Facing Difficult but Unavoidable Choices: Blood Safety, Donor Selection, and MSM deferral

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Abstract

The Netherlands and many other countries categorically defer men who have had sex with other men (MSM) in the previous months from donating blood. Such deferral policies are criticized as being unduly discriminatory and stigmatizing. In December 2019, the Dutch Parliament adopted a motion requesting the Dutch blood service to re-examine its MSM deferral policy. Patient associations, on the other hand, are very reluctant to accept less strict donor selection criteria, because this could reduce the safety of 'their' blood products. This report discusses the question how to address two conflicting fundamental human right: the right to equal treatment versus the right to health. We distinguish four policy options, and conclude that only two of these can be supported on ethical and legal grounds: either to do an individual risk assessment of sex behavior of MSM, or to rely on biomedical screening of blood and abandon questions about sex behavior altogether. Which of these two options is most defensible should ultimately be a matter of democratic decision making.

1. Introduction

In order to protect the health of recipients of blood components, it is essential to minimize the risk of transfusion-transmissible infections (TTIs) like HIV, HTLV, Hepatitis B, C & E and syphilis.[1] This can largely be done by antibody testing and nucleotide amplification testing (NAT) of donor blood. However, a small residual risk will always remain, due to very recent infections which cannot yet be detected with NAT (Cappy et al., 2019). For this reason, most blood services also apply additional non-technical prescreening methods to further reduce the risk of transmission, and thus to increase transfusion blood safety. Firstly education: providing relevant information to perspective donors, enables them to understand their risk factor and might dissuade candidates from donation if there is a possible risk of infection. Secondly non-renumeration: donors donate voluntarily and do not receive payment in cash or in kind in order to preclude attracting specific high-risk groups who might donate just for the money, e.g. sex-workers and intravenous drug users.[2] This paper discusses the legal and ethical justification of the third and most controversial prescreening method: the selection of donors based on a standardized questionnaire, also known as the donor health questionnaire (DHQ).

Depending on the answers given to a series of questions about (recent) risk-behavior and possible exposure to blood-borne and sexually transmitted infections, candidate donors can (temporarily) be excluded from donating blood. In this way, blood banks hope to minimize the number of recent infections in blood donors, preferably to a number close to zero. The Netherlands and many other countries therefore categorically defer men who have (had) sex with other men (MSM) in the recent past: MSM are allowed to donate blood, provided there has been no sexual contact with another man in the

[1] EU Directive 2002/98, §24. These discussions concern blood components: red blood cells, platelets and freshly frozen plasma. Blood products are 100% safe nowadays due to virus inactivation. Methods of reducing that risk is the selection of donors and subjecting each donation to testing and to virus-attenuation treatment. Opinion AG C528/13, §17.

[2] Most blood banks – including Sanquin in the Netherlands – only accept voluntary donations. A donation is considered voluntary or non-remunerated 'if the person gives blood, plasma or cellular components of his/her own free will and receives no payment for it, either in the form of cash or in kind, which could be considered a substitute for money. This would include time off work other than that reasonably needed for the donation and travel. Small tokens, refreshments and reimbursements of direct travel costs are compatible with voluntary, non-remunerated donations.' Paragraph 9 (d) of 98/463/EC Council Recommendation of 29 June 1998 on the Suitability of Blood and Plasma Donors and the Screening of Donated Blood in the European Community (OJ L 203, 21.7.1998, p. 14). Some blood banks pay for donations, a policy that is not unproblematic from an infection perspective, when such payments attract drug users. The argument in this paper only refers to systems of voluntary blood donation.

previous four months. This deferral period coincides with the maximum estimated window period of relevant TTIs, in this case of HBV. The epidemiological rationale for primarily deferring MSM is that TTIs are much more common among MSM than non-MSM.[3] Thus, exclusion of MSM for as long as the maximum window period after their most recent sexual contact, reduces the risk of transmission of these infections.[4] Although MSM indeed are at increased risk for HIV, HBV, HCV as well as syphilis, the public debate on MSM-deferral predominantly focuses on HIV. The estimated average infectious window period of HIV NAT is 6-10 days and does not exceed 20 to 25 days in over 95% of cases. With the current donor screening algorithm in the Netherlands, the risk of acquiring HIV is so low that it can only be estimated for example using incidence rate window period models.

Notwithstanding the fact that exclusion policies towards MSM have been relaxed in recent years, from permanent deferral to twelve months initially, and four months now, they remain under severe public scrutiny. These 'blatant' deferral policies are criticized for being stigmatizing and discriminatory towards MSM. Screening and selection might be necessary but, so it is argued, it could be based upon individual risk-behavior of each and every donor, and not be a categorical separation on the basis of collective characteristics. For example, a monogamous male donor in a sexual relationship with another man may not pose an increased risk of TTI at all, provided that the partner is monogamous too. The current policy offends many MSM personally, and in solidarity with the MSM community, a growing number of non-MSM. In a newspaper article, Yair da Costa complains: "What about heterosexual men with a promiscuous lifestyle? Aren't they also an increased risk of infection? In my opinion, heterosexual men with multiple casual sex partners are a greater risk than the risk-conscious man who has sex with other men" (Costa, 2019).[5] In a newspaper interview, lawyer Sidney Smeets argues that the deferral policy towards MSM is on a par with slut-shaming: "The leading question should be: have you had unprotected sex in the past four months? But Sanquin doesn't ask that question, because that would exclude too many non-MSM donors" (Misérus & Ruiter, 2019).

