



Published in final edited form as:

Transfusion. 2015 December ; 55(12): 2835–2841. doi:10.1111/trf.13268.

Saving Lives, Maintaining Safety, and Science-Based Policy: Qualitative Interview Findings from the Blood Donation Rules Opinion Study (Blood DROPS)

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Abstract

Background—Indefinite deferral from donation for any man who discloses having had sex with another man even once since 1977 (MSM77) is the US FDA’s standing policy. This qualitative component of the Blood Donation Rules and Opinion Study was designed to provide insight into the perceptions and practices of current or previous donors with MSM history.

Methods—Forty HIV-negative MSM completed an online survey, indicating they had donated blood and were willing to be interviewed. Semi-structured, individual interviews with these key informants covered donation experience and motivations, perceptions of MSM77, policy change preferences, and possible impact of a change to a time-limited deferral. Transcripts were coded deductively and inductively, following a modified Grounded Theory approach. Analysis identified recurrent and divergent themes.

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The authors have no conflicts of interest to disclose.

Results—Ninety-five percent of participants endorsed modifying MSM77. Preferred deferral length ranged from none to five years; a common opinion was that a science-based deferral period would be less than one year. Other policy change recommendations included incorporating questions about specific HIV risk behaviors to the donor questionnaire for all potential donors. Interviewees recognized HIV infection rates are higher in MSM than the general US population, but participants considered themselves low-risk for HIV, donated blood “to save lives”, and justified their recommendations as being more effective ways to identify donors at-risk for HIV.

Conclusion—Results suggest that MSM donors are concerned with blood safety; they can be appealed to as such. Communications about a new deferral policy should include scientific explanations and acknowledge altruistic motivations of potential donors.

Introduction

The policy of indefinite deferral from blood donation for any man who discloses having had sex with another man (MSM) even once originated in 1983, in response to evidence suggesting blood products were associated with hemophiliacs developing AIDS. At that time, basic knowledge around AIDS—including even the existence of HIV—was lacking, although gay men were over-represented among AIDS cases and inferential evidence suggested, relative to their proportion of the general population, may have been among blood donors.¹⁻⁴ In 1983, with modifications in 1985, the FDA established a policy to indefinitely defer any man who had had sex (defined as oral or anal penile penetration) with another man since 1977 from donating blood or tissue products (MSM77). However, data from several countries suggest that a significant percentage of donors fail to disclose MSM activity,⁵⁻⁸ and that this may have increased in recent years. The topic of donation by MSM has received widespread attention recently as Canada, the UK, and other countries have modified their MSM deferral policies to allow donation by MSM who report being same-gender celibate over specific time intervals.^{9,10}

The US has also re-examined indefinite MSM deferral. At the June 2010 meeting, the Health and Human Services (HHS) Advisory Committee on Blood Safety and Availability (ACBSA) issued a statement which indicated inadequate data to support a change to a specific alternative policy.¹¹ ACBSA recommended further research on MSM perspectives on MSM77. This manuscript presents results from the Blood Donation Rules and Opinions Study (Blood DROPS). The preliminary results of this study were among those presented on November 13, 2014 at the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) which voted 16-2 in favor of a 1-year deferral. In December 2014, the US FDA announced that the policy for male donors reporting MSM would change to a 1-year deferral from last sexual contact.^{12,13} Here we report qualitative data on policy change recommendations by donors reporting MSM contact, and the potential impact of the policy change on MSM blood donation behavior.

