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3 Title: Improved Deferral Periods for Blood Donors
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5 Introduced by: Charles J. Barone II, MD, for the Wayne County Delegation
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7 Original Author: Samantha Rea
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9 Referred to: Reference Committee D
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11 House Action: **APPROVED**
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14 Whereas, someone in the United States needs a blood product every two seconds, yet less than
15 three percent of eligible donors will donate blood each year¹, and
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17 Whereas, there are constantly blood supply shortages that deprive patients of lifesaving blood
18 products¹, and
19

20 Whereas, American Medical Association (AMA) policy H-50.990, "Blood Shortage and Collection,"
21 calls for encouragement of blood donation to meet these increased demands and prevent shortages, and
22

23 Whereas, the current Food and Drug Administration (FDA) blood donation guidelines require a 12-
24 month deferral period from the most recent sexual contact with a man who has had sex with another man
25 (MSM)², and
26

27 Whereas, 2.1 million potential MSM donors are unable to donate blood because of the 12-month
28 deferral, and a reduced deferral period could potentially allow 317,000 more pints of blood to be collected
29 each year³, and
30

31 Whereas, 90 percent of surveyed MSM individuals were interested in donating blood, yet only five
32 percent reported that they would remain abstinent for an entire year to be eligible to donate⁴, and
33

34 Whereas, significant stigma still exists surrounding the 12-month deferral period in the MSM
35 community, and it is essential to establish trust in the medical community by advocating for policy that is
36 scientifically based^{5,6}, and
37

38 Whereas, no evidence supports the effectiveness of the current FDA 12-month deferral period, and a
39 less stigmatized approach to blood donation criteria could simultaneously maintain the safety of the blood
40 supply⁷, and
41

42 Whereas, the Center for Disease Control and Prevention (CDC) claims nucleic acid testing (NAT) for
43 HIV, the technology currently used by blood banks, is reliable to detect HIV within 10 to 33 days of
44 exposure^{8,9}, and
45

46 Whereas, results from mathematical modeling studies, and empirical data from Italy, the United
47 Kingdom (UK), and Australia predict that altering Canada's MSM blood donation policy from a five- to a one-
48 year deferral would not increase the number of transfusion-transmitted HIV infections¹⁰, and
49

50 Whereas, switching from a lifetime ban to a deferral period has a minute risk (one transfusion
51 transmissible infection in 200 years) of increasing the number of HIV transmissions¹¹, and
52

53 Whereas, a review of current evidence for a deferral period before donation in Australia found that a
54 12-month deferral for gay and bisexual men exceeds what is required to maintain blood safety¹², and

55 Whereas, the UK changed their 12-month deferral to a three-month deferral in November 2017,
56 reflective of a modeling study that predicted an increased risk of HIV positive donations after reducing the
57 deferral to three months to be 0.18-0.67 per 1 million, which is within the acceptable threshold of one per
58 million¹³, and

59
60 Whereas, there are no cases of HIV transmission through plasma-derived products in the United
61 States in the last 20 years¹⁴, and

62
63 Whereas, reducing the deferral period from 12 months would increase lifesaving blood donations,
64 prevent blood shortages, and contribute to reducing harmful stigma experienced by the MSM community,
65 and

66
67 Whereas, AMA policy H-50.973, "Blood Donor Deferral Criteria," does not specifically address the
68 ability of updated, current HIV testing technology in its potential to decrease the deferral period for MSM;
69 therefore be it

70
71 RESOLVED: That the Michigan Delegation to the American Medical Association (AMA) ask our AMA
72 to amend AMA policy H-50.973, "Blood Donor Deferral Criteria," by addition and deletion to read as follows:

73
74 Our AMA: (1) supports the use of rational, scientifically-based blood and tissue donation deferral
75 periods that are fairly and consistently applied to donors according to their individual risk; (2) opposes all
76 policies on deferral of blood and tissue donations that are not based on the scientific literature; ~~and~~ (3)
77 **supports a blood donation deferral period for men who have sex with men that is representative of**
78 **current HIV testing technology; and (4)** supports research into individual risk assessment criteria for blood
79 donation.

80
81
82 WAYS AND MEANS COMMITTEE FISCAL NOTE: \$1,000 or more for costs related to the adoption of new or
83 revised MSMS or AMA policy.

Relevant MSMS Policy:

Lift the FDA's Ban on Men Who Have Sex with Men Blood Donors

MSMS supports lifting the Food and Drug Administration's lifetime ban against men who have sex with men blood donors.

(Res72-13)

Relevant AMA Policy:

Blood Donor Deferral Criteria H-50.973

Our AMA: (1) supports the use of rational, scientifically-based blood and tissue donation deferral periods that are fairly and consistently applied to donors according to their individual risk; (2) opposes all policies on deferral of blood and tissue donations that are not based on the scientific literature; and (3) supports research into individual risk assessment criteria for blood donation.

