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REPORT TO THE NZ BLOOD SERVICE:

BEHAVIOURAL DONOR DEFERRAL
CRITERIA REVIEW

February 2014

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Preface

In 2013 the New Zealand Blood Service (NZBS) asked an independent review group, of similar constitution to the group that undertook the previous review in 2008, to re-examine the current criteria for the deferral of people from blood donation based on sexual behaviour.

A draft of the review report was made publicly available in November 2013.¹ At that time, it was also distributed to specific individuals and agencies for comment and two consultation meetings were held. Following consultation feedback, a draft final report was prepared that gave due consideration to the matters raised through the consultation process. This revised review document has been reviewed by Dr Roger Dodd, Vice President Biomedical Services Research and Development, American Red Cross, for scientific accuracy and comment on the appropriateness of the recommendations. Comments from that review have been incorporated in the finalised report to the NZBS.

This final review report is submitted to the NZBS Board. That Board may seek formal legal review if appropriate. The decision whether to accept the recommendations of the review group is for the NZBS Board and subsequently the regulator, Medsafe. The review group members are advisors to the decision makers.

CONSULTATION: ISSUES AND RESPONSES

This report was first distributed in draft form in November 2013. We thank the groups and individuals who commented on the draft and who attended the two consultation meetings held in Auckland and Wellington. The consultation raised issues that were further considered by the review group and some amendments and clarifications have been made to the final report. The particular matters raised and how they have been addressed are described below. We were constrained by our terms of reference to restrict our review to deferral on the basis of sexual behaviour. Some submissions on, for instance, deferral on the basis of risk of variant Creutzfeldt-Jakob Disease (vCJD) were outside the scope of our review and have not been considered further.

1. There was concern that in questioning potential donors, especially men who have sex with men (MSM), about broad behavioural risks, many individuals would be deferred despite being at little risk. The alternative proposed was a risk-based assessment of actual behaviours. In particular the recent (June 2013) resolution by the American Medical Association (AMA) was brought to our attention. The report

¹ Available at

http://www.google.co.nz/url?sa=t&rct=j&q=&esrc=s&source=web&cd=2&ved=0CC4QFjAB&url=http%3A%2F%2Fwww.nzblood.co.nz%2Fcontent%2Fdownload%2F4053%2F53455%2Ffile%2FConsultation%2520Document%2520for%2520Donor%2520Deferral%2520Criteria%2520Nov%25202013.pdf&ei=2nrgUsljHYG-kAXU5YH4Aw&usq=AFQjCNG-Vi5Id_Tt1Jl_fy30hvDRFMKjPQ&bvm=bv.59568121,d.dGI

on the resolution included a statement by Dr William Kolber urging the FDA to apply deferral to donors “according to their individual level of risk”. We have examined the AMA document. The resolution (514) expresses support for the use of “rational, scientifically based deferral periods that are fairly and consistently applied to donors according to their level of risk rather than being based solely on sexual orientation”. The resolution responds to the current policy in the US which is a permanent deferral for any male-to-male sexual contact since 1977. There is a brief background to the resolution on the AMA website, but no detailed policy has been developed. Hence the document provides no evidence to support any specific questioning about individual risk that could aid our decision-making.

Our current proposal for deferral from blood donation of men who had oral or anal sex with a man in the previous 12 months is already based on risk behaviours and not solely on sexual orientation. Hence it is already congruent with the AMA resolution. (The issue of whether the question should continue to include deferral on the basis of both oral and anal sex is discussed below, 4.)

We have already considered, and rejected, assessment of individual risk based on number of sexual partners among MSM for the reasons given in the report. First, modelling studies in Australia show that the risk of *not detecting an HIV infection in donated blood* is substantially greater (in the order of 60 times) for an average MSM who reports himself as monogamous than for an average heterosexual with one new partner, due to the substantially higher risk of an unknown HIV positive partner (i.e. the partner’s HIV status is unknown). Second, there are disadvantages to in-depth questioning because it is intrusive and there is evidence that some MSM who do not comply with donor deferral already find questions about sexual risk too personal.

Any further change to make the deferral questions more specific will be dependent on research showing that such questions can reliably distinguish people at higher risk from those at little increased risk, and that the questions are acceptable. The FDA and Department of Health and Human Services have been reviewing the United States behavioural deferral criteria for MSM and have commissioned a number of studies to assess the risks of moving away from lifetime deferral, including a pilot operational study to assess alternative deferral criteria. These studies may provide relevant information in the future.

2. Many MSM who are at present deferred from donating blood would welcome the opportunity to donate. One submission noted that in New Zealand it is seen as a civic duty and an important part of being a full citizen. Two issues follow from this. The first is that there is considerable peer pressure to donate and it is embarrassing to be deferred particularly in a work place situation. We concur with this, but note that even detailed questioning to identify men at higher risk – if this were able to be done reliably - would leave some MSM unable to donate. It is not possible to get around this problem while any deferral exists. It must be ameliorated by the

sensitive attitudes of the NZBS staff and stressing to MSM who are deferred that there are many reasons for deferral. Secondly, people who are deferred for any reason may still be able to contribute to the NZBS in other ways, for instance as volunteers to help with recruitment drives.

3. It was suggested that MSM should be encouraged to participate in blood donation as a useful way of getting men to test themselves more regularly, given that all blood is tested for HIV anyway. This is at odds with the policy of the NZBS which is to discourage people from donating if they think they need an HIV test. We concur with the NZBS position. This is because the NZBS is not set up with appropriate facilities for follow up and counselling for people who have a positive result. It is also the case that people who think they need an HIV test may have a recent HIV infection that is in the window period, that is they may test negative for HIV despite being infectious, and may transmit HIV to a recipient. This is illustrated by a recent situation in Japan where a man donated in the window period and at least one recipient was infected. The man subsequently disclosed that he attended in order to have an HIV test.² Taking a small sample initially would not get around the problem.
4. The most vexed issue we have contended with is whether oral sex between men should remain a basis for deferral. One submission asked us to consider the scientific evidence further in determining whether oral sex with a condom, and possibly without, should be removed as grounds for deferral.

The main reasons to consider this change seriously are, first, that it is potentially discriminatory to defer MSM who practice lower risk activities from donating if their risk of acquiring and hence transmitting a transfusion-transmissible infection (TTI) is of the same order as heterosexuals who are not deferred. Such a change would also satisfy the ethical imperative to remove discrimination against donors if there is no meaningful increase in recipient risk. Second, compliance with deferral criteria might be higher if men perceive that the criteria are scientifically based and in accord with current safe sex guidelines for MSM. There is also the concern that, by extension, the entire deferral criteria might be seen as discriminatory and hence some MSM might not comply with any part of the deferral.

The epidemiological evidence for transmission of HIV (the most important relevant TTI) by oral sex is sparse. A systematic review has concluded that there are insufficient data to estimate precisely the risk but that it is low though not zero. One problem with the studies is that the risk may be over-estimated because men are less likely to disclose anal sex than oral sex because of social desirability bias or recall bias. In one such study 20 men initially denied anal sex in written questionnaires but 11 subsequently disclosed it in interviews.

To compare the risk of an HIV infected donation from a heterosexual practicing

² <http://www.promedmail.org/direct.php?id=20131201.2085239> Accessed 9.01.2014

vaginal sex with an MSM practicing oral sex, the prevalence of HIV in the respective populations, and the infectivity of HIV by vaginal sex and oral sex are relevant. In New Zealand the prevalence is in the order of 40 to more than 100 times higher among MSM than among heterosexuals who are not deferred. Hence the comparative infectivity would have to be at least 40 times lower for oral sex to make the risks comparable. This is plausible, given the estimates of infectivity from oral sex from individual studies, but uncertain because of the paucity of reliable information.

Hence, the epidemiological evidence suggests it is possible that MSM who have only had oral sex have a similar risk of transmission of HIV as heterosexuals who are not deferred.

Although we consider that the risk of HIV is very low, it is mainly other considerations that have made us decide not to recommend a change at this time. The reasons are uncertainty about the actual risk, uncertainty about the effects on compliance because of the framing of the question, the risk of other sexually transmitted infections (STIs), the precautionary principle, and the conservative nature of Blood Service activities.

Our view is that, in the context of such uncertainties, it is reasonable to give priority to minimising any potential infection risk to blood and blood product recipients, and that retaining the deferral of MSM for oral and anal sex is most likely to do this.

Executive Summary

BACKGROUND

The New Zealand Blood Service (NZBS) asked a group to review the current criteria for the deferral of people from blood donation based on behaviour. This relates to sexual behaviour which may put people at risk of transfusion transmissible infections (TTIs). There may be some risk to recipients of blood and blood products if these people donate blood. The review group is independent of the NZBS. Dr Peter Flanagan, Medical Director NZBS, provided expert input into the review, but did not participate in the decision-making.

RELEVANT ISSUES

The NZBS was established by the Health Amendment Act 1998. In discharging its responsibilities it is required to take all reasonable precautions to ensure that blood is safe for use. It is also required to meet a number of international standards. The first review of donor deferral criteria was undertaken in 1999 and the second in 2008. Regular reviews are required because of changes in the operation of the NZBS and in the external environment. In addition, questions continue to be raised about the justification for the current donor deferral criteria.

There are several steps involved in ensuring the safety of blood. Prior to presentation at a blood service people may self-defer. Self-deferral occurs when a person is aware the NZBS would decline their offer to donate blood. Once a potential donor presents there is a three-tier combination approach to safety: a questionnaire on behaviour followed by an interview, tests that are highly sensitive and specific carried out on the donated blood, and processing steps (including leucodepletion) that reduce the infectivity of some agents.

The reason for asking a potential donor not to donate at this time (“donor deferral”) is to reduce the risk that an infectious agent will be transmitted in a blood donation. The specific reasons given in the 2008 report were: (a) because if they have an infection in its very early stages it will not be detectable by testing (the window period); (b) because the test may, very rarely, miss a longer-standing infection which is present or the blood service system may inadvertently fail to remove such an infected donation from the system; and (c) because of the possibility of unknown or untested-for infectious agents.

At present HIV, hepatitis B and hepatitis C are the main sexually transmitted infections that pose a potential risk of transfusion transmission. In New Zealand HIV is mainly sexually transmitted, with a higher occurrence among men who have sex with men (MSM). Hepatitis C is mainly transmitted by injecting drug use, but sexual transmission among MSM has been documented. Hepatitis B can also be sexually transmitted. For HIV, the risks of transfusion have in the past related to both new window period infections (“incident infections”) and established infections (“prevalent infections”). The risk for the latter arose because of

potential errors in testing or in the quality system. Hence behaviours that place individuals at risk of both incident and prevalent infections were relevant.

In 2008, the previous review group recommended people should be deferred for five years from donating blood: after last male to male sex (reduced from ten years), or sex work overseas, or if they had lived in or come from an area with high HIV prevalence. People were deferred for one year after sex work in New Zealand. These recommendations were accepted and implemented by the NZBS.