Methods

Blood DROPS was a mixed-method study conducted in four US regions (Northern California, Western Pennsylvania, Connecticut, and Eastern Wisconsin) in 2013-14 as part of the Recipient Epidemiology and Donor Evaluation Study (REDS-III). Three phases of

data collection examined motivations for donating blood out of compliance with MSM77 and the potential impact of changes to the deferral policy on MSM blood donation behavior. During the first phase, we conducted 7 focus groups with MSM in 4 cities in REDS-III catchment areas. In the second phase, we conducted online surveys of male blood donors at the REDS-III blood centers (donor survey) and, for comparison, a sample of MSM via LGBTQ organizations and social networks (community survey). The study's third phase, reported here, consisted of 40 confidential, semi-structured, individual telephone interviews

Sampling and Recruitment

The 40 participants for the interview component were drawn from the pool of survey respondents who met eligibility requirements (HIV-negative MSM, aged 18+, reporting donation and willingness to be contacted for an interview). Half (n=20) of the interviewees were recruited from the donor survey and half from the community survey. Of 134 eligible donor survey respondents, 107 (79.9%) were willing to be interviewed; for the community survey, the proportion was 147 out of 190 (77.4%). Survey respondents reporting higher numbers of recent MSM partners and more recent blood donations were purposively sampled in order to maximize the variety of MSM risk and donation experiences.

Data Collection

Interviews took place between August 2013 and January 2014; all were conducted by one of the authors (NS) with extensive training and experience in qualitative methods for the evaluation of HIV risk assessment.¹⁴ The interview guide covered topics including donation history, motivations for donation practice, perceptions of MSM77, and policy change preferences. Interviews lasted approximately 60 minutes, were digitally recorded, and transcribed verbatim. One audio file was corrupted and not transcribable. Each participant received a \$50 [Amazon.com](https://www.amazon.com) electronic gift code. All interview guides and study procedures were approved by the IRBs at each of the four participating sites, and by the Office of Management and Budget (OMB Control No. 0925-0669).

Data Analysis

Transcripts were imported into a qualitative analysis software package (MAXQDA 10, 1989-2015, VERBI Software, Berlin, Germany) and read multiple times by a primary analyst (SH). A modified Grounded Theory approach was employed that used both deductive and inductive methods in coding and analysis.^{15,16} Deductively, elements from the interview guide were translated into codes and applied as relevant themes surfaced in each transcript. These included codes such as "Perception of MSM77," "Reasons to Donate," and "Desired Policy Changes." Other codes emerged inductively, from line-by-line analysis; examples include "Compliance," "Science," and "Discrimination." The transcript segments associated with each code were analyzed to identify recurrent and divergent themes. We selected quotes from a variety of interviewees to illustrate these themes, attributing them using the interview number (e.g., "Int27") to protect participants' confidentiality.

To examine possible within-sample differences regarding policy modification preferences, interviewees were stratified into groups based on recruitment method (donor or community

survey) and current donation practice. The accompanying electronic appendix reports analysis that revealed subtle differences regarding modified deferral period length and impact on future intention to donate.

Results

Recommendations for policy change

In 38 of 39 evaluable interviews, participants endorsed modifying MSM77. The only dissenter, who identified as heterosexual and had not had any same-sex activity for over ten years, indicated ambivalence about changing eligibility rules for MSM donors. Policy change recommendations fell into three categories: shortening the deferral period for donors who report MSM sexual contact; incorporating questions in the donor history questionnaire (DHQ) to assess sexual risk practices; and applying screening and deferral procedures to all donors, regardless of sexual orientation/practice. Many interviewees advocated some combination of these reforms. Thus, we report recommendations by category merely for clarity and not to convey the impression that interviewees favored one type of policy modification to the exclusion of the others.

Shortened Deferral Periods

There was overwhelming support among interviewees for reducing the deferral period for MSM donors. Preferred deferral length ranged from none (i.e., any deferral period for MSM was unacceptable) to five years. Only one interviewee insisted that deferral based on male-male sex should be eliminated entirely, and most interviewees thought five years was too long. For example, as Int35 explained, “To be perfectly honest, my partner and I have discussed getting married in the future. So, I’m not really all that happy with the one in Canada, where you’d be banned for five years, because I’m probably going to continue to have sex with my partner... Basically, that five-year ban would become a life sentence.”

