The risks and benefits of accepting men who have had sex with men as blood donors

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BACKGROUND: It has been suggested that men who have had sex with men (MSM) should become eligible to donate blood if they recently abstained from male-to-male sex.

STUDY DESIGN AND METHODS: The impact of a 12-month deferral policy for MSM on the risk of introducing contaminated units in the blood supply and the benefit of obtaining additional donations were estimated. Considered were the prevalence of HIV among MSM, the window period of infection, the rate of laboratory testing errors, and the occurence of other system failures. This was compared with the risk and benefit that currently results from accepting female donors who have had sex with MSM.

RESULTS: The revised policy for MSM would potentially result in one HIV-contaminated unit for every 136,000 additional donations (95% CI, 1 in 69,000 to 1 in 268,000), for an overall increase in HIV risk estimated at 8 percent. The number of donations would increase by 1.3 percent (95% CI, 0.9%-1.7%). The risk-benefit ratio of currently accepting female partners of MSM is approximately five times lower.

CONCLUSION: The risk increment of accepting 12-month abstinent MSM would be very small but not zero. From a risk-benefit perspective, the current deferral policy for MSM is more efficient compared to an analogous hypothetical criterion for female partners of MSM.

In the United States and in Canada, as in most other industrialized countries, men who have had sex with men (MSM), even once since 1977, are permanently excluded from blood donation. Many have criticized the discriminatory nature of the present policy, arguing that gay men are imposed a more stringent deferral criterion than are other groups at risk for HIV. For example, women are only deferred for a period of 12 months following a sexual contact with a MSM. In 1997, the AABB suggested that the deferral period for male-to-male sex be changed to 12 months for the sake of clarity and consistency of the donor screening process.[1]

The main concern expressed by those who oppose a change in the current MSM deferral policy is the possible increase in the risk of inadvertent HIV transmission by transfusion because of the potential failure of the overall screening process. In recent deliberations on this issue by the FDA, calculations were presented regarding this risk, but there was substantial uncertainty surrounding the estimates.[2]

In this report, a mathematical model is presented for evaluating the impact of a relaxation of the current MSM deferral policy. The risk of introducing contaminated units in the blood supply if sexually abstinent (12 months or more) MSM became eligible for donation was estimated. The potential benefit of a change in the current deferral policy as the increase in the number of active donors in the blood system was calculated. To assess the relative efficiency of the current deferral policy for MSM,

ABBREVIATIONS: FMSM = female partners of MSM; MSM = men who have had sex with men.

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Received for publication March 6, 2002; revision received August 6, 2002, and accepted August 23, 2002.

TRANSFUSION 2003;43:25-33.

the impact of a change in the MSM deferral policy was compared to the risk and benefit currently resulting from a 12-month, as opposed to lifetime, deferral of female sexual partners of MSM.

MATERIALS AND METHODS

The risk-benefit models

For the sake of simplicity, our models considered the impact of the policy change in the first year following their implementation. If 12-month-abstinent MSM were allowed to donate, this would have the benefit of adding a certain number of donors to the donor pool (N_{1y}). This number would be determined by the total population of MSM (MSM_{tot}), of which a proportion would become eligible according to the revised criterion (P_{elig}). Of those newly eligible donors, only a fraction would actually donate (P_{don}). Therefore,

$$N_{1y} = MSM_{tot} \times P_{elig} \times P_{don}.$$

The risk of the revised policy was calculated as the additional number of HIV-contaminated units that would escape detection and become available for transfusion (U_{1y}). This would depend on the proportion of newly eligible men (N_{1y}) infected by HIV (P_{hiv}) and also on the proportion of HIV infected units for which the screening would fail. Such failures were ascribed to two different categories, namely, failures of the screening tests to detect infected units and failures to remove correctly identified HIV-positive units from the inventory. The first category included the rate of false-negative results ($P_{falseneg}$), the proportion of undetectable variant viral strains ($P_{variant}$), the proportion of window-period donations (P_{window}), and the rate of errors in laboratory techniques (P_{tech}). In the second category of system failures, we considered the proportion of correctly identified HIV-positive units that are released because of a clerical error (P_{errinv}) and those that are transfused on an emergency basis, that is, before the screening test results become available (P_{urgent}). These various failure rates add to each other, such that

$$U_{1y} = N_{1y} \times P_{hiv} \times (P_{falseneg} + P_{variant} + P_{window} + P_{tech} + P_{errinv} + P_{urgent}).$$

The risk-benefit ratio U_{1y}/N_{1y} therefore represents the probability that any given unit obtained from an eligible MSM would be contaminated by HIV, escape detection, and become available for transfusion.

