

The ethics of ordinary and exact justification in blood donation deferral categories for men who have sex with men

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Abstract

In 2015, the United States Food and Drug Administration (FDA) changed their indefinite deferral policy towards donors who were men who had sex with men (MSM). I develop an empirical case for the current, revised MSM deferral policy and show that rights-based objections fail. This empirical case, however, misleadingly accounts for an elevated risk for MSM donors because it lumps two distinct kinds of MSM donors into the same category. Building on some recent work that has been published since the revision, I introduce and defend a distinction between MSM donors who have what I call 'exact justification' and those who have what I call 'ordinary justification'. MSM donors with exact justification present no risk with respect to the deferral and should be allowed to donate. I conclude by addressing a practical issue about how primary partner testimony is not enough to create exact justification, but it is enough to sustain it.

KEYWORDS

blood donation, deferral category, HIV, MSM

1 | INTRODUCTION

In 2015, the United States Food and Drug Administration (FDA) revised its policy towards potential male blood donors who had had sex with other men (MSM). The previous policy indefinitely deferred MSM as blood donors; the current policy requires MSM to refrain from sex with men for one year before they are eligible to donate. The FDA should refine the current policy and reformulate the MSM category so that it can better parse, exactly, what behavior puts MSM at risk.

The key point of contention is what categories we should use to screen potential donors in terms of risk. In Section 2, I will argue that we should use both testing and deferral categories to screen risks. After that, in Section 3 I will introduce some current statistics from the United States Centers for Disease Control and Prevention (CDC) about new HIV infection rates to build what I call 'the empirical case' for the current MSM policy. I use the empirical case in Section 4 to show why rights-based objections fail. In Section 5, I show how the empirical case for the current MSM deferral category misleadingly accounts for risk by lumping two distinct kinds of MSM donors into the same category. In order to accurately titrate these categories, I introduce and defend a distinction between MSM donors based on their serostatus, namely whether they have HIV or not. I argue that MSM donors with 'exact justification' use medical tests to determine their serostatus and are not exposed to the elevated risk that the empirical case purports to track.

Donors with 'ordinary justification' rely on spurious methods to determine their serostatus. Even though donors with ordinary justification are still exposed to the elevated risk, improved testing methods commit the FDA to reducing the deferral from one year to a two-week period. Even though MSM donors may use medical tests to initially establish their exact justification, they are likely to switch to a primary partner's testimony as time goes on. I conclude that while testimony alone is not enough to create exact justification, it can be sufficient to sustain it.

2 | CATEGORIES AND QUESTIONNAIRES

The FDA uses deferral policies, popularly called 'blood bans', as part of a multi-layer strategy to safeguard the blood supply. Donors answer brief questionnaires when they donate blood to see if they are at risk for passing along an illness or infection to recipients; if they are, then they are deferred as donors. Donors who travel to countries where malaria is present, for example, are at risk for passing along the disease to the recipient, even if they took precautions beforehand, for example Malarone, and are temporarily deferred. Some policies indefinitely defer donors. Donors who have ever tested positive for hepatitis B or C or for HIV are indefinitely deferred.

Other policies indefinitely defer donors if they have engaged in behavior that strongly correlates with the risk of health problems that can compromise a donor's blood. For example, the FDA indefinitely defers donors who have taken intravenous drugs, unless they were



under doctor or hospital supervision. This policy is not making a causal claim for every individual case: even though there have been people who have taken drugs intravenously and not contracted HIV or hepatitis C, the policy guards against the risks that commonly correlate or coincide with intravenous drug use in a non-hospital setting, for example (re)used needles or mixed substances. Furthermore, this policy is not making any moral claim about drug use. Donors who snort cocaine are not deferred, because what matters in terms of health risk to the recipient is how users/donors take the drugs: as a method, intravenous use constitutes a higher risk for HIV, hepatitis, or other medical issues.

In addition to the deferral categories, the FDA also implements other safety measures. Charlene Galarneau explains that the FDA uses 'a registry of deferred donors, blood testing, blood quarantine (holding blood until it shows acceptable test results), and oversight of blood manufacturing processes.¹ If the FDA quarantines all the donated blood until it can be safely tested, then it seems like the questionnaires and risk-based deferral categories are redundant from a safety perspective. Not only do the tests screen out everything the questionnaires would, they also catch cases where a donor lies or is unaware of a medical issue, for example not knowing if she had hepatitis. It might be tempting, therefore, to conclude that we can eliminate the questionnaires and instead simply rely on the tests.

However, we should not be so quick to accept this conclusion. Even though the tests are extremely effective at screening out blood that would put recipients at risk, the questionnaires are still useful so long as they are designed to effectively track and reduce risk. Healthcare systems have limited resources, in terms of both time and money, and testing blood requires both. If the questionnaires would screen out the blood that was going to be rejected by the tests anyway, and the questionnaires can do it for a very minimal cost, then we have a reason to keep the questionnaires because they conserve resources. Questionnaires, then, are an inexpensive first line of defense because the deferral categories act as an initial proxy for the health risks that tests will later screen for. This conclusion, however, depends on whether the questionnaires and deferral categories accurately assess the behavioral or health risks that the tests are screening for.

But there is more to justifying donor deferral categories from the questionnaires than just being an accurate proxy. If the reason we justify donor questionnaires is because they conserve resources, then we have to assume that donors answer the questions honestly. If donors lie or misreport their health, then it does not matter how predictive the deferral categories are because inaccurate self-reporting means that donors do not self-sort into the categories that were supposed to conserve resources by preventing their blood from being tested. Even if we accept that blood donors are not duplicitous, people misreport information about themselves all the time, for example concerning² dental

hygiene,³ weight, alcohol consumption, sexual behavior, how often they wear their seatbelt, cancer screening history,⁴ donations to charity,⁵ and even the amount of fruit and vegetables they eat.⁶ If the misreporting of information is this prevalent, and the questionnaires are effective only if people accurately self-report, then there is at least a *prima facie* concern that the deferral categories are not effective and so not justified.

