

REPORT 5 OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH (A-08)
Revision of the Lifetime Deferral for Blood Donation of the Men Who Have Sex with Men (MSM)
Population
(Resolution 515, A-07)
(Reference Committee E)

EXECUTIVE SUMMARY

Objectives. To review the data on the prevalence of human immunodeficiency virus (HIV) in the men who have sex with men (MSM) population, examine the potential increase in the blood supply that would result from increased donations by the MSM population, and discuss any increased risk to the safety of the blood supply should the lifetime deferral of MSM from blood donation be removed.

Data Sources. Literature searches were conducted in the PubMed database for English-language articles published between 1998 and 2008 using the search term “men who have sex with men blood donation” or “men who have sex with men blood deferral.” The World Wide Web was searched, using the “Google” search engine, using the search term “men who have sex with men blood donation deferral.”

Results. Current Food and Drug Administration (FDA) blood donor deferral criteria require that men who have had sex with men even once since 1977 be permanently deferred from blood donation. A policy change with respect to blood donation deferral is a risk management decision wherein the risks of introducing additional infected units for transfusion over the current residual risk must be balanced against the benefits of increasing the pool of blood donors. Also important are ethical and societal factors. Current prevalence rates of HIV in the MSM population and the residual risk with the current deferral policy suggest an unacceptable increase in risk should the MSM population no longer be deferred. Targeting blood donation deferral to a set of high risk behaviors is not practical. While, the increased risk with a 1-year abstinence from blood donation from the last MSM contact would be very small, it is not zero. This small but scientifically real increase in risk represents a clear violation of ethical principles and therefore is not tolerable. If a 5- or 10-year deferral policy is considered, risk management calculations would yield risks at a level that many might consider acceptable. Data suggest that men who have abstained from sex with other men for more than 5 years essentially present no greater risk than the general population and that while it is a matter of judgment as to whether a 5-year deferral period would pass the risk hurdle, it may be reasonable to consider. However, many argue that the rights of blood transfusion recipients outweigh any asserted rights of blood donors and that the right to receive safe blood is the overriding responsibility of blood collection agencies.

Conclusions. Men who have had sex with men since 1977 are currently permanently deferred from blood donation. This FDA policy recommendation has generated controversy due concerns that it may be discriminatory and that it stigmatizes the MSM population. Any policy decision on blood donation deferral of the MSM population must be governed by the best available scientific evidence but there are inherent weaknesses in mathematical models used in the risk assessments on this issue that continue to generate some uncertainty. With respect to the MSM population, it appears that a policy change from a permanent lifetime deferral to a 5-year deferral following the last MSM contact may be supportable, but societal and ethical consequences must be analyzed should this decision be advanced.

REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 5 -A-08

Subject: Revision of the Lifetime Deferral for Blood Donation of the Men Who Have Sex with Men (MSM) Population
(Resolution 515, A-07)

Presented by: Mary Anne McCaffree, MD, Chair

Referred to: Reference Committee E
(Shannon M. Kilgore, MD, Chair)

1 Resolution 515 (A-07), introduced by the New York Delegation and referred to the Board of
2 Trustees, asked:

3
4 That our American Medical Association (AMA) advocate to the Food and Drug
5 Administration (FDA) that its guidance is discriminatory to large populations of potential
6 blood donors and that this policy has not kept pace with screening technology and with the
7 spread of specific diseases; and

8
9 That our AMA advocate to the FDA that a uniform screening of donors be put in place for
10 all populations and that the lifetime restriction for men who have had sex with men since
11 1977 be eliminated.

12
13 This Council report reviews data on the prevalence of human immunodeficiency virus (HIV) in the
14 men who have sex with men (MSM) population, examines the potential increase in the blood supply
15 that would result from increased donations by the MSM population, and discusses any increased risk
16 to the safety of the blood supply should the lifetime deferral from blood donation be removed. The
17 report does not discuss social and ethical issues that surround the current FDA guidance on this
18 issue.

19
20 Data Sources

- 21
22 • Literature searches conducted in the PubMed database for English-language articles published
23 between 1998 and 2008 using the search terms “men who have sex with men blood donation” or
24 “men who have sex with men blood deferral” yielded a total of 95 references; 45 articles/reviews
25 directly relevant to the risk management of blood donations were selected for further review. An
26 additional 11 references were culled from the articles selected for further review.
- 27 • The World Wide Web was searched, using the “Google” search engine, using the search term
28 “men who have sex with men blood donation deferral.” Relevant Web references were examined
29 for accuracy and appropriateness. Electronic references cited in this report were revisited to
30 verify availability as of March 5, 2008.