Safety of Blood Donations and Transfusions H-50.975

Our AMA:

- (1) Supports working with blood banking organizations to educate prospective donors about the safety of blood donation and blood transfusion;
- (2) Supports the use of its publications to help physicians inform patients that donating blood does not expose the donor to the risk of HIV/AIDS;
- (3) Encourages physicians to inform high-risk patients of the value of self-deferral from blood and blood product donations; and
- (4) Supports providing educational information to physicians on alternatives to transfusion.

Blood Donor Recruitment D-50.998

1. Our AMA shall encourage the Food and Drug Administration to continue evaluating and monitoring regulations on blood donation and to consider modifications to the current exclusion policies if sufficient scientific evidence supports such changes.
2. Our AMA encourages the U.S. Food and Drug Administration to engage in dialogue with the American Association of Blood Banks and relevant stakeholders to reanalyze their therapeutic phlebotomy policies on variances, including but not limited to hereditary hemochromatosis.

Blood Shortage and Collection H-50.990

In response to a continuing need for blood for transfusion and decreasing supplies of allogeneic blood, our AMA supports programs that encourage donation of blood to the allogeneic supply by health volunteer donors; and the AMA encourages physicians to participate in promotional efforts to encourage blood donation, and urges the American Blood Commission to actively participate in these programs.

Voluntary Donations of Blood and Blood Banking H-50.995

Our AMA reaffirms its policy on voluntary blood donations (C-63); and directs attention to the need for adequate donor selection and post-transfusion follow-up procedures. Our AMA (1) endorses the FDA's existing blood policy as the best approach to assure the safety and adequacy of the nation's blood supply;

- (2) supports current federal regulations and legislation governing the safety of all blood and blood products provided they are based on sound science;
- (3) encourages the FDA to continue aggressive surveillance and inspection of foreign establishments seeking or possessing United States licensure for the importation of blood and blood products into the United States; and
- (4) urges regulatory agencies and collection agencies to balance the implementation of new safety efforts with the need to maintain adequate quantities of blood to meet transfusion needs in this country.

¹ American Red Cross Blood Services. Blood Needs and Blood Supply.

² Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products - Questions and Answers.

³ Pathogen inactivation and removal methods for plasma-derived clotting factor concentrates. Klamroth R, Gröner A, Simon TL. *Transfusion*. 2014 May;54(5):1406-17. Epub 2013 Sep 30.

⁴ The beliefs and willingness of men who have sex with men to comply with a one-year blood donation deferral policy: a cross-sectional study. Walter Liszewski, Christopher Terndrup, Nicole R. Jackson, Sarah Helland, Bridget C. Lavin. *Transfusion*. 05 July 2017.

⁵ Saving lives, maintaining safety, and science-based policy: qualitative interview findings from the Blood Donation Rules Opinion Study (Blood DROPS) for the NHLBI Recipient Epidemiology and Donor Evaluation Study-III (REDS-III). Shana Hughes, Nicolas Sheon, Bob Siedle-Khan Brian Custer. *Transfusion*. 14 August 2015.

⁶ Rethinking the Ban — The U.S. Blood Supply and Men Who Have Sex with Men. Sacks, Chana A; Goldstein, Robert H; Walensky, Rochelle P. *The New England Journal of Medicine*; Boston. Vol. 376, Iss. 2, (Jan 12, 2017): 174-177.

⁷ Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products. Guidance for Industry. U.S. Department of Health and Human Services Food and Drug Administration Center for Biologics Evaluation and Research December 2015.

⁸ Centers for Disease Control and Prevention. HIV/AIDS. October 31, 2018.

⁹ American Red Cross Blood Services. Infectious Disease Testing.

¹⁰ Jubran, Bellal, et al. "Reevaluating Canada's Policy for Blood Donations from Men Who have Sex with Men (MSM)." *Journal of public health policy* 37.4 (2016): 428-39. ProQuest. Web. 1 Jan. 2019.

¹¹ Cahill, Sean, and Timothy Wang. "An End to Lifetime Blood Donation Ban in Israel for MSM would be a Major Step Toward a Science-Based Policy that Reduces Stigma." *Israel Journal of Health Policy Research* 6 (2017) ProQuest. Web. 1 Jan. 2019.

¹² Blood donor deferral for men who have sex with men: still room to move. Haire B, Whitford K, Kaldor JM. *Transfusion*. 2018 Mar;58(3):816-822.

¹³ Update: Effects of Lifting Blood Donation Bans on Men who Have Sex with Men. Miyashita, Ayako. Gates, Gary. The Williams Institute. September 2014.

¹⁴ What is the evidence for the change in the blood –donation deferral period for high-risk groups and does it go far enough? Beattie RH Sturrock, Stuart Mucklow. *Clin Med (Lond)*. 2018 Aug; 18(4): 304–307.