

# Facing difficult but unavoidable choices: Donor blood safety and the deferral of men who have sex with men

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## Abstract

Blood service organizations employ various ways to ensure transfusion blood safety, including the testing of all donations for transfusion-transmissible infections (TTI) and the exclusion of donors who are at increased risk of a recent infection. As some TTIs are more common among men who have sex with men (MSM), many jurisdictions (temporarily) defer the donation of blood by sexually active MSM. This boils down to a categorical exclusion of a large group solely on the basis of their sexual orientation, which is seen as unduly discriminatory and stigmatizing. Blood service organizations in the U.K. and the Netherlands have recently changed their deferral policies for MSM. The problem of the MSM deferral involves a conflict between fundamental rights: the right of MSM to equal treatment and the right to health of the recipients of blood and blood products. We distinguish and discuss three broad alternative options to the current categorical deferral of MSM donations: (1) completely abandoning donor selection on the basis of sexual behavior, (2) individual risk assessment of the sexual activities of each potential donor, and (3) individual risk assessment of the sexual activities of MSM only. The new U.K. policy falls within the second category, and the new Dutch policy is in the third category. We argue that each approach comes with moral costs but that the most reasonable option is different from the policies of both the U.K. and the Netherlands.

## KEYWORDS

blood donation, blood safety, equal treatment, ethics, human rights, law, sexual orientation

## 1 | INTRODUCTION: CHANGING POLICIES TO ENSURE THE SAFETY OF DONOR BLOOD

Blood service organizations employ various methods to protect blood recipients against transfusion-transmissible infections (TTIs) such as HIV, Human T-lymphotropic virus, the hepatitis B, C, and E viruses

(HBV, HCV, and HEV, respectively), and syphilis. Antibody tests can detect antibodies (markers for active or past infection) in donor blood, and nucleotide amplification tests (NATs) detect the DNA or RNA of pathogens (markers for active infection). Normally, such diagnostic screening tests are preceded by a preselection of donors based on a standardized donor health questionnaire (DHQ). If particular answers are given about recent risk behavior and possible

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exposure to blood-borne and sexually transmitted infections (STIs), the blood donation of candidate donors can be deferred temporarily.<sup>1</sup> By following this procedure, blood banks hope to minimize the number of donors who have had recent infections. This is considered necessary because laboratory tests cannot detect all recent infections.

Most countries categorically defer blood donations of male persons who engage in sex with members of the same sex (MSM, where non-MSM denotes men who do not have sex with other men). The epidemiological rationale for deferring blood donations of MSM is the much higher incidence of blood-borne infections and STIs among MSM compared with non-MSM, and temporary exclusion for as long as the maximum window-period after the most recent male-to-male sexual contact reduces the risk of transmission. The current deferral period of 3–4 months is based on the longest maximum estimated window-period, which in the context of blood donation is that of HBV.<sup>2</sup> Although MSM in the Netherlands are at increased risk for HIV, HBV, HCV and syphilis compared to non-MSM,<sup>3</sup> public debate and the primary concern with regard to blood safety is mostly about HIV. For that reason, this article focuses solely on HIV, but it is good to realize that it concerns these other TTIs as well. In the Netherlands, the HIV incidence among MSM is approximately 100 times higher than that among the general Dutch population.

This unequal treatment of MSM by blood service organizations has been criticized for many years for being stigmatizing and discriminatory.<sup>4</sup> Requiring MSM to abstain from sex for 3–4 months prior to donation implies a de facto permanent exclusion of donorship for many MSM. More fundamentally, MSM are not treated on equal terms with other citizens, because the deferral policy affects

MSM disproportionately and leaves other categories of donors relatively unaffected. Donor selection might be necessary, but, many argue, it should be based on the individual risk behavior of each donor rather than being a categorical separation on the basis of assumed collective characteristics.<sup>5</sup> For example, a monogamous male donor who is in a stable sexual relationship with another man may not pose an increased risk of TTIs. In a Dutch newspaper article, Yair da Costa complains: “What about heterosexual men with a promiscuous lifestyle? Aren't they also at increased risk of infection? In my opinion, heterosexual men with multiple casual sexual partners are a greater risk than the risk-conscious man who has sex with other men.”<sup>6</sup>

The U.K. and the Netherlands have both recently decided to discontinue a *categorical* deferral of blood donations by MSM, and both countries allow all MSM in stable monogamous relationships to donate blood.<sup>7</sup> The difference between the two is that the U.K. policy aims to be truly neutral about sexual orientation by removing all questions about the gender of sexual partners from the DHQ, while in the Netherlands, men will still be asked whether they have had sex with another man in the previous 4 months. In this respect, the U.K. is following recommendations from the recent FAIR report: “the updated donor deferral criteria will focus on identifying a wider range of ‘highest risk behaviours,’ which will apply to all donors, regardless of sexuality.”<sup>8</sup> In practice, this implies that (a) all persons in a stable monogamous relationship will be able to donate, and (b) donors who have had a new sexual partner or multiple partners in the last 3 months can donate, unless they have had anal sex. In the Netherlands, only MSM must answer specific questions about sexual activity, but MSM in stable monogamous relationships will be able to donate. All MSM who have had a new partner or multiple partners in recent months are excluded from donation.<sup>9</sup>

Which policy provides the best ethical, legal, and epidemiological alternative to current categorical deferral policies aimed at MSM? Although we applaud the attempts of both countries to move away from this type of deferral, we argue in this article that these policies are insufficiently justified and to some extent ethically indefensible.