One common and unifying explanation for why people misreport information is social desirability bias. Broadly, social desirability bias is when a respondent identifies the expected or socially approved answer to a question and adapts their answer with respect to that expectation, rather than reporting what is actually true. Impression management is a paradigmatic example of social desirability bias because someone willfully misrepresents information in order to appear more favorable. Managing impressions, however, depends on the context and the person we are interacting with: people may brag about a certain behavior with their friends, for example being drunk on New Year's Eve, that they would deny in a different context or conceal with a different group, for example at the church social.⁷ So, we should not think of social desirability bias as a uniform or invariable disposition; it can change depending on what is at stake or how specific situations and interactions are set up. Even so, there is a generally accepted effect of people not wanting to admit to stigmatized behavior, especially if they believe that it will disappoint the person they are interacting with.⁸

Although we can never wholly eliminate social desirability bias from donor responses, we can take steps to guard against it. Studies have found that participants give more accurate answers when they believe that the interaction is confidential, and even more accurate answers when they believe that it is anonymous.⁹ Even though health questionnaires are not anonymous, they are confidential, and so donors may be less susceptible to social desirability bias about stigmatized

¹Galarneau, C. (2010). Blood donation, deferral, and discrimination: FDA donor deferral policy for men who have sex with men. *The American Journal of Bioethics*, 10(2), 29–39.

²Sjöstöm, O., & Holst, D. (2009). Validity of a questionnaire survey: Response patterns in different subgroups and the effect of social desirability. *Acta Odontologica Scandinavica*, 60(3), 136–140.

³Moshagen, M., Musch, J., Ostapczuk, M., & Zhao Z. (2010). Reducing socially desirable responses in epidemiological surveys: An extension of the randomized-response technique. *Epidemiology*, 21(3), 379–382.

⁴Lofters, A., Vahabi, M., & Glazier, R. H. (2015). The validity of self-reported cancer screening history and the role of social disadvantage in Ontario, Canada. *BMC Public Health*, 15(28). Retrieved from <https://bmcpubhealth.biomedcentral.com/articles/10.1186/s12889-015-1441-y>.

⁵Lee, Z., & Woodliffe, L. (2010). Donor misreporting: Conceptualizing social desirability bias in giving surveys. *Voluntas: International Journal of Voluntary and Nonprofit Organizations*, 21(4), 569–587.

⁶Miller, T. M., Abel-Maksoud, M. F., Crane, L. A., Marcus, A. C., & Byers, T. E. (2008). Effects of social approval bias on self-reported fruit and vegetable consumption: A randomized controlled trial. *Nutrition Journal*, 7(18). Retrieved from <https://nutritionj.biomedcentral.com/articles/10.1186/1475-2891-7-18>.

⁷Fisher, R. J. (2000). The future of social-desirability bias research in marketing. *Psychology & Marketing*, 17(2), 73–77.

⁸Latkin, C. A., Mai, N. V. T., Ha, T. V., Sripanan, T., Zelaya, C., Minh, N. L., ... Go, V. F. (2016). Social desirability response bias and other factors that may influence self-reports of substance use and HIV risk behaviors: A qualitative study of drug users in Vietnam. *AIDS Education and Prevention*, 28(5); Rao, A., Tobin, K., Davey-Rothwell, M., & Latkin, C. A. (2017). Social desirability bias and prevalence of sexual HIV risk behaviors among people who use drugs in Baltimore, Maryland: Implications for identifying individuals prone to underreporting sexual risk behaviors. *AIDS Behavior*, 21(7), 2207–2214.

⁹Lowndes, C. M., Jayachandran, A. A., Banandur, P., Ramesh, B. M., Washington, R., Sangameshwar, B. M., ... Alary, M. (2012). Polling booth surveys:



behaviors, for example MSM, drug use. Respondents also give more accurate results when they believe that their answers will be subject to 'lie detectors', even if no such 'lie detector' is actually used.¹⁰ If we emphasize that all donated blood is tested, then we are *eo ipso* emphasizing a 'lie detector' to donors. In addition, giving prior warnings about the consequences of faking results can also improve response accuracy.¹¹ Warnings do not have to be threats to donors, but rather a reminder that the recipients are the ones who bear the consequences for faked results. A large part of impression management is managing the impression we make on the person we are interacting with. If a nurse administers the questionnaire, then we increase the likelihood of impression management because a donor is interacting with a particular person. Although not a uniform practice now, some organizations allow donors to fill out questionnaires in private terminals, like we do with voting, while others, viz. the American Red Cross, allow donors to complete questions for a 'rapidpass' online. These kinds of measures can further reduce the likelihood of impression management because there is not another person to impress with our answers.

We do not have to justify deferral categories as a standalone safety measure, absolutely guaranteeing that no blood will later be removed by the tests. Even though there are risks about response bias and donor misrepresentation, many standard practices around donor questionnaires help reduce these risks. Now that we have discussed donor compliance, we can turn to the issue of whether the MSM deferral category accurately and efficiently corresponds to a later test.

3 | THE EMPIRICAL CASE

Most of the existing literature about the MSM deferral policy was written before the 2015 revision. Three major criticisms were: (1) the FDA unfairly singled out gay men as victims of HIV/AIDS, (2) the indefinite deferral policy conflated risky sex with gay sex,¹² and (3) the deferral policy reflected cultural prejudice towards gays.¹³ Galarneau, marshalling all of these criticisms, doubted that the FDA had any empirical justification.¹⁴

¹⁰Lee and Woodliffe, *op. cit.* note 5. Although there are obvious ethical concerns about lying to participants about 'lie detectors', since the blood is actually tested, we can leave these concerns aside. See Nancarrow, C., Brace, I., & Wright, L. T. (2001) 'Tell me lies, tell me sweet little lies': Dealing with socially desirable responses in market research. *The Marketing Review*, 2(1), 55-69.

¹¹Hough, L. M., Eaton, N. K., Dunnette, M. D., Kamp, J. D., & McCloy, R. A. (1990). Criterion-related validities of personality constructs and the effects of response distortion on those validities. *Journal of Applied Psychology*, 75 (5), 581-595; Dwight, S. A., & Donovan, J. J. (2003). Do warnings not to fake reducing faking? *Human Performance*, 16(1), 1-23.

¹²Fischer, C., & Schonfield, T. (2010). Sex and blood: A deeper exploration of discrimination in the FDA blood donor policy. *The American Journal of Bioethics*, 10(2), 40-42.

