



Blood donation by MSM in New Zealand: Understanding the roles of populational HIV prevalence, individual risk behaviours, and risk reduction versus risk elimination

Executive summary

- Protection of the blood supply is achieved by a combination of donor deferral, biological testing for known pathogens, and careful management of the blood banks themselves. None of these are foolproof on their own, but together they provide near complete protection of the blood supply for known pathogens;
- Donor deferral criteria is based on the prevalence of blood-borne pathogens in different population groups, and engagement in activities that place individuals at risk of infection;
- The sexual partners of MSM in New Zealand have an estimated 40 times greater prevalence of undiagnosed HIV infection, compared to the sexual partners of heterosexual individuals;
- The activities that place MSM at risk of HIV acquisition are receptive or insertive anal sex and, on very rare occasions, receptive oral sex;
- While anal sex *with* a condom and oral sex without a condom constitute “safe sex”, there is still a very small risk of HIV transmission if a condom breaks (i.e. it is risk *reduction*, it is not risk *free*);
- “Safe sex” via risk reduction will almost certainly protect individuals from HIV infection, and will be sufficient to end the sexually-transmitted HIV epidemic among MSM if consistently practiced. However, risk reduction is not sufficient to fully protect the blood supply, which instead requires a “higher bar” of 100% risk elimination to ensure blood safety;
- A “higher bar” for the blood supply is required because of the very high risk of infection via blood transfusion, and because people in urgent need of blood services have little or no choice as to whether they accept blood given to them;
- The New Zealand Blood Service defers *groups* of people at higher potential risk of infection prior to donation rather than on a case-by case basis, because of the impracticality of assessing individual cases and the difficulty of verifying a person’s actual risk profile;

- For instance, a number of studies have found undiagnosed HIV infections among MSM who had strong convictions about their own HIV negative status, or who believed they were in a mutually monogamous relationship;
- The recent review of the donor deferral criteria has made important changes to the deferral system. This recommended a reduction from 10 years deferral following “any sex with a male” down to 5 years for “anal or oral sex, with or without a condom”; an equalisation of the deferral period for these MSM to individuals who have lived in countries with a high HIV prevalence (previously, the deferral period for the latter group was only 1 year); and no deferral for MSM who have only engaged in mutual masturbation or other non-penetrative sexual activities in the previous 5 years;
- If accepted, these changes will mean that the new NZBS policies will be updated to reflect current local and global realities, and position New Zealand as having one of the least restrictive deferral criteria in the world, while still ensuring the safety of our blood supply.

Introduction

Earlier this month the New Zealand Blood Service Donor Referral Criteria Review Group released its recommendations. The issues involved in establishing donor deferral criteria are complex and the full rationale behind the Group’s decision is best explored by reading the *Final Report to the New Zealand Blood Service* (see references at end).

The desire to donate blood versus the right to receive uncontaminated blood products, the level at which donor deferral for groups is set, and the relative positioning of deferral for groups posing different risks to the safety of the blood supply were factors considered in the review, among other things. The *Final Report* has recommended important changes to the donor deferral policies, and many of these recommendations have recently been the subject of community and stakeholder discussion. The New Zealand AIDS Foundation (NZAF) supports the main recommendations of the Blood Donor Review Group. This discussion paper by the Research Unit at NZAF aims to summarise what the authors believe are the most relevant issues for men who have sex with men (MSM).

The central importance of the prevalence of blood-borne infection in population groups

A recent New Zealand study of individuals attending sexual health clinics found that the prevalence of HIV was 4.4% among men who have sex with men (MSM), 0.3% among injecting drug users (IDU), 0.1% among heterosexual women, and 0.1% among heterosexual men. Just under half of these groups had undiagnosed infections (AIDS Epidemiology Group, 2007; see also Table 2, p.27 of the *Final Report*). It is very important to understand what the estimated 40 times higher HIV prevalence among New Zealand MSM means compared to that in heterosexual New Zealanders.

Consider the following hypothetical example. One group has 10% unprotected anal sex and 60% HIV prevalence (i.e. 60% of them are infected). A second group has 10% unprotected anal sex and 10% HIV prevalence.

It is clear that *within* the first group, the risk of HIV acquisition will be six times higher, even though the amount of unprotected anal sex is the same as in the second group. This is what is meant by individual risk being dependent not only on individual behaviour, but on the prevalence of infection among one's sexual contacts.

In New Zealand, not everyone's sexual partner is equally likely to be infected with HIV. The likelihood that your next sexual partner will have an undiagnosed HIV infection is on average 40 times higher if you are a man having sex with other MSM than if you are heterosexually active. HIV prevalence is in fact far higher among MSM than it is among female commercial sex workers in New Zealand (AIDS Epidemiology Group, 2007).