The modal response regarding length of deferral period was that one year following a donor’s last MSM encounter would be “acceptable as a compromise.” As Int17 noted, “I think a year is maybe even too long itself. But it’s better than never.” Explaining his openness to incremental change as the safety of a new policy is confirmed, Int06 echoed this sentiment: “I think pretty much any change at this point would be better than it is now.”

Approximately 20% of interviewees stated that the length of the donation deferral period should reflect the “window period,” that is, the length of time after infection that HIV remains undetectable in donated blood. Most interviewees considered the window period to be 3-6 months, based on their understanding of routine HIV screening in clinical settings. But when the shorter window period of 7-10 days made possible by nucleic acid testing (NAT) was explained, they suggested much shorter deferral periods. For example, Int02 stated: “I’m not a scientist but my immediate reaction is no more than twice [the length of the window period] should even be talked about. So, one month seems borderline acceptable, given the number is 7-10 days.”

Overall, common themes that emerged from interviewees’ responses were that 1) a deferral period based on science would be less than one year, 2) a deferral period applied to all

MSM, without considering individual HIV risk behaviors, was too blunt an instrument to assess risk to the blood supply, and 3) deferral periods based solely on being sexually active discriminate against MSM in monogamous relationships. Further, specifically regarding the institution of a one-year deferral, most participants in this study anticipated little change in their current donation practice, whether they were Continuing or Inactive donors (see electronic appendix for more details).

Risk Assessment Questions

Twenty-seven interviewees recommended the incorporation of questions about specific HIV risk behaviors to the DHQ. MSM are accustomed to routine HIV testing, which includes detailed HIV risk assessment since it is ultimately behavior, rather than sexual preference, that poses HIV risk. Though such a radical change in the scope of the DHQ may be beyond what blood centers are willing or able to implement, this policy recommendation was forcefully advocated by our sample.

Interviewees took issue with the current screening question, not only because it was seen as discriminatory, but also—and more importantly to many—because it was felt to be ineffective in identifying donors at risk for HIV. As Int20 noted, “you’re not screening for HIV, you’re just screening for who’s gay and sexually active. That means absolutely nothing.” Echoing this theme, Int18 said, “HIV is not just a gay disease” and recommended “asking the questions maybe in a more specific way . . . , to target people that are low-risk or high-risk regardless of their sexual orientation.” Int23 suggested: “follow-up questions could [correspond to] varying levels of deferral, because a man who has been in a monogamous relationship since 1970 practicing safe sex is clearly at a very different risk than someone who doesn’t use safe sex practices today.”

Interviewees differed on the topics they felt the DHQ should cover. Questions about unprotected sexual contact within a particular time frame, as well as number of sexual partners and/or being in a monogamous relationship were the most common suggestions. Fewer interviewees endorsed explicit questions about type of sex (e.g., oral vs. anal) or sexual positioning, and fewer still mentioned questions about recent HIV testing. Deferring donors who reported potential exposure to HIV was seen as reasonable by those advocating more detailed questions.

Non-compliant donors in this sample often held themselves to similar standards, citing low-risk sexual practices and/or frequent HIV testing—every 3 or 6 months—as key to donation-related decision-making. Over a quarter of Continuing donors (INT09, INT11, INT15, INT18, INT19, INT35) spontaneously talked about such a conscious process of individualized risk assessment. For example, INT18 mentioned his regular HIV testing and low-risk sexual practice (exclusively oral sex) as bolstering his confidence that the blood he donates is safe. Another Continuing donor agreed about the importance of such considerations and concluded, “I can’t knowingly be at risk and subject someone to it by donating my blood. That’s against my character to do that” (INT09). INT19 also emphasized the importance of HIV testing, saying, “I choose not to donate unless I really know what my current status is.” Further, a bisexual, Inactive donor specified that it was the lack of HIV

testing after a recent same-sex contact that was keeping him from donating: “I’ve avoided giving blood ... because I don’t want to put anyone at risk without knowing” (INT05).