31
32 Introduction

33
34 Over the past few years, interest has been expressed in changing the current FDA blood donor
35 deferral criteria for the MSM population. Men who have had sex with men even once since 1977 are
36 permanently deferred from blood donation. It has been proposed that permanent deferral be changed
37 to a specific time of abstinence from MSM behavior, after which the individual should be allowed to

1 donate blood. Several time lengths have been proposed for the deferral period; however, a 1-year
2 deferral has received the most interest. The primary reasons why this policy change is being
3 considered are the view that the current policy is discriminatory toward the gay population and that
4 the volatility of the US blood supply would be eased by relaxation of the current policy.

5
6 This matter is difficult to address based purely on scientific data. Clearly, this is a risk management
7 decision where the best available scientific evidence must be balanced against the needs of society,
8 both in terms of the blood supply itself (i.e., safety and quantity) and in terms of cultural and ethical
9 norms.

10
11 This report presents the current scientific data on blood donation deferral and the MSM population.
12 It recommends that an analysis of the societal and ethical implications of revising the lifetime
13 deferral policy for MSM populations be undertaken by the Council on Ethical and Judicial Affairs in
14 order that the risk management equation be balanced. Indeed, the FDA suggests that this risk
15 management decision is constantly changing based on new scientific data and has committed to
16 convening expert panels to review the evidence regularly. It is also reasonable to expect that
17 changing societal norms will play a major role in public acceptance of any such policy change. The
18 FDA states that should future information support a change in the current policy for the MSM
19 population, it will be seriously considered. Additionally, the FDA has stated that it is working with
20 the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health to reach
21 consensus on this issue. Of note, both Canada and the European Union have a similar lifetime blood
22 donation deferral policy for the MSM population and following recent review have chosen to
23 maintain the status quo.

24 25 Blood Donation in the United States

26
27 The current US blood supply is remarkably safe. However, the potential for new, as yet unidentified,
28 bloodborne pathogens for which no tests exist, analogous to hepatitis C in the late 1980s and West
29 Nile virus in this decade, requires that stringent donor selection criteria remain firmly in place.
30 While the ultimate responsibility for keeping the US blood supply safe lies with the individual
31 establishments that collect the blood, the FDA is tasked with keeping blood donations as safe as
32 possible. To accomplish this, the FDA has issued guidance that recommends multi-layered
33 protections for donated blood to ensure its safety.¹ There are five levels:

34
35 Donor Screening: Donors are first informed about potential risks that may compromise the blood
36 supply, and then through a detailed questionnaire are required to answer questions about factors that
37 may bear on the safety of their blood.² For example, donors with a history of intravenous (IV) drug
38 abuse are permanently deferred. Studies indicate that donor screening is effective; for example, one
39 study indicates that donors deferred via standard blood donor questions regarding risk of viral
40 hepatitis as well as those with a history of IV drug use were more likely to have higher hepatitis
41 marker rates than those who were not deferred.² Of note, prior to the availability of tests for HIV
42 and hepatitis C, the risks of post-transfusion hepatitis C and HIV infection were managed via donor
43 selection criteria, such as the use of voluntary donors and deferral of those with known risk
44 conditions.³

45
46 Blood Testing: After donation, every unit of donated blood undergoes a series of tests for hepatitis B
47 and C viruses (HBV and HCV), HIV 1 and 2, human T-lymphotropic virus (HTLV types I and II),
48 West Nile virus, and syphilis. These tests have become more and more sophisticated, and the current
49 use of nucleic acid testing (NAT) has dramatically reduced the risk of contracting HIV and HCV
50 from the blood supply.^{4,5} However, despite the improved bloodborne pathogen testing, there still
51 remains a “window” period for several of these pathogens during which the tests will *not* detect

1 recent infection of the donor. For HIV, this window is now about 11 days and for HCV 10 days
2 (although a range of 10 to 30 days is possible).⁴

3
4 Donor Lists: All blood collection establishments are required to keep a current list of deferred donors
5 and use it to ensure they do not collect blood from anyone on the list.

6
7 Quarantine: Donated blood must be quarantined and not used for transfusion until it is tested and
8 shown to be free of known infectious agents.

9
10 Problems and Deficiencies: Should manufacturing problems occur, blood collection establishments
11 are required to investigate immediately and correct all deficiencies. The FDA must be notified when
12 product deviations occur in distributed products.