¹³Bayer, R. (1989). *Private acts, social consequences: AIDS and the politics of public health*. New York, NY: The Free Press; Bayer, R., & Oppenheimer, G. M. (2000). *AIDS doctors: Voices from the epidemic: An oral history*. Oxford, UK: Oxford University Press; Bayer, R. (2015). Science, politics, and the end of the lifelong gay blood donor ban. *The Milbank Quarterly*, 93(2), 230-233.

¹⁴Galarneau, *op. cit.* note 1. Galarneau, C. (2010). 'The H in HIV stands for human, not Haitian': Cultural imperialism in US blood donor policy. *Public Health Ethics*, 3(3), 210-219.

The question now, however, is whether or not these criticisms still work against the revised policy, which defers potential MSM donors for one year after their last sexual encounter with another man owing to a heightened risk of their contracting hepatitis or HIV.¹⁵ Because the FDA justifies this policy by appealing to this heightened risk, we have to frame our objection or justification for it on the empirical facts of whether or not that elevated risk obtains.

Although commonly perceived as a 'gay ban', the MSM deferral category is entirely behavioral. This point is common knowledge among public health officials and researchers, but the 'gay ban' narrative is still ubiquitous in news stories, blogs and public discourse. Adam Pulver notes that this narrative is common on college campuses among students who are inclined towards social justice, but who have no historical connection to the early days of the HIV epidemic.¹⁶ This narrative treats MSM as a quick substitute for gay, bisexual, or queer. Even though these categories can overlap, they are distinct: if gay, bisexual, or queer men can be virgins, celibate, or just not have sex with another man for a year, then there are gay, bisexual, or queer men who can donate blood. Furthermore, straight men who are sex workers might also have sex with men, but only do so because those clients will pay, not because of any desire, preference, or orientation. If the categories MSM, gay, straight, and bisexual are not substitutable, then arguments that claim that the deferral policy is based in social prejudice or homophobia need to be adjusted to accurately reflect these categorical differences.¹⁷ Protesting that it is unreasonable to expect adults to not have sex for one year changes the objection from the policy being discriminatory to its being unreasonable, and does not advance the claim that the FDA prohibits gay or bisexual men from donating.

There is nothing about being gay or bisexual that puts someone at risk for contracting HIV or hepatitis. The deferral policy is based on the claim that sex between men puts those men at higher risk for hepatitis and, especially, HIV. The rationale, then, for the policy stands or falls on the empirical case and whether or not this elevated risk obtains. The CDC's 2013 HIV Surveillance Report found that 37,887, about 80%, of the new HIV cases that year were in men.¹⁸ A total of 30,689 of those cases, about 81%, were MSM.¹⁹ Putting that statistic about MSM in

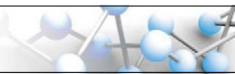
¹⁵Food and Drug Administration. (2018). *Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products - Questions and Answers*. Retrieved from <https://www.fda.gov/biologicsbloodvaccines/bloodbloodproducts/questionsaboutblood/ucm108186.htm>

¹⁶Pulver, A. R. (2008). Gay blood revisionism: A critical analysis of advocacy and the 'gay blood ban', *Law and Sexuality: A Review of Lesbian, Gay, Bisexual and Transgender Legal Issues*, 17, 107-130.

¹⁷Bayer, *op. cit.* note 13; Fischer and Schonfield, *op. cit.* note 12.

¹⁸Centers for Disease Control and Prevention. (2013). *2013 HIV Surveillance Report*. Retrieved from <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2013-vol-25.pdf>

¹⁹Center for Disease Control and Prevention. (2018). *HIV Among Gay and Bisexual Men*. Retrieved from <https://www.cdc.gov/hiv/group/msm/index.html>



the larger context of all new cases of HIV infections in 2013, the CDC found that MSM accounted for about 65% of the new cases. Another HIV Surveillance Report, in 2014, found that infection percentages had increased. In 2014, 70% of new infections were attributed to MSM, 11% were due to injection drug use, 10% to heterosexual contact, 7% to MSM and injection drug use, and 1% were because of perinatal transmission.²⁰ Because sexual contact between men makes up an overwhelming percentage of the new cases of HIV infection, both by category of possible infection and by demographic, it seems that sexual contact between men is a substantial factor in exposure to an elevated risk of contracting HIV.

The CDC is fully aware, and the numbers show, that any sexual contact can put someone at risk for contracting HIV. But, the FDA uses deferral policies to track likely risks. Donors who took drugs intravenously are not categorically deferred: the FDA distinguished between donors who took intravenous drugs in a hospital setting and donors who took intravenous drugs in a non-hospital setting. The FDA does not defer donors who take intravenous drugs under doctor supervision because the usual or normal conditions of administering drugs in a hospital generally rule out the risk, for example of hepatitis C or HIV. The same kind of precautions, for example sterilized/single-use needles, clean substances, are not accounted for in non-hospital settings, and so there is a reason to defer that specific sub-category. The FDA does not defer intravenous drug use simpliciter because not all intravenous drug use is equally risky. Analogously, sexually active male donors are not deferred as a category, even though sexual activity exposes them to a risk of contracting HIV, because there are certain conditions within that category that present an elevated risk, viz. sex with another man, and constitute a separate subcategory.

Because sexual behavior is what both constitutes MSM as a category and exposes MSM to an elevated risk in terms of a deferral category, we can ignore other features that may coincide with being MSM but are not relevant from a risk-based perspective. MSM may go to gay pride parades, go on dates only with other men, raise children with other men, or come out as gay, bisexual, or queer to friends and family, but none of these behaviors or attributes constitutively contribute to being MSM.²¹ As a result, they do not factor into questions about deferring a blood donor who happens to also be MSM.

We would have less reason to think that sexual behavior between men constitutes an elevated risk if HIV infection rates were more

evenly distributed across other demographics. Although absolute numbers are hard to come by, the CDC estimates that MSM make up about 4–7% of the male population.²² The proportion of risk to percent of population is extremely pronounced: 4–7% of men accounting for 77% of new HIV infections. Despite the demographic disparity, the worry is not that every sexual act between men will result in an HIV diagnosis. The MSM policy is designed to track general risks commonly associated or correlated with the behavior. Going back to the intravenous drug policy, even though there are some people who have taken heroin or crystal meth but did not contract hepatitis or HIV, the FDA structures the policy on the grounds that, generally speaking, the behavior typically exposes someone to certain risks. Pointing to cases where men have sex with other men but do not contract HIV is no more argumentatively effective than pointing to intravenous drug users who were clean after injecting outside a hospital.