<sup>1</sup>The Official Journal of the European Union. (2004). Commission Directive 2004/33/EC. Implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components (Annex III:31-4); de Kort, W., van den Burg, P., Geerligs, H., Pasker-de Jong, P., & Marijt-van der Kreek, T. (2014). Cost-effectiveness of questionnaires in preventing transfusion-transmitted infections. *Transfusion*, 54(3), 879–888; Slot, E., Janssen, M. P., Marijt-van der, K. T., Zaaier, H. L., & van de Laar, T. J. (2016). Two decades of risk factors and transfusion-transmissible infections in Dutch blood donors. *Transfusion*, 56(1), 203–214. <https://doi.org/10.1111/trf.13298>; Cutts, J. C., Quinn, B., Seed, C. R., Kotsiou, G., Pearson, R., Scott, N., ... Hellard, M. E. (2021). A systematic review of interventions used to increase blood donor compliance with deferral criteria. *Transfusion Medicine and Hemotherapy*, 48, 118–129. <https://doi.org/10.1159/000509027>

<sup>2</sup>Kleinman, S. H., Lelie, N., & Busch, M. P. (2009). Infectivity of human immunodeficiency virus 1, hepatitis C virus and hepatitis B virus and risk of transmission by transfusion. *Transfusion*, 49(11), 2454–2489. <https://doi.org/10.1111/j.1537-2995.2009.02322.x>; Busch, M. P., Bloch, E. M., & Kleinman, S. (2019). Prevention of transfusion transmitted infections. *Blood*, 133(17), 1854–1864.

<sup>3</sup>Staritsky, L. E., van Aar, F., Visser, M., Op de Coul, E. L. M., Heijne, J. C. M., Götz, H. M., ... van Benthem, B. H. B. (2020). *Sexually transmitted infections in the Netherlands in 2019*. Retrieved from <https://www.rivm.nl/bibliotheek/rapporten/2020-0052.pdf>; ECDC, & WHO Regional Office for Europe. (2020). *HIV/AIDS surveillance report 2020 – data 2019*. Retrieved from <https://www.ecdc.europa.eu/sites/default/files/documents/hiv-surveillance-report-2020.pdf>; Offergeld, R., Kamp, C., Heiden, M., Norda, R., & Behr-Gross, M. E. (2014). Sexual risk behaviour and donor deferral in Europe. *Vox Sang*, 107(4), 420–427.

<sup>4</sup>Sacks, C. A., Goldstein, R. H., & Walensky, R. P. (2017). Rethinking the ban—The U.S. blood supply and men who have sex with men. *New England Journal of Medicine*, 376(2), 174–177; Brailsford, S. R., Kelly, D., Kholi, H., Slowther, A., & Watkins, N. A. (2015). Who should donate blood? Policy decisions on donor deferral criteria should protect recipients and be fair to donors. *Transfusion Medicine*, 25(4), 234–238; Grace, D., Gaspar, M., Lessard, D., Klassen, B., Brennan, D. J., Adam, B. D., ... Hart, T. A. (2019). Gay and bisexual men's views on reforming blood donation policy in Canada: a qualitative study. *BMC Public Health*, 19(1), 772.

<sup>5</sup>O'Brien, S. F., Goldman, M., Robillard, P., Osmond, L., Myhal, G., & Roy, É. (2021). Donor screening alternatives to men who have sex with men time deferral: Potential impact on donor deferral and discomfort. *Transfusion*, 61(1), 94–101; Suligoi, B., Pupella, S., Regine, V., Raimondo, M., Velati, C., & Grazzini, G. (2013). Changing blood donor screening criteria for permanent deferral for men who have sex with men to individual risk assessment: No evidence of a significant impact on the human immunodeficiency virus epidemic in Italy. *Blood Transfusion*, 11(3), 441–448; Haire, B., Whitford, K., & Kaldor, J. M. (2018). Blood donor deferral for men who have sex with men: Still room to move. *Transfusion*, 58(3), 816–822.

<sup>6</sup>Costa, Y. d. (2019, August 8). Ik mag geen bloed doneren bij Sanquin. De reden? Ik heb seks met mannen. *Het Parool*. See also Schmidt, F. (2020, January 17). *Homophobic bias in conditions for donating blood*. Retrieved from <https://leidenlawblog.nl/articles/homophobic-bias-in-conditions-for-donating-blood>; Behrmann, J., & Ravitsky, V. (2011). Do Canadian researchers have “blood on their hands”? *Canadian Medical Association Journal*, 183(9), 1112.

<sup>7</sup>Besides these MSM-directed limitations, most donor selection policies also exclude other categories of donors that pose a risk to blood safety, but these are not discussed here because they are less controversial or uncontroversial from a moral perspective.

<sup>8</sup>For an explanation, see the FAIR report. Retrieved June 21, 2021 from <https://www.blood.co.uk/news-and-campaigns/news-and-statements/fair-steering-group>

<sup>9</sup>For an explanation (in Dutch), see <https://www.sanquin.nl/over-sanquin/nieuws/2021/03/loedbank-opent-de-deur-voor-msm> (accessed June 21, 2021).

We sketch out the legal–ethical context of the issue and discuss three broad alternatives to the deferral of donations from MSM. Our conclusion is that the most appropriate approach would involve a more in-depth and individual risk assessment of the sexual behavior of MSM. This would still amount to unequal treatment, but it would avoid some of the major pitfalls of the U.K. approach and would be more inclusive than the new policy in the Netherlands. Another alternative is to avoid unequal treatment altogether by excluding all sex-related screening questions. This would come with a significantly larger residual risk, although in absolute terms the risk would still be small.