13 14 Current Lifetime Blood Donation Deferral Criteria

15
16 Current FDA guidance is followed in an FDA-approved AABB- (formerly known as the American
17 Association of Blood Banks) developed Donor History Questionnaire, which is used by blood
18 collection agencies, such as AABB members, America's Blood Centers, and the American Red
19 Cross. This recommends that any person fitting the following conditions be permanently deferred for
20 blood donation;⁶

- 21
22 ▪ Is repeatedly reactive to screening tests for HBV, HCV, HIV, HTLV-I/II (on two
23 independent donations), and has antibodies to core antigen of HBV (on two independent
24 donations);
- 25 ▪ Has a history of hepatitis since age 11 years;
- 26 ▪ Has a history of hemophilia or other inherited bleeding disease;
- 27 ▪ Has a history of IV drug use;
- 28 ▪ Has a history of Chagas' disease;
- 29 ▪ Has a blood relative with Creutzfeldt-Jakob disease;
- 30 ▪ Has received growth hormone of human pituitary origin or dura mater graft;
- 31 ▪ Has lived in the United Kingdom for 3 months or more between 1980 and 1996, or in
32 Europe for 5 years overall or more since 1980;
- 33 ▪ Has received a transfusion in the United Kingdom or France since 1980;
- 34 ▪ Has a history of hematologic cancer;
- 35 ▪ Is a male who had sex with a male even once since 1977; or
- 36 ▪ Has received money or drugs for sex.

37
38 In addition to these permanent deferrals, there are also deferrals for specific time periods, which are
39 determined by the risk factor and may be implemented at the medical director's discretion. Thus, if
40 someone self-identifies as having had acupuncture, electrolysis, or a body piercing, they are deferred
41 from donating blood for 1 year. Even ear piercings, if not performed in a physician's office, may
42 necessitate a 1-year deferral. Dental work may require a 1-day deferral while a root canal procedure
43 may call for a 3-day deferral.⁶

44 45 Residual Risk of Contracting a Bloodborne Pathogen from a Blood Transfusion

46
47 Despite these efforts, certain challenges to efficacy of the donor screening process remain. First, the
48 potential donor must be able to fully understand the screening questions in order to answer them
49 accurately. For example, it has been shown that donors have a varying range of definitions of sex
50 that may be due to different concepts of risk activities.⁷ Second, there will always be some
51 underlying level of unreported deferrable risk, with younger donors more likely to not report

1 deferrable risk.^{8,9} Third, there is the risk of quarantine release errors, in which a unit of blood
2 waiting for testing is accidentally released. Finally, despite donor screening, rare testing errors will
3 occur, although some experts believe these to be so low in frequency as to be inconsequential.¹⁰
4

5 When all factors are considered, the risk that an infectious unit of blood will be undetected and enter
6 the blood supply is called the residual risk. In the United States, this residual risk is currently
7 estimated to be about 1 in 1,935,000 donations for HCV and 1 in 2,135,000 donations for HIV, with
8 the combined use of NAT and serologic screening of donations.^{11,12} Hepatitis B virus residual risk,
9 using a combination of anti-hepatitis B core and hepatitis B surface antigen testing, is about 1 unit in
10 200,000 to 500,000 donations.¹² NAT is available for HBV but is not required as a routine screen due
11 to the marginal added benefit of its use with pooled donor samples. However, it is being performed
12 under an investigational new drug (IND) application in selected blood centers. It is important to note
13 that incidence rates for all these pathogens and for HTLV are twice as high in first-time donors,
14 which emphasizes the importance of the testing process, even after donor deferral.¹¹
15

16 At this time, the residual risk of West Nile virus is estimated to 1 in 350,000 donation.¹³ While six
17 cases of transfusion-associated transmission of West Nile virus have been identified since 2003
18 (when minipool NAT was introduced), there have been no cases since individual donation NAT in
19 endemic regions was implemented.^{12,14}
20

21 Prevalence of the MSM Population in the United States

22

23 Although few definitive reports exist on the prevalence of MSM in the US population, one carefully
24 performed and frequently cited survey from 1994 reported that 2.8% of males aged 18 years or older
25 self-identified as being homosexual or gay.¹⁵ Data from the General Social Surveys conducted
26 between 1996 and 2000 indicate the rate of MSM to be in the range of 3.1% to 3.7%.¹⁶
27