4 | RIGHTS-BASED OBJECTIONS

A common criticism of the MSM deferral is that it is discriminatory. Ryan Nelson argues that although several states prohibit discrimination based on sexual orientation, these states stand in violation of the non-discrimination clause because the MSM policy prevents MSM blood donors from receiving certain benefits or services provided during blood donation, for example mini-physicals and screening for disease.²³ This objection does not work for a number of reasons. First, gay and bisexual men could still have access to those benefits if they refrained from sex with other men, for example if they are gay virgins or bisexual but only sexually active with women. Because there is a distinction between sexual orientation and sexual activity, and the MSM policy only defers men who actually have sex with other men, the state is not discriminating against sexual orientation by upholding the deferral policy – new or old. Second, it is not clear that there is a right to donate blood. But, even if we suppose that there is such a legal right, the empirical case demonstrates a heightened risk for MSM contracting HIV. The state can abrogate a right based on public interest. Just as my right to speech does not give me the right to incite a riot or yell 'Fire!' in a crowded theater, so too would my right for the benefits Nelson is arguing for be constrained by public health concerns. Pharmaceutical and medical advances have, however, transformed HIV from a 'death sentence' into a manageable chronic condition. Even though public health officials and HIV activists warn against premature or triumphalist 'end of AIDS' narratives,²⁴ someone

²⁰Centers for Disease Controls. (2014). *2014 HIV Surveillance Report*. Retrieved from <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-us.pdf>

²¹For a more detailed discussion of how constitutive features can create a new social category, or alternatively urge us to dissolve a currently accepted social category when those features cease being constitutive, informative, or useful for identifying the category, see Haslanger, S. (2012). *Ontology and social construction*. In *Resisting reality: Social construction and social critique* (pp. 83–112). Oxford, UK: Oxford University Press; Haslanger, S. (2012). *Feminism in metaphysics: Negotiating the natural*. In *Resisting reality: Social construction and social critique* (pp. 139–157). Oxford, UK: Oxford University Press; Haslanger, S. (2012). *Social construction: Myth and reality*. In *Resisting reality: Social construction and social critique* (pp. 183–218). Oxford, UK: Oxford University Press.

²²Purcell, D. W., Johnson, C. H., Lansky, A., Prejean, J., Stein, R., Denning, P., ... Crepez, N. (2012). Estimating the population size of men who have sex with men in the United States to obtain HIV and syphilis rates. *The Open AIDS Journal*, 6, 98–107.

²³Nelson, R. H. (2014). An indirect challenge to the FDA's 'gay blood ban'. *Law and Sexuality*, 23, 1–16.

²⁴Havir, D., & Beyre, C. (2012). The beginning of the end of AIDS? *The New England Journal of Medicine*, 367(8), 658–687. El-Sadr, W. M., Harripersud, K., & Bayer, R. (2014). End of AIDS – hype versus hope. *Science*, 345(6193), 166; Cohen, J. (2016). Obstacles loom along path to the end of AIDS: International meeting highlights clash between ambitious goals and wobbly funding. *Science*, 353(6298), 432–433.



might cite these advances as reasons against the legal ability to abrogate a right based on public health concerns.

Ian Franklin points out that, even if there were a right to donate blood, it would have to be balanced, and trumped, by a patient's right to refuse blood that she deems at risk.²⁵ Recipients could, therefore, cite numerous long-term health complications from antiretroviral treatment (ART) as reasonable grounds for refusing the blood, both as individual recipients and on a policy level. Studies that track long-term ART are fairly new because the demographics are still emerging, but they consistently show that 'manageable' is misleading for a few reasons. First, ART does not fully restore immune health. Patients on ART are living, and living longer, but they are also showing higher levels of non-AIDS comorbidity: kidney disease, cardiovascular disease, cancer, liver disease, neurocognitive disease, anemia, and osteopenia/osteoporosis.²⁶ Second, ART is not curative: the fact that patients live longer means longer exposure to ART toxicity. Although each successive generation of ART has shown less toxicity, long-term exposure has measurable and adverse effects on metabolism, kidney function, and insulin resistance.²⁷ Third, while there is debate over whether an HIV infection *per se* and its therapy make the aforementioned diseases more likely to occur earlier or make them more likely at any given age, a combination of the long-term infection itself with its therapy 'likely exhibits long-term effects on the mitochondrial genome and many of the observed deleterious events result from, are triggered by, or are enhanced by oxidative stress and mitochondrial dysfunction'.²⁸ These concerns over what is popularly called 'early aging', point to both cellular stress and phenotypic frailty, for example weight loss, exhaustion, low physical activity, muscle weakness.²⁹ Lastly, even if HIV is a manageable chronic condition, we still uphold other donor deferral categories that track communicable chronic conditions, such as hepatitis C, because the donation would endanger recipients.

Galarneau contends that donating blood is an important expression of solidarity in times of crisis. Unjustly excluding a group from being able to help after events like 9/11 'can be a form of discrimination leading to social marginalization and stigmatization'.³⁰ This concern was especially relevant after the Pulse nightclub shooting because gay or bisexual MSM donors wanted to donate blood to other people in the affected community. There was a strong sense of solidarity, but a stronger sense of outrage when the Red Cross turned away MSM donors. But, if the empirical case holds, then these donors were deferred because they were exposed to a risk: there would not be similar outrage if, for example, all the donors were deferred because they

happened to be recovering from the flu that morning. Furthermore, other gay or bisexual men who had not had sex in a year could have donated. So, if the empirical case holds, then we would have to treat the MSM deferral policy like any other.