A similar model was utilized to evaluate the decrease in risk and the loss of donors that would result from imposing a lifetime deferral for female partners of MSM (FMSM), as opposed to the current 12-month deferral policy. If sex with a MSM resulted in a lifetime deferral for women, the decrease in the number of female donors (NF_{1y}) would be determined by the number of adult women who ever had sex with a MSM ($FMSM_{tot}$), the proportion of such women who are currently eligible but who would become ineligible according to the revised criterion (PF_{inelig}), and the rate of donation of currently eligible FMSM (Pf_{don}). Therefore,

$$NF_{1y} = FMSM_{tot} \times PF_{inelig} \times Pf_{don}.$$

The risk that would be avoided by a lifetime deferral policy for female sexual partners of MSM is the number of HIV-contaminated units, obtained from these women, which currently escape detection over a period of 1 year (UF_{1y}). This is determined by the number of female sexual partners of MSM currently donating (NF_{1y}), the proportion of those women who are infected by HIV (PF_{hiv}), and by the overall failure rate of the screening process, such that

$$UF_{1y} = NF_{1y} \times PF_{hiv} \times (P_{falseneg} + P_{variant} + P_{window} + P_{tech} + P_{errinv} + P_{urgent}).$$

The risk-benefit ratio UCF_{1y}/NF_{1y} represents the probability that, under the current 12-month deferral policy for female partners of MSM, a unit obtained from such donor is contaminated by HIV, escapes detection, and becomes available for transfusion.

The quantities U_{1y}/N_{1y} and UF_{1y}/NF_{1y} can serve as a measure of the efficiency of each deferral criterion. Therefore, the relative efficiency of a lifetime deferral policy for MSM was calculated, in comparison to a similar policy applied to female sexual partners of MSM, simply by computing the ratio between U_{1y}/N_{1y} and UF_{1y}/NF_{1y}.

Study population

We obtained data for the parameters in the models from several sources, including published and unpublished studies. The point estimates, the range, and the distribution features of these parameters were chosen to reflect as best as possible the prevailing situation in the United States and Canada. The age criterion for donor eligibility (18-60 years) is the range applied for first-time donations in Canada. For some parameters, estimates were derived from data collected in 2000 to 2001 by Héma-Québec, the transfusion agency that supplies the province of Quebec (population, 7.4 million).

Value of parameters in the models

Table 1 summarizes the values, ranges, and sources for the parameters included in the models. A more detailed discussion of each parameter is presented in Appendix I.

For all practical purposes, it was assumed that the number of men who ever had male-to-male sex (MSM_{tot}) is equivalent to the number of men who are excluded based on the current criterion (male-to-male sex, even once, since 1977). It was also assumed that eligible MSM would donate at a rate similar to that of the general male population (P_{don}). To estimate P_{hiv}, only HIV-infected MSM who would not be aware of their infection were