## 2 | UNDERSTANDING THE NORMATIVE CONFLICT

The availability of blood used for therapeutic purposes generally depends on citizens who are prepared to donate blood voluntarily out of altruism. The decision to donate blood is a precious act of citizenship and a gesture of selfless generosity and solidarity.<sup>10</sup> By offering citizens the possibility of donating, blood service organizations—under European Union (EU) law—engage in the legal act of offering or granting access to goods and services, and this means that they are legally prohibited from engaging in discrimination. MSM experience current exclusionary policies as stigmatizing and discriminatory and feel disadvantaged by policies that label all sexual intercourse involving two men as high risk. They want to be treated on equal terms with non-MSM citizens. One aspect of the perceived discriminatory character lies in the fact that deferrals are too generic: they apply in the same way to every MSM and ignore the diversity within the MSM population. Some MSM have multiple sexual partners, but many others are in long-term monogamous relationships. Some engage in unprotected sex, but many do not. In contrast, non-MSM are accepted as donors much more easily and are not subject to in-depth questioning about their sexual behavior. This unequal treatment of MSM reinforces stereotypes of gay men as carriers of communicable diseases just because of their sexual orientation.<sup>11</sup>

On the other hand, recipients of blood and blood products depend on a steady supply of safe donor blood, and this is especially true for regular recipients, such as hemophilia patients in the past and hematological patients nowadays. The AIDS epidemic of the 1980s affected not only the gay community but also hemophilia patients: nearly half of all patients died as a result of HIV infections transmitted via donor blood.<sup>12</sup> The question of the supply of blood, however, potentially affects us all: anyone could be in an accident

tomorrow and require blood. The traumatic experience of the mid-1980s, however, made blood services organizations very reluctant to accept less strict donor selection criteria, as this could reduce the safety of blood products.<sup>13</sup> Their responsibility to ensure blood safety was recognized in the opinion of the Attorney General in the *Léger* case, which was heard by the Court of Justice of the European Union (CJEU):

I can imagine that the rejection of a gesture of selfless generosity and solidarity, such as the donation of blood, may cause a reaction of misunderstanding on the part of the person whose donation is refused, but it must be recognized that giving blood is not, in itself, a right, that its universality has never been recognized, since donors are subject to selection and must, in that regard, satisfy a certain number of conditions, and that, in any event, it is the medical authorities, which alone shoulder full immediate responsibility for their decisions, which must have the last word.<sup>14</sup>

Yet, even though there is no moral or legal right to donate, exclusionary policies can still be stigmatizing and involve morally and legally problematic unequal treatment that is in tension with the obligations that blood services have towards their donors.<sup>15</sup> In this way, blood services must develop policies in the face of a variety of conflicting values: safety to recipients; the rights of candidate donors, including in relation to equal treatment, nonstigmatization and privacy; and maintaining a sufficient supply of donor blood. Below we will flesh out the moral problem in more detail, focusing on the conflicting fundamental rights at stake. The normative analysis and justification of unequal treatment of MSM is developed most thoroughly in legal discussions and jurisprudence. Given that these discussions revolve around weighing competing values and formulating conditions for the justified infringement of certain freedoms, they can be seen as encompassing legal as well as ethical evaluations. In the next section, we therefore focus on the analysis of recent legal sources. We refer to EU law, but the underlying ethical principles and arguments also apply to other liberal-democratic contexts.

### 2.1 | Unequal treatment: violating a fundamental human right

Unequal treatment by blood services can be considered to be a prohibited form of discrimination according to *The Charter of Fundamental Rights* of the EU.<sup>16</sup> As previously mentioned, by offering

<sup>10</sup>Titmuss, R. M. (1970). *The gift relationship: From human blood to social policy*. Allen & Unwin.

<sup>11</sup>Bensing, D. J. (2011). Science or stigma: potential challenges to the FDA's ban on gay blood. *Journal of Constitutional Law*, 14(2), 485–510.

<sup>12</sup>Jones, P., Hamilton, P. J., Bird, G., Fearn, M., Oxley, A., Tedder, R., ... Codd, A. (1985). AIDS and haemophilia: Morbidity and mortality in a well-defined population. *British Medical Journal*, 291(6497), 695–699.

<sup>13</sup>For a more general discussion, see Farrell, A.-M. (2016). *The politics of blood*. Cambridge University Press.

<sup>14</sup>Jugement of 29 April, 2015, *Geoffrey Léger v Ministre des, de la Santé et des Droits des femmes, Établissement français du sang*, C-528/13, ECLI:EU:C:2015:288 Case C-528/13 (Léger). This quote comes from the opinion of the advocate general Mengozzi delivered on July 17, 2014, §51.

<sup>15</sup>EU Directives 2002/98 & 2004/33.

<sup>16</sup>As a general rule, the organization and delivery of health services and medical care are the responsibility of the sovereign powers of the member states, meaning that the EU has limited regulatory powers in the area of healthcare. However, based on Article 168(4)(a) TFEU, the so-called Blood Directive sets more specific EU standards of quality and safety for the collection, testing, processing, storage, and distribution of human blood products. See also den Exter, A. (2016). Homosexuals and blood donation: A delicate issue for the

citizens the possibility of donating blood, blood service organizations engage in the legal act of offering or granting access to goods and services, which means that they are prohibited from engaging in discrimination. Article 21 states that “any discrimination based on [...] sexual orientation shall be prohibited.” As Kurt Blankschaen has convincingly argued, MSM itself is not a category of people with a specific sexual orientation, and one should be careful not to see MSM deferral as a “gay ban.”<sup>17</sup> Yet deferring all MSM from blood donation boils down to temporarily excluding, from this service, almost completely a category of people with specific sexual orientations (homosexual and bisexual men) and hardly anyone beyond those groups. Therefore, *in principle*, blood services are legally prohibited from treating MSM differently from non-MSM. This, however, is not an absolute legal norm. Differences in treatment are allowed if they are properly justified and proportionate. That is, limitations on the right to nondiscrimination “must be provided for by law and respect the essence of those rights and freedoms” (art. 52). Other rights that are to be respected include the right to health and safe healthcare. This means, though, that the right of some citizens (i.e., MSM) to equal treatment conflicts with the right to health of others (i.e., patients who need safe blood products).