Deferral for other reasons apart from sexual behaviour is already in place in New Zealand. Approximately 20% of all people who first present to donate blood are deferred. For instance, because of a theoretical risk of variant Creutzfeldt-Jakob Disease (vCJD) and the lack of a diagnostic blood test, people who resided in the United Kingdom (UK) during the time of the epidemic of Bovine Spongiform Encephalitis (BSE) are asked to defer from donating blood. This review does not address these wider issues. Nevertheless this deferral does illustrate the current level of precautions taken to protect the safety of the blood supply. In addition, potential donors will be deferred following activities such as ear piercing or tattooing. Many individuals are deferred for their lifetime if they are known to have certain conditions, if they have received certain treatments in the past, or for other medical reasons. Donors are usually deferred to reduce the risk of TTIs to a recipient and also sometimes to protect the potential donor.

People who have injected drugs (PWID) were not included in this review as internationally there has been consensus that the potential risks of known and unknown TTIs from current and past injecting drug use are unacceptably high, and there are no data on how a change in deferral time would impact on safety. Almost all countries with modern blood services have a permanent deferral for anyone who has ever injected drugs. Nevertheless some people who have injected drugs in the remote past are likely to have little increase in risk, and PWIDs are a stigmatised population. Thus, more data on the risks associated with blood donation in this group will be welcome and may lead to a future change in lifetime deferral.

A number of relevant matters that have occurred over the last five years have been considered in reviewing the criteria. These are: the impact of the last decision on the NZBS and on potential donors and recipients; advances in donation testing and handling; clarification of estimates of risk of HIV transmission to donors related to incident (window period) infections versus prevalent infections; current epidemiology of HIV; evidence from countries that have reduced their deferral periods for MSM; further consideration of ethical issues; opinions of MSM on deferral and the importance of compliance; and the context of human rights law.

The options we chose to consider were: to continue with the same deferral periods on the basis of sexual behaviour; to reduce the deferral periods to 12 months or 6 months; to lengthen the deferral periods; and to further specify male-to-male sexual behaviour that should be subject to deferral.

PROPOSED CHANGES TO THE DEFERRAL CRITERIA AND RATIONALE

Maintaining the safety of the blood supply, while at the same time interfering as little as reasonably possible with the rights and freedoms of potential donors, is the objective of the decision-making. Any restrictions must be rational and proportionate.

The review group recommends that the deferral periods for MSM, heterosexuals from countries with high prevalence of HIV, and all sex workers be changed from 5 years to 12 months.

In considering changing the deferral for MSM to 12 months we have taken particular account of: advances in donation testing and handling, such that errors have now been virtually eliminated from the system; new modelling studies that have identified the current risk of HIV in advanced Blood Services as almost entirely (95%) from window period infections; the reported experience of Australia which has had a 12 month deferral for more than 10 years and no identified transmissions of HIV or other relevant TTIs and indications of no worse compliance; and the apparent high compliance with current deferral criteria in New Zealand.

In addition, the views of MSM gained in other jurisdictions show that knowledge of the rationale for deferral is important and may improve compliance. The rationale for the previous five-year deferral was relatively complex, though it was explained in the previous report, relating to a risk of both window period infections, and to prevalent infections through test or quarantine release errors. The latter can now be considered negligible, and a 12-month deferral – based on the length of the window periods for the relevant infections plus a cautious margin of error – is easier to explain.

One of the alternatives we considered was a 6-month deferral, as has recently been recommended in Australia (though it has not been accepted by their regulatory authority, the Therapeutic Goods Administration [TGA]). We have decided against this largely on the basis that there is no evidence from either how it would work in practice, or from modelling, and there is less margin for error in mis-judging time since last sexual contact.

The other alternative was further specifying sexual behaviour that should be subject to deferral. In 2008 we rejected this approach because there was no research showing that such questions can distinguish people at higher risk from those at little increased risk. Since that time, no such research has been published. In addition, modelling studies show that the risk of *not detecting an HIV infection in donated blood* is substantially greater (in the order of 60 times) for an average MSM who reports himself as monogamous than for an average heterosexual with one new partner, due to the substantially higher risk of an unknown HIV positive partner. There are also disadvantages to in-depth questioning because it is intrusive, and there is evidence that some MSM who do not comply with donor deferral already find questions about sexual risk too personal. Furthermore, people are not reliable at assessing their own risk. A recent survey in New Zealand found that most MSM

who had undiagnosed HIV infection believed that they were definitely or probably uninfected, and many had had a recent negative HIV test.

Deferral for either oral or anal sex has been retained because, though the risk of HIV transmission by oral sex is very low, it is uncertain, and other considerations caution against a change. These are uncertainty about the effects on compliance because of the framing of the question, the risk of other STIs, the precautionary principle, and the conservative nature of Blood Service activities. Although the information is limited, removing the oral sex deferral appears more likely to increase the risk of TTI transmission than to reduce it. In this situation, a precautionary or conservative approach to blood safety argues for staying with the oral sex deferral.

For heterosexuals and sex workers from countries with higher prevalence of HIV, the relevant evidence is similar to that mentioned above in relation to MSM. As there is now a negligible risk from missing established or prevalent infections, a longer deferral period than 12 months cannot be justified. A change to a 12-month deferral for all people who come from, or who have lived in, areas of higher HIV prevalence, and all sex workers, also simplifies the process of donor selection.

In 2008, the possibility of unknown or untested-for sexually transmitted TTIs was part of the rationale for a longer deferral period, with expert opinion suggesting novel infections would be diagnosed within five years. We have reconsidered this issue in the light of the new infections which have emerged since that time. In addition, a review of emerging infections has noted no consistent pattern to predict emergence and magnitude of threats to blood safety. These facts, together with the current intensive surveillance for emerging infections and the decisions of Australia and the UK not to base deferral periods for MSM on risks of unknown TTIs, has led us to decide that keeping a five year deferral period on this basis is not proportionate.

RECOMMENDATIONS

Recommendations on deferral criteria

Men who have sex with men

It is appropriate to have ongoing exclusion based on specific sexual behaviour. The current deferral period for men after having had sex with a man should be shortened to 12 months. The stipulation that this applies to oral or anal sex, with or without a condom, should be retained.

Heterosexuals from geographical areas with a high prevalence of HIV

The deferral of heterosexuals who have lived in or come from an area with a generalized epidemic of HIV should continue but should be shortened to 12 months.

Sex workers

The deferral of current sex workers should continue. The deferral period for people who have engaged in sex work in New Zealand should remain at 12 months, and for those who have engaged in sex work elsewhere, it should be shortened to 12 months.

Sex with someone at higher risk of STIs, especially HIV

A 12 month deferral should be continued for women who have had sex with a bisexual man, men or women who have had sex with a person who carries the hepatitis B or C viruses, or with a PWID, a sex worker, a person with haemophilia or related condition who has received treatment with plasma-derived clotting factors at any time, or with a person who lived in or comes from a country with high HIV prevalence.

Amendment of one other related deferral criterion is recommended. Question 1 of the Health Questions states “You must never give blood if you or any of your current (**or past**) sexual partners have (had) AIDS or a positive test for HIV” [emphasis added]. The permanent deferral of people with current sexual partners with HIV is appropriate, but the permanent deferral for people with past sexual partners with HIV should be shortened to 12 months since last sexual contact, in line with the other recommendations. Nevertheless, it should be made clear that anyone who has had sex with someone with HIV and has not been tested subsequently should not donate.

Recommendations on communication with the relevant populations

Advice on effective communication tools to improve overall compliance with the deferral criteria, and to explain the reasons for their ongoing use, was given at the time of the 2008 review. Further recommendations for 2014 depend partly on an evaluation of the current communication methods. The review group recommends that:

- Public information to inform people of the new criteria and to enable self-deferral among MSM, sex workers, and people from geographical areas with high HIV prevalence should be developed, extending the approach already used by NZBS.
- Improvements in the questionnaire for clarity and understanding should proceed.
- The issue of translation of the questionnaire into languages relevant to the increasingly diverse New Zealand population should be considered again. We appreciate that potential donors must be able to be interviewed and that it may be impracticable to have specialist nurses available who can speak the relevant languages. Nevertheless interpreters are used in many other areas of the health system.

Recommendations on research

The most important issues are acceptability and compliance with the deferral criteria. Compliance depends on understanding the deferral criteria, agreeing with them sufficiently, and feeling comfortable enough to disclose the risk behaviour. Surveys of MSM on knowledge and attitudes to deferral, and of blood donors asking about compliance with deferral criteria and reasons for non-compliance, would be valuable.

While excellent information is available for MSM on sexual behaviour and HIV risk, and risk of other STIs, there is a paucity of information on heterosexual behaviour and on sex work. The Ministry of Health's proposed national survey of sexual and reproductive health should include questions about sex work, for both workers and clients and should provide comparable data on sexual behaviours among MSM and heterosexuals; and more information on STI risk among sex workers would be valuable. The review group has already raised these matters with the Ministry of Health.

Recommendations on future review of deferral criteria

These criteria should be reviewed again when there is information which might materially affect future decisions.

Section One

1. BACKGROUND AND PROCESS

Background

Blood transfusion emerged as an essential part of medical care for treating blood loss and deficiencies during the 20th century. The emergence of HIV and recognition of its ability to be transmitted by transfusion during the early 1980s is recognised as a pivotal point in the development of modern transfusion medicine.

In the blood donation system, the most vulnerable people are the blood recipients. Decisions about blood safety need to be made with the best interests of the recipients in mind. Blood recipients face an “imposed risk” concerning safety and find themselves in a position of having to trust decisions on blood safety made by others, as they frequently have no alternatives to transfusion. If blood is infected then the risk of acquiring an infection when exposed through a blood transfusion is very high. For example, the risk of transmission of HIV from an infected blood transfusion is estimated to be 9,000 per 10,000 exposures.

There have been instances in which recipients have become infected through blood transfusion. For example, in New Zealand many recipients were infected with hepatitis C prior to the implementation of hepatitis screening of all donors in 1992. As a consequence, most people with severe haemophilia over the age of 25 years have had chronic hepatitis C. In Canada in 1997 a Commission of Inquiry on the Blood System reported on events that led to more than 1,000 persons in Canada being infected with HIV through the blood supply during the late 1970s and 1980s. Following events such as these, a philosophy of giving priority to safety has underlined how blood services operate internationally. One aspect of this philosophy relates to the precautionary principle, expressed in the statements of Lord Justice Krever³:

- Because safety implies the absence of risk and because risk is inherent in the use of blood and blood products, it can never be said that their use is absolutely without risk and therefore perfectly safe.
- Preventive action should be taken when there is evidence that a potential disease causing agent is or may be blood borne, even when there is no evidence that recipients have been affected.
- If harm can occur, it should be assumed that it will occur.

Today the precautionary principle, which, as applied to blood services is encapsulated in the second and third statements above, has been adopted by internationally recognised blood services.

³ Krever, The Honourable Mr. Justice Horace. Commission of Inquiry on the Blood System in Canada: Final Report. 3 volumes. Ottawa: Government of Canada. 1997.

The interests of the recipients are paramount, and hence the safety of the blood. We all benefit from the security of having a safe blood supply because no one knows when their life might depend on it. In the interests of safety many people are deferred from donating because they might have been exposed to a pathogen that might be transmitted by transfusion. Nevertheless, donating blood is a valued social activity and people should only be deferred from blood donation if there is good and proportionate cause.

The review process

The NZBS has a statutory obligation to keep up with developments and new technologies that relate to the services it provides. In doing so, the NZBS has an obligation to reassess donor exclusion criteria as developments alter the overall risk/benefit balance for those who donate blood. In addition there have been specific complaints raised about the current deferral criteria which require further consideration. In particular concerns continue to be raised about the justification for the deferral period for men who have sex with men (MSM), and about the rationale for broad deferral categories based on behaviour rather than on specific risk activities.

