REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Report 2-I-11

Subject: Deferral of Blood Donation by Men Who Have Sex with Men (MSM)

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Policy D-50.997 ("Societal and Ethical Consequences of a Five-Year Blood Donation Deferral Policy for Men Who Have Had Sex With Men," AMA Policy Database) instructs the American Medical Association to work with relevant organizations and agencies "to analyze the societal and ethical consequences of a shift to a five-year deferral policy for blood donation from men who have sex with men [MSM]." To inform that effort, the Council on Ethical and Judicial Affairs was asked to examine ethical considerations with respect to the proposed change in deferral policy. The AMA's Council on Science and Public Health (CSAPH) previously concluded that such a change is scientifically supportable "based on existing scientific evidence and risk assessment models," but that the ethical and social implications of changing deferral policy warranted further exploration.[1,2]

Calls for revisiting the blanket deferral of donation from MSM have argued that it is discriminatory, perpetuates stereotypes and stigma in relation to gay men, and could adversely affect the availability of blood/blood products by eliminating a population of potential blood donors.[3] The request that CEJA analyze ethical implications of broad questions of public policy calls on the Council to consider issues beyond the usual scope of its deliberations, which focus primarily on providing guidance for practicing physicians and setting ethical standards for the profession of medicine. In first looking at these policy matters, CEJA identified the need for ethical analysis of deferral as a strategy to protect the blood supply and criteria for defining ethically justifiable risk with respect to blood safety.[4] The present report examines key ethical issues germane to these questions and to public policy, namely: blood safety, risk assessment, key ethical considerations in public health, and the effect of public policy in perpetuating or ameliorating stigma.

PROTECTING THE SAFETY OF THE BLOOD SUPPLY: DONOR SCREENING

Donor screening and deferral of prospective donors who are at risk for transmitting blood borne pathogens is a key strategy for protecting the safety of the nation's blood supply and the welfare of patients who receive blood products. Screening is one step in the "multi-barrier" approach used to reduce the risk that an infectious unit of blood will be transfused.[5] Additional safety measures include donor education and voluntary self-deferral, donor health assessment, testing of donated blood for known infectious agents, quarantining donated units from distribution until such testing has been undertaken, and ongoing monitoring for emerging blood borne diseases.[5,6]

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Screening questionnaires focus on factors associated with risk of infectious disease, including sexual activity, intravenous drug use, and travel or residence in areas in which bloodborne pathogens are endemic, as well as health history, including prior treatment with human cell or tissue products. Deferral periods vary from as little as 8 weeks to indefinite (effectively lifelong) deferral. (Appendix 1) As a strategy for protecting the blood supply, donor screening is predicated on prospective donors' accurate understanding of screening questions and candid self-disclosure; the more so when there is no method reasonably available to test donated units directly. Although intended to pick out behaviors that pose risk for transfusion-transmitted infections, as currently structured screening questions in use in the US de facto define categories of persons as well. Where the behaviors are socially disvalued—such as use of intravenous drugs or (male) homosexuality, as opposed to, say, residence in the UK between 1980 and 1996—screening questions themselves arguably reinforce negative stereotypes and stigma toward individuals.[7,8,9]

ETHICS & PUBLIC HEALTH

Policies affecting public health and safety are often precautionary—the goal is to anticipate and prevent harm[5]—and must balance multiple, sometimes competing considerations.[10] To be ethically sound, public health policies must meet several key "justificatory conditions": effectiveness, proportionality, necessity, least infringement, and public justification.[10,11] That is, policies must be likely to protect public health; offer public health benefits that outweigh the other values at stake in the situation; be essential to achieving the public health goal, with no reasonable alternatives; and minimize the extent to which other values are infringed. Policymakers have a responsibility to "explain and justify" policy decisions to stakeholders, especially decisions that infringe on other values (e.g., when policy restricts individual autonomy). Sound policies, moreover, rest on careful assessment of risks and treat like risks alike.