28 Prevalence of HIV and Other Bloodborne Pathogens in the MSM Population

29

30 Surveillance data from the CDC indicate that three decades into the HIV epidemic, the MSM
31 population comprised more than two-thirds (68%) of all men living with HIV in 2005, even though
32 only about 5% to 7% of US men have reported having sex with other men.¹⁷ Additionally, data from
33 the National HIV Behavioral Surveillance system suggest that HIV prevalence ranges from about
34 18% to 40%, with a median of 25% in this population.¹⁸ This translates to about 500,000 to 800,000
35 MSM who are infected with HIV. Significantly, 48% of the MSM who were HIV-positive were
36 unaware of their infection,¹⁸ and more than half of those who were unaware had not had an HIV test
37 in the previous year.¹⁸ Other reports suggest a lower HIV prevalence (about 8%) in the MSM
38 population, perhaps reflecting differences in the sample populations studied,^{19,20} with 25% of HIV-
39 infected MSM unaware of their infection.²¹ However, the incidence of HIV in the MSM population
40 remains fairly stable, ranging between 2% to 3% per year for those with high risk behaviors and 1%
41 for those with low risk behaviors.^{22,23}
42

43 With respect to HBV and HCV prevalence, while levels have declined over the last 20 years, the
44 primary risk factors for infection have not. Thus, about 18% to 40% of MSM have markers of
45 previous HBV infection, while about 4% have markers of HCV infection.²³⁻²⁵ Incidence of HBV
46 infection in the MSM population averages about 13%.²⁶ Notably, HCV prevalence in the MSM
47 population is no more than twice that of the general population, and with the high sensitivity of anti-
48 HCV enzyme immunoassay and the redundancy of HCV NAT, deferral of blood donations from the
49 MSM population plays at best a marginal role in preventing HCV transmission.

1 With respect to HBV, it is important to recognize that 95% of HBV infections resolve, with an
2 average window period of about 80 days. Thus, with any deferral policy that is greater than 1 year
3 following the high risk activity, the primary risk to the blood supply lies in those who are chronically
4 infected. The prevalence of chronic HBV infection in the MSM population is about 1%. Even then,
5 these donors would test positive with the two HBV antibody tests and thus the primary risk defaults
6 to donation during the window period following infection.²⁷
7

8 Of more recent relevance to the MSM population is human herpesvirus 8 (HHV-8), the causative
9 agent for Kaposi's sarcoma. At the May 2006 meeting of the Department of Health and Human
10 Services (HHS) Advisory Committee on Blood Safety and Availability, it was reported that the
11 prevalence of HHV-8 in HIV-negative MSM was about 12% to 16%. However, it appears that while
12 HHV-8 may be transmitted via blood transfusions, the rate is about 2% to 3% of seropositive
13 units.^{28,29} Finally, the prevalence of HHV-8 among the general population of donors is quite high (at
14 least 3.5%) and there are no reports of increased Kaposi's sarcoma incidence, even when many of
15 these units are transfused into immunosuppressed patients.³⁰
16

17 Risk Assessment of the Donor Deferral Criteria for the MSM Population

18

19 Several factors must be considered in any decision to change the current lifetime deferral criteria for
20 blood donation for the MSM population. The first is whether a deferral standard can be created that
21 would result in no significant increase in risk over the current lifetime deferral criteria. This makes
22 the assumption that the US public would not accept any situation that would result in a blood supply
23 that is not as safe as reasonably possible. The second is whether any change in the deferral criteria
24 would increase donor numbers sufficiently to make a significant impact on the current blood supply.
25 In this regard, the 2005 Nationwide Blood Collection and Utilization Report indicates that while
26 blood shortages were less frequent, when they did occur they were more acute,³¹ and some studies
27 indicate that any change in deferral standards may only marginally improve recruitment of MSM
28 donors.³² Third, ethical and societal issues must be considered and these include the perception of
29 discrimination against the MSM population should deferral criteria not be supported by scientific
30 data. Indeed, lawsuits are beginning to be filed against blood collection agencies for refusing to
31 accept blood donations from the MSM population.³³
32

33 Several studies (some unpublished, but presented at the FDA's March 2006 Behavior-Based Donor
34 Deferrals in the NAT Era meeting) have examined these issues.²³ Leiss and colleagues examined
35 different deferral criteria that included: (1) No MSM deferral; (2) change to a 1-year deferral period;
36 (3) change to a 5-year deferral period; and (4) change to a 10-year deferral period.¹⁰ Their analysis
37 concluded that with the current prevalence rates of HIV in the MSM population and the residual risk
38 with the current deferral policy, there would be an unacceptable increase in risk should the MSM
39 population no longer be deferred, thereby making the safety of the blood supply rely solely on blood
40 testing. This finding is supported by a 2007 study in Australia, which reported that those potential
41 donors most likely to become infected with HIV and donate blood during the testing window period
42 were MSM.³⁴ The Leiss study also concluded that targeting blood donation deferral to a set of high-
43 risk behaviors is not practical. In particular, such a practice would require the screening process to
44 ask questions that focus "directly and in detail" on very sensitive and intimate sexual behavior,
45 questions that many donors would find awkward to answer truthfully. Furthermore, behaviors
46 change over time and this strategy would create many challenges for administrators of blood
47 collection agencies. The example used by the authors is an individual who has previously donated
48 but now declares a sexual behavior risk.¹⁰
49