Similarly, one act of unprotected sex by an MSM in Sydney carries - on average - a significantly higher likelihood of infection than the same unprotected sex event in Auckland. This is because the chance of randomly encountering someone with HIV among Sydney MSM is much higher than among Auckland MSM (13.9% of MSM recruited into a behavioural surveillance study in inner-east Sydney had been diagnosed with HIV, compared to 3.3% among MSM recruited in Auckland; see Madeddu et al., 2006, Saxton et al., 2006). It is a case of the same sexual act carrying different consequences, because of the difference in populational levels of HIV infection.

In an interconnected sexual network, it is not possible to divorce a person's risk of acquiring HIV from the pool of infection among their sexual partner/s, their sexual partners' partners, and so on.

This logic underpins why heterosexual individuals who have lived in or come from countries of high HIV prevalence (see Appendix 2, p.70 of the *Final Report*) are deferred from donating blood for the same period as MSM who engage in anal or oral sex i.e. it is *not* to do with nationality, but the higher potential prevalence of undiagnosed infection. This is also true regarding the presence of other blood-borne pathogens. Individuals who have lived in the UK between 1980 and 1996 are more likely to have been exposed to CJD, and are consequently deferred from donating blood permanently (i.e. for life).

It must also be remembered that in addition to HIV, MSM as a population group are known to have higher rates of several other potentially transfusion transmissible infections (TTIs) such as HHV8, Hepatitis B and Hepatitis C.

These issues are spelt out in more detail in the recent Review Group's *Final Report*, and are acknowledged to be a central consideration in the choice of deferral periods for prospective blood donors. *Relative* differences in the presence of blood-borne pathogens between population groups translate into *relatively* different blood donation deferral criteria.

The importance of differences in per-contact transmission risk

On top of these issues of the prevalence of various blood-borne infections, the per-contact risk of HIV being transmitted from an infected source to a susceptible individual varies greatly for different activities.

This is particularly critical in the case of HIV, which is transmitted extremely efficiently by blood transfusion. That risk is of a different order of magnitude to the likelihood of acquiring HIV through sexual activity with an HIV positive partner. Hierarchies of risk extend to sexual acts, with unprotected receptive anal sex being roughly 5 times riskier than unprotected receptive

vaginal sex. Although transmission risks are substantially higher in the early acute phase of HIV infection, in the presence of other biological co-factors such as STIs, and can vary greatly between individuals, epidemiological studies have determined that the per-contact risk of acquiring HIV through unprotected receptive anal sex with an HIV positive partner is roughly 0.5% (note that this is a population average; some people can and do become infected through their first episode of unprotected anal sex). Conversely, if an individual receives an HIV infected blood transfusion, transmission is likely to happen *on average* 90% of the time (CDC, 2005).

It is also important to understand that while using condoms for receptive anal sex reduces the probability of HIV infection by a factor of around 95%, it does not eliminate it entirely. NZAF has always said that even with condoms, there is a very small residual risk of HIV transmission if a condom breaks, and there is an even smaller HIV risk through oral sex under rare circumstances.

The flipside of this is that non-penetrative sexual activities that are frequently practiced by MSM such as mutual masturbation entail such negligible risks of HIV acquisition that they can be disregarded as mechanisms of HIV transmission. MSM in New Zealand who only engage in these activities are not subject to donor deferral under the new proposed NZBS policy, and will be able to donate blood.

The strategic objectives of the New Zealand Blood Service (NZBS) versus the New Zealand AIDS Foundation (NZAF), and the different tactical responses to achieving these goals

Because of the issues outlined above, the NZBS and NZAF have different objectives, and different approaches to reaching these goals.

The NZBS is charged with eliminating any risk of blood contamination by HIV and other transfusion transmissible infections. The strategic goal for NZBS is accomplished by a combination of high risk donor deferral, biological testing of donated blood, and careful management of the blood banks post-donation. None of these are completely effective on their own, but together they provide near complete protection of the blood supply for known pathogens.

An important reason for placing such a “high bar” for the blood supply is the very high probability of infecting someone through one act of blood transfusion as mentioned earlier. That is, the NZBS’s combination of cautious donor deferral and rigorous biological screening is proportional to the harm caused if their objectives are not achieved.

In contrast, one of NZAF’s two central goals is to prevent the sexual spread of HIV through the MSM population. A 100% *risk elimination* strategy is not necessary to achieve this, because the aim is to reduce the population-level risk of HIV transmission (what is called the “reproductive rate”) below a certain threshold, and *risk reduction* via condom use for anal sex is sufficient to do this. This is because although there are still very small transmission risks involved in anal sex with a condom (if it breaks) and also very rarely through oral sex, the consequences of these small residual risks are not nearly high enough to result in epidemic-level HIV transmission.