Risk Assessment in Public Policymaking

With respect to the safety of the blood supply, key considerations for policy are the welfare of those who receive blood products, who will uniquely bear the health risks if infectious units are transfused; the welfare of the community at large, for whom ensuring an adequate blood supply and minimizing the incidence of infectious disease are important interests; and the welfare of blood donors themselves. In addition to being rooted in scientifically well-grounded estimations of risk, such policies must take into account the benefits to be gained by a proposed policy (risk-benefit and risk-risk comparisons) and how risks/burdens and benefits will be distributed among stakeholders.[5,12]

Thus a key initial question is whether and to what extent changing deferral policy would increase the risk of transfusion-transmitted infection. A 2007 analysis by the McLaughlin Centre for Population Health Risk Assessment concluded that there was "no clear evidence" of increased risk with a five-year deferral, although the possibility of a small increase could not be ruled out.[5] CSAPH concluded in 2008 that the available 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."[1]

The benefits looked for from reducing the deferral period for men who have sex with men include an increase in the number of blood donors and decrease in the stigmatization of gay men to which lifetime deferral may contribute. Traditionally, gay men have been reliable donors, and estimates in the UK in 2003 suggested that blood donations would increase by two percent if policy there

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were changed from lifetime to a one-year deferral.[3] The demand for blood has increased five percent in the last decade, while the pool of eligible donors has decreased from 60 percent of the population to less than 40 percent;[13] but there are at present no published data on the likely impact on numbers of donors of changing to a five-year deferral policy. (One study suggested that changing to a one-year deferral would yield an estimated 219,000 additional units of blood annually.[14])

Who will bear a risk, and whether that risk is voluntary or involuntary, is also germane to policy decisions.[5,15] As the New Zealand Blood Service has noted, "In the blood system, the most vulnerable people are the blood recipients. . . [who] face an 'imposed risk' around safety and find themselves in a position of having to trust decisions on blood safety made by others, as they frequently have no alternatives other than transfusion."[15] For some, any potential increase in risk, especially involuntary risk, is unacceptable. As the McLaughlin Centre noted, "For most members of the public, the formulation beloved of experts, de minimis risk, simply does not apply, where involuntary risk is concerned. And, if one puts a (very low) number on the risk, it will soon become apparent that no number is low enough."[5] The US Food and Drug Administration (FDA) maintains that any change in policy affecting blood safety must ensure improved or equivalent safety.[16]

When significant social and equity factors are at stake, as in the case of deferral of blood donation by MSM, these "deserve at least as careful attention in an uncertainty analysis as do the technical factors."[5] The extent to which negative stereotypes of gay men are reinforced to the public by the current lifetime deferral process has not been explored empirically. Thus, whether changing from a lifetime to a five-year deferral would affect public attitudes is not known, but doing so might remove one channel through which negative stereotypes can be transmitted.[7,9]

Treating Like Risks Alike

A fundamental tenet of ethics is that like cases should be treated alike (and different cases differently). This "principle of formal equality" does not delineate criteria for determining when cases (or individuals) are relevantly alike, nor particular respects in which equals must be treated equally, but only asserts that "whatever aspects are relevant, persons equal in those respects should be treated equally."[10, 17]

Arguably, current deferral criteria violate this principle. In part, they reflect not the contemporary realities of HIV/AIDS, but rather the state of knowledge in the early years of the epidemic, before the disease was well characterized epidemiologically and, importantly, before the advent of the highly sensitive and specific methods now used to test all units of donated blood. In the absence of accurate tests, deferring donation by behaviorally defined populations among whom prevalence of a given infectious disease is high can be justified, as can imposing different deferral periods for different populations on the basis of relative prevalence or rate of transmission of the disease across those populations.

When donated blood can be tested directly, how the donor acquired the infection is not relevant in terms of the threat to the blood supply—each infected donor poses the same, detectable risk outside the "window period" for the given disease. With nucleic acid testing (NAT) that period is now 11 days for HIV.[1] Yet despite mandatory NAT screening of all units of donated blood, under current policy men who have had any sexual contact with another male since 1977 are deferred indefinitely, while heterosexuals who have had sexual contact with anyone known to have

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HIV/AIDS or women who have had sexual contact with a man who has ever had sexual contact with another male are deferred from donating blood for 12 months (from date of last contact).