Galarneau might appeal to the fact that from 1983 to 1990 the FDA deferred Haitians as donors owing to concerns about HIV. The FDA retained their policy, even though the CDC declared in 1985 that there was not sufficient epidemiological evidence linking Haitian nationality to risk factors for HIV.³¹ Just as the FDA relied on cultural prejudice, instead of scientific facts, to defer Haitians as a group, so too does it rely on cultural or moral prejudice to defer MSM. Because this policy has an aura of medical authority, it also contributes to, and reinforces, other kinds of prejudice and discrimination.³² While Galarneau cites the FDA's struggle for empirical justification as a reason to reject their MSM deferral policy, the analogy breaks down because nearly every study, CDC or otherwise, continues to show that MSM bear the biggest burden of new and current HIV infections, which is unlike the CDC's 1985 conclusion that there was no epidemiological evidence connecting Haitian national origin to HIV risk factors.

5 | INTRODUCING NEW DEFERRAL (SUB)CATEGORIES

As many other researchers have argued, the MSM category misstates which MSM donors are actually at risk. Mike Kesby and Matt Sothorn argue that health officials invoke and impose a circular logic on risk-based populations because they ignore that a larger demographic that is at lower risk can, in fact, present more cases of infection and, thus, present more absolute risk than the smaller demographic.³³ There is nothing, then, inherently meaningful about the smaller risk-based population being exposed to an elevated risk except for our initial assertion that they are – hence the 'circular logic'. Health officials treat larger demographics as diverse and parse risk based on details or specific practices, while they treat smaller demographics as uniform blocs. Kesby and Sothorn are right to argue that we should refine the MSM donor category to accurately present what puts MSM donors at risk, but, in light of the empirical case I presented in Section 3, they go too far in suggesting that deferral categories themselves are not predictive for later testing.

Although what actually matters for health risks is someone's serostatus, if we are going to use deferral categories or questionnaires, then we have to ensure that they are predictive for later testing and that donors have a way to self-sort by self-reporting. As we saw in Section 2, deferral categories are only effective if we presuppose donor compliance. Even if we grant donor compliance, we still need to figure out how donors can accurately self-report their health, which means that

²⁵Franklin, I. (2007). Is there a right to donate blood? Patient rights; donor responsibility. *Transfusion Medicine*, 17(3), 161–168. Cf. Brooks, J. P. (2004). The rights of blood recipients should supersede any asserted rights of blood donors. *Vox Sanguinis*, 87(4), 280–286.

²⁶Deeks, S. G., Lewin, S. R., & Havlir, D. (2013). The end of AIDS: HIV infection as a chronic disease. *Lancet*, 382(9903), 1525–1533.

²⁷Deeks, Lewin and Havlir, *op. cit.* note 26.

²⁸Torres, R. A., & Lewis, W. (2014). Aging and HIV/AIDS: Pathogenetic role of therapeutic side effects. *Laboratory Investigation*, 94, 120–128.

²⁹Deeks, Lewin and Halvir, *op. cit.* note 26.

³⁰Galarneau, *op. cit.* note 14, 29.

³¹Galarneau, *op. cit.* note 14.

³²Cf. Fox, D. (2010). The expressive dimension of donor deferral. *The American Journal of Bioethics*, 10(2), 42–43.

³³Kesby, M., & Sothorn, M. (2014). Blood, sex and trust: The limits of the population-based risk management paradigm. *Health and Place*, 26, 21–30.



we have to frame the questions in terms of justification: when are donors justified to accurately report on their HIV status?

I will start by distinguishing 'exact justification' from 'ordinary justification'. This distinction helps in tracking constitutive features that accurately separate two distinct sub-groups in the larger MSM population. Donors with exact justification are not exposed to the elevated risk from the empirical case. Although donors with ordinary justification are still exposed to the elevated risk, we should revise the deferral period to coincide with the window period required for an accurate test reading.

An MSM donor has exact justification if, after a sufficient window period, he uses a medical test to determine his serostatus. A donor has ordinary justification when he appeals to safer sex practices that merely reduce the risk for HIV transmission. Exact justification is a fairly easy, and the most reliable, way for a donor to learn his serostatus. Many cities and colleges have clinics that provide free and anonymous HIV testing. Someone could have exact justification and multiple sexual partners. Having multiple sexual partners complicates the process because it requires a donor to keep track of more variables, namely his serostatus and his partner(s) serostatus, but a MSM donor has exact justification when he knows that his serostatus is negative and when, after a sufficient window period, he knows that each of his current sexual partners also have a negative serostatus. Obtaining exact justification, then, is neither onerous nor moralizing. More importantly, exact justification accounts for the elevated risk that being MSM allegedly exposed a donor to: if neither man has HIV, then neither man can contract HIV from the other, no matter how many times they have sex with each other. So, the elevated risk from the empirical case was not due to men having sex with each other, but to serodiscordant men (i.e., one is HIV-positive and one is HIV-negative) having sex with each other.

R.T. Berkman and Li Zhou have argued along similar lines: the FDA policy conflates risky sex with gay sex, and once we separate these two categories, there is no reason to uphold the MSM deferral category. One problem, however, is that Berkman and Zhou motivate their conclusion in terms of civil rights and a more accurate way to test for HIV.³⁴ In Section 4, I showed why rights-based objections were insufficient. Berkman and Zhou are, however, undoubtedly correct about reducing the deferral period: older tests may have taken months to detect a sufficient number of HIV-antibodies, but the FDA uses modern nucleic acid tests that detect HIV within an average of 12 days, and so the FDA should reduce the deferral from one year after sexual contact with another man to a 12-day deferral.³⁵ Faster testing alone, however, does not justify dissolving a deferral category: as I showed in Section 2, if the deferral category is an accurate proxy for a later test,

then we can justify the category as part of a multilayer strategy to protect the blood supply. So, even though gay sex is distinct from risky sex, all we have shown so far is that some MSM donors are not exposed to the elevated risk; if the empirical case holds, then some still are.

Even though improved tests can screen out at-risk blood faster, MSM donors who do not have exact justification are still exposed to the elevated risk from the empirical case. Donors who have ordinary justification are still at risk because it utilizes unreliable methods to stand-in for learning someone's serostatus. Public health officials found that MSM attitudes towards safer sex often precluded the use of condoms. MSM tended to emphasize ways to make 'unprotected sex' safer, even when men knew that their partner was HIV-positive.³⁶ Ariel Shidlo, Huso Yi, and Boaz Dali found that MSM who opted for these methods instead of condoms tended to erroneously assess risk because they relied on faulty physical markers for their partner's serostatus, for example 'he does not look like he has HIV', 'I assumed he was HIV-negative too'.³⁷ But the point is not just that we make faulty assumptions about people with respect to their serostatus. Sometimes, people may not know that they have HIV, and so unknowingly misreport that they are HIV-negative. Because we cannot learn whether we have HIV through introspection, replacing assumptions about physical markers with testimony, about ourselves or others, without referencing a test, does not provide us with any additional information. So, our ability to assess serostatus, in ourselves or others, without a test is in question.