In 2015, the CJEU determined in the *Léger* case that the medical, scientific, and epidemiological knowledge clearly showed that HIV infections were disproportionately prevalent among MSM and that a “deferral [of MSM] from blood donation aims to minimize the risk of transmitting an infectious disease to recipients [and] contributes to the general objective of ensuring a high level of human health protection.” The court concluded that

sexual behaviour covers the situation in which a Member State, having regard to the prevailing situation there, provides for a permanent contraindication to blood donation for men who have had sexual relations with other men where it is established, on the basis of current medical, scientific and epidemiological knowledge and data, that such sexual behaviour puts those persons at a high risk of acquiring severe infectious diseases and that, with due regard to the principle of proportionality, there are no effective techniques for detecting those infectious diseases or, in the absence of such techniques, any less onerous methods than such a counter indication for ensuring a high level of health protection of the recipients. It is for the referring court to determine whether, in the Member State concerned, those conditions are met.<sup>18</sup>

The deferral of donations by MSM thus infringes on the right to equal treatment, but this restriction can be justified as it is necessary to protect the right to health and safety of patients who are critically dependent on blood products. Hence there is a principled ground for unequal treatment, and according to the CJEU, this could even include permanent deferral of all MSM donations. The court's verdict, however, was not set in stone:

As regards the principle of proportionality, it follows from the case-law of the Court that the measures laid down by national legislation must not exceed the limits of what is appropriate and necessary in order to attain the objectives legitimately pursued by that legislation; when there is a choice between several appropriate measures, recourse must be had to the least onerous among them, and the disadvantages caused must not be disproportionate to the aims pursued.<sup>19</sup>

Note that the emphasis on proportionality of measures implies that, even if there is a justification for MSM deferral, the legal problem of unequal treatment should not be considered “off the table.” The Court might also have argued that, since no one has a legal right to donate blood, excluding specific groups on the basis of relevant medical reasons is not an issue of discrimination at all. Such a line of reasoning would fit in many liberal traditions that hold that discrimination only makes sense against a backdrop of rights.<sup>20</sup> Instead, the reference to the requirement of proportionality makes clear that the unequal treatment of MSM, though not unreasonable, remains legally and morally problematic, and should therefore be minimized. One plausible way to explain the remaining problem is that, even if it is not discrimination in the most basic sense, it still involves unequal treatment of a group that is confronted with much stigmatization, social discrimination, prejudice, and even violence in many contexts. All in all, we conclude that the legal verdict of the CJEU offers a justification of unequal treatment of MSM, but this justification does not imply that legal and moral concerns about discrimination have disappeared completely.

Since 2015, many blood services in Europe and Northern America have changed their MSM donor policies from permanent to temporary deferral.<sup>21</sup> To what extent is a further relaxation of blood safety policies now justified?

## 2.2 | Proportionality and precaution

The principle of *proportionality* implies that blood donor services are only allowed to treat MSM unequally if doing so is necessary to protect the right to health of recipients of blood products and when the infringements of the right not to be discriminated against are not disproportionate. This implies opting for the lowest level of unequal treatment that is necessary to protect the right to health of recipients of blood products. In other words, if blood safety can be maintained while relaxing the current restrictions on MSM blood donors, such a step would be ethically and legally justified *and* required.

European Union Court of Justice. *Blood Transfusion*, 14, 500–503. <https://doi.org/10.2450/2015.0155-15>

<sup>17</sup>Blankschaen, K. M. (2018). The ethics of ordinary and exact justification in blood donation deferral categories for men who have sex with men. *Bioethics*, 32(7), 445–453.

<sup>18</sup>Léger, op. cit. note 14, §70.

<sup>19</sup>Léger, op. cit. note 14, §58.

<sup>20</sup>See, for example, Dworkin, R. (1977). *Taking rights seriously*. Duckworth. We are grateful to one reviewer for pointing this out.

<sup>21</sup>Schink, S. B., Offergeld, R., Schmidt, A. J., & Marcus, U. (2018). Blood donor deferral policies across Europe and characteristics of men who have sex with men screened for human immunodeficiency virus in blood establishments: data from the European men-who-have-sex-with-men Internet Survey (EMIS). *Blood Transfusion*, 16(1), 7–16.

A second principle that is relevant to public health law is *precaution*, best summarized in the proverb *better safe than sorry*.<sup>22</sup> This principle offers specific support for interventions that protect the greater good in specific circumstances of uncertain yet potentially grave risk, even if these interventions are at the expense of individual rights. There is no single authoritative formulation of the principle, but the basic gist is that agencies are required to take decisive action to forestall or prevent threats of serious and irreversible harm as soon as there is evidence that such threats are genuinely plausible rather than after the harm has occurred.<sup>23</sup> Since such decisions are inherently made in a context of uncertainty, the lack of complete scientific assurance cannot be a reason to refrain from making a decision. In our context, social identities are used as proxies for risk behaviors to minimize the risk that infected donor blood will be “missed” and could result in TTIs.<sup>24</sup> However, since the principle requires action *before* a threat has actually struck, it may induce blood services to take precautions that are too restrictive. For example, Sircar argues as follows:

There are approximately 4.5 million MSM in the United States, among whom roughly 14 percent have HIV using current estimates. To be sure, the HIV-positive MSM community is a sizeable population warranting a proper public health response, yet deferring the other 86 percent of the MSM community is not necessary to achieve safety for the blood supply today while accepting a lower, but non-zero, risk for other groups.<sup>25</sup>

Moreover, if measures that are too restrictive are already in place, strict compliance with the precautionary principle could stand in the way of change, even if such change has the potential to generate an overall improvement. The implementation of new technologies, or in this case a renewed risk assessment, often comes with some kind of uncertainty. Holding back changes to prevent possible harm might result in the continuation of a safe but suboptimal condition, and it would never be known whether alternative strategies might in fact lead to improvement. To use an analogy, you could wear water wings every time you swim for the rest of your life to prevent drowning, but you will never learn how to swim properly. If we translated this to the case at hand, we would ask whether the current categorical deferral policy that is directed toward MSM is still proportional. Or is it *too* precautionous and are there less onerous measures available that still adequately protect the fundamental right to blood safety?