Unlike what these critics suggest, sexual behavior *as such* does not determine infection risk. Much more important are the prevalence and incidence of sexually transmitted infections (STI) within the network of one's potential sex-partners. Since the background prevalence of HIV in the Netherlands is much higher in MSM than in heterosexuals, and HIV is more efficiently transmitted through receptive anal sex compared to vaginal intercourse (de Kort, 2016, p. 488), HIV still disproportionally affects the Dutch MSM community. Hence, with the same number of random unprotected sexual contacts a Dutch MSM statistically has a higher chance to acquire HIV than someone with exclusively heterosexual contacts. Indeed, over the past 5 years the HIV-incidence in the Netherlands (based on the annual number of newly diagnosed infections HIV-infections) is more than 100 times higher in MSM (1 in 750 MSM) compared to heterosexuals (1 in 75.500 heterosexuals).[6]

The current selection criterion requires MSM candidate blood donors to abstain from sex for four months prior to donation, and thus remains a *de facto* permanent exclusion of donorship for the majority of MSM. More fundamentally, MSM are not treated on equal terms with other citizens, because the exclusion is overinclusive towards MSM, while underinclusive to other categories. In December 2019 Dutch parliament adopted, with a large majority, a proposal (the

[3] The term 'men who have sex with men' (MSM) was developed in the 1990s by epidemiologists to describe men who have sex with other men, regardless of their possible sexual relations with women or their identity as bisexual or gay at a personal or social level. 'UNAIDS Terminology Guidelines', revised version, October 2011, p. 19.

[4] It should be emphasized here that the level of risk differs from country to country, because their epidemiological situation, in particular with regard to HIV infection, is very diverse.

[5] See also Schmidt (2020), Behrmann and Ravitsky (2011).

[6] HIV Monitoring Report 2020, Stichting HIV monitoring (https://www.hiv-monitoring.nl/application/files/7716/0571/6500/Netherlands_HIV_Monitoring_Report_2020.pdf).

motion Ellemeet[7]) requesting the Dutch blood services organization Sanquin to re-examine its (alleged) discriminatory policy towards MSM:

> to carry out an independent study into the impact on blood safety of donor selection policies based on sexually hazardous behavior, and the possibilities of transforming Dutch donor selection policies based on target groups into a donor selection policy based on hazardous sexual behavior without compromising the safety of blood.[8]

This motion seeks to find ways to include low risk MSM as eligible donors and to ensure that the donor selection policy is not unnecessarily discriminatory. At the same time, the proposal explicitly emphasizes that the current level of safety of blood must be maintained. The question is whether these goals can be achieved simultaneously.

In section 2 we seek to explain the depth of the dilemma, by expounding the legitimately of claims made on both sides of the conflict. On one side are persons whose lives depend, literally, on the stable provision of safe blood, anxious to prevent any possible risk of infection with a disease. On the opposite side are groups who have already experienced a long history of marginalization, and who see this enduring policy as yet another stigma. In section 3 we will analyze the dilemma in terms of the clash between fundamental rights it represents: the right to health versus the right to equal treatment. In section 4 we will explain that there is no painless way to solve the dilemma. We present four scenario's for future policy and explore to what extent these can be ethically and legally justified. It will become clear that a choice for any of them comes with certain costs. Policy choices have to be made on the basis of conflicting values, and under uncertainty. At present, there is no option to avoid uncertainty and risk, and any policy will involve some compromise between the values of blood safety and equal treatment.

2. Understanding the dilemma in terms of clashing interests

The availability of blood used for therapeutic purposes in most countries primarily depends on citizens who are prepared to donate blood voluntarily out of altruism. The choice to donate blood is a precious act of citizenship and a gesture of selfless generosity and solidarity (Titmuss, 1970). By offering the possibility to donate blood, Sanquin engages in the legal act of offering or granting access to goods and services which falls under the legal prohibition of discrimination. MSM experience current exclusionary policies as stigmatizing and discriminatory and feel disadvantaged by policies that make the inextricably link between sexual intercourse involving two men and risky sexual behavior. They want to be treated on equal terms with non-MSM citizens. MSM in (long term) monogamous relationships, or MSM who consistently practice safe sex with casual partners, argue for donor selection policies that are not based on sexual preference but, instead, based on actual individual high-risk sexual behavior. One aspect of the perceived discriminatory character lies in the fact that these bans are general, meaning that they apply in the same way to every MSM, and ignore the diversity within the MSM population. Some have multiple sex partners, but many others are engaged in long term monogamous relationships. Some engage in unprotected sex, but many do not. Another aspect is that non-MSM are accepted as donors much more easily, hence without in-depth questioning on sexual behavior. Discrimination on the basis of being MSM reinforces stereotypes that gay men are carriers of communicable diseases just because of their orientation (Bensing, 2011, pp. 487-488).

On the other hand, recipients of blood and blood components are dependent on a steady supply of donor blood with a high, if possible 100%, level of safety. Regular recipients, such as hemophilia patients in the past, and nowadays especially hematological patients, are critically dependent on high quality products and components from donor blood. The AIDS-epidemic of the 1980s not only affected the gay community but also the group of Dutch Hemophilia-patients: nearly half of them died from AIDS through contaminated donor blood. This question, however, not only affects hemophilia patients:

[7] Motions in Dutch Parliament usually concern policy issues and are equivalent to resolutions in some other legislatures and are used by Members of Parliament when they oversee the government and as a way to request government policy changes (Louwerse & Otjens 2016).

[8] 29 447 Nr. 53 motie van het lid Ellemeet c.s. … "verzoekt de regering, om een onafhankelijk onderzoek in te stellen naar het effect van het donorselectiebeleid op basis van seksueel risicogedrag op de veiligheid van bloed, en de mogelijkheden om het Nederlandse donorselectiebeleid op basis van doelgroepen te veranderen in een donorselectiebeleid op basis van seksueel risicogedrag zonder dat daarbij de veiligheid van het bloed in het geding komt."

anyone could get involved in an accident tomorrow and require blood. In the last decade, blood banks have been successful in protecting recipients of blood and blood product from unsafe blood, by maintaining strict donor selection measures in combination with increasingly sensitive laboratory screening procedures and new technologies such as virus-inactivation for e.g. clotting factor. The question is whether these technological improvements enable more lenient deferral policies towards MSM-donors.