TABLE 1. Summary of parameters included in the risk-benefit models

Parameter	Point estimate	Range	Source
Total number of adult MSM (MSM_{tot})*	4.5†	3-6	Published population-based surveys conducted in the United States and Europe[5-8] and unpublished surveys: National AIDS Behavioral Survey (1990-1), National Health and Social Life Survey (1992), National Survey of Adolescent Males (1995), and National Household Survey of Drug Abuse (1996)
Proportion of MSM_{tot} who would become eligible (P_{elig})*	0.5	0.44-0.56	Unpublished population-based surveys (as above) and unpublished data on temporary abstinence in a prospective cohort study of sexually active gay men in Montreal[9]
Proportion of eligible MSM_{tot} who would actually donate (P_{don})*	3.7		Demographic data for the province of Quebec and Héma-Québec annual statistics
Proportion of eligible MSM donors who would be unknowingly infected with HIV (P_{hiv})*	0.6	0.2-1.0	Unpublished data on unrecognized HIV infection in subjects recruited in a prospective cohort study of sexually active gay men in Montreal[9]
Proportion of false negative test results; analytical sensitivity ($P_{falseneg}$)	1 in 200,000	1 in 1,000,000-1 in 40,000	Test manufacturers (Package inserts)
Proportion of window period donations (P_{window})	1 in 2,000	1 in 10,000-1 in 1,000	Mathematical extrapolation from HIV seroconversion study[11]
Proportion of false negative test results; clinical sensitivity (P_{tech})	1 in 10,000	1 in 100,000-1 in 1,000	Study of false-negative testing errors in blood donor screening[13]
Proportion of HIV positive units released for transfusion due to a clerical error (P_{errinv})	1 in 30,000	1 in 300,000-1 in 3,000	New York Blood Center data, presented at the Blood Products Advisory Committee meeting[2]
Proportion of units that are released on an emergency basis (P_{urgent})	1 in 100,000	1 in 1,000,000-1 in 10,000	Héma-Québec annual statistics
Total number of women who ever had sex with a MSM ($FMSM_{tot}$) (of adult female population)*	1.6	1.2-2	Extrapolation from published data on bisexual practices among MSM[14] and unpublished survey data in women undergoing an abortion
Proportion of $FMSM_{tot}$ who would become ineligible (PF_{inelig})*	75	65-85	Extrapolation from published data on bisexual practices among MSM[14]
Proportion of currently eligible $FMSM_{tot}$ who donate (PF_{don})*	2.8		Héma-Québec annual statistics
Proportion of FMSM who are currently eligible but unknowingly infected with HIV (PF_{hiv})*	0.1	0.05-0.5	Published study of heterosexual transmission of HIV in the U.S.[15] and HIV epidemiology in the province of Quebec[16]

* Data shown are percentages.
† Percentage of adult male population.

considered. This is because a known HIV infection will always remain an exclusion criterion and there is no reason to suspect that a 12-month deferral policy would elicit more donations from MSM aware of being infected.

We estimated the analytical sensitivity of HIV testing ($P_{falseneg}$) based on the current practice in Canada and in the United States, where donations are screened by three different tests: an EIA antibody assay, the p24 antigen assay, and NAT. Estimates for $P_{variant}$ and P_{window} were extrapolated from limited observational data. Estimates for P_{tech} were derived from studies conducted before the era of NAT and needed to take into account the redundancy of current assays. In our estimate of P_{errinv}, the increasingly stringent manufacturing practices that prevail in most transfusion agencies were considered. P_{urgent} was estimated primarily from Héma-Québec's experience in this regard.

We are unaware of any study that directly assessed the proportion of women who ever had sex with a MSM in their lifetime or in the previous 12 months ($FMSM_{tot}$ and PF_{inelig}); however, population-based survey data were used to estimate these parameters. Similar to the MSM model, it was assumed that the proportion of women who had sex with a MSM in their lifetime is the same as the proportion of women who had sex with a MSM since 1977. We also assumed that eligible FMSM would donate at a rate comparable to that of the general female population (PF_{don}).

Monte Carlo simulation

We defined a distribution of the possible values for each parameter in the model, within the ranges mentioned previously. Depending on the data that could be used to estimate each parameter, the distribution was triangular, binomial, or lognormal. A triangular distribution was used for parameters with the highest level of uncertainty.

The model was then run 10,000 times using computer software (SAS, version 8.0, SAS Institute, Cary, NC) each time by assigning a random value based on the distribution hypothesized for each parameter. From this iteration, the model generated a distribution of estimates. The most likely estimate was taken as the mean of the normalized distribution, and the 95 percent CIs were calculated.