In a joint statement to the FDA in March 2006, the AABB, America's Blood Centers, and American Red Cross argued for changing the deferral policy for male to male sex to 12 months to "make that deferral period consistent with the deferral period for other high risk sexual exposures," noting that "[i]t does not appear rational to broadly differentiate sexual transmission via male-to-male sexual activity from that via heterosexual activity on scientific grounds." [18]

New Zealand uses behavioral criteria for donation deferral, and in its 2008 report on behavioral criteria for donor deferral, the New Zealand Blood Service noted policymakers' responsibility to justify treating a group differently on behavioral grounds.[15] The report reaffirmed existing New Zealand policy, which imposes 10-year deferrals (from last occasion) for both men who have had sex with another man and all donors who have worked as sex workers or accepted money or drugs for sex.

Current US criteria are further not able to distinguish between individuals who are at lower or higher risk for infection within, or across, the categories of "at risk" donors the criteria establish. As the Advisory Committee on Blood Safety and Availability (ACBSA) noted in its June 2010 recommendations to the Secretary, Department of Health and Human Services (HHS), "the current donor deferral policies are suboptimal in permitting some potentially high risk donations while preventing some potentially low risk donations" (although the Committee also concluded that current data are not adequate to support a specific policy alternative).[19] To illustrate, known HIV-negative homosexual men in a monogamous relationship are prevented from donating blood, while a woman with multiple partners of unknown status is a high-risk donor for whom there is currently no deferral because this behavior is not targeted by screening questions.

Finally, current deferral criteria may violate the principle of formal equality in construing HIV/AIDS as a uniquely serious health threat to recipients of blood products. HIV infection is hardly insignificant, but with advances in treatment over the past 20 years and more, HIV/AIDS has been transformed from a disease that is lethal in the relatively short term to a chronic illness that can be managed.[20] Yet in this respect, deferral criteria appear still to reflect knowledge—and fears—of the early years of the epidemic. Whether it is justifiable to treat HIV/AIDS differently from, say, Hepatitis C or other chronic illnesses depends on careful comparison not only of risk, but equally of the relative morbidity and mortality associated with each condition and the availability, cost, and burden to patients of treatment.

Discrimination, Stigma & Public Policy

It has been argued that lifetime deferral from blood donation wrongfully discriminates against men who have sex with men.[8] It is unclear that current deferral policy is based on illegitimate attitudes (e.g., homophobia) or that it has an unambiguous, decisive discriminatory effect—men who have (or have had) sex with men are at increased risk for HIV.[7] But it has been argued that lifetime deferral does involve discriminatory "expression," that is, it sends a demeaning message; it imparts the idea that "all gay men—including those who practice safe sex and have monogamous relationships—should be treated as if they have HIV."[7]

While there is no "right" to express one's altruism specifically in the form of donating blood, doing so is a "valued social activity,"[15,7] from which men who have (or have ever had) sex with

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another man are categorically precluded under current deferral policy. Moreover, blood donation campaigns routinely emphasize the "gift of life" and trade in the metaphor that "giving blood makes one morally virtuous," with the corresponding insinuation that "those who do not donate may be morally suspect."[9] Consider that the majority of blood donations occur during drives that take place at workplaces and schools, causing MSM to be concerned about the possible employment or social ramifications of not participating in the process.[21]

Public health policies or programs that arguably create or perpetuate stereotypes give rise to (or sustain) social harms.[11] It has been argued that when policies and practices send the kind of "illegitimate messages" that lifetime deferral does, they "constitute a genuine wrong,"[7] especially when there are other effective methods to achieve the public health goal.

CURRENT POLICY INITIATIVES

In June 2010, the ACBSA declined to recommend changing current deferral policy, but called for further research to "develop and validate candidate alternative policies."[19] The Committee recommended research in several areas, including modifying the donor questionnaire (to better differentiate low versus high risk MSM and heterosexuals), determine the feasibility of donor pre-testing to limit risk, and examine the impact of revised donor criteria on the supply of blood products. Among other efforts, the Committee also recommended linking analysis of demographic, behavioral, and other risk factors to ongoing national hemovigilance for transfusion-transmitted infectious disease markers in donors; adopting pathogen reduction technologies previously recommended; and enhancing donor education programs, especially with respect to high risk behaviors.