<sup>22</sup>Wainberg, M. A., Shuldiner, T., Dahl, K., & Gilmore, N. (2010). Reconsidering the lifetime deferral of blood donation by men who have sex with men. *Canadian Medical Association Journal*, 182(12), 1321–1324.

<sup>23</sup>Sunstein, C. R. (2005). *Laws of fear: Beyond the precautionary principle*. Cambridge University Press; Resnik, D. B. (2004). The precautionary principle and medical decision making. *Journal of Medicine and Philosophy*, 29(3), 281–299; Kramer, K., Zaaijer, H. L., & Verweij, M. (2017). The precautionary principle and the tolerability of blood transfusion risks. *American Journal of Bioethics*, 17(3), 32–43.

<sup>24</sup>Deleuran, I., Sheikh, Z. A., & Hoeyer, K. (2015). Tainted blood: Probing safety practices in the Danish blood system. *Health*, 19(5), 490–506. <https://doi.org/10.1177/1363459314556901>

<sup>25</sup>Sircar, N. (2018). Good public health policy, better public health law: Blood donation, individual risk assessments, & lifting the deferral for men who have sex with men. *Food and Drug Law Journal*, 73(1), 103–133.

## 2.3 | Weighing competing rights

The EU Blood Directives seek to attain and maintain a level of risk for recipients of blood products that is *as low as reasonably achievable*.<sup>26</sup> If the only factor to take into account was the right to health of recipients of blood products, every advancement in screening techniques and all political choices should be employed to reduce the risk of infections for such recipients. Indeed, scientific and technological advances in the area of blood safety to the time of writing have been employed to further reduce transfusion risks. Recital 29 in the preamble to EU Directive 2002/98 states:

Tests should be carried out in conformity with the latest scientific and technical procedures that reflect current best practice as defined by, and regularly reviewed and updated through, an appropriate expert consultation process. This review process should also take due account of scientific advances in the detection, inactivation and elimination of pathogens which can be transmitted via transfusion.

On the other hand, scientific and technological advances in the area of blood safety can also be applied to make current measures less discriminatory—and hence more proportional.<sup>27</sup> Technological advances have, over time, enabled the window for the deferral of donations by MSM to be reduced from an indefinite period to 4 months. Future advances in epidemiological knowledge, in pathogen reduction or inactivation techniques, in the manufacturing of artificial blood, and further developments in evidence-based donor selection might help to further reduce the necessity for discriminatory measures.

In the context of weighing the right to health of blood recipients against the right of MSM to equal treatment, we cannot single-mindedly focus on minimizing the risk of transmitting an infectious disease. Instead, our aim should be to determine the maximum residual risk of acquiring a TTI that is deemed acceptable and reasonably achievable. We should make it clear that the risk of acquiring an infection under the current 4-month deferral policy is not zero and will never be zero. We hold that when determining the level of acceptable risk, the interests not only of blood recipients but also of MSM donors need to be taken into account. In other words, the concept in the EU Blood Directives of “a level of risk for recipients of blood products that is as low as reasonably achievable” is to be understood in the light of a reasonable equilibrium between the interests and rights of the two groups of stakeholders. The questions we address next are as follows: which policy options that consider the interests of both groups of stakeholders are available and which are deemed reasonable?

<sup>26</sup>Hoeyer, K. (2015). Regulatory anatomy: How “Safety Logics” structure European Transplant Medicine. *Science, Technology & Human Values*, 40(4), 516–538.

<sup>27</sup>Note that in the Netherlands the risk of transfusion-transmitted HIV, HBV, and HCV infections could be reduced further by switching from NAT screening in pools of six donations to individual NAT screening. But this improvement would come with a considerable price tag. Moreover, this technological change would only slightly decrease the residual risk and would not remove the need for donor selection.

### 3 | THREE BROAD ALTERNATIVES

The right of MSM to nondiscrimination must be weighed against the right of recipients of blood products to a safe and sufficient blood supply. Reaching an equilibrium will inevitably come with some costs for one or both groups. If the categorical deferral of donations by MSM is too blunt a measure, what alternatives are available?

We see three broad alternatives. The most radical option is to abandon all preselection questions about risky sexual behavior and rely fully on laboratory testing. The second is to abandon unequal treatment of MSM but to continue with questions relating to sexual behavior in questionnaires. This would mean doing an individual risk assessment of every single donor—male, female, MSM, or non-MSM. Every potential donor would receive the same set of questions, which would concern only the nature and frequency of sex—not whether it was with men, women, or both. The new U.K. policy could be considered to be an example of this approach, although we will argue later that in practice it might not be. The third option also involves individual risk assessments of every donor, but it would include specific questions for MSM, and this implies that MSM would still be treated unequally. The new Dutch approach is an example of this third alternative: MSM are only allowed to donate if they are in a stable monogamous relationship. We will discuss these alternatives in turn.

#### 3.1 | Abandoning all questions about sexual behavior

The best way to avoid unequal treatment and stigmatization of MSM is to remove the DHQ altogether and to rely completely on laboratory tests. This would inevitably increase the risk of TTIs being in transfusion blood because very recent infections are usually missed by laboratory testing. There are also some additional disadvantages that may result in a somewhat higher risk. DHQs create awareness of risk factors and risk behavior and thus force (aspirant) donors to assess whether they have run a potential risk of acquiring a TTI. If preselection through risk questionnaires disappears, awareness of the TTI risk may decrease, which could lead candidate donors to overlook or underestimate their own risk. In addition, eliminating sex-related questions in the DHQ removes the barrier of having to truthfully answer questions about TTI risks. This is problematic because it might promote test-seeking, and test-seekers typically have an increased risk of (recent) TTIs. Hence, abandoning all questions about sexual risk behavior may cause an influx of donors at increased risk of TTIs that cannot all be detected by laboratory tests.