RESULTS

Predicted impact of a 12-month deferral policy for MSM

For the population of Quebec (220,000 donations per year), the model predicts that a 12-month deferral policy for MSM would bring in 1952 new donors, with 95 percent CIs of 1407 to 2497. Since donors contribute on average 1.5 donations per year, this represents an increase of 1.3 percent in the total number of donations (95% CI, 0.9%-1.7%), an estimate that would also apply approximately elsewhere in Canada and in the United States. The additional number of HIV-infected units that would escape detection is estimated at 1 unit every 69 years (95% CI, 34-147 years) in Quebec. Based on the annual number of donations in Canada (n = 960,000) and in the United States (n = 14,000,000), this would extrapolate to an additional 1 unit escaping detection every 16 years in Canada (95% CI, 8-34 years) and once every 1.1 years in the United States (95% CI, 0.5-2.3 years). The risk-benefit ratio (U_{1y}/N_{1y}), representing the "per-unit" risk of introducing an undetected HIV donation, for each additional donation that would result from the 12-month deferral criterion, is estimated at 1 in 136,000 (95% CI, 1 in 69,000-1 in 268,000). Figure 1A shows the Monte Carlo distribution of this ratio. Table 2 compares this risk and that of a random donation from a pool of donors that would result from this deferral policy to the current residual risk of HIV transmission.

Comparison with women who had sex with a MSM

If all women who ever had sex with a MSM were excluded from blood donation, it is predicted that one infected unit would be prevented from entering the blood supply every 980 years in Quebec (95% CI, 306-3104 years). This would be achieved at the expense of losing 758 donors or 0.52 percent of all donations (95% CI, 0.40%-0.64%), for a risk-benefit ratio (UF_{1y}/NF_{1y}) estimated at one HIV contaminated unit avoided for every 734,000 donations (95% CI, 1 in 235,000-1 in 2,290,000). The Monte Carlo distribution of UF_{1y}/NF_{1y} is shown in Fig. 1B.

Figure 1C illustrates the Monte Carlo distribution of the relative efficiency of a lifetime deferral policy for MSM, in comparison with a similar policy applied to female sexual partners of MSM, or mathematically speaking, the ratio between (U_{1y}/N_{1y}) and (UF_{1y}/NF_{1y}). This ratio is estimated at 5.4 (95% CI, 2.0-15), meaning that, for each donor lost to the system, a lifetime deferral