50 A 1-Year Deferral Policy: Germain and co-workers have examined the impact on the US blood
51 supply of a 1-year deferral policy.³⁵ They calculate an 8% increase in HIV risk or 1 additional HIV-

1 contaminated unit for every 136,000 additional donations and estimate that the number of donations
2 would increase by 1.3%. The authors conclude that while the increased risk with a 1-year abstinence
3 from blood donation from the last MSM contact would be very small, it is not zero.

4
5 A study by Soldan and Sinka estimated that in the United Kingdom the risk of an HIV-infected unit
6 being released to the public would increase by 60% with a policy change from lifetime deferral to a
7 1-year deferral from last MSM contact, reflecting an increase from the current risk of 0.45 per year
8 to 0.75 per year.³⁶ These authors also state that the increase in non-infected donations with such a
9 policy shift would be small (perhaps 2% of current donations), and they favor maintaining permanent
10 de-selection of MSM, irrespective of the risk of HIV-infectious donations.

11
12 Finally, in 2006, Andrew Dayton summarized to the HHS Advisory Committee on Blood Safety and
13 Availability the findings from a March 2006 FDA workshop on deferral of the MSM population.^{23,28}
14 His mathematical modeling using data from the FDA's Biological Product Deviation Report
15 suggested that a 1-year deferral policy would increase HIV risk by 2.5% of the current risk.
16 However, the same model using older data from New York state yielded an increased HIV risk of
17 40% of the current risk, which translates to an increase of about 5 infectious units transfused (in this
18 model, Dr. Dayton assumed a background residual risk of 12 infected units). Analysis of such a
19 policy change in 2000 indicates that the pool of blood donors could be increased by 112,000.²⁷

20
21 Leiss and colleagues suggest that similar to changing to a no-deferral policy, this small but
22 scientifically real increase in risk is a clear violation of ethical principles and therefore not
23 acceptable.¹⁰ However, testimony from Celso Bianco representing the AABB at the May 2006
24 Advisory Committee on Blood Safety and Availability meeting argued that assumptions made in
25 these studies have been too conservative; the AABB's analysis suggests that moving to a 1-year
26 deferral policy would increase the number of HIV-infected donations being transfused by 1 in 46
27 million donations, or 1 case every 32.8 years.²⁸

28
29 A 5-Year Deferral Policy: If a 5- or 10-year deferral policy is considered, risk management
30 calculations would yield risks at a level that many might consider acceptable. A study by Sanchez
31 and colleagues found that compared to blood donors who did not report MSM contact, the
32 prevalence of reactive screening test results was fivefold higher among those who reported the
33 behavior within the past 5 years.³⁷ However, in those who last practiced male-to-male sex more than
34 5 years ago, no significant difference was found. The authors suggest that a 5-year deferral
35 following MSM contact may be a good starting point for consideration in changing blood donation
36 deferral policy.

37
38 At the March 2006 FDA workshop, Andrew Dayton presented data indicating that a 5-year deferral
39 policy would increase HIV risk by 1.7% of the current risk. This is using the newer data from the
40 FDA's Biological Product Deviation Report. Using the older New York state data yielded an
41 estimate of increased HIV risk of 25% over the current residual risk (allowing 3 more infectious
42 components to be transfused).²³ With respect to HHV-8, the FDA estimates that changing the MSM
43 deferral to 1 to 5 years would increase blood recipient exposure to HHV-8 by 2% to 5%.²⁸ Michael
44 Busch presented information indicating that with abstinence of less than 12 months or for 1 to 5
45 years, the presence of positive infectious disease markers was 3 to 4 times that of the general donor
46 population.²⁸ However, with abstinence for 5 years or longer, the marker rate was similar to that of
47 the general donor population.²⁸

48
49 Thus, data suggest that men who have abstained from sex with other men for more than 5 years
50 essentially present no greater risk than the general population.^{10,23,28} Additionally, at the May 2006
51 Advisory Committee on Blood Safety and Availability meeting, data were presented indicating that a