The first review of behavioural donor deferral criteria was undertaken in 1999, shortly after the NZBS was established. At that time regional policies were reappraised and a national policy developed. The first review group made a recommendation that the NZBS review the policy criteria once it had fully implemented its centralised approach to blood donation testing using its computerised Blood Management system, Progesa. The last District Health Board completed installation of Progesa in 2005, which contributed to the decision by the NZBS to undertake a further review in 2007/2008. Among other recommendations, the 2008 review group recommended that the deferral period for men who have sex with men be shortened from 10 to five years, and the deferral period for those having heterosexual sex with partners from countries with a high HIV prevalence be increased to five years. A further recommendation from the 2008 review was to undertake a similar process five years later, given that new information following changes in international practice was likely to be available. Another review would also provide an opportunity to reflect on the impact of changes made to the deferral criteria at that time. For a full copy of the 2008 review report, see <http://nzblood.co.nz/Give-blood/Donating/Am-I-eligible/Review-of-donor-criteria>

In 2013 the New Zealand Blood Service (NZBS) asked an independent review group of similar constitution to the 2008 group to re-examine the current criteria for the deferral of people from blood donation based on behaviour. This relates to sexual behaviour that may put people at risk of Transfusion Transmissible Infections (TTIs) such that there may be some risk to recipients of blood and blood products if certain donations were used. For this 2013 review, the review group was asked only to comment on deferral periods that relate to sexual behaviours, and not other risks such as injecting drug use.

People who have injected drugs (PWID) were not included in this review as internationally there has been consensus that the potential risks of unknown TTIs from current and past

injecting drug use are unacceptably high, and there are no data on how a change in deferral time would impact on safety. Almost all countries with modern blood services have a permanent deferral for anyone who has ever injected drugs. Nevertheless some people who have used injecting drugs in the past will be at low risk, and PWID are a stigmatised population. Thus more data on the risks associated with blood donation in this group will be welcome and may lead to future change in lifetime deferral.

The process of this review is based on the terms of reference (see Appendix 1). The review group is independent of the NZBS; however Dr Peter Flanagan, Medical Director NZBS, has provided expert input into the review. Dr Flanagan was not present during discussion sessions or when recommendations were developed. The review group has also had expert legal advice from Professor Paul Rishworth, Barrister, Auckland. The names of review group members and the group secretariat/ researcher are in Appendix 2.

A draft of the report was distributed to specific individuals and agencies for comment and two consultation meetings were held. The names of the organisations that were consulted are in Appendix 3. The names of people and organisations who responded during the consultation period are in Appendix 4. Following consultation feedback, a draft final report has been prepared that gives due consideration to the matters raised in the consultation process. This revised review document has been reviewed by Dr Roger Dodd, Vice President Biomedical Services Research and Development, American Red Cross, for scientific accuracy and comment on the appropriateness of the recommendations. Comments from that review have been incorporated in the finalised report to the NZBS.

The final report is submitted to the NZBS Board. The Board may seek formal legal review if appropriate. The decision whether to accept the recommendations of the review group is for the NZBS Board and subsequently the regulator, Medsafe. The review group members are advisors to the decision makers.

2. THE NEW ZEALAND BLOOD SERVICE

The NZBS was established in 1998 by the Health Amendment Act 1998. The NZBS is a Crown Entity (Statutory Corporation) with specific responsibility for the collection, manufacture and distribution of blood products. The specific responsibilities of NZBS are outlined in the New Zealand Public Health and Disability Act 2000 and the associated Gazette notice. The second schedule of the Gazette notice outlines a series of terms and conditions that the NZBS must meet when discharging its responsibilities. These include:

(b) While carrying out the functions as specified in the First Schedule of this authorisation the New Zealand Blood Service shall ensure those functions are carried out safely and to a high level of quality, and shall take all reasonable precautions with a view to ensuring that the blood, controlled human substances, bone, skin and sperm⁴ are safe for use.

(g) The New Zealand Blood Service shall continue to develop relationships with interested parties and consumer groups to facilitate communication, co-operation and community appreciation of the services it provides or arranges for the purposes of its functions under this authorisation.

(h) The New Zealand Blood Service [shall] ensure that it keeps up with developments and new technologies that relate to the services it provides and arranges for the purposes of its functions under this authorisation, and that it fully considers introduction of these developments and technologies.

Blood products

New Zealand is largely self sufficient in blood and blood products. Two main types of blood products are manufactured:

- Blood components:
 - These are derived from single blood donations using simple centrifugal and separation techniques. Component manufacture is undertaken at four sites in Auckland, Hamilton, Wellington and Christchurch.
 - The safety of the components is assured by a combination of donor selection and testing of donations. Testing is undertaken at two sites in Auckland and Christchurch
- Plasma derivatives:
 - These are manufactured from large pools of plasma (7.5-10.00 tonnes). Plasma collected in New Zealand is sent to CSL Behring Australia in Melbourne where it is manufactured into a range of products. These include coagulation factor concentrates used in the treatment of people with haemophilia and Immunoglobulin products used in the treatment of a variety of disorders.
 - The safety of plasma derivatives is assured by a combination of donor selection and testing undertaken by NZBS on the contributing donations. In addition each

⁴ This has since changed and the NZBS is no longer responsible for sperm banking.

product is subject to a number of specific viral inactivation processes designed to destroy/remove any viruses that might be present in the primary manufacturing pool.

Regulation

Blood products in New Zealand are treated as registered medicines and are subject to the requirements of the Medicines Act (1981) and Medicines Regulations (1984). Medsafe is the Regulatory Authority. Regulatory control is achieved through two main mechanisms:

- Standards
 - The Council of Europe Guide to the preparation, use and quality assurance of blood components (CoE Guide) is utilised as a primary external reference standard. NZBS maintains Collection and Manufacturing Standards that broadly align to the requirements of the CoE Guide. Changes to these standards require review and endorsement by Medsafe. Donor selection criteria, including the behavioural donor criteria, are included in the Collection Standards.
 - CSL Behring Australia is required to meet European Pharmacopoeial requirements and also European Medicines Agency Guidance on manufacture. This includes compliance with the EP Monograph on plasma for fractionation. This document refers to the CoE Guide for recommendations on donor selection criteria.
- Good Manufacturing Practice (GMP)
 - Medsafe inspects NZBS manufacturing sites on an annual basis. Manufacturing licences are issued on the basis of the inspection.

The Australia and New Zealand Therapeutics Products Agency (ANZTPA)

The governments of New Zealand and Australia have committed to the development of a joint medicines regulatory system. They intend that this will be achieved by the establishment of the Australian and New Zealand Therapeutic Products Agency (ANZTPA). Current plans are for the new agency to commence its activities in 2016.

Initial efforts to establish a joint regulatory agency were postponed in 2007 as a consequence of concerns relating to the inclusion of complementary medicines in the scheme. A joint statement by both governments in 2011 signalled agreement to progress development of the scheme. Complementary medicines in New Zealand will be excluded from consideration. This may however be re-visited at a later date.

The Minister of Health requires NZBS to support the establishment of ANZTPA. A consultation paper on the proposed arrangements for the new agency was published in January 2013. This contained only limited information on proposed mechanisms for regulation of blood and blood components. It does however seem likely that the current arrangements in place in Australia will form the basis of the systems adopted by the agency. Signals from Medsafe indicate an expectation that standards used in both countries will converge over time.

Information systems

NZBS utilises the MAK e-Progesa information system. This is also used by many other international blood services including Canada, Ireland, Scotland and Australia. The current version of the e-Progesa software was implemented in New Zealand in mid-2012.

e-Progesa is considered a very safe system and it will support a range of developments including an automated electronic donor questionnaire. This will potentially allow a more elaborate questionnaire system to be utilised and may, in some circumstances, remove the need for a face-to-face interview prior to deferral. No firm timelines for implementation have been determined at this stage.

e-Progesa controls all critical information. The Codabar ABC system is used for barcoding of critical steps. This provides a link between the donor, donation and the ultimate recipients of the blood products. Automated interfaces are used for transfer of test results into Progesa which then determines the suitability of individual components based on testing algorithms. Manual intervention and the consequent impact of human error is limited.

NZBS also uses e-Progesa in all DHB Blood Banks. This provides, in international terms, a unique opportunity to control release of individual blood components across the whole national blood network.

Current approach to safety

In line with recommendations produced by the World Health Organization and Council of Europe, the NZBS collects blood and plasma donations only from voluntary non-remunerated donors.

There are several steps involved in giving blood. Prior to presentation at a blood service, many people self-defer. Self-deferral occurs where a person is aware the NZBS would decline their offer to donate blood, so they do not present for donation. Once a potential donor presents to the service, the NZBS uses a tiered combination approach to safety. This involves:

- (1) Selection of potential donors prior to donation
- (2) Testing of all donations

In addition, all blood components provided for direct clinical transfusion in New Zealand are leucodepleted. This process was introduced in 2000 and will effectively remove, or at least dramatically reduce levels of, intracellular viruses such as cytomegalovirus (CMV), HTLV-1 and HHV-8. Pathogen reduction systems are also becoming available for some, but currently not all, blood components. These are not however used in New Zealand at this time. The systems involve the addition of photo-chemicals which when exposed to forms of light effectively inactivate any nucleic acid present in the component. They are effective in markedly reducing pathogens present in the component. Implementation of these systems will require regulatory approval and will be associated with significant cost.

Donor Selection

The general approach used by NZBS to assess donor eligibility is similar to that adopted by blood services internationally. NZBS provides information for prospective donors on its website (www.nzblood.co.nz). This includes copies of the 'Safe Blood Starts with You' leaflet and the Donor Questionnaire. The leaflet was developed in conjunction with the New Zealand AIDS Foundation in 2008 prior to implementation of the current behavioural criteria.

Donor selection involves two main steps:

- The Donor Session Record (DSR).
 - This is a Medsafe-controlled document.
 - It includes the consent for testing of donated blood.
 - The DSR includes a donor questionnaire and declaration. Donors are required to read two leaflets.
 - Safety of Blood leaflet; this provides information on blood borne viruses and the reason for exclusion of 'high risk' donors.
 - Donor information leaflet; this provides information on the process and adverse events associated with donation.
- The Donor Interview
 - Each donor undergoes a confidential interview undertaken by a Registered Nurse each time a donor presents for donation.
 - The interview focuses on responses in the questionnaire and also reinforces key safety criteria through the use of standardised questions.
 - Donors sign the declaration on the DSR at the end of the interview.

Significant efforts have been made to improve the way in which the NZBS engages with prospective donors with possible risks related to sex between men.

- In collaboration with the New Zealand AIDS Foundation (NZAF), NZBS introduced a series of workshops for registered nurses aimed at improving understanding of HIV behavioural risks and communication with prospective donors with possible 'high risk' behaviours. These commenced in March 2009 and are run every two months. The workshops are held at the NZAF Burnett Centre in Auckland. As of August 2013 a total of 195 registered nurses have participated in the workshop.

- A leaflet on '*Blood Donation and MSM in New Zealand – An Explanation*' was developed with the assistance of the NZAF. This is given to all donors who are deferred on the basis of MSM.