So, this approach does not discriminate against MSM but will likely increase the TTI risk. Note, however, that the residual risk for transfusion-transmitted HIV is already extremely low at the time of writing.<sup>28</sup> For example, in the Netherlands, the blood service

organization Sanquin calculates the risk of HIV to be 1 in 6–8 million donations (or, with the current number of donations, once every 20–30 years).<sup>29</sup> Without any donor selection procedures and assuming that a representative cross-section of the general Dutch population will donate, the residual risk of transfusion-transmitted HIV could increase five- to 10-fold to 1 in 1–3 million donations (or once every 3–4 years).<sup>30</sup> The latter assumes that there will be no self-exclusion of individuals at increased risk of HIV, suggesting that the absolute risk of getting infected with HIV after abandoning all questions about sexual risk behavior will still be very small. In the early days of HIV, when there were only insensitive HIV tests and long infectious periods, most reduction in HIV transmission was achieved by using deferral methods. The impact of these methods is nowadays limited because NAT testing is highly sensitive in identifying infections in donated blood.<sup>31</sup> Although it would be difficult for responsible blood organizations and governments to abandon deferral methods altogether and accept a somewhat increased risk of infections in transfusion blood and blood products, we think this option should not be dismissed out of hand, and we will return to this alternative in our conclusion.

#### 3.2 | Sexual risk assessment of each and every donor

Another alternative to current deferral policies relating to MSM donations is to abandon the specific assessment of MSM prior to their potential blood donation and instead use the same set of questions about sexual activity for all donors. All candidates whose sexual activity is not considered to pose an increased risk for TTIs would then be eligible to donate. This is what critics of the categorical deferral of MSM donations often propose.<sup>32</sup> Although this looks like a way to avoid discrimination without increasing the risk of infected donor blood, this approach is problematic for a variety of reasons.

The approach involves asking all candidate donors questions about their recent sexual activity, and thus differentiating between donors whose sexual activity is considered low risk and those whose

HBV incidence and residual risk in US blood donors before and after implementation of the 12-month deferral policy for men who have sex with men. *Transfusion*, 61(3), 839–850; Germain, M., Grégoire, Y., Custer, B. S., Goldman, M., Bravo, M., Kamel, H., ... BEST Collaborative. (2021). An international comparison of HIV prevalence and incidence in blood donors and general population: A BEST collaborative study. *Vox Sanguinis*, 116(10), 1084–1093. <https://doi.org/10.1111/vox.13107>

<sup>29</sup>Using an incidence rate/window period model with a window period of 9.5 days and the HIV incidence in repeat donors (period 2017–2019).

<sup>30</sup>Based on the number of HIV diagnoses between 2017 and 2019, the size of the eligible donor population, and the estimated number of HIV infections acquired in the Netherlands for both MSM and heterosexuals. See Bezemer, D., Blenkinsop, A., Hall, M., van Sighem, A., Cornelissen, M., Wessels, van Kampen, J., van de Laar, T., Reiss, P., Fraser, C., & Ratmann, O. (2022). Many but small HIV-1 non-B transmission chains in the Netherlands. *AIDS* 36(1), 83–94.

<sup>31</sup>McMichael, A. J., Borrow, P., Tomaras, G. D., Goonetilleke, N., & Haynes, B. F. (2010). The immune response during acute HIV-1 infection: Clues for vaccine development. *Nature Reviews Immunology*, 10(1), 11–23.

<sup>32</sup>Berkman, 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.

<sup>28</sup>Steele, W. R., Dodd, R. Y., Notari, E. P., Haynes, J., Anderson, S. A., Williams, A. E., ... Transfusion-Transmissible Infections Monitoring System (TTIMS). (2021). HIV, HBV and

activity is seen as high risk, but it does not take into account whether or not the sexual activity was between two men. This means that for all donors, the DHQ should, as a minimum, ask questions about a combination of potential HIV risk factors such as the number of recent sexual partners the candidate donor has had, whether they have had anal sex, whether they always or usually used a condom, whether they have had a previous diagnosis of an STI, and whether they have used drugs during sex.<sup>33</sup>

The new U.K. policy is an example of this approach. Everyone in an established monogamous relationship is eligible for blood donation. People who, in the preceding 3 months, have had sex with a new partner or sex with more than one partner can donate unless they have engaged in anal sex. Given that anal sex is much more common among MSM than among non-MSM, this raises the suspicion that the question about anal sex is simply employed as a proxy for singling out MSM. In one way that would make sense, because the risk contracting STIs and specifically HIV is much higher for sex that takes place between men than for sex that non-MSM engage in. However, if anal sex is indeed a proxy for MSM, then classifying the U.K. policy as an approach that treats MSM on an equal footing with non-MSM is at best incorrect and at worst insincere.

Let us therefore set the U.K. policy aside for now and focus on possible policies that can rightly be seen as treating all donors equally but as still involving an individual risk assessment of each donor. This approach can only be successful in avoiding unequal treatment if risk assessors at blood services completely ignore essential knowledge about the epidemiology of TTIs that has been the basis of these policies for the last few decades. In the Netherlands, HIV-incidence is about 100 times higher among MSM than among the general population.<sup>34</sup> Given these figures, the same sexual behavior—unprotected sex with multiple partners—generates a much higher risk of contracting TTIs in MSM than in non-MSM. The risk of contracting STIs is determined not just by *what* one does, but, most importantly, by the prevalence of infections among the people *with whom* one has sex. A good analogy is that although driving through a red traffic light at any time is a risky act, doing so in the downtown

morning rush hour is much more dangerous than at 2 AM in the suburbs.