In July 2011, HHS outlined actions planned or currently being taken in response to the ACBSA recommendations.[22] These include initiating a baseline study of data on risk of blood transmissible disease in relation to behavioral risk factors in current donors and proposed studies to evaluate donor understanding of the current history questionnaire and to explore attitudes and motivations among men who have a history of sexual contact with men who have donated blood or might donate under a revised deferral policy. Also proposed is design of a screening strategy to permit donation by some MSM through a pilot project involving pre- and post-donation screening for deferred donors. As HHS noted, whether and when proposed research can be implemented is dependent on availability of funding.

CONCLUSION

The foregoing analysis suggests that current US policy and practice with respect to screening and deferral of blood donors is ethically problematic in that it does not clearly treat comparable risks to blood safety in a consistent manner, may unduly restrict the opportunity of some populations to engage in the socially valued activity of blood donation, and perpetuates unfair stereotypes even though it may not be discriminatory in intent or effect.

A comprehensive examination of current policy and practice with respect to blood safety should carefully consider certain key areas, including:

- Comparison of transfusion-transmissible diseases with respect to
  - morbidity & mortality
  - availability of treatment

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- cost of treatment
- burdens of treatment for the patient

- Likely effects of changes in deferral policy
  - on the donor pool
  - on the adequacy of the blood supply
- Revision of donor screening questions to differentiate low(er) from high(er) risk behaviors
- More thoughtful articulation of deferral criteria to minimize the potential for discrimination

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APPENDIX 1. Deferral of Blood Donation

Deferral period	***Risk behavior***	***Disease/ pathogen***
8 weeks	Oneself has had • vaccination in the past 8 weeks • contact with someone who had a small pox vaccination in the past 8 weeks	
12 months	Sexual contact with anyone who: • has HIV/AIDS or has had a positive test for HIV • has ever used needles to take drug, steroids, or anything not prescribed by a doctor • has hemophilia or used clotting factor concentrates • has hepatitis • has ever taken money, drugs, other payment for sex • (female) a male who has ever had sexual contact with another mail (from date of last contact)	HIV HCV, HBV "(other) infectious diseases"
	Oneself had/used: • accidental needlestick • contact with another person's blood • ear/body piercing (except single-use equipment) • tattoo (except sterile needles, non-reused ink) • bone/skin graft • organ, tissue/bone marrow transplant • blood transfusion • syphilis/gonorrhea in the past 12 months	HIV HCV, HBV "(other) infectious diseases"
	Oneself: • lived with a person who has hepatitis • traveled to a country outside US/Canada • traveled to Iraq	Viral hepatitis Malaria Leishmaniasis (Iraq)
3 years	• Is oneself an immigrant/refugee/resident/citizen from outside U.S./Canada • Has oneself had malaria (3 yrs	Malaria

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	asymptomatic)	
Indefinite	Is oneself a male who has • had sexual contact with another male since 1977 • ever taken money, drugs, other payment for sex since 1977	HIV HCV, HBV "(other) infectious diseases"
	Oneself has: • ever used needles to take drug, steroids or anything not prescribed by a doctor • used clotting factor concentrates • received a dura matter graft • received a blood transfusion in the UK/France since 1980 • spent >/= 3 months (cumulative) in UK, 1980–1996 • spent >/= 5 years (cumulative) in Europe since 1980 • been a member of the US military/civilian military employee/military dependent, 1980–1996 • a relative who has CJD (except neg lab for mutation associated with familiar CJD) • been in juvenile detention/lockup/jail/prison for > 72 hrs • been in Africa	HIV HCV, HBV vCJD CJD "(other) infectious diseases" variant strains HIV (Africa)
	Oneself ever had: • hepatitis • Chagas • babesiosis • malaria • AIDS/positive HIV test • sex with anyone born in/lived in Africa (since 1977)	HCV, HBV Chagas disease Babesiosis Malaria HIV Variant strains HIV (Africa)

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