The traumatic experience of the mid-eighties has made the Dutch association of Hemophilia patients, as well as the responsible blood donor services, very reluctant to accept less strict donor selection criteria as this could reduce the safety of 'their' blood products, which they have dismissed as *experimenting with patients receiving blood*. Anne-Maree Farrell (2016, p. 189) concludes that this traumatic episode has determined blood policies for decades to come:

> [t]he loss of public trust that occurred in the wake of national HIV blood contamination episodes has meant that the benchmark for public, political and regulatory expectations involving blood safety has now been set and it is high. This is likely to involve continuing (over-) reliance on technology at high cost, as well as maintaining adherence to restrictive donor selection criteria which may have unfortunate consequences, including the continuing stigmatisation of certain donor groups and the potential for blood shortages.

This precautious approach can also be recognized in the opinion of the Attorney General of the In *Léger-case* before 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.[9]

The question remains whether the consideration of blood safety can justify the categorical implementation of the four months deferral period for all MSM. Is it possible to find a compromise that does justice to the various interests at stake? Before we outline and discuss the various policy options available, we first flesh out the underlying legal and normative context of the debate.

3. Normative questions

This dilemma is not just one of conflicting interests. Ultimately it concerns an issue of competing fundamental rights and, connected, basic legal obligations that blood service organizations have towards their donors.[10] The MSM-deferral *categorically* excludes citizens with specific sexual orientation from donating blood, which might be contrary to fundamental human rights such as the equal treatment and non-discrimination principle, recognized by Dutch and EU law.[11]

3.1. Unequal treatment: violating fundamental rights

The normative analysis and justification of unequal treatment, i.e. deferring MSM, is developed in most depth in legal discussions and jurisprudence. Given that these discussions specifically include weighing competing values, and

[9] HvJ 29 April 2015, nr c-528/13, ECLI:EU:C:2015:288 (Geoffrey Léger/Ministre des Affaires sociales, de la Santé et des Droit des femmes, en Établissement Français du sang). Based on Article 19 of Directive 2002/98, entitled Examination of donors, stating: "An examination of the donor, including an interview, shall be carried out before any donation of blood or blood components. A qualified health professional shall be responsible, in particular, for giving to and gathering from donors the information which is necessary to assess their eligibility to donate and shall, on the basis thereof, assess the eligibility of donors."

[10] The procedures aimed at the "attainment of certain objectives and in particular that of adopting measures setting high standards of quality and safety of blood and blood derivatives" are laid down in Directive 2002/98, and was adopted on the legal basis of Article 152(4)(a) EC, now Article 168(4)(a) TFEU. The technical requirements are set out in Directive 2004/33.

[11] As we will show, not all policy options involve a categorical exclusion of MSM and therefore one could argue that therefore the dilemma does not necessarily constitute a conflict of competing fundamental rights. We come back to this in our conclusion.

formulating conditions for justified infringement of certain values, they can be seen as a combination of legal and ethical evaluation. In this section we restrict ourselves therefore to an analysis of the relevant legal sources.

In principle, unequal treatment by blood services can be considered as a prohibited form of discrimination according to *The Charter of Fundamental Rights* of the European Union and Article 2 of the Dutch *Algemene Wet Gelijke Behandeling*.[12] By offering the possibility to donate blood, Sanquin engages in the legal act of offering or granting access to goods and services which falls under the prohibition of discrimination. Article 21 of the Charter states that "any discrimination based on […] sexual orientation shall be prohibited." So, *in principle* it is legally prohibited for blood services to treat MSM differently from non-MSM, as it involves discrimination based on sexual orientation. This is, however, not an absolute legal norm. Differences in treatment are allowed if properly justified and proportionate. That is, limitations on the right not to be discriminated against "must be provided for by law and respect the essence of those rights and freedoms." (article 52 of the Charter). These rights also include the right to health and safe health care which is at stake here as well. Hence, one can argue that the right to equal treatment of some conflicts with the right to health of others.

In *Léger*, the Court of Justice of the European Union (CJEU) has ruled on such a case.[13] The court determined that the medical, scientific and epidemiological knowledge evidently showed that HIV infections are disproportionally prevalent among MSM and that a "deferral [of MSM] from blood donation aims to minimize the risk of transmitting an infectious disease to recipients. That deferral thereby 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.[14]

Therefore, if unequal treatment of MSM is inevitable to maintain the threshold of blood safety, is a restriction to the right of equal treatment, but a justified restriction, because it is necessary to protect the right to health and safe health.

3.2. Proportionality

At the same time, the principle of proportionality requires national policies to opt for the least level of unequal treatment that is necessary to protect the right to health of recipients of blood components. In 2015, permanent deferral of all MSM was deemed acceptable in the *Léger*-decision by the CJEU. But this baseline is 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.[15]

So, if technological or other advancements make that less onerous measures can protect the right to health to the same extent, for example temporary instead of permanent deferrals, the more intruding measures are no longer justified. Indeed, around the same time Léger was decided, the Dutch legislature, based on new scientific insights, started discussing the

[12] As a general rule, the organization and delivery of health services and medical care belong to the sovereign powers of the member states, meaning that the EU has limited regulatory powers in the health area. 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 and blood products (den Exter, 2016, p. 501).

[13] Jugement of 29 April 2015, L. v Ministre des Affaires sociales, de la Santé et des Droits des femmes, Établissement français du sang, C-528/13, ECLI:EU:C:2015:288.

[14] Léger, §70.

[15] Léger, §58.

permanent ban, which was ultimately replaced with a twelve-months ban in 2015, which itself was replaced by the current four-months ban in 2019 (den Exter, 2016, p. 502).

To summarize: the principle of proportionality implies that blood donor services are allowed to treat MSM unequally if this is necessary to protect the right to health of recipients of blood components, and when the infringements of the right not to be discriminated against are not disproportionate.