Some interviewees saw adding detailed risk questions to the DHQ as problematic, however. Three interviewees cited privacy concerns. For example, Int17 felt that this approach, while “fair,” would not change his continuing donation practice because he is not “out” as a bisexual. Int09 explained, “I would rather be able to provide [an HIV] test to show that I’m negative in the time frame rather than give them all my business.” An additional six interviewees responded favorably to the idea of asking more detailed questions but felt broaching such topics might not be acceptable for some donors, or that people would simply answer in a way that allowed them to donate. Int39 concluded, “I feel like once you start asking really personal questions of people, they may be less likely to answer them honestly.” Other interviewees felt people might actually be *more* forthcoming in response to more specific questions. They explained that screening questions targeting behaviors they perceived as “high-risk and a red flag” (Int34), such as unprotected anal intercourse (UAI), would be key to a policy that “makes sense” (Int36) in terms of identifying real infection risk. Int35 acknowledged the potential discomfort some donors might experience but insisted, “I really don’t think it would turn people off to [donation] because I feel like it would make people feel a little more secure in that what they are donating, they are making sure that it is clean, and it’s suitable for people that need it.”

Universality

A third broadly desirable change to MSM77 emerged from the data, with 22 participants stating that any changes to the policy should be applied to all donors. Specifically, they suggested universal application of a deferral period to all donors reporting specific risks, asking everyone more detailed screening questions about sexual risk behavior, or a combination of the two. For example, Int04 suggested that, along with questions about travel, paying for sex, etc., the screening process should include a universally applied deferral of 10 days since a donor’s most recent sexual encounter. Int24 advocated deferring all donors reporting UAI in the past year:

Int24 I’m all for a deferral for that. But yeah, I guess what I’m saying is asking about specific sexual practices in specific time frames and making some determinations based on what people have done.

Interviewer Yeah, and that would be applied to everybody or just to gay men?

Int24 It should be applied to everybody.

Though many interviewees noted that universal screening procedures would lessen discrimination against sexual minorities, social justice was positioned as a subsidiary justification for universal applications of policy. Rather, participants emphasized that neither HIV, nor the behaviors most likely to lead to seroconversion, are exclusive to MSM. Not acknowledging non-MSM sources of potentially “infected blood” (Int18), it was argued, put the safety of the blood supply in jeopardy. The following comment exemplifies the nuance in this type of response:

On one hand, it is more of a, you know, homosexual activity, and/or an associated disease...but I think to focus [screening] on, you know, one side or the other is discriminatory, you know, at its heart, because it could just as well be that, you know, straight people end up with HIV/AIDS from unprotected sex. But, you know, they would go completely under the radar [if they are not asked] those questions. (Int27)

As in the above segment, many interviewees readily acknowledged the fact that in the U.S., “MSM” are more likely to be seropositive than other groups. There was disagreement, however, about whether higher HIV prevalence could justify differential treatment. For instance, when asked whether it would be a “deal breaker” if the deferral period for MSM were reduced, but the deferral periods for women and straight men remained unchanged, Int16 responded, “No, I would be fine with that.” In contrast, when asked if it would be acceptable to target additional screening questions to MSM, Int28 replied, “I would say err on the side of asking everyone [more detailed questions]. I mean, I do realize that MSM are at increased risk, but obviously, there are plenty of straight people who are HIV positive.”

Other interviewees brought statistics into reasoned consideration of universal screening procedures. One participant acknowledged differential HIV risk according to sexual positioning, and when asked if that should impact whether people can donate, he responded, “The rights activist in me is saying, ‘No, there shouldn’t be [a difference],’ but the mathematician in me is also saying, ‘Well, there is a statistical difference between the two’” (Int35). In another example, Int32 focused on HIV prevalence rates within US subpopulations. He observed, “There are other demographics that are at high-risk for having HIV, like Latino women or African American women...if we are going by this logic of, you know, at-risk groups, high-risk groups unable to donate, then why aren’t those groups also barred from donating?” This participant was not advocating deferral for these groups of women, but rather pointing out the selectivity of current deferrals.