1 5-year deferral period would provide a temporal safety net that would allow unidentified pathogens
2 that may emerge to be recognized before they enter the blood supply.²⁸ A policy change consistent
3 with these data was examined by the FDA in 2000 and it was estimated that about 62,300 new
4 donors would be added to the donor pool.²⁷ In their risk management analysis, Leiss and co-workers
5 suggest that while it is a matter of judgment as to whether a 5-year deferral period would pass the
6 risk hurdle, it may be “within the ballpark “ for discussion.¹⁰ They also suggest potential societal
7 and ethical benefits from considering this policy change. These include the utilitarian benefit of
8 potentially increasing the pool of blood donors, and the social benefit of reducing the perceived
9 stigma associated with the MSM population. However, it must be noted that this remains
10 controversial. Many argue that the rights of blood transfusion recipients outweigh any asserted
11 rights of blood donors,³⁸ that the right to receive safe blood is the overriding responsibility of blood
12 collection agencies,³⁹ and that there is no direct discrimination in the current lifetime deferral policy
13 since the purpose of selection is to prevent virus infections, including HIV, with which the MSM
14 population are disproportionately affected.²⁸

15 16 A Perspective on Risk Assessment

17
18 Any mathematical model for risk management can only provide an estimate of the potential risk. To
19 put this into perspective, the residual risk that an HIV-infected unit of blood will enter the blood
20 supply is estimated at about 1 infected donation for every 2.1 million donations, which translates to a
21 residual risk of about 7 infected units every year – there are about 14.5 million blood donations
22 annually.³¹ However, it is clear that 7 HIV-infected units do not enter the US blood supply annually
23 undetected. In fact, since the implementation of NAT in 1999, there have been four incidences
24 where HIV has been transmitted via a blood transfusion, with the last in 2002 (C. Bianco, America’s
25 Blood Centers, personal communication, April 2008). In all four of these transmissions, the donors
26 denied any risk factors at screening, rendering the length of donor deferral moot (J. MacPherson,
27 America’s Blood Centers, personal communication, April 2008). In the eight years since the
28 implementation of NAT, more than 14 million units of whole blood/red blood cells, and about 28
29 million total blood components, have been transfused annually. A rudimentary analysis would
30 suggest that out of more than 112 million whole blood units transfused, only 4 resulted in HIV
31 transmission. Clearly, this is far lower than is predicted by the risk models. Whether this is due to
32 the lifetime deferral or to the fact that there is short, finite 11-day window period during which the
33 risk of an infected donor’s blood cannot be adequately tested, cannot be determined. In the absence
34 of actual data to supplement the risk assessments, these risk assessments will only be as good as the
35 assumptions used in the modeling. Indeed, this is a position echoed by the blood collection agencies.

36 37 The Position of Blood Collection Agencies

38
39 Blood collection agencies do not support the current lifetime deferral recommendation for men who
40 have had sex with men even once since 1977. In a statement submitted to the March 2006 FDA
41 Workshop on Behavior-Based Donor Deferrals in the NAT Era, the American Red Cross, America’s
42 Blood Centers, and the AABB stated that they “believe that the current lifetime deferral for men who
43 have had sex with other men is medically and scientifically unwarranted and recommend that
44 deferral criteria be modified and made comparable with criteria for other groups at increased risk for
45 sexual transmission of transfusion-transmitted infection.”⁴⁰ These three organizations, which
46 represent virtually all the blood collection agencies in the United States, also specify that they
47 “acknowledge the concern that relaxation of deferral criteria may increase the number of presenting
48 donors who are marker positive.” They go on to state, “[h]owever, this impact has not been
49 measured directly; it has only been modeled using what may be incomplete assumptions. The blood
50 collectors are willing to assist in collecting data regarding the actual impact of changes in the

1 deferral, in order to allow for informed decision-making, and/or for the development of additional,
2 appropriate interventions to ameliorate the impact.”