3.3. Precaution

A second legal principle relevant to public health law, is *precaution* (Wainberg, Shuldiner, Dahl, & Gilmore, 2010, p. 1322). The principle of precaution can offer specific support for interventions for the greater good, in specific circumstances of uncertain risk, even if these interventions are at the expense of individual rights. It is best explained in the proverb *better safe than sorry* and usually employed in situations where decisions to avoid threats of serious or irreversible damage must be made in a context of uncertainty (Marchant, 2003; Resnik, 2004; Steel, 2014; Sunstein, 2005). 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 this threat is genuinely plausible, not just after the harm has occurred. 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 such a decision. In this context, the precautionary principle in employed to minimize the risk that infected donor blood will be 'missed' and could result in transfusion-transmitted infections. The four months categorical deferral of MSM is an example: "The use of social identities as proxies for risk behaviors in order to manage the risks is in line with the precautionary principle" (Deleuran, Sheikh, & Hoeyer, 2015, p. 495).

However, since it requires action *before* a threat actually has struck, it may induce blood services to take precautions that are too restrictive. For example, Sircar argues that:

> 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 (Sircar, 2018, p. 113).

Secondly, if too restrictive measures are already in place, strict compliance with the precautionary principle could stand in the way of change, even if it could 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, never knowing whether alternative strategies might in fact lead to improvement. To use an analogy: if one can safely swim using water wings, you can keep on wearing them for the rest of your life to prevent drowning, but in the end, you will never learn how to swim properly. Translated to the case at hand: is the current categorical deferral policy towards MSM still proportional? Or is it *too* precautious and are there less onerous measures available that still adequately protect the fundamental right to blood safety?

3.4. Weighing competing interests and 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* – ALARA (Hoeyer, 2015). If one would only take the right to health of recipients of blood components and blood products into account, each and every advancement in screening techniques and all political choices should be employed to reduce the risk of infections for recipients of blood. Indeed, scientific and technological advances in the area of blood safety up to now have been employed to further reduce transfusion risks. Recital 29 in the preamble to Directive 2002/98 states that:

> 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 – hence more proportional.[16] Technological advances have enabled over time to reduce the window period for MSM deferral from indefinite to four months. Future advances in epidemiological knowledge, in pathogen reduction techniques (such as universally applying pathogen inactivation methods to all blood products, leukodepletion and virus inactivation, or manufacturing artificial blood), and further developments in evidence-based donor selection might help to further reduce the necessity of discriminatory measures.

In the context of weighing the right to health of blood recipients against the right to equal treatment of MSM, we cannot single-mindedly focus on minimizing the risk of transmitting an infectious disease. Instead our aim should be to determine, as a political community, the maximum residual risk of acquiring a transfusion-transmitted infection that is deemed acceptable and reasonably achievable. It should be clear that the risk of infections under the current four months-deferral policy is not zero and will never become zero. Making that risk zero should not be the policy goal, as it is unachievable.

It could be the case that if we as a political community would explicitly determine this threshold level, that the current level of protection of health of recipients of blood components is already (way) below this threshold level. Imagine that specific changes would greatly reduce the discriminatory effect of donor policies but would only lead to a slight increase of the residual risk, which would still remain below the threshold level. In such a situation, considerations of proportionality would suggest implementing the more risky but non-exclusive donor policy.

This second interpretation takes the rights of MSM into consideration and sees the concept of 'a level of risk for recipients of blood products that is as low as reasonably achievable' in the light of a reasonable equilibrium between the interests of both stakeholders. This is what the parliamentary motion Ellemeet aims at in the Dutch context: a further decrease of the level of unequal treatment of MSM without unnecessary compromising the safety of blood. The question, then, is: which policy options in which the interests of both stakeholders are taken into consideration are available?

4. A range of policy options

The rights of MSM not to be discriminated must be weighed against the rights of recipients of blood products to a safe and sufficient blood supply. Striking such an equilibrium will inevitably come with some costs at one or both sides of the dilemma. In this section we will review the four most relevant policy options, ranging from a complete rejection of all donor selection measures, relying fully on laboratory screening, to the current policy of four-months-deferral of all MSM. Each of these options strikes a different balance between securing safety and avoiding discrimination.

(1) Abandoning all questions concerning sexual behavior

A first, most radical option is to abandon all questions about recent sexual conduct in the selection process of donors and rely fully on laboratory screening. The obvious advantage is the complete elimination of discrimination on the basis of sexual orientation. A disadvantage is that it will probably increase the residual risk of acquiring transfusion-transmitted infections as more donors with an increased risk of TTIs will donate, including those with very recent infection and a TTI viral load below the limit of detection of currently used NAT-screening.

(2) Evaluate the risks of each and every potential donor

In a second option, the donor health questionnaires (DHQ) still contain questions on sexual risk behavior during the past four months, but these questions need to be answered by each and every (candidate) donor: male and female, MSM and non-MSM. The apparent advantage is that this procedure seems to avoid discrimination

[16] Note that in the Netherlands the risk of transfusion-transmitted HIV, HBV and HCV infections could be reduced further by switching form NAT screening in pools of 6 donations to individual NAT screening. But this improvement comes with a considerable price tag. Moreover, it is questionable if this technological change can take away the need for donor selection.

without increasing the risk of infected donor blood. A disadvantage might be that it results in the exclusion of such a large number of potential donors that this undermines the availability of donor blood.