Richard Wolitski found that MSM adopted harm-reduction strategies that were based on their partner's serostatus and reduced risks in case their partner misrepresented or did not know his serostatus.³⁸ One strategy, 'strategic positioning', is based on the likely risk of sexual positions. Since 'bottoms', namely men who receive anal sex, are at a higher risk for contracting HIV than 'tops', namely insertive men, a top will be at less risk for contracting HIV, whether he knows his partner's serostatus or not.³⁹ Withdrawal is another strategy that reduces the likelihood of a top, irrespective of his serostatus, infecting a bottom.⁴⁰ Ordinary justification, then, claims that these sexual practices adequately protect someone from contracting HIV.

These methods might reduce the chance of infection for certain MSM donors, for example tops or bottoms who practice withdrawal,

³⁴Berkman, R. T. W., & Zhou, L. (2015). Ban the ban: A scientific and cultural analysis of the FDA's ban on blood donations from men who have sex with men. *Columbia Medical Review*, 1(1), 2–9.

³⁵Ibid. See also Cohen, G., Feigenbaum, J., & Adashi, E. Y. (2014). Reconsideration of the lifetime ban on blood donation by men who have sex with men. *Journal of American Medical Association*, 312(4), 337–338; Yang, Y. T., Wiley, E., & Duvivier, R. J. (2014). US policy on blood donation by men who have sex with men. *The Lancet*, 388(10057), 2236–2237.

³⁶Halkitis, P., Wilton, L., & Drescher, J. (2005). Introduction: Why Barebacking? In Halkitis, P., Wilton, L., & Drescher, J. (Eds.), *Barebacking: Psychosocial and public health approaches* (pp. 1–8). Binghamton, NY: The Hayworth Medical Press.

³⁷Shidlo, A., Yi, H., & Dalit, B. (2005). Attitudes toward unprotected anal intercourse: Assessing HIV-negative gay or bisexual men. In Halkitis, P., Wilton, L., & Drescher, J. (Eds.), *Barebacking: Psychosocial and public health approaches* (pp. 107–128). Binghamton, NY: The Hayworth Medical Press.

³⁸Wolitski, R. J. (2005). The emergence of barebacking among gay and bisexual men in the United States: A public health perspective. In Halkitis, P., Wilton, L., & Drescher, J. (Eds.), *Barebacking: Psychosocial and public health approaches* (pp. 9–34). Binghamton, NY: The Hayworth Medical Press.

³⁹Benn, P., et al. (2011). UK guideline for the use of post-exposure prophylaxis for HIV following sexual exposure. *International Journal of STD & AIDS*, 22(12), 695–708.

⁴⁰Wolitski, *op. cit.* note 38.



and so offer more protection, but strategic positioning does not eliminate the risk, and withdrawal is not that effective. Studies that examined both perfect use, namely in a clinical setting,⁴¹ and typical use, namely conditions in real life,⁴² found that couples who relied on withdrawal techniques became pregnant about 18% of the time. While becoming pregnant is different from contracting HIV, each involves exchanging bodily fluids, and so the failure rates for withdrawal are just as applicable. So, although these methods do reduce risks, they still expose potential MSM donors to an elevated risk that compromises their donation.

Condoms, when used properly, are about 98–99% effective in preventing sexually transmitted infections (STIs) or pregnancy, so why would they not also provide exact justification? Kavita Arora has suggested that preventative measures, like always wearing condoms or taking prophylaxis such as PrEP, could displace the risk MSM face, and would justify changing the donor deferral category. I will take each of Arora's proposals in turn.⁴³ Condoms, in typical use, are not that effective. One study found that condoms were only slightly more effective than withdrawal methods in preventing pregnancies: withdrawal failed 18% of the time; condoms, 17%.⁴⁴ While condoms are fairly successful in perfect-use cases, people find them, in typical use, difficult to use consistently or correctly.⁴⁵ So, while condoms do reduce HIV transmission rates, they do not constitutively contribute to a new MSM subcategory that accounts for that risk. Donors who rely on condoms alone to know about their own, or their partner's, serostatus only have ordinary justification.

Prophylaxis, such as PrEP or IPrex, are a more promising proposal. One worry, however, is that people may not consistently take the drugs to ensure efficacy. This worry is common to most medication: people do not finish antibiotic prescriptions and end up with resistant infections, for example. Arora might point out that because drugs such as PrEP are preventative, missing a dose does not leave a donor worse off because there is no present infection to become worse. This response is inadequate because, as the CDC explains, 'PrEP is much less effective when it is not taken consistently'.⁴⁶ One representative study in 2010 found that while 93% of people in the study said they took the drugs correctly, blood tests later revealed that only 51% actually took the pills

as recommended.⁴⁷ One reason respondents misreport their actual pill intake is social desirability bias: people do not want to risk being ejected from the trial early or upset the people running the trial, so they respond with the answer they think administrators expect.⁴⁸ Another reason for misreporting is that respondents simply misremembered how many pills they actually took.⁴⁹ We tend to remember events that we believe are salient. Initial adherence might be memorable, but people can get bored or distracted as time goes on, misremembering the first dosages as indicative of the rest of their pill intake.