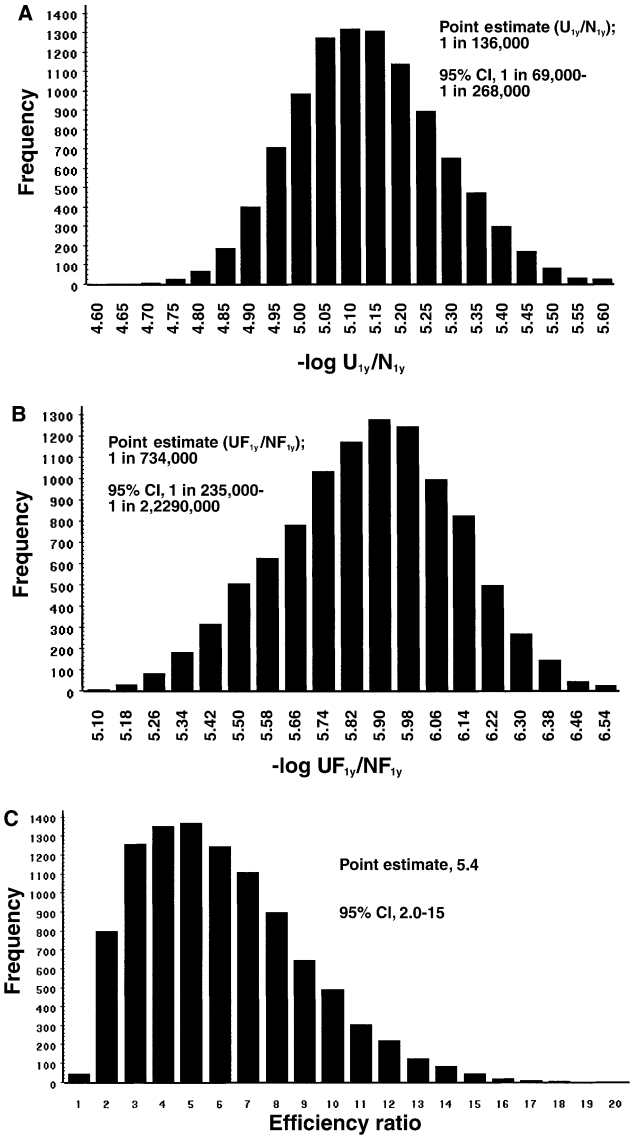

Fig. 1. (A) Monte Carlo distribution of the risk of introducing an undetected HIV donation for each additional donation that would result from a 12-month deferral criterion for MSM (negative logarithm of U_{1y}/N_{1y}). (B) Monte Carlo distribution of the risk of introducing an undetected HIV donation for each donation obtained from women who ever had sex with a MSM (negative logarithm of UF_{1y}/NF_{1y}), under the current 12-month deferral policy. (C) Relative efficiency in terms of risk avoided per unit of blood of a lifetime deferral policy for MSM, in comparison with a similar policy applied to female sexual partners of MSM. The graph shows the distribution of this ratio in a Monte-Carlo simulation of the model (10,000 runs).

TABLE 2. Impact of implementing a 12-month deferral policy for MSM in a hypothetical transfusion service collecting 1,000,000 units per year

Source of donations	Number	HIV risk per unit	Number of HIV-infected units
Current donors	1,000,000	1 in 1,000,000*	1.000
12-month abstinent MSM	13,000	1 in 136,000	0.096
Aggregate	1,013,000	1 in 925,000	1.096
Marginal risk ÷ current risk, 7.35			
Aggregate risk ÷ current risk, 1.08			
Aggregate number of units ÷ current number of units, 1.01			

* As estimated by mathematical modeling, according to Busch.[3]

policy for MSM achieves a risk reduction that is five times higher compared to the reduction that would result from a lifetime deferral of female sex partners of MSM. The comparison of these risk-benefit ratios is insensitive to variations in estimates of the system failure rates, since these variables cancel out in the calculation.

DISCUSSION

Our model estimated the increase in risk and also the potential benefit that would result from a 12-month deferral criterion for MSM. It was found that the risk of inadvertent HIV transmission from these new donors would be 1 in 136,000 and that the number of donations would increase by 1.3 percent. Therefore, if such donors were included in the pool, the mean risk increment for a random donation would be in the order of 1 in 11,000,000. This can be compared to the current residual risk of HIV transmission, which is estimated to be no higher than 1 in 1,000,000,[3] as shown in Table 2. Based on these numbers, it is clear that the incremental risk of a revised deferral policy for MSM would be very low, although not zero.

Temporary deferrals are applied to donors who report activities that may reflect a higher risk for HIV and other blood-borne infections. The main goal of such deferrals is to eliminate recent infections (window period donations) that might otherwise be undetected by the blood screening assays. The recent implementation of minipool NAT has reduced but probably not completely eliminated the residual risk associated with window period donations.[3] At least for this reason, the practice of temporarily deferring people at risk for certain infections is not likely to be abandoned. In addition to protecting against window period donations, temporary deferrals also have the effect of reducing the number of donors with prevalent blood-borne infections, because of the strong correlation that exists between recent and lifetime behavior.

There is some evidence that window period donations are not the only source of potential failures of the donor screening process. In addition to the possibility of a false-negative test result, clerical and administrative errors occasionally occur and may lead to the inappropriate release of infectious blood components. Such errors are probably extremely rare because of the increasing level of control in the process of screening and handling donations, but a low risk will always remain, at least in theory. Furthermore, emergency situations sometimes require that blood products be transfused before laboratory screening for transmissible diseases. Because of the potential failure of the screening process beyond and above the issue of window period donations, any reduction in the prevalence of infection among potential donors can only lead to a safer blood supply, assuming that donor availability is not an issue. However, donor availability does put a limit to the level of stringency that we can apply when screening on the basis of certain risk factors. Where that limit resides exactly is another issue, and it is probably dependent on other factors, such as efforts to recruit and retain eligible donors.