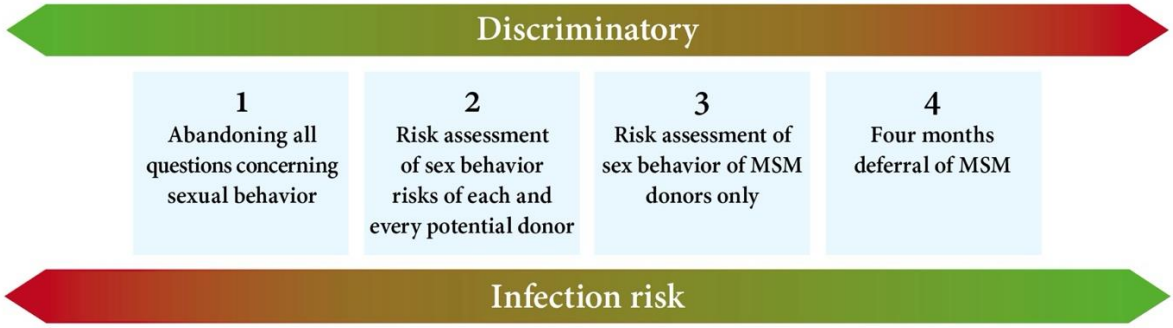
(3) Focus on risk contacts of MSM

The third option holds on to the question "Are you MSM?" and asks further relevant questions about potentially hazardous sexual behavior only to MSM. Accept MSM who abstained from sex during the last 4 months, or only had sex (protected or unprotected) in a longer-term monogamous relationship, or if not in a long-term monogamous relationship exclusively practiced safe sex during the last 4 months. This option minimizes the risk of recent TTIs among donors but still implies treating MSM differently – but to a lesser extent than in option 4.

(4) The status quo: four months deferral of MSM

In the fourth option, questionnaires contain questions "Are you MSM?" Only MSM who report they have had no sex in the past four months are accepted, at least if they meet all other donor eligibility criteria. This boils down to continuing the current policy in the Netherlands.[17]

These four policy options can be ranked as follows:



Option 1 and 2 do not involve unequal treatment of MSM – at least not at first sight – option 3 certainly does and option 4 is the most discriminatory. At the same time, option 1 (probably) generates the highest risk of TTI for recipients of blood products, followed by 2, 3 and 4.[18] It is important to acknowledge that infection risks can never be ruled out completely and that 100% blood safety is an illusion. It should also be clear that the differences in risk for recipients of blood products cannot be determined precisely; it is an ordinal scale: the ranking of the options does not actually establish the degree of variation between them. How should policy makers rank these various options?

5. Ethical review of policy options

The status quo: four months deferral of MSM

The first option is to hold on to the current policy of the four-months deferral period for sexually active MSM. It is assumed that this minimizes the risk for transfusion-transmitted infections, and it avoids asking detailed impertinent questions about sexual activities. The obvious drawback is that it excludes men simply for the fact that they report sex with another man. The discriminatory character lies in the fact that *these deferrals are categorical*, meaning that they apply in the same way to every MSM, and ignore the diversity within the MSM population. However, in many cases, the chance that a candidate donor who reports male-to-male sex, will have been recently exposed to HIV, may be zero. Many MSM take precautions

[17] There might be another option between 3 and 4 which is to limit the deferral period further if that is technically possible. England, Scotland, Wales and Canada have recently reduced the deferral period to three months.

[18] Cf. note 16. Again, note that the Netherlands have not opted for individual NAT screening that would have reduced the risk of transfusion-transmitted infections even further.

to prevent STIs or only have sex in an STI-safe, monogamous relationship. A categorical exclusion of MSM might therefore be considered too blunt a measure and this is the reason why the policy is subject to social and political scrutiny.

Evaluate the risks of each and every potential donor

Most critics of the status quo of four months deferral argue for donor selection policies that do not categorically target specific subpopulations but, instead is based on the assessment of individual sexual (risk) behavior. One example is the Ellemeet-motion in Dutch Parliament discussed above. Berkman and Zhou present a similar proposal and argue that:

> After assessing the donor's personal sexual practices, a deferral may be given only for those in whom a risk of infection has been identified, such as individuals who have engaged in frequent, unprotected sex with multiple partners since their prior HIV test. For this risky group, a short period of abstinence may be appropriate to allow for reliable test results. For donors who are not high risk, the deferral should be eliminated altogether. This model can be applied to both homosexual and heterosexual donors and would not consider monogamous or safe sex to be risky, mirroring the current protocol for straight donors (Berkman & Zhou, 2015, p. 5).

Such proposals seek to forgo discrimination towards MSM without increasing the risk of infected donor blood. This is done on the basis of questionnaires to assess the risk of sexual behavior of each and every candidate donor: male or female, MSM and non-MSM. In this procedure donors are only eligible if they report to have abstained from sex in the last four months, or had a long-term monogamous relationship, or had safe sex only, irrespective of whether this concerned partners of the same or the opposite sex.

By asking the same set of questions to all donors, this approach treats all donors equally – at least at first sight. It can only be successful in avoiding unequal treatment if risk assessors at blood services fully ignore essential knowledge about epidemiology of TTIs. Such an individual risk-based assessment has the veneer of neutrality, but it remains an epidemiologic reality that the same sexual behavior – unprotected sex with multiple partners – generates a much higher risk of TTIs in MSM, compared to heterosexuals. To make an analogy: crossing the street with a red traffic light is a risky act, but much more dangerous in the morning rush hour downtown, than at 2 am in the suburbs.

This generates a dilemma for blood services. Either professionals at blood services apply relevant epidemiological knowledge in their assessment of responses to sexual health questionnaires – but that would lead right back to unequal treatment of MSM. Or they refrain from such evidence-based risk assessments and exclude all candidate donors who have recently engaged in unsafe sex unless it was within a monogamous relationship. This horn of the dilemma raises several problems.

A first problem is about professional ethics. Requiring health professionals, in this case epidemiologists and donor physicians, to ignore what they know about the prevalence of infections precisely when they are doing an individual risk assessment, is indefensible – it would be an affront to their expertise. The second problem is that, albeit non-discriminative with regards to sexual orientation, it has an essential similarity to the current categorical MSM deferral. This policy will lead to the unnecessary exclusion of many individuals: all women and heterosexual men who had unsafe sex, but based on the epidemiology of HIV in the Netherlands, do pose a negligible risk to blood safety. In addition, this unnecessary exclusion could have dire consequences, as it might lead to a significant shortage of the blood supply, which is a threat to the health of patients who depend on blood products: the blood that is available is safe, but there might be too little safe blood available to meet the demand.