NZAF’s other central goal as it relates to MSM is to provide effective and practical safe sex advice. At an individual level, NZAF’s guidelines concerning “safe sex” (e.g. condom use for anal sex) will also be sufficient to remove virtually all of the already small transmission risk entailed in that activity *each time it is performed*. Note however that “virtually all” is not the same as “all”.

Condoms break very infrequently, but they do sometimes. And while oral sex is very low risk for HIV infection, it is not completely risk free.

Whereas most sexually active MSM will be comfortable running a risk-reduction approach that provides this magnitude of protection, the safety of the blood supply requires 100% elimination of risk. In other words, safe sex is sufficient to both considerably reduce personal risk of HIV infection, and will be sufficient to end the HIV epidemic among MSM if it is practised consistently by everyone, but it is still too low a bar for the protection of the blood supply.

An equivalent “100% risk elimination” position for NZAF would be to advise MSM to abstain entirely from all anal and oral sex. Complete risk eradication is not realistic or attainable, because oral and anal sex are important sexual activities for the majority of gay and bisexual men. We are also fortunate that complete abstinence is not required to stop the epidemic spread of HIV among MSM.

Nor can the different strategies of i) protecting the blood supply and ii) HIV prevention among MSM fail to take account of the difference in free will involved in each of these enterprises. Gay and bisexual men have a choice about whether or not they are sexually active (i.e. move from zero HIV risk to some HIV risk), and the degree of risk they are willing to run when having sex (from minimal risk during safe sex to high HIV risk during unprotected anal sex). People who are in urgent and/or long-term need of blood transfusion are unable to exercise a parallel set of personal choices, thus the need for the “high bar” of risk elimination for the blood supply in a just society.

Drawing these three issues together

We do not believe it is possible to avoid the implications of the three issues discussed above. Because of the combined effect of the much higher risk associated with receptive anal sex than vaginal sex, and the much higher endemic levels of HIV infection among gay and bisexual men, MSM remain at very much higher risk of potential HIV infection than heterosexual people in New Zealand.

This same general point about heightened risk for MSM has been made over the past month in internationally reported media comment from three independent and experienced HIV epidemiologists – Dr James Chin (UCLA), Dr Elizabeth Pisani, and Dr Kevin de Cock (WHO). Note also that in 2007 the number of new HIV diagnoses in MSM where infection occurred in New Zealand was 2.5 times higher than that reported in 2000 (AIDS Epidemiology Group, 2008). The local epidemic of HIV transmission amongst MSM has without question worsened over the last seven years.

This means that the very small risk an individual runs even when engaging in *protected* anal sex in New Zealand in 2008 is also now somewhat higher than it was in 2000.

Putting this into even sharper perspective: In New Zealand, the average 40 year old gay man who has one new male sexual partner a year will be at significantly higher risk of acquiring HIV than a 20 year old heterosexual woman who has 5 different casual partners over the space of a year with heterosexual men of a similar age to herself. We believe that the ongoing lack of appreciation of this epidemiological reality can explain some people’s confusion about the blood donor issues in relation to equality arguments, and may also help to explain why some gay men do not understand why it is important for all MSM to use condoms for anal sex in all sexual encounters if they are to successfully avoid HIV throughout their whole life.

Those who claim for example that there is no underlying difference in HIV risk between MSM and heterosexually-active individuals in New Zealand need to explain why a locally-acquired heterosexual HIV epidemic has not materialised here over the last 25 years. This, despite the tendency for MSM to use condoms far more often during sex with casual and regular sexual partners than do the majority of heterosexual men and women. We have enjoyed considerable success at limiting the impact of the HIV epidemic among MSM in New Zealand to date, but this has not been achieved by pretending that MSM are no different in our vulnerability to infection.

To recap: Not everyone is equally at risk from HIV infection. HIV is a virus that *does* in fact “discriminate” between people, based on their practices and their underlying prevalence of infection.

Therefore, population groups who engage in activities that involve a greater risk of HIV transmission, and who also have high levels of HIV prevalence, will inevitably pose a greater risk to the blood supply.

As a result, blood safety policy must take account of the prevalence of HIV in specific population groups as well as individual risk behaviours, and the only practical way to do this is by epidemiologically-based donor deferral.

But surely all we need to do is test the blood from all donors?