Testing of blood donations

The NZBS tests each and every blood donation for a range of infectious diseases. Testing is undertaken using 'state of the art' proprietary test systems that are specifically designed for high throughput sensitive testing of blood donations. The testing equipment and the assays themselves are all approved by a number of international regulatory authorities including the US FDA and the European Union (CE marking). The NZBS donation testing laboratories hold licenses to manufacture medicines issued by Medsafe and are inspected annually against the New Zealand Code of Good Manufacturing Practice. The laboratories are also GMP certified by the Australian Therapeutic Goods Administration (TGA) for serological testing based on compliance with the relevant sections of the Australian Code of GMP for blood and tissues.

Two different but complementary types of tests are used to detect the presence of pathogens (micro-organisms capable of causing disease).

- The first involves serological testing which involves testing blood for the presence of pathogen proteins or for the body's immune response to a pathogen (detection of antibodies). This type of testing has been the mainstay of blood donation testing for decades. Testing for antibodies against syphilis was introduced more than 60 years ago; Hepatitis B surface antigen (HBsAg) in the 1970s, for antibodies against HIV in 1985, and for antibodies against Hepatitis C in 1992. NZBS currently utilises the Abbott Prism Chemiluminescence system for serological testing for viruses. Syphilis serology is undertaken using the chemiluminescence method on the Abbott Architect system.
- The second type of test detects the presence of the pathogen's nucleic acid in an infected donor's blood sample. The NZBS introduced Nucleic Acid Testing (NAT) in 2000 using the Chiron Procleix assay. This assay detected both HIV-1 and HCV RNA. Testing was initially undertaken through semi-automated systems using donation samples in small pools of up to 16 donations. In September 2007 a fully automated system was introduced that enabled testing of all donations individually. The fully automated system also allows detection of Hepatitis B virus nucleic acid.

All blood donations are tested individually. Donations that give initial reactive results are then tested in duplicate. If either or both of the repeat tests are reactive then the donation is designated as repeat reactive. Donations giving an initial reactive result in the nucleic acid test are discarded as are those donations giving repeated reactive results in serological testing. In all instances samples from the donations are then submitted to an external reference laboratory for confirmatory testing. The Institute of Environmental Science and Research (ESR) in Wellington is the primary reference laboratory for NZBS for HIV, HBV and HCV. Syphilis reference work is undertaken by Auckland and Canterbury DHB laboratories. Current testing profiles are shown in Table 1.

Table 1 Current testing profiles

VIRUS	SEROLOGICAL TESTING	NUCLEIC ACID TESTING
HIV	Antibody to HIV 1 and 2. The assay also detects HIV subtype O	HIV 1 RNA tested in individual donation format
HCV	Antibody to HCV	HCV RNA tested in individual donation format
HBV	HBsAg	HBV DNA tested in individual donation format
HTLV	HTLV I/II antibody testing. Undertaken on first time donors only	
Syphilis	Antibody to <i>Treponema pallidum</i> using a chemiluminescence assay	

The Window Period

Almost all infections begin with a very small amount of a pathogen entering a person’s body. It takes time for the amount of pathogen to reach a level that can be detected by a laboratory test; it also takes time for a person’s immune system to react to the pathogen and create specific antibodies. The ‘window period’ can be thought of as the time from when a person became infected until laboratory tests can reliably detect that infection (Figure 1). Although people often have no symptoms of illness during the window period, they are potentially infectious to others – particularly if they donate blood.

The test systems utilised by NZBS are highly sensitive and hence are able to detect almost all cases of established infection. No test is perfect however and there is a possibility that some cases might not be detected. This particularly applies to the early period following an individual becoming infected: the window period. The availability of nucleic acid tests has significantly reduced the length of the window period.

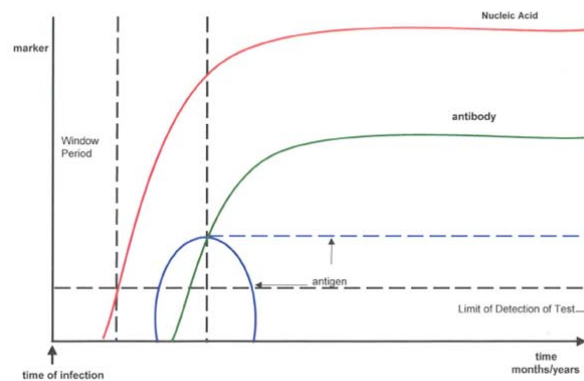


Figure 1 Diagnostic markers during early phase of infection

The average window periods and the upper bounds for nucleic acid tests currently utilised by NZBS, and for HAV (which is not tested for) the incubation period, are shown in Table 2.

Table 2 Window and incubation periods for selected TTIs

Agent	Testing window period (WP)		Incubation period Mean days (range)	Upper WP/Incubation period estimate (days)
	NAT Mean days (range)	Serology Mean days (range)		
HIV	5.6 (5.0-6.4) ⁵	22 (6-38) ⁶		38
HAV			28 (10-50)	50
HBV	23.9 ⁷	HBsAg 38 (95% CI 33-43.7) ⁸		48 ^a
HCV	3.1 ⁷	66 (38-94) ⁹		94
HTLV		51 (36-72) ¹⁰		72
<i>T. Pallidum</i> (syphilis)		28 ¹¹		28

^a This is the upper 99% confidence limit, not the upper 95% confidence limit.

^b IgM antibodies detected at 14 days, IgG antibodies detected at 28 days

Source: Adapted with permission from Review of Australian blood donor deferrals relating to sexual activity. An independent review commissioned by the Australian Red Cross Blood Service. 2012.

The window period has important implications for blood transfusion. Pathogens in blood donations given by infected donors during the window period are not detectable by current test systems (and would not become detectable if the blood is stored – an apparent misconception). Nonetheless the donation will be capable of transmitting the infection to the recipient of the blood. The risk is increased because of the large volume of blood transfused. Thus, people who are more likely to have been exposed to syphilis, HBV, HCV or HIV are required to defer their blood donation. To date, no window period transmissions of either HIV or HCV infection have been documented in New Zealand since testing was introduced for these viruses. However, occasional transmission of HIV and HCV continues to occur overseas. These cases usually occur in blood services using either mini-pool testing or non-proprietary nucleic acid test systems.

Prevalent and incident infections

The implications of recent (incident) infections and established infections (prevalent) in blood donations are different.

⁵ Busch MP et al. A new strategy for estimating risks of transfusion-transmitted viral infections based on rates of detection of recently infected donors. *Transfusion* 2005;45(2):254-64.

⁶ Schreiber GB et al. The risk of transfusion-transmitted viral infections. The Retrovirus Epidemiology Donor Study. *New England Journal of Medicine* 1996;334(26):1685-90.

⁷ Australian Red Cross Blood Service. Updated residual risk estimates for transfusion-transmitted infections, in Medlink March 2011, Transfusion Medicine Services.

⁸ Kleinman SH, Busch MP. Assessing the impact of HBV NAT on window period reduction and residual risk. *Journal of Clinical Virology: the official publication of the Pan American Society of Clinical Virology* 2006;36 Suppl 1:S23-9.

⁹ Pillonel J, Saura C, Courouce AM. Screening of viral markers for HIV HBV and HCV infections in blood donor in France and residual risk of viral transmission by blood transfusion. *Euro surveillance: Bulletin europeen sur les maladies transmissibles = European Communicable Disease Bulletin* 1998;3(7):76-9.

¹⁰ Manns A, et al. A prospective study of transmission by transfusion of HTLV-1 and risk factors associated with seroconversion. *International Journal of Cancer* 1992;51(6):886-91.

¹¹ Seña AC, White BL, Sparling PF. Novel *Treponema pallidum* serological tests: A paradigm shift in syphilis screening in the 21st century. *Clinical Infectious Diseases* 2010;51(6):700-8.

Incident infections are cases of new infections in blood donors that may be undetected if donation occurred during the window period. Because the window period is short (Table 2), most incident infections are identified by the NAT test. However, some will not be detected at the time but become apparent when a regular donor who previously tested negative donates again and is then found to have a positive result in one of the tests. This happens a few times each year and the implications are very significant. There is a possibility that the most recent negative donation might have been given during the window period. NZBS therefore needs to follow up the recipients of this donation in order to determine whether infection has been transmitted. This is called a 'lookback investigation'. The risk increases as the frequency between donations becomes shorter and is a particular concern with regular plateletpheresis donors. These lookback investigations are stressful for the patients involved. Incident infections can also have implications for the plasma fractionation programme. Examples of both types of issue were included in the report of the 2008 review.

Prevalent infections are cases of established infection in blood donors. The implications of established (or prevalent) type infections is different. These infections are reliably identified by NZBS test systems. No system is however perfect and the possibility, albeit rare, that an infected donation might either not be detected in the test, or else be detected but inadvertently released for clinical use must be considered. Such incidents are not known to have occurred in New Zealand. However incidents have been described in the international literature and it is important that NZBS aims to minimise the risk that this might occur. This type of incident relates to system errors. Possible sources of error are discussed below.

1. *The test system may fail to detect the infection even though the marker is present.*

Problems can occur because the machine fails to properly sample the donation, or problems can occur during the test such that a positive result is not obtained. The risk is very low because the modern testing equipment utilised by NZBS includes systems to detect this type of error. The risk is further reduced because NZBS now undertakes two independent tests for each major virus. The likelihood that both tests will fail for any single donation is very low indeed.

2. *The test system may be unable to detect a rare form of the virus*

NZBS test systems are validated before use to ensure that they are able to detect the most common forms of the viruses. This means that well over 99% of cases will be detected by current tests. However, new forms of a virus occasionally emerge. Current test systems may not be able to detect the new variant. Considerable efforts are devoted by the manufacturers of the test systems, and also the regulatory authorities, to monitor the development of these variants and to update the test systems to ensure their detection. An example of this was the emergence of a new variant of HIV in the late 1990s: HIV subtype O. The number of cases of this form of HIV was low, but many test systems initially failed to detect them. Blood services, including NZBS, use HIV antibody tests that are updated when required to detect emergent variant subtypes.

Similar problems have recently been reported for some HIV RNA test systems. HIV-1 is characterized by a high mutation rate and rapid generation of new viral variants. Non-

proprietary assays that detect only one target region have been reported to miss early HIV infections. In Germany three HIV transmissions associated with the use of non-proprietary assays have been reported since 1999. The NAT system used by NZBS is proprietary in nature and targets two different regions of the viral genome. Problems have not been reported with this assay.

3. The test system may detect the infection but the Blood Service fail to take steps to remove the donation from the system

This type of error is called either a 'quarantine' or 'release' error. The risk of this occurring is now very low. NZBS uses a fully integrated IT system (e-Progesa) to track the results of testing and to prevent the release of blood components manufactured from infected donations. Using e-Progesa probably means that the risk of this type of error is lower than in many other international blood services, because e-Progesa is utilised in both NZBS manufacturing centres and also hospital blood banks. This provides, in international terms, a unique opportunity to control release of individual blood components across the national blood network.

Blood services internationally are risk averse regarding blood safety. Systems are defined to identify possible risks and reduce the likelihood of their occurring. NZBS in common with other international blood services aims to reduce the risks identified above by reducing the likelihood that prospective donors with established or prevalent type infections will donate. Use of behavioural donor criteria has been an important component of this.