A third problem with this policy option is that it involves asking sensitive questions about recent sexual contacts, which may be inconvenient and uncomfortable to many donors. Talking about unprotected sex might be much less a taboo in MSM-circles in which there is more experience with HIV risk than among heterosexual donors. Some questions can even scare off people, especially in the older age cohorts, who might have been loyal and trusted donors for decades. This will again reduce the donor pool and cause a shortage in blood supply, which is extra problematic in times of blood scarcity. Many loyal donors may feel offended or their privacy invaded. We discuss the problem of asking impertinent question in more detail in section 6 as it is also relevant to the next option.

A fourth problem is that current data suggest that European countries without a categorical MSM deferral, like Italy and Spain, have a substantially higher HIV-incidence among donors, compared to many other European countries, even after correction for the increased HIV incidence in their general population.[19] The latter suggests that the individual risk assessment of all donors might be inferior in selecting a low risk donor population compared to categorical deferral or a (more detailed) individual risk assessment of a specific subset of donors.

All in all, this approach of individual risk assessment, asking the same set of questions on sexual risk behavior to all prospective donors, is only non-discriminatory if epidemiology professionals in blood services ignore their professional knowledge of the much higher prevalence of TTIs among MSM. Moreover, it requires blood supply services to ask (potentially) impertinent questions that are epidemiologically irrelevant, which leads to the unnecessary exclusion of many donors. Ultimately this will impede blood supply. Even though this option is often considered the best alternative to the current MSM deferral approach, on closer analysis, this approach appears highly problematic, if not unacceptable. Are the other two options more defensible?

Abandoning all questions about sexual behavior

Instead of asking all donors the same set of questions indiscriminately, another way of treating all potential donors as equals is to refrain from questions about sexual behavior altogether. However, the prevalence of TTIs among the donor population is correlated to the prevalence of these TTIs in the general population. An obvious disadvantage of this strategy is that this will increase the risk of TTIs among blood donors, including very recent infections that will not yet be detected by laboratory testing but are infectious for the recipient. The donor health questionnaire that is currently used to select donors with a low risk of TTIs is not a perfect safeguard and strongly relies on donor education, and the accurate and truthful disclosure of risk behavior. Nevertheless, the estimated prevalence and incidence of TTIs among the general Dutch population is much higher than among (candidate) donors, suggesting that current procedures are effective in selecting a low-risk subpopulation.[20] In addition, the DHQ will increase TTI awareness among repeat donors and is likely to induce self-deferral after risky situations in the future. However, donor deferral is not limited to MSM, exclusion of other groups at risk also attribute to the differences in TTIs between donors and the general population. Moreover, certain groups with a higher burden of TTIs, including first generation migrants, are underrepresented in the donor population. For one thing, these DHQ deters so-called test seekers, persons who come to donate blood with the primary motivation to be tested for TTIs. The requirement to answer questions on (past) risk behavior generates an 'intuitive' threshold. Since test-seekers often have higher rates of TTI than the average population, they represent a risk to the safety of the blood supply. When pre-selection through questionnaires is eliminated, this barrier also disappears. For all these reasons it is plausible to assume that abandoning all questions about sexual risk behavior will cause an influx of donors at increased risk, resulting in increased rates of TTIs, that cannot all be detected by laboratory tests.

So, this approach does not discriminate MSM, but it is likely to increase TTI risk. Note that the current discussion on MSM deferral mainly focuses on limiting the risk of transfusion-transmitted HIV. With the current donor screening algorithm the estimated residual risk for transfusion-transmitted HIV in the Netherlands currently is extremely low: one transfusion-transmitted HIV infection per 6 to 8 million donations (or with the current number of donations once every 20 to 30 years).[21] Without any donor selection procedures and assuming that a representative cross-section of the general Dutch population will come and donate the residual risk of transfusion-transmitted HIV could increase five- to tenfold to one in 1 to 3 million donations (or once every 3 to 4 years).[22] The latter assumes no self-exclusion of individuals at increased risk of HIV, and indicates that the absolute risk of getting infected with HIV via transfusion after abandoning

[19] Germain et al (forthcoming): *An international comparison of HIV prevalence and incidence among blood donors*. Work in progress, on file with the authors.

[20] Arguably, the difference in prevalence will also be caused by the fact that some subpopulations where the prevalence is higher, it is less common to be a blood donor.

[21] 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).

[22] Based on the number of HIV diagnoses in the period 2017-2019 (SHM monitoring report), the estimated number of HIV-infections acquired in the Netherlands for both MSM and heterosexuals (Bezemer et al, submitted to AIDS), and the size of the eligible donor population (CBS).

all questions on sexual risk behavior will still be very small. In other words, where in the early days of HIV with insensitive HIV tests and long infectious window-periods most reduction in HV transmission was achieved with deferral methods, their impact might be limited in the era of highly sensitive NAT testing.

Focus on risk contacts of MSM

The previous two policy options quite clearly highlighted the dilemma for policy makers. Both options could backfire in different ways. They might undermine either the quality or the quantity of available blood and blood derivatives. Another possibility involves asking intimate questions on sexual risk behavior, but only to MSM. No additional questions on sex behavior will be asked to female donors, and male donors will be first asked if they have had sex with other men. Only if they respond positively, more detailed questions will be asked about sexual risk behavior. On the basis of the answers a risk-assessment is made, which results either in deferral (e.g. in case of unprotected sex with casual sex partners in the previous months) or donor eligibility (e.g. MSM in a long-term monogamous sexual relationship or MSM who only practiced safe sex during the preceding 4 months).