An alternative approach to the issue of MSM and blood donation is to compare the risk and benefit of the 12-month deferral policy to other exclusion criteria that address the same risk. In several countries including Canada and the United States, women are deferred from blood donation if they had sex with a MSM in the previous 12 months. This exclusion criterion is aimed at the same goal, that is, reducing the likelihood of collecting an HIV-positive unit from a donor who is at risk because of a particular behavior. We calculated that the risk-benefit ratio of a lifetime deferral as opposed to 12-month deferral of women who had sex with a MSM is approximately five times lower than the risk-benefit ratio associated with a relaxation of the current MSM deferral criterion. In other words, our model shows that, for each donor lost to the blood system, the current policy for MSM achieves a higher yield in safety compared to the yield that would result from a similar measure for women who had sex with a MSM. This comparison demonstrates that a consistent deferral policy, such as a 12-month temporary deferral for anyone at risk for HIV, might not necessarily be consistent from a risk-benefit perspective. In fact, the impact on risk reduction versus donor loss will depend on the specific risk group to which the deferral is applied.

Based on these considerations, what conclusion

should be drawn concerning the current deferral policy for MSM? As mentioned previously, the risk of changing to a 12-month deferral criterion would be very low, but it can never be shown to be zero. It is probable, given today's paradigm in blood safety, that even a minuscule increment in risk would be unjustified and undesirable, even though some benefit would result from a revised policy due to an increase in the number of eligible donors. Some will argue that the benefit of increasing the donor pool is not large enough or that such benefit could be reached by other means that would not have a negative impact on safety. In contrast, if a lifetime deferral is appropriate for MSM because it screens out prevalent infections, why not do the same with all groups at risk for HIV, for example, female sex partners of MSM? We showed that it would be much less efficient to impose a lifetime deferral for FMSM, in comparison with MSM. In itself, that does not necessarily provide a justification for the current MSM deferral policy, nor does it justify a 12-month deferral for FMSM. However, it shows that if we were in a situation where only one of these two groups could be imposed a lifetime deferral, for example, if donor availability would constrain our options, the MSM group would be the logical choice.

From a risk-benefit point of view in which the risk of a system failure is assumed to be greater than zero and the availability of donors is put in the balance, the relative efficiency of deferral criteria depends essentially on two factors: the proportion of people with specific activities at risk in the general population and the different rates of infection in these various groups. It is also interesting to note that the relative efficiency of such criteria does not depend on the actual level of the risk of system failure, because this risk is usually constant across donations. A formal risk/benefit analysis, as was used in our study, might be a useful approach in the overall evaluation of existing and future deferral criteria. Some have expressed the concern that the growing length and complexity of the donor questionnaire might jeopardize the efficacy of the screening process.[4] Indeed, there is a limit to the number of specific criteria that can be used to screen donors, even putting aside the shrinking effect on the donor pool. If or when that limit is reached, choices will have to be made about which items should remain in the questionnaire. Existing or potential deferral criteria could be ranked according to their relative efficiency, and priority would be given to those achieving the best risk reduction to donor loss ratio. The ratios would also need to be weighed according to the morbidity associated with the specific infection or condition targeted by the criterion. For example, items directed at HIV risk factors would be weighed more heavily compared to HCV risk factors. This approach, however, would have limited usefulness to evaluate criteria targeted toward hypothetical or poorly defined risks (variant CJD, leishmaniosis, simian foamy virus, etc.), simply because the risk side of the equation would be much more difficult, if not impossible, to quantify.

There are some important limitations to our analysis. Sources for the data used to estimate the parameters included in the models were varied and not necessarily representative of the situation in both the United States and Canada. Regional differences may exist, in particular, regarding the epidemiology of HIV, but also with respect to operational characteristics of the transfusion service. The study that was used to estimate some of the most influential parameters in the MSM model is limited to a single, large urban center. However, we ensured that our parameter estimates were consistent with data obtained from population-based studies, where such data were available (e.g., the 12-month abstinence rate in the overall MSM population). Furthermore, rather than using only a point estimate for the model parameters, the Monte Carlo simulation allowed us to take into account a wide range of possible values. Therefore, we feel confident that the results of the models are a plausible representation of the situation in most industrialized countries. Finally, for parameters that were more difficult to estimate, in particular, those related to potential system failures, we usually assumed a worst-case scenario. For example, we have little basis for our assumptions concerning the risk posed by unusually long window periods of infection or the possibility that screening tests miss variant strains. If we exclude these parameters from the model, the estimated risk is reduced by a factor of 5, although it is still not zero. Therefore, if some parameters were more accurately estimated, it is likely that the overall conclusion would remain unchanged, if not reinforced, namely that the risk associated with a 12-month deferral policy for MSM is very small, but not zero. Other factors were not considered in this analysis, such as the potential differences in validity of the information obtained from questioning donors about remote as opposed to recent behaviors or the possibility that the new policy might have an impact on the donation patterns of the general population. However, in the absence of any data that could help to quantify these factors, it was not possible to include them in the analysis.