Donor Notification

The DSR identifies that NZBS will contact the donor in the event that any positive result is found. Donors who are identified as HIV and HCV positive are contacted and individually counselled by an NZBS doctor. Additional specimens are taken and the donor referred to medical services for further counselling and treatment. NZBS maintains records to determine whether a presenting donor has been previously deferred.

3. TRANSFUSION TRANSMISSIBLE INFECTIONS THAT CAN BE SEXUALLY TRANSMITTED

Human Immunodeficiency Virus (HIV)

HIV is transmitted through (a) sexual contact, (b) the transfusion of infected blood or the use of contaminated transfusion/injection equipment, and (c) from an infected mother to her child. For sexual exposure, different acts carry different transmission risks. HIV risk during receptive anal intercourse is approximately 18 times higher than during receptive vaginal intercourse. The risk for oral sex is thought to be low but it is difficult to quantify.

In New Zealand, information on the occurrence of HIV is collected by the AIDS Epidemiology Group. New diagnoses since 1985 have been made using a Western Blot antibody test, and additionally since 2002 through a first viral load test. The number of diagnoses of HIV each year rose from the late 1990s to 2005, was relatively stable until 2008 (at about 200 per year; a rate of 5 per 100,000/year) and has dropped slightly since then. The recent decline is due to fewer heterosexually acquired infections being diagnosed.

MSM comprise the single largest group affected, followed by heterosexually infected men and women. Only a very small proportion of diagnoses has been among PWID or children infected through mother to child transmission.

The annual numbers of diagnoses among MSM by reported place of infection are shown in Figure 2. The number rose in the early 2000s and has been relatively stable since 2005. While some of those diagnosed have been infected several years earlier, there is evidence, based on a history of a previous negative test within the past two years and/or a seroconversion illness, that new infections are occurring.

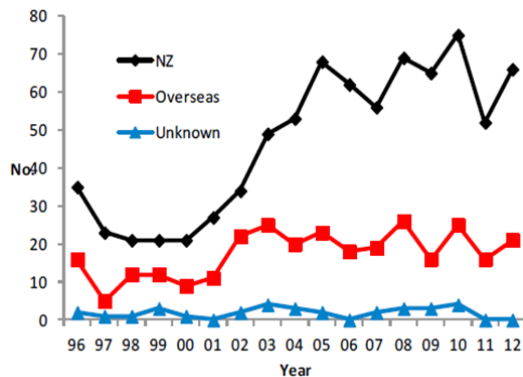


Figure 2 Place of infection of MSM diagnosed by antibody test and reported by viral load since 2002 whose place of diagnosis was New Zealand

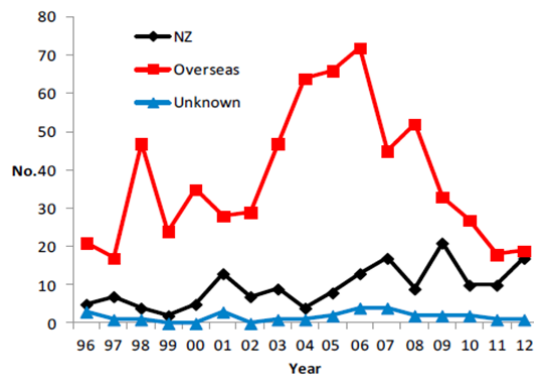


Figure 3 Place of infection of those heterosexually infected diagnosed by antibody test and those reported by viral load since 2002 whose place of diagnosis was New Zealand

The annual numbers of diagnoses among men and women heterosexually infected, by reported place of infection, are shown in Figure 3. The rise in the early 2000s of heterosexually acquired infections was predominantly among those infected overseas and was due to more people entering New Zealand from high prevalence areas. The drop since 2006 is due to a reduction in the number from these parts of the world, which is likely to have been influenced by revised migrant health screening requirements introduced in November 2005.

Overall, since 1996, there has been a small rise in the number of people diagnosed with HIV that was heterosexually acquired in New Zealand. The single commonest risk in this group was having sexual contact with a person from a high prevalence area. Based on initial CD4 counts, heterosexually acquired HIV tends to be diagnosed later than infections among MSM,¹² so a higher proportion will be undiagnosed.

From 2008 to mid June 2013, 230 people were diagnosed with HIV (through a Western blot) who had been heterosexually infected (222 had information on whether infected in New Zealand or overseas). Of these, 154 (67%) were infected outside New Zealand. Table 3 shows that those heterosexually infected outside New Zealand were most likely to have been infected in Africa (44%) or Asia (35%).

Table 3 Heterosexually acquired HIV outside New Zealand, 2008 to mid-2013: probable place of infection

Area of infection	Number (%)
Africa	67 (44%)
Asia	54 (35%)
Australia	2 (1%)
Europe	7 (5%)
Latin America	6 (4%)
Middle East	2 (1%)
North America	2 (1%)
Pacific Islands	9 (6%)
Unknown/NS	5 (3%)
	154 (100%)

Among those infected heterosexually in New Zealand (68), 31 were European, 12 were African, 9 were Asian, 9 were Maori and 7 were Pacifica.

¹² Dickson NP, McAllister S, Sharples K, et al. Late presentation of HIV infection among adults in New Zealand: 2005-2010. *HIV Medicine* 2012;13:182-9.

Hepatitis B virus (HBV)

HBV is transmitted by exposure to infected blood or other body fluids. Transmission can occur from mother-to-child around the time of birth, and through sexual contact, needle sharing, haemodialysis, occupational exposure to blood, close contact among young children, and through blood transfusion.¹³ Infection, especially in adults, can lead to acute hepatitis. Infection in infancy and childhood is more likely to lead to chronic infection. Chronic HBV infection is an important problem because it can lead to cirrhosis and primary liver cancer (hepatocellular carcinoma).¹³ The majority of cases of HBV infection are asymptomatic. It is estimated that 100,000 people in New Zealand are chronically infected with Hepatitis B¹⁴; an overall prevalence of about 2%. Many carriers are not aware that they have the virus.¹⁵

Some ethnic groups in New Zealand have higher prevalence of HBV because of higher rates of mother to child transmission. The NZ Hepatitis B Screening Programme tested eligible Maori, Pacific and Asian adults living in the North Island for HBsAg in 1999-2002 and found an overall prevalence of carriage of 5.7%. People of Tongan ethnicity had the highest prevalence (13.1%) followed by Chinese (8.9%), South East Asians (8.1%) and Pacific overall (7.3%); Maori prevalence was 5.6%.¹⁶ Since 1988, all infants born in New Zealand have been offered protection against HBV infection through the universal vaccination programme, which is likely to be the cause of a decline in HBV carriage among pregnant women.¹⁷

Other groups with a higher prevalence of hepatitis B include PWID, MSM and people born in countries with high rates of chronic HBV. A national study examining the prevalence of hepatitis B in PWID found that 14% of PWID using a needle exchange had been infected with HBV in the past, though none were carriers of HBV.¹⁸ A national survey of MSM found 8% reported a history of hepatitis B.¹⁹ Other countries have also reported higher rates of HBV in MSM.^{20, 21} Of asylum seekers screened during 1999-2000, 3% were HBsAg positive, indicating either recent infection (within six months), or a state of chronic carriage.²²

¹³ Shephard CW, Simard EP, Finelli L, et al. Hepatitis B Virus Infection: Epidemiology and vaccination. *Epidemiologic Reviews* 2006;28:112-125.

¹⁴ <http://www.hepfoundation.org.nz/index.html> Accessed 11.10.2013

¹⁵ Ministry of Health. The feasibility of screening for and surveillance of Hepatitis B in a single geographic area – Report to the Director-General of Health of the working party of Hepatitis B. Wellington: Ministry of Health. 1996.

¹⁶ Robinson T, Bullen C, Humphries W, et al. The New Zealand Hepatitis B Screening Programme: Screening coverage and prevalence of chronic hepatitis B infection. *New Zealand Medical Journal* 2005;118(1211).

¹⁷ Addidle M. Impact of universal hepatitis B vaccination on antenatal hepatitis B prevalence in the Midlands region of the North Island, New Zealand. *New Zealand Medical Journal* 2011;124(1332). ISSN 1175 8716.

¹⁸ Brunton C, Mackay K, Henderson C. Report of the national needle exchange blood-borne virus seroprevalence survey. Department of Public Health and General Practice, Christchurch School of Medicine and Health Sciences, University of Otago and Needle Exchange New Zealand. August 2005.

¹⁹ Saxton PJW, Hughes AJ, Robinson EM. Sexually transmitted diseases and hepatitis in a national sample of men who have sex with men in New Zealand. *New Zealand Medical Journal* 2002;115(1158). ISSN 1175 8716.

²⁰ Gilbert LK, Levandowski BA, Scanlon KE, et al. A comparison of hepatitis A and hepatitis B measures among vaccinated and susceptible online men who have sex with men. *International Journal of STD & AIDS* 2010;21:400-5.

²¹ MacKellar DA, Valleroy LA, Secura GM, et al. Two decades after vaccine license: Hepatitis B immunisation and infection among young men who have sex with men. *American Journal of Public Health* 2001;91(6):965-71.

²² Hobbs M, Moor C, Wansbrough T, et al. The health status of asylum seekers screened by Auckland Public Health in 1999 and 2000. *New Zealand Medical Journal* 2002;115(1160). ISSN 1175 8716.

Notifications of acute illness due to HBV infection in New Zealand from 2000 to 2013 inclusive are shown in Table 4. Overall, notified rates have reduced over time in all groups. Maori, Pacific and Asian ethnic groups have higher notification rates than Europeans.

Table 4 Hepatitis B notifications (acute illness, probable and confirmed) by year of notification and prioritised ethnic group, ages 15-65 years

Year of notification	2000-2007		2008-2013	
Ethnic Group	Number of cases	Rate per 100000/year	Number of cases	Rate per 100000/year
Maori	92	3.36	45	2.29
Pacific Peoples	70	5.63	34	3.80
Asian	51	2.44	31	2.06
European	179	1.33	109	1.13
Other	8	0.30	4	0.21
Unknown	31		11	
Total	431	2.02	234	1.53

Source: Numerator: EpiSurv (National Notifiable Disease Database operated by ESR on behalf of the Ministry of Health)

Denominator: Ethnic Group (grouped total responses) by age group for the census usually resident population count 2006, Statistics NZ

The risks of transfusion transmission of HBV relate to either recent infection in adults (and hence likely to be either sexual or injecting drug use transmission) or to chronic infection. HBV infection is detected by positive HBsAg tests and (since 2007) HBV DNA in donor blood.

The first implication of the above observations about HBV is that donor deferral of people with behaviours placing them at elevated risk of acute infection in adults (sex between men and PWID), or their sexual partners, will reduce risk to the blood supply. Secondly, the risk of not detecting chronic HBV infection has reduced since 2007 with the introduction of HBV nucleic acid testing. Deferral on the basis of sex with someone from an ethnic group at higher likelihood of chronic infection might further reduce risk, but this would result in deferral of many people from a wide range of ethnic groups that make up a substantial minority of the New Zealand population. This could threaten the supply of blood.