Again, the disadvantage of this approach is that it involves asking intimate or impertinent questions. In this context, however, these questions are highly relevant from an epidemiological point of view, because they separate MSM at low-risk for TTI from MSM at increased risk for TTI. Moreover, in the next section we argue that there is little reason to assume that asking such questions in this subgroup is inappropriately impertinent. The second obvious disadvantage is that MSM are still being treated differently compared to non-MSM, because only MSM have to answer questions that may be considered as stigmatizing. At the same time, from a perspective of equal treatment, this option is a significant improvement compared to the status quo. Focusing on specific risk behavior rather than on just 'having had sex with another man' *does not amount to categorical exclusion of all MSM*, only of potential donors that have recently engaged in high-risk sexual behavior. This proposal can be justified in terms of blood safety and is more proportional than a categorical deferral of all MSM.

Let us take stock. It is clear that none of the options comes without cost – all strike some compromise, either at the cost of maintaining the safety and availability of blood components, or at the cost of excluding – if not discriminating – MSM. Moreover, all of them – presumably with the exception of the status quo – involve uncertainties about how they affect the risk of transmission. We consider risk assessment of sex behavior of all donors irrespective of their sexual orientation, to be the least justifiable. It will either result in a significant reduction of donations and thus impede blood supply, or it will involve unequal treatment after all. Moreover, avoiding unequal treatment implies that health professionals should completely ignore their professional expertise, which would be as such is indefensible.

6. Impertinent questions

The fourth policy option focuses on risk contacts of MSM and seeks to limit the exclusion of candidate donors who have specific high-risk sex behavior. For example, this would involve excluding MSM who report unprotected anal sex, while allowing MSM in a monogamous relationship (even if they have unprotected sex) or MSM who only engage in low-risk sex (mutual masturbation or oral sex only, etc.). Obtaining information about such specific sexual activities involves asking uneasy questions. How to evaluate this from an ethical perspective? Can it be justified to ask such intrusive questions? If not, Sanquin would need to fall back to the status quo of MSM deferral, or abandon sex behavior questions altogether.

We distinguish three different but interrelated ethical issues with asking such uneasy questions: (1) they might be considered as unjustifiably invading privacy, (2) they can be considered as offensive or embarrassing to the donor, hence as unrespectful, and (3) due to the offensive, embarrassing or otherwise intrusive nature of such questions, the selection practice might deter candidate donors and thus be harmful for maintaining the blood supply .

6.1. Unjustified invasion of privacy?

Sexual behavior and intimate relations with other people belong, for many if not most people, to their sphere of privacy. This however does not imply that seeking information about someone's behavior involves a violation of privacy: whether or not it is a violation of privacy, fully depends on whether that person consents to the 'invasion'. In other words, if someone wants to volunteer as a donor, and blood safety makes it necessary to have these questions answered, we can presume donors to agree with answering the questions. Our assumption is that Sanquin maintains strict confidentiality. If candidate donors do *not* agree with sharing the information – and thus refuse to answer the uneasy questions – there is no access to private information and therefore no intrusion of donor privacy either. This only stops the donor selection process prematurely. Given that there is no pressure on people to donate, (candidate) donors can freely decide whether to share their information or not. In other words, the argument that Sanquin asks specific explicit questions about sex behavior violates privacy, does not hold.

6.2. Unjustified embarrassment or offence?

Even if privacy in a strict sense is not at stake in conducting the donor questionnaire, simply being confronted with such questions *might still be felt as being intrusive* by many people. The intrusion is then much more a matter of being pushed in a state of embarrassment, or of feeling offended, than one of privacy. This is ethically undesirable in as far as it causes unpleasurable feelings. The candidate donor might consider being asked questions about a topic he or she does not want to talk about (because for him/her it is a highly private matter), as unrespectful.

However, the fact that *some* people may experience this as burdensome or unrespectful is not sufficient for concluding that it would be wrong to ask these questions. For one thing, certain 'private' questions in the screening process are inevitable given the importance of donor blood safety. Moreover, certain questions that *some* may see as impertinent have been asked for decades, for example: *have you ever had sex in exchange for money or goods?* Or: *have you ever injected drugs intravenously?*

The ethical problem of uneasy questions is not to be solved by avoiding them altogether, but by ensuring the appropriate conditions for asking them. This involves (a) seeing to it the questions are necessary and not disproportionally intrusive, (b) ensuring that candidate donors understand the rationale of these questions given the aim of blood safety, and (c) creating an appropriate, 'safe' environment for exchanging the information.

The first condition implies offering a clear justification in terms of protecting blood safety and also minimizing unequal treatment. To maintain blood safety, it is necessary to avoid donations from persons who might have been exposed to TTIs in the past four months. This risk can be effectively minimized without asking 'impertinent questions' if all MSM would be excluded categorically, but that alternative is a much more fundamental violation of ethical values (equality of persons) than the asking of 'impertinent questions' is.

The second condition can be fulfilled relatively easily. Given the prevalence of certain diseases, MSM, like no others, can be expected to understand that certain sexual practices – those that the questions are about – involve a significantly increased risk of exposure to HIV, HBV and other STI's. It is of course important that the rationale is explained to them; Sanquin cannot remain silent and simply assume they know; or even if Sanquin can assume that, it is a matter of respect to explain why they ask questions that one would normally deem inappropriate.

The third condition focuses on *how* the impertinent questions are asked. There is probably not one single best manner to do that. For some candidate donors, the least intrusive manner to be asked about their sex activities is via a rather impersonal written survey. For others, the least intrusive manner might be to discuss these intimate issues in a face-to-face meeting with a person they can trust. The important thing is that candidate donors experience the situation as safe and confidential, and this is something that blood services organizations must be capable to achieve.