In conclusion, our analysis was not intended to determine whether the deferral policy for MSM should be made less stringent or not. It provides a basis, however, for decision making on the probable magnitude of the risk and benefit involved in such a change. Furthermore, the risk-benefit perspective provides a rational basis for evaluating the relative merits of various deferral criteria.

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APPENDIX I. ESTIMATION OF MODEL PARAMETERS

MSM_{tot}

Published population-based surveys suggest that the proportion of men who ever had male-to-male sex is from 3 percent to 6 percent.[5-8] Unpublished data from several surveys conducted in the United States (see Table 1) also suggest a similar estimate of approximately 5 percent (L. Doll, PhD, personal communication, Division of HIV/AIDS Prevention, Centers for Disease Control and Prevention, October 2000).

P_{elig}

In the US population-based surveys cited above, approximately 55 percent of MSM had abstained from male-to-male sex in the past 12 months. We refined the evaluation of this parameter within MSM groups defined by the level of their sexual activity and hence by their risk of unrecognized HIV infection. The Monte Carlo simulation included this risk stratification. In sexually active MSM, who represent a group at higher risk for HIV, the prevalence of 12-month abstinence was estimated from the data collected in an ongoing prospective cohort study of sexually active gay men in Montreal, the Omega cohort,[9] in which participants are questioned extensively at 6-month intervals on their sexual activities. Interim results show that only 3.1 percent of MSM had been sexually abstinent during a period of 12 months or more (R. Remis, personal communication, January 2002). For groups of less sexually active MSM, we assigned higher values to P_{elig}, such that the point estimate for the overall MSM population was made consistent with population-based surveys.

P_{don}

Based on demographic data for the province of Quebec and the Héma-Québec annual statistics for the fiscal year 2000 to 2001, 3.7 percent of adult men donated at least once.

P_{hiv}

In the Omega cohort mentioned above,[9] only seronegative MSM were eligible for follow-up. At the time of their initial evaluation, among those who thought that they were not infected, 1.45 percent tested positive for HIV. This prevalence estimate was assigned to the sexually active group of MSM defined earlier. For less sexually active MSM, unrecognized HIV infection would be much lower because of their lower level of exposure. Further, among those who are HIV positive, the probability of an unrecognized infection would also be lower because of the longer mean time since infection and the increased likelihood of detection through clinical progression or

screening. We therefore assumed that, in comparison with the higher risk group, the prevalence is between 5 and 10 times lower, such that the most likely estimate for this parameter is approximately 0.6 percent overall.

$P_{falseneg}$

We assumed that all p24-antigen-positive donations will be captured by NAT, that is, that p24 antigen testing does not provide any additional sensitivity. Therefore, we calculated the combined sensitivity of EIA testing and NAT. Current EIA screening tests have an analytical sensitivity of 99.99 percent or better. The experience with NAT has shown that it is at least 95 percent sensitive in comparison with EIA. The joint probability of a false-negative result was based on the product of these two estimates.

$P_{variant}$

Some strains of HIV, in particular, those belonging to serogroup O, might escape detection by the current screening assays.[10] However, such strains are rarely encountered in industrialized countries, although their precise frequency is not known. Depending on the specific assay, it may be that NAT would detect units infected by variant HIV. However, our model used the worst-case scenario where both EIA and NAT would fail to detect such strains.