Hepatitis C Virus (HCV)

Hepatitis C Virus is also transmitted by exposure to infected blood or other body fluids. Transmission may occur through blood transfusion, haemodialysis, acupuncture, intravenous drug use, accidental needle stick injuries, from tattooing or from mother to child and rarely sexually.²³ Sexual transmission appears to be more common among MSM, and especially those who are infected with HIV.²⁴ Of those infected with HCV, 50-70% go on to become chronic carriers.²³

²³ *Harrison's principles of internal medicine*. 16th edition. Kasper, DL, Fauci, AS, Longo, DL et al, editors, New York: McGraw-Hill. 2005.

²⁴ Witt MD, Seaberg EC, Darilay A, et al. Incident hepatitis C virus infection in men who have sex with men: A prospective cohort analysis, 1984-2011. *Clinical Infectious Diseases* 2013;57(1):77-84.

At risk groups for infection include PWID, recipients of unscreened blood products and some immigrant groups. In New Zealand 52% of PWID using a needle exchange were HCV antibody positive.²⁵ In asylum seekers from 1999-2000, 1.1% tested positive for HCV antibody, indicating current infection or past infection. Those of African origin were significantly more likely to be HCV antibody positive than those from other regions.²² A national survey of MSM found 1.8% reported a history of hepatitis C, but this risk was considerably higher in men with a past history of injecting drug use.¹⁹

Table 5 shows notifications of HCV in New Zealand from 2000 to 2013. Notification is for acute infection (probable and confirmed) and documented seroconversion only, so these figures under represent all new HCV diagnoses in New Zealand, as symptoms of acute infections are rare for HCV. There has been a decline over the two time periods and there are no marked differences in new hepatitis C infections by prioritised ethnic group.

Table 5 Notified cases of acute and seroconversion hepatitis C infections by year of notification and prioritised ethnic group, ages 15-65 years

Year of notification	2000-2007		2008-2013	
	Number of cases	Rate per 100000 /year	Number of cases	Rate per 100000 /year
Maori	44	1.61	25	1.27
Pacific Peoples	5	0.40	5	0.56
Asian	4	0.19	2	0.13
European	161	1.20	114	1.18
Other	3	0.11	1	0.05
Unknown	42		3	
Total	259	1.21	150	0.98

Source: Numerator: EpiSurv (National Notifiable Disease Database operated by ESR on behalf of the Ministry of Health)

Denominator: Ethnic Group (grouped total responses) by age group for the census usually resident population count 2006, Statistics NZ

In 2012, 83% of new notifications had a history of injecting drug use and 24% had a history of sexual contact with a confirmed case or carrier.²⁶ These data show the critical risk behaviour for hepatitis C in New Zealand is injecting drug use, but that sex between men also appears to increase risk of infection. Donor deferral of PWID and MSM will reduce risk.

²⁵ Henderson C, Brunton C, Lauzon C. Report of the national needle exchange blood-borne virus seroprevalence survey. Needle Exchange Services Trust and Department of Public Health and General Practice, School of Medicine and Health Sciences, University of Otago, Christchurch. November 2011.

²⁶ The Institute of Environmental Science and Research Ltd. Notifiable and Other Diseases in New Zealand: Annual Report 2012. Porirua, New Zealand.

Other infectious agents

Syphilis

This is caused by infection with *Treponema pallidum*. It is predominantly transmitted sexually and from mother to child. The clinical signs of syphilis are varied and at times may go unnoticed. Testing for syphilis is reliant on detecting antibodies against *T pallidum*. Internationally, there has been an increase in the number of reported cases of syphilis. In New Zealand there has also been a resurgence of the disease especially since the late 2000s; nationwide surveillance in 2011 showed 72 cases of infectious syphilis of which 83% were among MSM, who were mainly infected in New Zealand.²⁷ While in the past there were documented cases of transfusion transmitted syphilis, *T pallidum* is rapidly destroyed by refrigeration and there have been no cases of transmission by blood products reported in the US in the last 40 years.²⁸

Human T-Lymphotropic Virus (HTLV)

HTLV is a retrovirus that can cause myelopathy and adult T cell leukaemia/lymphoma. It can be transmitted by blood transfusion, sexual intercourse, and from mother to child. HTLV is endemic in parts of the world, including Japan, sub-Saharan Africa, South America and the Caribbean,²⁹ but it is not prevalent in the South Pacific. HTLV is only tested for in new donors in New Zealand because there is a very low rate of seroconversion in established donors internationally, it is likely that pre-storage leucodepletion reduces the risk of transmission significantly, and because transmission only occurs effectively with relatively fresh blood.

Untested TTIs

A number of pathogens are occasionally transmitted by transfusion that are not routinely tested for by NZBS or blood services in comparable countries. Hepatitis A and HHV8 are examples of such TTIs.

Hepatitis A

Hepatitis A is an enteric virus that is transmitted by the faecal oral route. Outbreaks have been described in MSM relating to sexual behaviours.²⁹ Transmission of Hepatitis A by transfusion is a rare event.³⁰

Human Herpes Virus 8 (HHV8)

HHV8 is a virus that occasionally contributes to causing a range of cancers. HHV8 is common in some tropical countries, is transmitted through saliva and although often not considered

²⁷ Psutka R, Dickson N, Azariah S, et al. Enhanced surveillance of infectious syphilis in New Zealand sexual health clinics. *International Journal of STD & AIDS* 2013;24(10):791-8.

²⁸ Orton SL, Liu H, Dodd RY, et al. Prevalence of circulating *Treponema pallidum* DNA and RNA in blood donors with confirmed-positive syphilis tests. *Transfusion* 2002;42(1):94-99.

²⁹ Gessain A, Cassar O. Epidemiological aspects and world distribution of HTLV-1 infection. *Frontiers in Microbiology* 2012;3; article 388.

³⁰ Skidmore SJ, Boxall EH, Ala F. A case report of post-transfusion Hepatitis A. *Journal of Medical Virology* 1982;10;223.

to be sexually transmitted, it has a higher prevalence in MSM. However, this may be a marker for close contact, rather than due to sexual factors per se. HHV8 was originally identified as the cause of Kaposi Sarcoma amongst MSM, who have a much higher prevalence of HHV8 infection than the general population. Transmission of HHV8 by blood transfusion is also rare. The lack of universally accepted laboratory assays to diagnose HHV8 infection impedes routine testing of blood donors.³¹ However, HHV8 is an intracellular virus and the current practice of pre-storage leucodepletion should remove it, although it is unknown what level of protection this provides.

Unknown TTIs

TTIs fall into two broad categories: those that are known and a test is available, which allow risk reduction strategies to be applied, and those that are unknown or cannot be tested. Prior to their identification, HIV and HCV were unknown TTIs that were transmitted via transfusion of blood products. Thus, blood transfusion services internationally remain vigilant to the possibility of the emergence of unknown or untested TTIs (uTTIs).

Epidemiological modelling has shown that population groups containing individuals who have a high number of sexual partners can amplify and increase transmission of novel infectious diseases or uTTIs.³² In particular MSM have high risks of transmitting and acquiring TTIs because of the high transmission probabilities of anal intercourse and the highly connected nature of their sexual networks. Experts have conjectured that any significant novel uTTI would be able to be diagnosed and characterized within five years of causing human illness. Nevertheless, HIV had a very extended incubation period *before* causing clinical illness, during which transmission occurred. For this reason a major epidemic was underway before the first cases of AIDS were recognised. It remains a theoretical possibility that a novel sexually transmitted TTI with similar characteristics to HIV could arise which might take more than five years to be diagnosed.

³¹ Uldrick TS, Whitby D. Update on KSHV epidemiology, Kaposi Sarcoma pathogenesis, and treatment of Kaposi Sarcoma. *Cancer Letters* 2011;305:150-162.

³² Kamp C. Untangling the Interplay between Epidemic Spread and Transmission Network Dynamics. *PLoS Computational Biology* 2010;6:e1000984.

4. GROUPS WITH POTENTIALLY ELEVATED RISKS OF SEXUAL TRANSMISSION OF TRANSFUSION TRANSMISSIBLE INFECTIONS

Men who have sex with men (MSM)

There are few estimates of the prevalence of male to male sexual contact in the New Zealand population. Four percent of men in the Dunedin birth cohort reported any same-sex contact in the previous 12 months at age 38.³³ In Australia, 1.9 percent of men aged 16 to 59 reported genital same sex contact in the previous 12 months.³⁴

MSM are disproportionately affected by HIV infection in New Zealand, and the majority of both prevalent and incident HIV infections are concentrated within this population. An anonymous unlinked study of HIV prevalence among individuals attending New Zealand sexual health clinics in 2005/6 found that MSM were 40 times more likely to be HIV infected (4.4%) compared to heterosexual male (0.1%) and heterosexual female (0.1%) attenders.³⁵ A recent anonymous study of MSM conducted in community settings in Auckland in 2011 found 6.5% of participants were infected with HIV, being higher among those aged 45 and over (8.9%) than those aged under 30 (3.3%), and higher among MSM residing in Auckland (6.0%) than those usually resident in other parts of New Zealand (4.8%). The prevalence of undiagnosed HIV infection (i.e. being unaware that one has HIV) was 1.3% of all participants, or 1 in 5 (20.9%) of those found to have HIV.³⁶

The number of prevalent HIV cases among MSM has also risen considerably in the last two decades, a result of ongoing HIV transmissions combined with improved life expectancy following diagnosis. Prevalence is estimated to have increased 79% between 1989 and 1999, and 137% between 1999 and 2009.³⁷ The growing burden of prevalent HIV infection among MSM, both in absolute numbers and relative to other groups, is reflected in domestic HIV transmission patterns. Although comprising less than 5% of the New Zealand population, between 1996-2008 MSM accounted for approximately 75% of newly diagnosed HIV infections that were believed to have been acquired within this country.³⁸

A growing body of research is advancing our understanding of why gay and bisexual male communities are particularly vulnerable to the emergence and persistence of HIV epidemics.

³³ Personal communication Nigel Dickson

³⁴ Grulich AE, de Visser RO, Smith AMA, et al. Sex in Australia: Homosexual experience and recent homosexual encounters. *Australian and New Zealand Journal of Public Health* 2003;27(2):155-63.

³⁵ McAllister SM, Dickson NP, Sharples K et al. Unlinked anonymous HIV prevalence among New Zealand sexual health clinic attenders: 2005-2006. *International Journal of STD & AIDS*. 2008;19(11):752-7.

³⁶ Saxton P, Dickson N, Griffiths R, Hughes A, Rowden J. Actual HIV prevalence and undiagnosed infections in a community sample of men who have sex with men in Auckland, New Zealand. *BMC Public Health*. 2012;12:92.

³⁷ Saxton P, Dickson N, McAllister S, Hughes A, Sharples K. HIV prevalence among men who have sex with men in New Zealand 1985-2005: 25 years of public health monitoring. *International Journal of STD & AIDS*. 2012;23:274-279.

³⁸ Saxton P, Dickson N, McAllister S, Sharples K, Hughes A. Increase in HIV diagnoses among men who have sex with men in New Zealand from a stable low period. *Sexual Health* 2011;8:311-318.