7. Conclusion: two viable policy options – a matter for political deliberation and judgement

This paper discussed the unequal treatment of MSM in blood donation policies. Since policies that defer sexually active MSM categorically are considered by many as discriminatory and stigmatizing, they are subject of much critique, and the question is asked whether less discriminating policy options are available without undermining the level of blood safety. We discussed the issue in terms of two conflicting fundamental human rights that are acknowledged in EU-law: the right to equal treatment and the right to health. We conclude that the principle of proportionality implies that policies should not single-mindedly focus on minimizing the risks for blood recipients. Instead, policies should weigh the right to health of blood recipients against the right to non-discrimination of MSM-donors. We have shown that avoiding unequal treatment cannot be achieved without accepting an increase risk regarding either the quality or quantity of safe blood.

It must be emphasized, however, that unequal treatment of MSM who want to donate blood does not *as such* constitute unlawful or unethical discrimination. Given the limitations of blood screening to prevent TTIs and given clear evidence of a significantly higher prevalence of HIV and other TTIs among MSM, it is acceptable to treat MSM differently. The *Léger-case* before the CJEU offered a legal justification for unequal treatment. An alternative analysis of the problem is therefore *not* to see it as a conflict of fundamental legal rights – notably a violation of non-discrimination, but at best, as a conflict between the right to health of blood recipients versus the blood bank's moral obligation to avoid stigmatization. On the other hand, even if we accept blood safety as a justified ground for unequal treatment, differential policies can still be disproportionate and therefore amount to discrimination after all. Differential policies (e.g. only asking questions about sexual behavior to MSM) would be disproportionate if the risks that can be averted are judged to be too small to justify the unequal treatment of MSM.

Whatever the analysis, it is highly questionable whether the current status quo in the Netherlands (four months deferral of sexually active MSM) is justified: it involves *categorical* unequal treatment while the added risk of a less discriminatory policy (assessment of risk of MSM) is, presumably, negligible. There is also another policy option that we have shown to be ethically untenable: to do a risk assessment of *every* blood donor's recent sex behavior. This option either involves covert unequal treatment, thus missing its core rationale, or it requires professionals to ignore their own expertise about risk, precisely when they are supposed to make a risk assessment. Such flawed risk assessments would, moreover, create significant problems for the supply of blood, and thus also impede health.

This leaves us with two ethically and legally viable options: (a) to do a risk assessment of each MSM donor, or (b) to refrain from donor selection on the basis of reported sex behavior altogether. Refraining from donor selection is clearly preferable from the perspective of equal treatment but it will inevitably result in a higher risk of transfusion-transmitted HIV-infections. The rise in HIV residual risk cannot exactly be determined, as it also depends on knowledge and TTI-awareness among newly eligible donors, their ability to self-assess and self-exclude if at risk, as well as the dynamics and epidemiology of HIV itself. The absolute risk of transfusion-transmitted HIV will however remain very low. Is this residual risk acceptable? This question cannot be answered on the basis of ethical and legal analysis. The final judgement about which of both policies is preferable is ultimately one for society at large to decide: it is about how to balance minimizing risks for blood recipients on the one hand, and treating all citizens as equals on the other hand. This is essentially a matter for democratic decision making, in the political arena.

Acknowledgement

This study was commissioned by Sanquin, and carried out by Roland Pierik (UvA) and Marcel Verweij (Wageningen University), with substantive feedback by Thijs van de Laar and Hans Zaaijer (Sanquin). The authors are grateful to van de Laar and Zaaijer for their support and feedback, and to the members of two research colloquia, one at the Paul Scholten Centre for Jurisprudence, University of Amsterdam, and one at the Philosophy group of Wageningen University. Special thanks to Govert den Hartogh, emeritus professor of Ethics (UvA) who gave in-depth comments in the first colloquium.

Bibliography

Behrmann, J., & Ravitsky, V. (2011). Do Canadian researchers have "blood on their hands"? *Canadian Medical Association Journal, 183*(9), 1112.

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.

Berkman, R. T. W., & Zhou, L. (2015). Ban the Ban: A scientifi c 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.

Cappy, P., Barlet, V., Lucas, Q., Tinard, X., Pillonel, J., Gross, S., . . . Laperche, S. (2019). Transfusion of HIV‐infected blood products despite highly sensitive nucleic acid testing. *Transfusion, 59*(6), 2016-2053.

Costa, Y. d. (2019, August 8th). Ik mag geen bloed doneren bij Sanquin. De reden? Ik heb seks met mannen. *Het Parool*.

de Kort, W. (2016). On risk appraisal of behaviour. *Blood Transfusion 14*, 487-489. doi:DOI 10.2450/2015.0287-15

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

den Exter, A. (2016). Homosexuals and blood donation: a delicate issue for the European Union Court of Justice. *Blood Transfus, 14*, 500-503. doi:DOI 10.2450/2015.0155-15

Farrell, A.-M. (2016). *The Politics of Blood*. Cambridge: Cambridge University Press.

Hoeyer, K. (2015). Regulatory anatomy how "Safety Logics" structure European Transplant Medicine. *Science, Technology & Human Values, 40*(4), 516–538.

Marchant, G. E. (2003). From General Policy to Legal Rule: Aspirations and Limitations of the Precautionary Principle. *Environmental Health Perspectives, 111*(14).

Misérus, M., & Ruiter, M. d. (2019, 5 December). Moet een man sneller bloed kunnen doneren na seks met een andere man? *De Volkskrant*.

Resnik, D. B. (2004). The Precautionary Principle and Medical Decision Making. *Journal of Medicine and Philosophy, 29*(3), 281–299.

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

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.

Steel, D. (2014). *Philosophy and the Precautionary Principle: Science, Evidence, and Environmental Policy*. Cambridge: Cambridge University Press.

Sunstein, C. R. (2005). *Laws of Fear: Beyond the Precautionary Principle*. Cambridge: Cambridge University Press.

Titmuss, R. M. (1970). *The gift relationship: From human blood to social policy*. London: Allen & Unwin.

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.