Saving Lives, Safety, and Science

Our interviewees described their motivations for donating blood with the same altruistic discourse ascribed to heterosexual donors, that is, in order to save lives. They acknowledged competing demands of quantity and safety, and downplayed protest of homophobia as a motivation for donating. While most did note their perception that MSM⁷⁷ is discriminatory, they accepted the basic premise that donors at risk for HIV should be excluded. Thus, in recounting their decision-making along the donation trajectory, they prioritized their concern for blood safety. In doing so, they challenged and reframed conceptions of “risk” based on risk group discourses that were prevalent when the policy was enacted. Their main concern with the current policy was that—as implemented—it was ineffective as a safety measure. MSM donors and would-be donors alike contested the blanket labeling of MSM as vectors of disease because this constructs HIV risk as exclusively a homosexual phenomenon, and fails to differentiate between potential donors with dramatically different degrees of risk. As Int02 said:

“[The policy is] really counterintuitive to the whole process, you know, because we’re trying to help people, we’re trying to save lives, you know, and protect them

at the same time. So the policy is not invalid. But doing it in a way that, you know, excludes people [based exclusively on MSM contact] and doesn't really fulfill the end goal.... It's being [protective], but it's not being that as well as it could be."

While science-based policy was held up as an ideal, there was strong consensus within our sample that a one-year deferral period constitutes a compromise between authoritative knowledge and political palatability. This was clearly articulated by Int35, who said, "In an ideal situation one would simply look at the science... basically allow the experts to tell us what's right and then everyone else can just live with it. But I guess that's where the politics comes in." This quote typifies the nuance of the views participants expressed on the question of policy change: the need for a system that ensures a safe blood supply is viewed primarily as a scientific problem, but one embedded in a broader political context.

Discussion

Little qualitative research on the perspectives of men who donate out of compliance with MSM-related deferrals has been reported. Nonetheless, some of our findings are consistent with those from previous studies. In interviews with MSM in the US and UK who comply with deferral policies, as well as those who do not, participants in both countries described the deferral policy as "unfair" and "discriminatory," and donors reported their own assessment of their blood's safety as a primary justification for non-compliant donation.^{5,17} Such self-assessment, and the importance of donors' beliefs about risk are not limited to MSM donors, however. O'Brien et al. have found analogous dynamics in studies of Canadian donors who do not disclose injection drug use,¹⁸ as well as in a sample of whole blood donors.¹⁹ One striking difference between our findings and other reported results specific to the topic of MSM⁵ was the relative accuracy and sophistication that characterized many of our interviewees' statements about HIV testing and epidemiology.

Overall, Blood DROPS interviewees overwhelmingly supported modifying MSM77. While this is perhaps unremarkable, attending to their reasoning, as well as the specific changes they recommend, can shed light on how MSM donors may respond to revised screening processes. This is of the utmost relevance, given changes to the deferral policy announced by the FDA in December 2014. Thus, we briefly relate reported motivations for non-compliant donation to policy change recommendations, focusing on common underlying values. Cognizance of and respect for these values—namely, saving lives, safety, and science—can be instructive as the new 1-year deferral policy is implemented.

Rather than talk of equal rights, interviewees primarily deployed scientific and technological discourses to argue that the current policy is flawed. In essence, they contend that MSM77 does not adequately balance sensitivity and specificity; it does not accurately identify those who pose a "true" risk. Though a subpopulation of MSM has been found to be more at risk for acute HIV infection potentially not detectable by NAT if very recently infected, this does not mean that all MSM are equally at risk. MSM77 makes no distinction between MSM who have multiple, unprotected sex partners, those who are in exclusive (monogamous) relationships, those with a single MSM experience, or those who routinely test for HIV. It also fails to screen for some other sources of risk for HIV. The recommendation to apply the

same screening questions to all donors was proposed as more scientifically valid, more specific and sensitive, than the blunt measure that distinguishes only between heterosexual and homosexual sex, while ignoring known correlates of HIV risk such as numbers of partners, use of condoms, and sexual positioning.