This generates a dilemma for blood services. Professionals working for blood services can apply relevant epidemiological knowledge when they assess responses to sexual health questionnaires—but that would lead straight back to unequal treatment of MSM. Alternatively, they can refrain from making evidence-based risk assessments and exclude all candidate donors who have recently engaged in higher-risk sex unless it was within a monogamous relationship. The latter horn of the dilemma raises several other problems.

The first problem concerns professional ethics. Requiring health professionals who assess donors to ignore what they know about the prevalence of infections when they are doing a risk assessment would be an affront to their expertise and integrity. One cannot require a professional to leave out the most important evidence if she is to make a professional judgment about the magnitude of risk. Professional integrity implies being able to make decisions in line with one's expertise and professional duties, and this is what is undermined if donor physicians are required to ignore what they know about the prevalence of infections.

The second problem is that this policy would lead to the unnecessary exclusion of many individuals: all women and men who had engaged in unprotected vaginal or anal sex outside a stable relationship would be ineligible to be donors. This may be a very large group, even though the majority of them do not pose a significant risk to blood safety. This unnecessary exclusion of a potentially very large group of donors could lead to a significant shortage in the blood supply, which in turn would threaten the health of patients who depend on blood products: the blood that was available would be safe, but there would be too little safe blood available to meet the demand.

The third problem with this policy option is that it involves asking all donors sensitive questions about recent sexual contacts; this is especially the case if some of the questions are about anal sex, which may be embarrassing and uncomfortable for some of them.<sup>35</sup> Many loyal donors may feel offended or believe that the questions are an invasion of their privacy. Such questions can even scare people off, especially in the older age cohorts, who might otherwise have been loyal and trusted donors for decades. If this occurs the donor pool is reduced, and this may cause a shortage in blood supply.

The fourth problem is that current data suggest that European countries without a categorical deferral for the donations of MSM, such as Italy and Spain, have a substantially higher HIV incidence among donors than many other European countries, even after correction for the increased HIV incidence in their general population.<sup>36</sup> This suggests

<sup>33</sup>Johnson, W. D., O'Leary, A., & Flores, S. A. (2018). Per-partner condom effectiveness against HIV for men who have sex with men. *AIDS*, 32(11), 1499–1505; Slurink, I. A., Benthem, B. H. B. v., Rooijen, M. S. v., Achterbergh, R. C. A., & Aar, F. v. (2020). Latent classes of sexual risk and corresponding STI and HIV positivity among MSM attending centres for sexual health in the Netherlands. *Sexual Transmitted Infections*, 96(1), 33–39; Jansen, I. A. V., Geskus, R. B., Davidovich, U., Jurriaans, S., Coutinho, R. A., Prins, M., & Stolte, I. G. (2011). Ongoing HIV transmission among men who have sex with men in Amsterdam: A 25-year prospective cohort study. *AIDS*, 25(4), 493–501; Marcus, U., Nöstlinger, C., Rosińska, M., Sherriff, N., Gios, L., Dias, S. F., ... Sialon II Network. (2018). Behavioural and demographic correlates of undiagnosed HIV infection in a MSM sample recruited in 13 European cities. *BMC Infectious Diseases*, 18(1), 16; Meng, X., Zou, H., Fan, S., Zheng, B., Zhang, L., Dai, X., ... Lu, B. (2015). Relative risk for HIV infection among men who have sex with men engaging in different roles in anal sex: A systematic review and meta-analysis on global data. *AIDS and Behavior*, 19(5), 882–889.

<sup>34</sup>Slot, E., Janssen, M. P., Tanneke, M.-v. d. K., Zaaijer, H. L., & van de Laar, T. J. (2016). Two decades of risk factors and transfusion-transmissible infections in Dutch blood donors. *Transfusion*, 56(1), 203–214. <https://doi.org/10.1111/trf.13298>; van Sighem, A. I., Wit, F. W. N. M., Boyd, A., Smit, C., Matser, A., & Reiss, P. (2020). *Monitoring Report 2019. Human immunodeficiency virus (HIV) infection in the Netherlands*. Retrieved from <https://www.hiv-monitoring.nl/nl/resources/monitoring-report-2020>

<sup>35</sup>O'Brien, S. F., Goldman, M., Robillard, P., Osmond, L., Myhal, G., & Roy, É. (2021). Donor screening alternatives to men who have sex with men time deferral: Potential impact on donor deferral and discomfort. *Transfusion*, 61(1), 94–101.

<sup>36</sup>Germain, M., Grégoire, Y., Custer, B. S., Goldman, M., Bravo, M., Kamel, H., ... BEST Collaborative. (2021). An international comparison of HIV prevalence and incidence in blood donors and general population: A BEST Collaborative study. *Vox Sanguinis*, 116(10), 1084–1093. <https://doi.org/10.1111/vox.13107>

that an approach that uses individual risk assessment of all donors might be inferior in terms of selecting a low-risk donor population than an approach that uses a categorical deferral or a more detailed individual risk assessment of a specific subset of donors.

All in all, the approach that uses individual risk assessment, putting the same set of questions about sexual risk behavior to all prospective donors, is only nondiscriminatory if epidemiology professionals working in blood services ignore their professional knowledge of the much higher prevalence of TTIs among MSM. Moreover, such an approach requires blood supply services to ask sensitive questions that are epidemiologically irrelevant, which leads to the unnecessary exclusion of many donors. Ultimately, this would impede the blood supply. Even though this option is often considered to be the best alternative to the current MSM donation deferral approach, on closer analysis, this approach appears highly problematic, and maybe even unacceptable. Are the other two options more defensible?