Biological testing of the blood donor pool identifies infections in almost all cases (see pp.34-39 of the *Final Report*). One circumstance where testing may miss an infection is when a person has been recently infected (“incident” infections) and the individual is said to be in the “window period”. For this reason, groups who have recently engaged in activities that place them at higher potential risk of infection are deferred for one year, which is usually long enough to detect these incident infections.

A second circumstance where biological screening is not completely foolproof is that long-standing undiagnosed infections (called “prevalent” infections) may be identified by the tests but then subsequently mishandled by human or system error. This could mean for example that an infected donation was identified, but then inadvertently transfused into a blood recipient. It is also possible that novel variants of a virus are not as effectively detected by the conventional tests used. In order to protect against this possibility, blood safety authorities around the world also defer groups where there is a higher likelihood of prevalent infections, including MSM in relation to HIV. The purpose of this is to dissuade groups with high prevalent infections from presenting for donation, since the aim is to *not* have these higher-risk group’s blood in the blood safety system at all. Testing, on its own, is therefore insufficient to protect the blood supply, but must be considered as a part of a safety process that also includes donor deferral and blood bank management.

We’ve discussed population groups, but what about individual cases?

Some individuals will no doubt feel that this is still unfair to them personally because they have been, for example, exclusively monogamous, and so they consider that they present no HIV risk at all if they donate blood. It must be acknowledged, however, that on occasions HIV transmission does happen among coupled MSM who genuinely believe that their relationship is sexually monogamous and/or their partner is HIV negative. At the point of blood collection, it is practically impossible to verify by questionnaire or interview whether a relationship involving two

individuals has in fact been mutually exclusive for five years, and whether both partners are indeed HIV negative as they believe, especially when one of the partners may not be present. For this reason, the goal of 100% protection of the blood supply requires that the recommendations for donor deferral cover all MSM who have engaged in anal or oral sex in the last five years, regardless of relationship status.

Other MSM who, in addition to believing they are in a mutually exclusive relationship, also use condoms when they engage in anal sex with their partner, may feel even more aggrieved about the deferral. These individuals have been following NZAF's safe sex guidelines about condom use for anal sex in all circumstances. Here we would point out again that there is still a very small risk of HIV transmission if a condom breaks and even more rarely through oral sex. While their behaviour satisfies NZAF safe sex guidelines, and will almost certainly protect them from HIV, the bar must of necessity be higher for the NZBS.

Another way to look at this is that although an individual might use condoms with every single partner, his personal HIV risk is still going to be dependent on the prevalence of HIV infection among his sexual contacts. This incidentally means that every MSM has an interest in promoting condom use among his peers as well, since MSM community-level HIV prevalence will decrease over time the more that condom use is practiced.

Similarly, individuals who have regularly received HIV negative tests, or have had negative HIV tests very recently, may feel completely confident about their HIV negative status. This will greatly reduce the probability that the individual is HIV positive, but does not eliminate it if anal or oral sex, protected or not, has occurred since that last test.

In fact, recent research has found that some MSM who possess strong beliefs about being HIV negative have in fact been living with undiagnosed HIV infection. In the UK, 41.2% of MSM infected with HIV were unaware of their infection, and the majority of these (62.3%) thought they were HIV negative (Williamson et al., 2008). In the US, 77% of young MSM with HIV had unrecognised infections, and 59% of these perceived themselves to be at low risk of infection (MacKellar et al., 2005). In the context of blood donation, these findings clearly exemplify the problem of relying on an individual's convictions about their own personal lack of risk.

These issues also illustrate why the NZBS defers people based on their membership of broad, epidemiologically-determined groups rather than on an individual case-by-case basis. Individually-tailored deferral decisions would be impractical to implement at the point of blood collection, as it would inevitably involve lengthy, intrusive questioning about risk activities for different pathogens (not just HIV), and even then would not be able to verify the safety of certain behaviours. Some individuals might also become uncomfortable or embarrassed and lie about specific acts.

Instead, the NZBS strategy is to develop clear guidelines as to who should be deferred from blood donation and to communicate these widely. The purpose of this is to encourage groups at higher potential risk of HIV infection to self-defer *prior* to going to the blood donation clinic, i.e. to *not* present in the first place. The NZBS strategy consequently requires the formulation of simple, broad deferral criteria that inevitably cannot take account of all individual variation (note for example that vegetarians who lived in the UK between 1980-1996 are still deferred for life, even though they are not at risk of CJD). Group-based rather than individual-based deferral is standard practice around the world with the exception of Italy (see p.4 of the *Final Report*).

Human rights issues

We believe that human rights and discrimination are important considerations when designing blood deferral criteria. Gay and bisexual males deserve policies that are fair and which do not unjustifiably curb the contribution to society many want to make in the form of blood donation. In particular, the deferral period for MSM who engage in anal or oral sex should be the same as that for any other groups who pose equivalent risks to the blood supply.