The drugs have, however, shown incredible promise and results since these earlier trials. More recent studies have shown that when MSM take two doses of Truvada before sex and two more doses after, one within 24 hours and another within 48 hours, they are able to cut the risk of contracting HIV by 97%.⁵⁰ Arora, then, could grant that MSM who take PrEP on a regular schedule are vulnerable to 'pill fatigue' but respond that MSM who take 'on-demand' Truvada do not have to remember how many times they took pills in the last 12 days, but if or how many times they had sex. Assuming that pill intake coincides with sexual activity, and having sex is more memorable than a pill regimen alone, and perceived salience helps guard against misremembering,⁵¹ then we can conclude with Arora that MSM who take 'on-demand' Truvada are not as vulnerable to the same kind of misremembering worry. If, as we saw in Section 2, questionnaires about blood donation are designed to reduce the effects of social desirability bias, then, at least in the context of donating blood, we do not have to worry as much about MSM donors misreporting their 'on-demand' intake.⁵² We can, then, make the case with Arora that MSM on prophylaxis can have exact justification only if they take 'on-demand' Truvada as prescribed. The reason why exact justification matters is that it allows donors to effectively know their serostatus. Even though donors may not know their partner's serostatus when they take Truvada 'on-demand', the drug constitutively contributes to sustaining someone's initial negative serostatus.

⁴¹Trussel, J. (2011). Contraceptive failure in the United States. *Contraception*, 83, 397–404.

⁴²Kost, K., et al. (2008). Estimates of contraceptive failure from the 2002 National Survey of Family Growth. *Contraception*, 77(1), 10–21.

⁴³Arora, K. S., Brotherton, S. L., Blake, V., & Douglas, S. P. (2015). In R.E. Domen (Ed.) *An ethical analysis of blood donation policies by men who have sex with men*. *Ethical issues in blood transfusion* (pp. 108–128). Bethesda, MD: AABB Press; Arora, K. S. (2017). Righting anachronistic expectations: The ethics of blood donation by men who have sex with men. *Journal of Gay & Lesbian Social Services*, 29(1), 87–90.

⁴⁴Jones, R. K., Lindberg, L. D., & Higgins, J. (2014). Pull and pray or extra protection? Contraceptive strategies involving withdrawal among US adult women. *Contraception*, 90(4), 416–421.

⁴⁵Trussell, J., & Vaughan, B. (1999). Contraceptive failure, method-related discontinuation and resumption of use: Results from the 1995 National Survey of Family Growth. *Family Planning Perspectives*, 31(2), 64–72.

⁴⁶Ibid. note 19.

⁴⁷Grant, R. M., Lama, J. R., Anderson, P. L., McMahan, V., Liu, A. Y., Vargas, L., ... Gidden, D. V. (2010). Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. *The New England Journal of Medicine*, 363(27), 2587–2599.

⁴⁸Corneli, A. L., McKenna, K., Perry, B., Ahmed, K., Agot, K., Malamatscho, F. ... Van Damme, L. (2015). The science of being a study participant: FEM-PrEP participants' explanations for overreporting adherence to the study pills and for the whereabouts of unused pills. *Epidemiology and Prevention*, 68(5), 578–584.

⁴⁹Lee and Woodliffe, *op. cit.* note 5.

⁵⁰Molina, J. M., Charreau, I., Spire, B., Cotte, L., Chas, J., Capitant, C., ... Meyer, L. (2017). Efficacy, safety, and effect on sexual behavior of on-demand pre-exposure prophylaxis for HIV in men who have sex with men. *The Lancet HIV*, 4(9). Retrieved from <https://www.ncbi.nlm.nih.gov/pubmed/28747274>

⁵¹Lee and Woodliffe, *op. cit.* note 5.

⁵²Even if Truvada intake coincides with sexual activity, I ruled out that condom usage, which would also coincide with sexual activity, as being sufficient for exact justification. The reason condoms were not sufficient was not because people did not use them, but that they did not use them correctly. Assuming that pills are easier to use than condoms, I assume that they would not have a similar failure rate.



But now there is a further, practical problem with sustaining, rather than establishing, exact justification. Suppose a monogamous MSM couple is tested together and the two partners find out that they have exact justification. Most likely, they are not going to continue getting tested and instead presume each other's fidelity. But this presumption relies on testimony. If we accept that people can misrepresent their fidelity, and MSM donors rely on testimony rather than on testing in long-term monogamous or exclusive relationships, then MSM donors would lose their exact justification when they switch to someone else's testimony. If exact justification is what allowed us to draw the distinction between MSM donors, then losing it would erase that distinction.

6 | SUSTAINING EXACT JUSTIFICATION

The central issue now is not whether someone's testimony is sufficient to *establish* exact justification, but whether it is enough to *sustain* it. The reason that testimony was not enough to establish or initially secure exact justification was because it was not referencing anything that could verify someone's serostatus. But, if someone's testimony is referencing a test that verified their negative serostatus, then the testimony is doing two things: first, it is assuring the negative test result; second, it is reporting that the test result is still accurate, no matter what events happened in the meanwhile. Some recent statistics about MSM HIV infection rates from primary partners, however, may cause some concern about how reliable 'sustaining testimony' is in reporting on a negative test still being accurate. These statistics, while concerning, are a red herring, because they focus on the 'cost' of cheating, rather than showing that infidelity is more common in MSM relationships than in others. If sexual behavior in committed or exclusive MSM relationships is similar to that in non-MSM relationships, and we do not assume that non-MSM blood donors are particularly vulnerable to unfaithful sexual partners, then we should extend that assumption to MSM donors.

Recent statistics about infection rates in MSM relationships challenge testimony as sufficient to sustain exact justification for MSM donors. One 2009 study of MSM in five U.S. cities found that that 68% of MSM contracted HIV from a main partner, and concluded that 'transmissions mostly arise from partners believed to be negative (partners with unrecognized infection).'⁵³ Someone might honestly (mis) report a negative serostatus, not knowing that he, in fact, has HIV because he never got tested or because he did not wait for a sufficient window period to obtain an accurate result. In these cases, the person never had exact justification because his testimony is not referencing anything that can verify it. Alternatively, someone might get tested with their partner, and so have exact justification, but not disclose an affair he had that would undermine his exact justification (assuming he does not know the paramour's serostatus). Even if one partner, call him 'Faithful', does not cheat, the other partner, call him, 'Unfaithful', may

cheat. Even if Faithful does nothing wrong, Unfaithful's infidelity would, on this objection, be enough to invalidate Faithful's exact justification.

