanità
Recommendations/Questions

- Screen all donors for high risk behavior, and thereby confront the threat currently posed to the blood supply by high risk heterosexuals. Thoroughly review and evaluate behavior-based deferrals in other countries.

- Expand existing research to support change, such as more effective ways to identify high risk individuals by cognitively testing alternative screening questions. Consider revising donor questionnaire to include more detailed questions about sexual behavior (e.g., how many sexual partners have you had in the past year? were they male, female, or both?) Could a pilot program be commissioned that would try an alternative policy, such as a risk-based deferral, in a community setting such as a gay community center or health clinic?

- Consider broader societal implications of MSM deferral policy beyond its impact on gay men.

- When will the FDA review and issue a determination on pathogen reduction technology of whole-blood units, already in use in a number of countries in Europe and Asia?