P_{window}

Based on 51 HIV seroconversion cases in health care workers, the seroconversion rate at 6 months is 95 percent.[11] Although prolonged immunosilent infections have never been substantiated,[12] we assumed conservatively that the reduction in the proportion of immunosilent infections would be logarithmic, meaning that 1 in 400 infections would still remain undetectable at 12 months. However, the mean time since infection in newly eligible HIV-infected MSM would likely be much longer than 12 months. In addition, the mean window period for HIV in blood donors is reduced even further by the recent implementation of minipool NAT.[3] Therefore, we assigned an even lower probability in the model.

P_{tech}

Two recent studies examined the rate of technical and clerical errors that might result in a falsely negative screening test. One study showed that among 2015 samples confirmed positive by serology for HIV, HCV, or HTLV, the screening test had given a falsely negative result in one case only (0.05%).[13] In a similar study presented by Busch,[2] this rate was measured at 0.13 percent (three false-negative results among 2300 confirmed positive samples). In each study, it was demonstrated that a technical error was the most likely explanation for the false-negative results. The upper limit of our estimate of P_{tech} was therefore derived from the combined data reported in the two studies. The redundancy of EIA testing and NAT has considerably reduced this risk. However, there may be situations in which such errors do not happen independently for each assay (e.g., mislabeling of all test tubes from a given donation). Furthermore, the redundancy is not perfect since, as previously mentioned, NAT would miss some serologically confirmed HIV-positive donations. Therefore, the lower limit of the estimate for P_{tech} was chosen accordingly.

P_{errinv}

In the past, blood products have been erroneously released for transfusion, in spite of having tested positive for a transmissible disease marker. Based on data from New York State,[2] this type of event occurs at a rate of approximately 1 in 3000 at the blood center level, and the rate was 1 order of magnitude higher at the blood bank level. We estimate that even a rate of 1 in 3000 represents an overestimate compared to the situation that prevails in most transfusion agencies, where manufacturing procedures are computerized and highly controlled. We therefore assigned a lower probability in the model.

P_{urgent}

Occasionally, a specific blood product needs to be transfused immediately, before the transmissible diseases test results become available (e.g., granulocyte transfusions, rare phenotypes). At Héma-Québec, approximately 1 in every 5000 units is released to a hospital blood bank on an emergency basis. Although it is difficult to obtain complete information on the fate of these products, we estimated that only 50 percent of these units are in fact transfused before the test results are obtained and passed on to the hospital blood bank. Furthermore, such donations usually come from frequent, or at least repeat donors, which would basically exclude newly eligible MSM. Therefore, the value of this parameter was estimated to be even lower by 1 order of magnitude.

$FMSM_{tot}$

Surveys indicate that approximately one-third of MSM are bisexual.[14] In addition, a survey conducted among women undergoing an abortion in Montreal revealed that 1.46 percent reported a sexual contact with a bisexual man (R. Remis, personal communication, November 2001). Based on the total population of MSM, and assuming a one-to-one ratio, we also estimated that between 1.2 and 2 percent of women ever had sex with a MSM.

PF_{inelig}

To estimate this proportion, we need to take into account those women who are already ineligible as a result of a

sexual contact with a MSM in the previous 12 months. This information is not readily available; however, published data indicate that 27 percent of bisexual MSM had a woman as their primary sex partner in the previous year.[14] Through the same reasoning as applied above, we therefore presumed that approximately 25 percent of $FMSM_{tot}$ are already excluded from donation as a result of the 12-month deferral policy.

PF_{don}

Héma-Québec statistics indicate that 2.8 percent of adult women donate once or more over a period of 1 year.

PF_{hiv}

This proportion was indirectly derived from a mathematical modeling study recently published in the United States, in which it was estimated that among 40,000 incident cases of HIV, only 1 percent could be attributed to heterosexual transmission to women.[15] By extrapolating this proportion to the estimated number of prevalent HIV infections among adults in Quebec[16] and taking into account the recent trends in HIV incidence, we estimated that approximately 150 infections would be found in women who had sex with a MSM and assumed that at least 50 percent are aware of their HIV seropositivity. Based on the estimated number of women who ever had sex with a MSM in Quebec, the prevalence of unrecognized HIV infection in women who ever had sex with a MSM would be in the order of 0.2 percent. Based on the observed prevalence of HIV among female blood donors at Héma-Québec, this likely represents an overestimate. We therefore assigned a lower value to this parameter in the model.