At least five broad factors are implicated³⁹: (i) the approximately 18 times higher per-contact probability of HIV transmission during receptive anal intercourse than receptive vaginal intercourse,^{40,41} (ii) the highly-connected nature of sexual networks between MSM,³⁹ (iii) the relatively higher prevalence of HIV infection among the sexual contacts of MSM (i.e. other MSM); (iv) the relatively higher prevalence of rectal STIs that are often asymptomatic and which can facilitate HIV transmission; (v) a social context in which MSM continue to experience stigma and discrimination, and lack access to appropriate services.³⁹ These factors are believed to have a synergistic effect on HIV transmission risk for MSM in almost all parts of the world. For example, HIV prevalence has been found to be higher among MSM than among other population groups even in settings where heterosexual transmission is common, such as in sub-Saharan Africa.³⁹

It is the relative difference in proximity to potentially HIV infected sexual partners that helps explain why MSM are at greater risk of acquiring HIV and hence having undiagnosed infection than heterosexual individuals. This is illustrated in a mathematical modelling study from Australia. That analysis compared the relative risk of *not detecting an HIV positive infection in donated blood* for various risk groups with a reference case of an average heterosexual person who had a new sexual partner (in the last 12 months, where the partner is not from a high prevalence country). In all permutations the risk is substantially greater for a sexually active MSM, with an average risk more than 100 times higher relative to the heterosexual person. In some cases this arises because of imperfect knowledge of a current partner's sexual practices which may not have been disclosed, and the relatively greater probability of this occurring in an MSM partnership compared to a heterosexual partnership, based on available data. In the scenario of a man, who is himself monogamous, the relative risk of donating with an infection that would be undetected is still 60 times greater, due to the higher risk of an unknown HIV positive partner.⁴² Musto et al⁴³ estimated that the risk of a donation being made by an HIV seronegative male in the window period was higher for an MSM who used condoms during anal intercourse than it was for a heterosexual male who did not use condoms during vaginal intercourse.

Some MSM may consequently underestimate their own risk of HIV infection. The 2011 community HIV prevalence study in Auckland provides information on the 14 MSM found to have unrecognised infection. Eleven (79%) had previously tested for HIV, three in the past 6 months, five between 11 and 6 months prior, and three more than a year prior. Most of these men (12/14, 86%) believed they were "definitely" or "probably" HIV negative at the time of survey, similar to the uninfected men. Eight of the participants who were unaware they had HIV had a regular sexual partner at the time. Of the 14 MSM, the authors argue

³⁹ Beyrer C, Sullivan P, Sanchez J, et al. The increase in global HIV epidemics in MSM. *AIDS* 2013;27:2665-78.

⁴⁰ Baggaley R, White R, Boily M. HIV transmission risk through anal intercourse: systematic review, meta-analysis and implications for HIV prevention. *International Journal of Epidemiology* 2010;39(4):1048-63.

⁴¹ Grulich AE, Zablotska I. Commentary: probability of HIV transmission through anal intercourse. *International Journal of Epidemiology*. 2010;39(4):1064-5.

⁴² Review of Australian blood donor deferrals relating to sexual activity. An independent review commissioned by the Australian Red Cross Blood Service. 2012, pp32-37. Available at:

<http://www.transfusion.com.au/sites/default/files/Blood%20Review%20Report.pdf> accessed 30.10.2013

⁴³ Musto J, Seed C, Law M, et al. Estimating the risk of blood donation associated with HIV risk behaviours. *Transfusion Medicine* 2008;18:49-54.

that “[m]any had had a quite recent HIV test, and may consequently have held strong but incorrect convictions about their absence of HIV infection”.³⁶

In considering compliance with MSM deferral, the stigmatised history and changing socio-legal climate experienced by gay and bisexual men are also relevant factors. While New Zealand legalised same sex marriage in 2013, social attitudes regarding homosexuality can be more conservative and gay and bisexual men may still feel stigmatised. Perceptions of prejudice can make it difficult for some MSM to self-defer by disclosing same-sex contact in front of colleagues. Conversely, many MSM wish to donate blood and may increasingly view deferral as a barrier to full civic participation. Although motivated by different concerns, both these factors could lead to reduced compliance in some circumstances.

Sex workers

The proportion of the population engaged in sex work is uncertain, though 8.2% of heterosexual women attending Sexual Health Clinics in 2005 reported current sex work.¹⁸ A series of regional surveys of sex workers in 2006, following decriminalisation (the Prostitution Reform Act 2003) suggested that, in Auckland, about 1 per 1000 total population was engaged in sex work. The research also showed that most sex workers always use condoms for vaginal and anal sex. Street-based workers were more likely to be requested sex without a condom than ‘managed’ workers, though more than half reported refusing sex if the client persisted.⁴⁴

The only data available on HIV among sex workers are from the unlinked anonymous HIV prevalence survey in 2005 (no positive in 298 sex workers, upper 95% confidence limit 12.3 per thousand) and from reports of new HIV diagnoses (19 people were reported infected through sex work, from 1990 to 2009; 14 were women, four men, and one transsexual; of those with a place of infection recorded, nine reported infection in Asia and three in New Zealand). There is no information on HIV prevalence for male sex workers in New Zealand.

Stigma of sex work is part of the experience of people working in the industry. It is dealt with by various strategies that may entail emotional risks for some people.⁴⁵

People from countries with a high prevalence of HIV

Most migrants to New Zealand are not known to be at high risk of STIs. The exception is migrants from countries with a high prevalence of HIV. The map (Figure 4) shows estimated HIV prevalence worldwide. Currently in New Zealand, new diagnoses of HIV transmitted heterosexually are disproportionately among people whose ethnicity is African or Asian and who have become infected in their countries of origin. For instance, from 2008 to mid-2013 the proportion of all new HIV infections among heterosexuals who were infected outside

⁴⁴ Abel G, Fitzgerald L, Brunton C. The impact of the Prostitution Reform Act on the health and safety practices of sex workers. 2007. Department of Public Health and General Practice, University of Otago, Christchurch.

⁴⁵ Abel GM. Different stage, different performance: The protective strategy of role play on emotional health in sex work. *Social Science & Medicine* 2011;72:1177-84.

New Zealand was 67%. The main world regions of infection were Africa (44%) and Asia (35%). (Within these geographical areas there is a wide range of prevalence by country.) Among those infected heterosexually in New Zealand, about half were European, followed by African, Asian, Māori and Pacific ethnicity.

The prevalence of HIV among Africans living in New Zealand has recently been estimated as 5%.⁴⁶ This compares to prevalence among all heterosexual Sexual Health Clinic attendees in 2005 of 0.1%.¹⁸ It is not expected that prevalence in the latter group will have changed markedly since that time.

There is no indication that the sexual behaviour of these groups of migrants is different from the population as a whole; the raised risk of acquiring HIV in these groups derives from the much higher prevalence in partners from the same geographical areas, either within or outside New Zealand.

Stigma is an issue for recent migrants from Africa. In the recent AfricaNZ study,⁴⁷ some members of the focus groups reported difficult challenges with the host culture, noting that they felt singled out and disadvantaged because of their nationality or colour. In addition, within many African communities there was a feeling that people with HIV were less valued. There was a major concern among many black Africans that as they are easily identified as such, and are also widely considered at risk of HIV, they face significant stigmatisation. There was also a general concern that the African community risks being held responsible (wrongly) for HIV in New Zealand.

⁴⁶ Dickson N, Henrickson M, Mhlanga F. AfricaNZ Count: An estimate of currently resident and HIV positive Africans in New Zealand. 2012.

⁴⁷ Personal communication, Nigel Dickson 5.11.2013

2010: A global view of HIV infection

33.3 million people [31.4–35.3 million] living with HIV, 2009

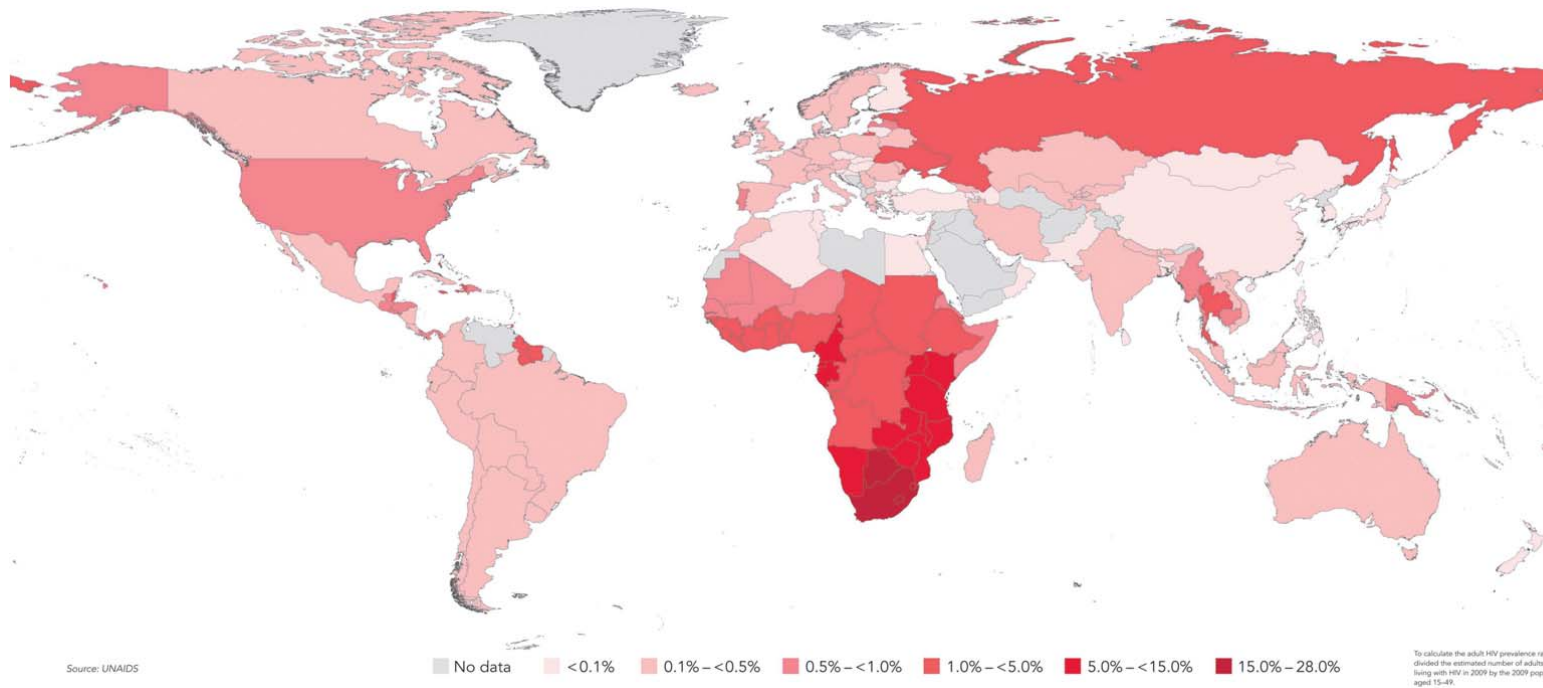


Figure 4 Global view of HIV infection⁴⁸

⁴⁸ Source: UNAIDS website. URL: http://www.unaids.org/globalreport/HIV_prevalence_map.htm accessed 11.11.2013

5. CURRENT DONOR DEFERRAL ON THE BASIS OF SEXUAL BEHAVIOUR

New Zealand: At time of last review in 2008

Men who have sex with men

At the last review, the ten-year deferral period for men who have had male-to-male sex was shortened to five years. The grounds were that a change to a five-year deferral would not increase risk to the blood supply, either from incident or prevalent HIV infection or from undetected novel infections. The reduction in the period of exclusion aimed to attain the least restrictive method of maintaining the safety of the blood supply.