### 3.3 | Individual risk assessment of all donors with a focus on the increased risk for MSM

A third alternative involves overtly treating MSM differently. The DHQ then only contains intimate questions for MSM, about their sexual risk behavior.<sup>37</sup> Female potential donors are not asked questions about their sexual behaviour, and neither are male potential donors who say that they have not had sex with another man. If a man has had sex with another man, more detailed questions are asked about their sexual risk behavior and associated risk factors for STIs. The new Dutch policy is an example of this approach: it seeks to differentiate between MSM who are in a stable monogamous relationship, who are considered to be low risk, and those who are not in such a relationship, who are considered to be high risk. The new Dutch policy is, however, rather superficial and unsatisfactory: it involves only a very crude risk assessment that does not do justice to the fact that sex can be safe outside a monogamous relationship. A more in-depth risk assessment could and should be made that also allows sexually active MSM not in a long-term monogamous relationship to donate, as long as they consistently practiced safe sex during the 3–4 months prior to donation. However, what in this case is the definition of safe sex? First of all, the success of individual risk assessments with regard to identifying potentially infectious donors strongly relies on donor education and the accurate and truthful disclosure of potential risk behavior. For example, if one thinks that only certain sexual activities (e.g., passive unprotected anal intercourse) are a risk for HIV, one could report consistent condom use while not using condoms with other sexual activities that also pose a risk for HIV. Even

the most detailed questionnaires on sexual practices will not result in zero risk. Actually, the longer and more detailed these questionnaires become, the higher the risk of noncompliance and the more likely they will be perceived as discriminatory. With the goal of risk reduction and not complete risk elimination in mind, the challenge will be to develop a limited number of validated questions that are easy to interpret, widely accepted, and address the most important risk factors that distinguish low-risk MSM from high-risk MSM.<sup>38</sup> The Netherlands is currently in the process of working out these specifics, with the goal of implementing them in September 2022.

MSM are still treated differently from non-MSM in this policy option though, because only MSM have to answer questions that may be considered stigmatizing. At the same time, from the perspective of equal treatment, this option is a significant improvement on the status quo, because it *does not amount to the categorical exclusion of all MSM*, only of MSM donors who have recently engaged in high-risk sexual behavior. The degree of stigmatization perceived by this approach strongly depends on the number of questions, how they are formulated, and whether the reasons why these questions remain necessary are well explained to the general public.

Disadvantages might be that this approach involves asking sensitive questions. When these questions do not correctly distinguish low-risk from high-risk MSM or when they are misinterpreted, they could lead to a higher residual risk of HIV transmission. Again it boils down to a compromise between risk reduction and equal treatment. For example, using a condom does not guarantee complete safety, and allowing MSM in monogamous relationships to donate blood implies accepting uncertainty about the possibility that the donor's partner has secretly had (risky) sex with other MSM. That said, the "extra" risk of this policy option resulting in TTIs, compared with the status quo of a categorical deferral of the donation of all men who have had sex with another man, is probably very small.

## 4 | CONCLUSION

Let us take stock. Starting from the judgment that the categorical deferral of MSM donations is a disproportionate infringement of the right to equal treatment, which alternatives can be justified? We consider the risk assessment of the sexual behavior of each and every donor (option 2, described in Section 3.2) to be indefensible. Either it will result in a significant reduction of donations and thus impede blood supply, or it will result in covert discrimination and unequal treatment anyway. Moreover, trying to avoid unequal treatment implies that health professionals should completely ignore their epidemiological expertise, which is indefensible. The U.K. policy of excluding donors who have recently had anal sex outside a monogamous relationship may not address the problem of excluding too many donors, and by focusing on anal sex it is in fact unequal treatment of MSM in disguise.

<sup>37</sup>Kurt Blankschaen offers an alternative route that does not require posing detailed questions to MSM about their sexual behaviour, namely by dividing MSM donors by their ability to accurately report an HIV negative serostatus. This is an interesting possibility that we disregard in this paper. As far as we know, there are no blood services considering this policy option. It would require MSM donors to test much more often prior to donation. Moreover, Blankschaen focuses on HIV only, but HBV and some other TTIs cannot be neglected. Blankschaen, K. M. (2018). The ethics of ordinary and exact justification in blood donation deferral categories for men who have sex with men. *Bioethics*, 32(7), 445–453.

<sup>38</sup>van Bilsen, W., Zaaijer, H. L., Matser, A., Hurk, K. v. d., Slot, E., van der Loeff, M. F. S., ... van de Laar, T. J. W. (2019). Infection pressure in men who have sex with men and their suitability to donate blood. *Clinical Infectious Diseases*, 68(6), 1001–1008.



A better justifiable option is to accept a restricted differential treatment of MSM that excludes only MSM whose sexual activity has resulted in an actual increased risk of TTIs. MSM who consistently practice safe sex or who are in an established monogamous relationship should be allowed to donate blood. But we still consider the new Dutch approach to be too restrictive—it excludes MSM from blood donation too easily. By doing a “tailor-made” individual risk assessment of all MSM, the unequal treatment that remains is necessary but is as minimal as possible and is proportionate regarding ascertaining and maintaining blood safety.

We do not rule out a priori the policy option that abandons all unequal treatment and stigmatization of MSM by refraining altogether from selecting donors on the basis of reported sexual behavior. This will inevitably result in a somewhat higher risk of transfusion-transmitted HIV infections, however. In addition, the residual risk of this approach cannot be determined because it involves too many uncertain factors; it depends on newly eligible donors' knowledge and awareness of TTIs and on their ability to self-assess and self-exclude if they think they are at risk. The dynamics and epidemiology of HIV itself are uncertain too. In a country like the Netherlands, the absolute risk of transfusion-transmitted HIV would probably remain very low if the new policy were implemented. But is this residual risk acceptable? This question cannot be answered on the basis of ethical and legal analysis alone and is ultimately the subject of democratic deliberation and decision-making.

#### CONFLICTS OF INTEREST

As employees of Sanquin, Thijs van de Laar and Hans Zaaijer have responsibility for research that contributes to blood safety. None of the authors have personal interests in the outcome of this study.

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