3
4 Conclusions

5
6 Men who have had sex with men since 1977 are currently permanently deferred from blood
7 donation. This FDA policy recommendation has generated controversy due concerns that it may be
8 discriminatory and that it stigmatizes the MSM population. It is clear that a policy change with
9 respect to blood donation deferral is a risk management decision wherein the risks of introducing
10 additional infected units for transfusion over the current residual risk must be balanced against the
11 benefits of increasing the pool of blood donors. Also important are ethical and societal factors,
12 which this report does not address. Any policy decision on blood donation deferral of the MSM
13 population must be governed by the best available scientific evidence but there are inherent
14 weaknesses in mathematical models used in the risk assessments on this issue that continue to
15 generate some uncertainty. With respect to the MSM population, it appears that a policy change
16 from a permanent lifetime deferral to a 5-year deferral following the last MSM contact may be
17 supportable, but societal and ethical consequences must be analyzed should this decision be
18 advanced. Such an analysis should include discussion of what society would consider acceptable
19 risk with respect to safety of the blood supply, as that will determine to what extent a precautionary
20 principle must be factored into any policy decision. Finally, should such a policy change occur,
21 blood collection agencies must be marshaled to collect data that will provide actual data for future
22 risk assessments to improve decision-making on this issue.

23
24 RECOMMENDATION

25
26 The Council on Science and Public Health recommends that the following statement be adopted in
27 lieu of Resolution 515 (A-07), and that the remainder of this report be filed:

28
29 That our American Medical Association (AMA) recognize that based on existing scientific
30 evidence and risk assessment models, a shift to a 5-year deferral policy for blood donation
31 from men who have sex with men (MSM) is supportable. (New HOD Policy)

Fiscal Note: \$5,200

REFERENCES

1. Food and Drug Administration. Keeping Blood Transfusions Safe: FDA's Multi-layered Protections for Donated Blood. Available at: <http://www.fda.gov/opacom/factsheets/justthefacts/15blood.html>. Accessed: 3-5-2008.
2. Zou S, Fujii K, Johnson S, et al. Prevalence of selected viral infections among blood donors deferred for potential risk to blood safety. *Transfusion*. 2006;46:1997-2003.
3. Tan L, Khan MK, Hawk JC, III. Use of blood therapeutically drawn from hemochromatosis patients. Council on Scientific Affairs, American Medical Association. *Transfusion*. 1999;39:1018-1026.
4. Stramer SL, Glynn SA, Kleinman SH, et al. Detection of HIV-1 and HCV infections among antibody-negative blood donors by nucleic acid-amplification testing. *N Engl J Med*. 2004;351:760-768.
5. Goodman JL. The safety and availability of blood and tissues--progress and challenges. *N Engl J Med*. 2004;351:819-822.
6. American Association of Blood Banks. Blood Donor History Questionnaire. Available at: http://www.aabb.org/Content/Donate_Blood/Donor_History_Questionnaires/AABB_Blood_Donor_History_Questionnaire. Accessed: 3-5-2008.
7. O'Brien SF, Ram SS, Yi QL, Goldman M. Donor's understanding of the definition of sex as applied to predonation screening questions. *Vox Sang*. 2008;
8. Damesyn MA, Glynn SA, Schreiber GB, et al. Behavioral and infectious disease risks in young blood donors: implications for recruitment. *Transfusion*. 2003;43:1596-1603.
9. Van der Bij AK, Coutinho RA, Van der Poel CL. Surveillance of risk profiles among new and repeat blood donors with transfusion-transmissible infections from 1995 through 2003 in the Netherlands. *Transfusion*. 2006;46:1729-1736.
10. Leiss W, Tyshenko M, Krewski D. Men having sex with men donor deferral risk assessment: an analysis using risk management principles. *Transfus Med Rev*. 2008;22:35-57.
11. Dodd RY, Notari EP, Stramer SL. Current prevalence and incidence of infectious disease markers and estimated window-period risk in the American Red Cross blood donor population. *Transfusion*. 2002;42:975-979.
12. Stramer SL. Current risks of transfusion-transmitted agents: a review. *Arch Pathol Lab Med*. 2007;131:702-707.
13. Bihl F, Castelli D, Marincola F, Dodd RY, Brander C. Transfusion-transmitted infections. *J Transl Med*. 2007;5:25
14. West Nile virus transmission through blood transfusion--South Dakota, 2006. *MMWR Morb Mortal Wkly Rep*. 2007;56:76-79.