It is therefore important to acknowledge the changes made to donor referral policy as recommended recently in the *Review*. For gay and bisexual males, these include a reduction from 10 years deferral following any sex with a male down to 5 years following anal or oral sex. This is now the same as the deferral period for heterosexuals who have lived in countries with a high HIV prevalence (previously such people were deferred indefinitely if they came to New Zealand with their partner, otherwise for one year). The recommended changes also enable MSM who have only engaged in mutual masturbation or other non-penetrative sexual activities in the previous 5 years to donate without any deferral at all.

If accepted, these recommendations will result in the NZBS policies being updated to reflect current local and global realities, and position New Zealand as having one of the least restrictive blood donor deferral criteria in the world, while still ensuring the safety of the blood supply (see Table 1, p.20 of the *Final Report*).

This does mean that the majority of MSM in New Zealand will continue to be subject to deferral and will not be able to donate. While there is no doubt this treats some MSM differently to other individuals, all anti-discrimination law is subject to justified limitations. In this instance, discrimination against men who have had anal or oral sex with another man in the last 5 years, with or without condoms, is justified for the epidemiological and practical reasons outlined in the *Review* and summarised in this discussion paper, not because of some arbitrary prejudice.

Another example of a justified limitation might be useful here. Barring a person with sight impairment from employment in the airline industry is discriminatory, but is clearly far more justifiable if they were seeking a position as a pilot than if they were seeking a position as a baggage handler. The difference is that sight impairment is highly relevant to the pilot fulfilling their objectives (to fly and land the plane safely), and there are different consequences involved if the pilot fails to execute his/her objectives (many people will lose their lives), compared to a failure of typical duties by the baggage handler. Discrimination due to sight impairment in the employment of pilots therefore does not constitute *illegal* discrimination, but is justified in the context in which it occurs.

It is also important to reiterate that the 5 year deferral is specific to a gay or bisexual man's sexual behaviour, not their sexual orientation or identity. Furthermore, it is only certain behaviours that result in deferral, namely anal or oral sex, with or without condoms. Gay and bisexual men who have only engaged in sexual activities that carry essentially no biological risk of transmission (such as mutual masturbation or kissing) in the past 5 years, or who have not engaged in sexual activity at all, will now be free to donate blood. The clearest expression of the fact that deferral is not based on sexual orientation is that lesbian women have no deferral period whatsoever, so long as they satisfy all the other criteria like everyone else.

We therefore believe it is incorrect to describe the *Review* recommendations as “homophobic”, as has been claimed by some. In our opinion, it is alarmingly counterproductive to downplay the

elevated risks MSM have in relation to HIV infection compared to other groups, and by doing so, ignore gay and bisexual men's greater HIV prevention needs.

We should also point out that there are two conflicting interests in play here (the *Final Report* highlights that there is no "right to donate", see p.12). Some commentators seem to be exclusively focussed on the personal wishes of MSM to donate blood. In our view, a significantly more important consideration is the right of those who require blood to receive products that are free from infectious pathogens. To our belief, any offence claimed by MSM who wish to donate blood and are refused is unquestionably outweighed by the fact that people in need of blood products typically have little or no choice, and that the transfusion of contaminated blood is likely to result in their infection.

For these reasons of proportionality, we believe it is illegitimate to accept even a "minimal" risk to the blood supply, and concur with the legal and ethical considerations articulated on pp.49-55 of the *Final Report*. We do not accept that the political claims of gay and bisexual men are best advanced by increasing the real and serious risk of harm to vulnerable people, who rely on a blood supply completely free from HIV. We also believe that any MSM who deliberately bypasses the deferral safeguards is unreasonably imposing their own personal HIV risk choices onto blood recipients, without the recipient's consent, thereby placing these individuals at an increased risk of HIV infection by that action.

Conclusion

The NZAF Research Unit supports the main recommendations of the Review Group. We believe that the recommendations strike an appropriate balance between the desire to donate and the rights of blood recipients to receive blood products that are free from HIV. We furthermore believe that the new donor deferral criteria are justifiable and are based on the most up-to-date scientific data that are available. We also note the final recommendation that the blood donor criteria should be reviewed again in five years time.

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Disclaimer: Tony Hughes, NZAF Research Director was a member of the Review Group. His position on that Group was not as an organisational representative of NZAF. This strategic analysis paper is an expression of the views of the NZAF Research Unit (Tony Hughes and Peter Saxton), and are not necessarily the perspectives of the Review Group.