Staggering as the 68% statistic is, it is a red herring. It does not matter what the potential consequences of the infidelity are, because it is the infidelity itself that is undermining the exact justification: if there is no infidelity, then there are no consequences, and, thus, no reason to think that the exact justification is in jeopardy. Drawing on the 2009 study above, Sonya Brady, Alex Iantaffi and Dylan Galos found in an additional 2012 survey of MSM that infection rates from primary partners depended on the particular *kind* of MSM relationship, rather than just being a MSM relationship.⁵⁴ Many of the self-reporting MSM in a continual monogamous relationship cited safety concerns about contracting HIV as a major motivation for being in a monogamous relationship, suggesting that 'agreements or arrangements involving continual monogamy do appear to confer protection'.⁵⁵ Although self-reported monogamy does not eliminate the risk for cheating, if it constitutively contributes to sustaining each partner's negative serostatus, then the worry about primary MSM partners accounting for 68% of new infections does not necessarily impugn exact justification for MSM donors in monogamous or sexually exclusive relationships.

The line of thought in this objection presupposes the belief that infidelity is more likely in MSM couples than in non-MSM couples. There is some truth to this presupposition: 'despite their endorsement of monogamy, 19% of men reported engaging in anal sex with at least one non-main partner in the last 90 days'.⁵⁶ This presupposition goes too far, because 'these patterns of sexual behavior in the context of a committed [open, closed, or other] relationship are similar to patterns seen in heterosexual couples'.⁵⁷ The notable difference, then, is not that MSM practiced non-monogamy more often than people in non-MSM relationships, but rather that these different models of relationships were more widely recognized and accepted in MSM communities. If, from a questionnaire perspective, we presume that non-MSM donors can rely on their partner's testimony of their fidelity, and there is no relevant difference between sexual practices within MSM relationships and non-MSM relationships, then we should treat like cases alike and extend the same courtesy to MSM donors.

There might still be a worry about the kind of extra-dyadic partners Unfaithful is eponymously unfaithful with. It will be easier to start with a block of terms to articulate this worry:

- MSW: men who have sex with women,

⁵³Sullivan, P. S. Salazar, L., Buchbinder, S., & Sanchez, T. H. (2009). Estimating the proportion of HIV transmissions from main sex partners among men who have sex with men in five US cities. *AIDS*, 23(9), 1153–1162, p. 1160.

⁵⁴Brady, S. S., Iantaffi, A., Galos, D. L., & Simon Rosser, B. R., (2013). Open, closed, or in between: Relationship configuration and condom use among men who use the internet to seek sex with men. *AIDS Behavior*, 17(4), 1499–1514. See also, Darbes, L. A., Chakravarty, D., Neilands, T. B., Beougher, S. C., & Hoff, C. C. (2014). Sexual risk for HIV among gay male couples: A longitudinal study of the impact of relationship dynamics. *Archives of Sexual Behavior*, 43(1), 47–60.

⁵⁵Brady, Iantaffi and Galos, *op. cit.* note 54, pp. 1510–1511.

⁵⁶*Ibid.* p. 1506.

⁵⁷*Ibid.*, p. 1500. See also Solomon, S. E., Rothblum, Esther D., & Balsam, K. (2005). Money, housework, sex, and conflict: Same-sex couples in civil unions, those not in civil unions, and heterosexual married siblings. *Sex Roles*, 52(9–10), 561–575 ; Adam, B. D. (2006). Relationship innovation in male couples. *Sexualities*, 9(1), 5–26

- MSWM: men who have sex with women and men,
- WSM: women who have sex with men,
- WSMW: women who have sex with men and women,
- WSW: women who have sex with women.

If Unfaithful has sex with other MSM, then he exposes Faithful to a risk of HIV infection that their MSW counterparts do not, because, by the empirical case, the MSW are not engaging in the behavior that exposes them and their WSM partners to the elevated risk.

But this objection is wrong. Granted, even though Faithful does not know that Unfaithful is cheating on him, his exact justification is nevertheless undermined. But there is no way to stop the same worry from emerging within the other behavioral categories. In his controversial landmark study, Laud Humphreys showed that some men married women and professed to be MSW in public, donning a 'breastplate of righteousness'. These same men were MSM in private, cruising public bathrooms for anonymous sex with men.⁵⁸ Updating Humphrey's findings for the digital age, men who are married to women use apps or online bulletin boards to find other men for sex. These MSM who were married to women often emphasized a desire for safe sex that was not only drug- and disease-free but was with other married men.⁵⁹ If MSM who are married to women only have sex with other MSM who are married to women, then, assuming their wives' fidelity, they would be insulated from the elevated risk we saw in the empirical case, even though they would still be MSM.

Given that online bulletin boards were anonymous by design, and that people can easily misrepresent their marital status online, the men in the above study could only verify their own marital status. The same could not be said of their anonymous sexual partners; they knew only what their partners told them. If Unfaithful's actions in the MSM relationship disqualified Faithful because of his potential exposure to HIV, then so too would the MSMW husband disqualify the unsuspecting WSM wife – she would be just as unaware and at risk as Faithful. Similarly, a WSW might cheat on her WSW partner with a WSWM who had had sex with a MSMW; other iterations are open to the exact same worry of Unfaithful's transgression. But, since we do not think that a non-MSM donor's ability to donate blood depends on their ability to detect a partner's infidelity, then we should not cast undue and unjustified aspersions on MSM donors.

7 | CONCLUSION

The FDA's 2015 policy revision towards deferring MSM donors was a step in the right direction, but it can still be improved. The empirical

case supporting the deferral policy misstates which MSM donors are at risk. One way we can improve the policy is by dividing MSM donors by their ability to accurately report a negative serostatus. Donors with exact justification about a negative serostatus are not at risk from the empirical case and should be allowed to donate blood. MSM donors with ordinary justification are still exposed to the risk from the empirical case, but improved testing commits the FDA to reducing the deferral period from one year to whatever timeframe coincides with accurate test results. Each of these measures can increase the blood supply without sacrificing safety precautions.

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CONFLICT OF INTEREST

The author declares no conflict of interest.

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⁵⁸Humphreys, L. (1975). *Tearoom trade: Impersonal sex in public places*. Chicago, IL: Aldine.

⁵⁹Cheeseman, K., Goodlin-Fahncke, W., & Tewksbury, R. (2012). 'Looking for a married hookup': An examination of personal ads posted by men seeking sex with married men. *The Journal of Men's Studies*, 20(2), 144–157.