15. Laumann EO, Gagnon JH, Michael RT, Michaels S. *The Social Organization of Sexuality in the United States*. Chicago: University of Chicago Press; 1994.
16. Anderson JE, Stall R. Increased reporting of male-to-male sexual activity in a national survey. *Sex Transm Dis*. 2002;29:643-646.
17. Centers for Disease Control and Prevention. Cases of HIV infection and AIDS in the United States and Dependent Areas, 2005. Available at: <http://www.cdc.gov/hiv/topics/surveillance/resources/reports/2005report/default.htm>. Accessed: 3-5-2008.
18. Sifakis F, Flynn CP, Metsch LR, et al. HIV Prevalence, Unrecognized Infection, and HIV Testing Among Men Who Have Sex with Men --- Five U.S. Cities, June 2004--April 2005. *MMWR*. 2005;54:597-601.
19. Pollack LM, Osmond DH, Paul JP, Catania JA. Evaluation of the Center for Disease Control and Prevention's HIV behavioral surveillance of men who have sex with men: sampling issues. *Sex Transm Dis*. 2005;32:581-589.
20. McQuillan GM, Kruszon-Moran D, Kottiri BJ, et al. Prevalence of HIV in the US household population: the National Health and Nutrition Examination Surveys, 1988 to 2002. *J Acquir Immune Defic Syndr*. 2006;41:651-656.
21. Unrecognized HIV infection, risk behaviors, and perceptions of risk among young black men who have sex with men--six U.S. cities, 1994-1998. *MMWR Morb Mortal Wkly Rep*. 2002;51:733-736.
22. McFarland W, Stoyanoff SR, Shehan D, et al. HIV Incidence Among Young Men Who Have Sex With Men -- Seven U.S. Cities, 1994-2000. *MMWR. Morb Mortal Wkly Rep*. 2001;50:440-444.
23. Food and Drug Administration. Behavior-Based Donor Deferrals in the NAT Era. Available at: <http://www.fda.gov/cber/minutes/nat030806t.htm>. Accessed: 3-5-2008.
24. Rhodes SD, DiClemente RJ, Yee LJ, Hergenrather KC. Hepatitis B vaccination in a high risk MSM population: the need for vaccine education. *Sex Transm Infect*. 2000;76:408-409.
25. Remis RS, Dufour A, Alary M, et al. Association of hepatitis B virus infection with other sexually transmitted infections in homosexual men. Omega Study Group. *Am J Public Health*. 2000;90:1570-1574.
26. Wasley A, Miller JT, Finelli L. Surveillance for acute viral hepatitis--United States, 2005. *MMWR Surveill Summ*. 2007;56:1-24.
27. Dayton, A. I. Deferral of MSM: Policy Analysis. Available at: <http://www.fda.gov/OHRMS/DOCKETS/AC/00/backgrd/3649b1t/index.htm>. Accessed: 3-5-2008.
28. Department of Health and Human Services. Blood Safety and Availability Advisory Committee May 2006 meeting transcript. Available at: <http://www.hhs.gov/bloodsafety/transcripts/ACBSA20060509.pdf>. Accessed: 3-5-2008.

29. Hladik W, Dollard SC, Mermin J, et al. Transmission of human herpesvirus 8 by blood transfusion. *N Engl J Med*. 2006;355:1331-1338.
30. America's Blood Centers. Study Finds Evidence of Transmission of HHV-8 by Transfusion. *ABC Newsletter*. 2006;37:1-2.
31. Department of Health and Human Services. 2005 Nationwide Blood Collection and Utilization Survey. Available at: <http://www.hhs.gov/bloodsafety/2005NBCUS.pdf>. Accessed: 3-3-2008.
32. Spencer B, Rios J, Cable R. Marginal recruitment impact of potential alterations to FDA deferral criteria for men who have sex with men. *Transfusion*. 2006;46:869-870.
33. Garmaise D. Gay man launches suit over refusal to accept blood donation. *HIV AIDS Policy Law Rev*. 2006;11:20-21.
34. Musto JA, Seed CR, Law M, Keller AJ, Kaldor JM. Estimating the risk of blood donation associated with HIV risk behaviours. *Transfus Med*. 2008;18:49-54.
35. Germain M, Remis RS, Delage G. The risks and benefits of accepting men who have had sex with men as blood donors. *Transfusion*. 2003;43:25-33.
36. Soldan K, Sinka K. Evaluation of the de-selection of men who have had sex with men from blood donation in England. *Vox Sang*. 2003;84:265-273.
37. Sanchez AM, Schreiber GB, Nass CC, et al. The impact of male-to-male sexual experience on risk profiles of blood donors. *Transfusion*. 2005;45:404-413.
38. Brooks JP. The rights of blood recipients should supersede any asserted rights of blood donors. *Vox Sang*. 2004;87:280-286.
39. Franklin IM. Is there a right to donate blood? Patient rights; donor responsibilities. *Transfus Med*. 2007;17:161-168.
40. Kleinman S: *Behavior-Based Blood Donors Deferrals in the Era of Nucleic Acid Testing (NAT): AABB Statement presented at the FDA Behavior-Based Blood Donors Deferrals in the Era of Nucleic Acid Testing (NAT) meeting, 2006.*