Implications for Policy Implementation

We are encouraged that interviewees recognized the increased HIV risk among some MSM as a common ground for a science-based discussion of changes to the MSM deferral policy. Further, as interviewees repeatedly asserted, they share the blood center's goals to improve both safety and availability of blood products.

These findings translate to three recommendations: First, communication about the new policy should primarily address epidemiological arguments and avoid those based on social equality for homosexual men. In this sense, precedents set by other industrialized Anglophone countries, such as Canada, Australia, and the UK can provide valuable context for a discussion of the selection of a one year deferral. The experience of Australia and Canada has confirmed what mathematical models predicted: reducing deferral periods to 1 or 5 years, respectively, allowed more people to donate, with no apparent increase in HIV risk to blood recipients observed so far in those two countries.^{10,20}

Second, given participants' recommendations to base any policy change on scientific evidence of safety, it should be emphasized that the 1-year deferral for male donors who report sexual contact with other men will be rigorously evaluated. For evaluation of the new policy to produce valid results, however, potential donors with deferrable behaviors must abstain from donation. This unavoidable truth can undergird a special appeal to potential donors to comply with the new MSM-related deferral period.

Third, all participants in this study described their motivation to donate in altruistic terms: to save lives. None of them characterized their non-disclosure of MSM contact as an ethical act of protest, despite stating their perception that MSM77 was unjust and ineffective. Instead, when faced with a choice between two incompatible ethical imperatives: donating blood that they believe to be HIV-negative versus answering honestly about their MSM behavior—Continuing donors (see electronic appendix) chose what they saw as the greater good: saving lives through donation. In terms of attempting to secure compliance with a revised deferral policy, this suggests that messages extolling the ethics of honesty in disclosing MSM may miss the larger moral context of altruism and thus have limited impact.

Limitations

Though this research produced timely and important findings from a sample of MSM blood donors, some limitations deserve mention. First, the study population was restricted; these interview results do not include the perspective of blood recipients, blood center workers, heterosexual donors, non-donor MSM, or donors who have tested HIV-positive (whether through blood donation or other venues). The perspectives of these groups deserve further research. Specifically, because male donors continue to be found HIV-positive, and MSM contact remains a primary risk factor in such cases³ the latter group may have important experiences to share in terms of safely implementing a modified deferral policy.

Regarding participants and perspectives that were included in the research, as with all approaches that rely on self-reported behavior, the effect of social desirability or selection bias cannot be ruled out. Those individuals who completed the survey and agreed to be interviewed might have tended to hold certain beliefs—for example, about the importance of science and safety. However, “generalizability” is not necessarily the goal of qualitative research, particularly with “hidden” populations.¹⁵ Additionally, the consistency of interviewees’ narratives suggests a meaningful and shared cognitive model of blood donation.²¹ Understanding this model is important even when individual behavior diverges from it.

Conclusion

Implementation of new guidelines for MSM donor eligibility should begin from the premise that anyone who desires to donate blood is primarily motivated by a desire to save lives. When considering outreach and modified screening procedures, the question that should be asked, paraphrasing Christian Bason, is: What would it look like “if success depended on *helping* [donors] comply with the [policy], rather than on *catching* people not complying” (italics in original)?²² Our results suggest that MSM donors are concerned with blood safety; they can be appealed to as such. Communications about a new deferral policy should include scientific explanations and acknowledge altruistic motivations of potential donors.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgements

We would like to thank Dan Hines and Anne Guiltinan (Blood Systems Research Institute), Bryan Spencer (American Red Cross), Walter Bialkowski (BloodCenter of Wisconsin), Pam D’Andrea (Institute for Transfusion Medicine), Marian Sullivan (RTI), Simone Glynn (NHLBI), and Alan Williams (US FDA) for their contributions to all aspects of this study.

This study was funded by the US FDA and NHLBI REDS-III Program.

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