Heterosexuals from countries with a high prevalence of HIV

The deferral for heterosexuals who had lived in, or who come from specified countries with an estimated prevalence of HIV of >1% in the population for five years from leaving the country was recommended. Because of the higher prevalence of infection, the risk was from both incident and prevalent HIV infections.

Sex workers

The deferral criteria for sex workers were amended such that people who had worked as sex workers only in New Zealand should not give blood for one year. But people who had worked as sex workers in any other country should not give blood for five years. The longer deferral period was justified on the basis of a higher, or unknown, risk of prevalent infection.

Sex with someone at higher risk of STIs, especially HIV

A one year deferral was recommended for a woman who has had sex with a bisexual man, and for men and women who have had sex with a person who carries the hepatitis B or C viruses, or an injecting drug user, a sex worker, a person with haemophilia or related condition, or with a person who has lived in or comes from a country with high HIV prevalence.

International donor deferral criteria

Table 6 below, lists the current deferral criteria internationally.

Table 6 International criteria for donor deferral on basis of sexual behaviour: MSM

COUNTRY	CURRENT DEFERRAL	NAT TEST STATUS	COMMENT
Australia	MSM deferred for 12 months 'oral or anal sex with or without a condom'	Individual donation testing for HIV RNA, HCV RNA and HBV DNA implemented in 2010.	Independent review undertaken during 2012 recommended shortening the deferral to 6 months subject to satisfactory outcomes in compliance studies. This recommendation is currently under review by the Australian Therapeutic Goods Administration. ⁴⁹
AMERICAS			
United States	MSM since 1977 permanently deferred	Mini-pool NAT for HCV and HIV in place. Many centres have implemented HBV DNA NAT but often maintained testing based on mini-pools of 16 donations or less	Position in US unchanged with on-going debate between USFDA and Blood Service providers.
Canada	MSM deferred for 5 years Male donors: In the last five years, have you had sex with a man, even once?	Minipool NAT for HCV and HIV in place	Change introduced in mid-2013 in response to the recommendations contained in the Risk management report undertaken in 2007 (considered in original NZ review of criteria). Canadian Blood Services (CBS) website identifies the recent change as 'a first and prudent step in incremental change on this policy'
Brazil	12 month deferral		
ASIA PACIFIC			
Hong Kong	MSM deferred for an indefinite period	Individual donation testing for HIV, HCV and HBV introduced 2007	Unchanged since 2007
Japan	MSM deferred for 6 months	Minipool testing for HIV, HCV and HBV in place	Deferral reduced from 12 months to 6 months in April 2011
Singapore	MSM permanently deferred	Individual donation testing for HIV, HCV and HBV introduced 2007	Unchanged since 2007
EUROPE			
Austria	MSM permanently deferred	Minipool testing for HIV,HCV and HBV	Unchanged since 2007
Belgium	MSM permanently deferred	Minipool testing for HIV and HCV	Unchanged since 2007
Denmark	MSM permanently deferred	No requirement	Unchanged since 2007
Finland	MSM permanently deferred	Minipool testing for HIV and HCV	Unchanged since 2007

⁴⁹ The TGA has not accepted this recommendation (2014).

COUNTRY	CURRENT DEFERRAL	NAT TEST STATUS	COMMENT
France	MSM permanently deferred	Minipool testing for HIV and HCV	Unchanged since 2007
Germany	MSM permanently deferred	Minipool testing for HIV and HCV in place.	
Ireland	MSM ever having oral or anal sex (even with condom) permanently deferred	Single donation testing for HIV, HCV and HBV introduced 2006	Unchanged since 2007
Italy	National policy is to exclude on basis of 'risky behaviour'.	Minipool testing for HCV	Unchanged since 2007 All donors are interviewed by a doctor. Interpretation of 'risky behaviour' is unclear and inconsistently applied. At least some centres continue to exclude MSM.
Netherlands	MSM permanently deferred	Minipool testing for HIV and HCV	Unchanged since 2007
Norway	MSM permanently deferred	HCV NAT only	Unchanged since 2007
Portugal	MSM permanently deferred	No requirement	Unchanged since 2007
Spain	No specific exclusion on MSM	No requirement	On-going concerns in relation to the number of HIV positive donors identified. No change to policy since 2007
Sweden	Policy complicated by divergent opinions from two national competent authorities. The Medical Agency, which controls plasma for fractionation, claims that the MSM deferral policy should be a permanent exclusion and for this reason MSM plasma is not able to be sent for fractionation. The National Board Health and Welfare supports a 6 month deferral for MSM	No requirement for fresh components	Current situation results in some Donor Centres allowing MSM to be bled for fresh component use but plasma not allowed to be used for fractionation.
Switzerland	MSM since 1977 deferred	Minipool testing for HIV and HCV	Unchanged since 2007
United Kingdom	England, Scotland and North Wales introduced a 12 month deferral in 2011.	Minipool HCV NAT introduced 1999. HIV variable, depends on test supplier	Change in deferral policy recommended by the Department of Health Advisory Committee for the Safety of Blood Tissues and Organs (SaBTO)
AFRICA			
South Africa	MSM deferral for 6 months (oral or anal sex with or without a condom)	Single donation testing for HIV, HCV and HBV introduced 2006	Unchanged since 2007

Source: Personal communication Peter Flanagan. Based on Benjamin R.J, Bianco C., Goldman, Seed C. et al . International Forum on Deferral of males who had sex with other males. Vox Sanguinis 2011;101:339–367.

Section Two

6. MATTERS RELEVANT TO CONSIDERATION OF DEFERRAL CRITERIA

Several relevant matters have occurred over the last five years that need to be considered in reviewing the criteria. These are: the impact of the last decision on the NZBS and on potential donors; advances in donation testing and handling; clarification of estimates of risk of HIV transmission to donors related to incident (window period infections) versus prevalent infections; current epidemiology of HIV; evidence from countries that have reduced their deferral periods for MSM; further consideration of ethical issues; opinions of MSM on deferral and the importance of compliance; and the context of human rights law.

The options for consideration are: to continue with the same deferral periods on the basis of sexual behaviour; to reduce the deferral periods to 12 months or 6 months; to lengthen the deferral periods; and to move to an individual risk-based assessment.

(a) Impact of the last decision

The 2008 decision to shorten the deferral period to five years for MSM and to lengthen the deferral period for heterosexuals from high HIV prevalence areas has had no measurable negative impact on the safety of the blood supply. There have been no known transmissions of any TTI, nor have there been any incident HIV infections occurring in regular donors that have required a look-back investigation to see whether transmission has occurred.

Table 7 shows the number of prevalent infections (detected in first time donors) and the number of incident infections (detected in repeat donors, who by definition have had a previous HIV negative test at the occasion of the last donation). HBV infections are the most common, though decreasing over time, probably due to HBV vaccination. The number of HCV infections detected has also fallen. Overall, very few HIV infections have been detected and fewer in the five years since 2008 (1) than in the five years before (10).

Table 7 Review of confirmed positive donor rates 2003-2012

Calendar year	Total no. of donors tested	HBV Confirmed Positive		Rate per 100,000 donors	HIV Confirmed Positive		Rate per 100,000 donors	HCV Confirmed Positive		Rate per 100,000 donors
		First Time	Repeat		First Time	Repeat		First Time	Repeat	
2003										
First Time	27353	73		266.9	2		7.3	33		120.6
Repeat Tested	75994		0	0.0		2	2.6		1	1.3
2004										
First Time	24339	67		275.3	0		0.0	29		119.2
Repeat Tested	75056		3	4.0		0	0.0		0	
2005										
First Time	24493	48		196.0	0		0	15		61.2
Repeat Tested	78689		0	0		2	2.5		4	5.1
2006										
First Time	22951	45		196.1	2		8.7	26		113.3
Repeat Tested	77774		2	2.6		1	1.3		3	3.9
2007										
First Time	21001	31		147.6	1		4.8	15		71.4
Repeat Tested	76646		2	2.6		0	0		2	2.6
2008										
First Time	21762	30		137.9	0		0	15		68.9
Repeat Tested	78090		1	1.3		0	0		1	1.3
2009										
First Time	18113	21		115.9	0		0	12		66.3
Repeat Tested	75745		1	1.3		0	0		1	1.3
2010										
First Time	18037	17		94.3	1		5.5	13		72.1
Repeat Tested	78446		0	0		0	0		1	1.3
2011										
First Time	17515	28		159.9	0		0	9		51.4
Repeat Tested	77777		1	1.3		0	0		3	3.9
2012										
First Time	16202	21		129.6	0		0	4		24.7
Repeat Tested	75600		1	1.3		0	0		0	0.0

The one HIV positive donor in the last five years subsequently disclosed male to male sex. In the five years before 2008, of the ten donors with HIV infection, all were reviewed and three (30%) disclosed sex between men which should have led to deferral, while a further three had possible reasons for deferral because of sex with someone from a high HIV prevalence area. These data suggest that the deferral criteria of 2008 are being complied with, though there is no systematic study in New Zealand of self-reported compliance. The number of deferrals of MSM has remained similar over the last 10 years at about 35 per year, though it is likely that many more men know about the deferral criteria and self-defer. The number of sex worker deferrals has remained at fewer than 10 per year, but the number of people

deferred because of sexual activity in areas with higher prevalence of HIV increased markedly after 2007, from fewer than 100 per year to over 200 per year. The latter is likely to have been a consequence of increasing the deferral period for this group.

Since 2009, significant efforts have been made to improve the way prospective donors disclosing possible risks associated with male to male sex are engaged with by the Blood Service. In collaboration with the NZAF, a series of workshops has been held for registered nurses aimed at understanding HIV behavioural risks and improving communication. Feedback from the nurses who have attended the workshop has been positive. There has not been any formal evaluation of how beneficial this has been for MSM.

The main difficulty reported by NZBS has been explaining the deferral for five years of people who have lived in a high HIV prevalence country.

There have been three complaints to the Human Rights Commission since the time of the last review. All are related to the deferral criterion for MSM, and one was also about the way in which he was treated at the donor session. The latter complaint was resolved through mediation, one complaint was withdrawn, and the other complaint is on hold pending the outcome of the present review.

These data imply that the 2008 deferral criteria have been safe and complied with. Therefore the option of lengthening the deferral period has not been considered further.

(b) Advances in donation testing and handling

Currently two different but complementary tests are used for each donation: serological testing for pathogen proteins or the body's immune response to a pathogen (antibodies), and tests to detect the presence of virus nucleic acid (Nucleic Acid Testing, NAT). In September 2007 a fully automated system was introduced to detect HIV-1, HCV RNA, and HBV nucleic acid on all individual donations. These two types of tests are highly sensitive and independent and are able to detect most, if not all, cases of established infection, with a dual test sensitivity for HIV of 99.995%, i.e. would only be expected to miss one in 20,000 infected donations.⁵⁰ In addition, the move from pooled to individual testing in September 2007 will also have improved sensitivity. The window period, the time between acquiring the infection and the development of detectable infectious markers, has reduced significantly with the availability of NAT testing. The estimated window periods for both tests for HIV, HCV and HBV are shown in Table 2 (page 24). The upper bound of the window period is longest for serological testing for HCV, 94 days. Incident infections may be missed during the window period.

The risk of not detecting a prevalent infection has continued to be very low and may have declined. This is the risk that an infected donation might not be detected in the test, or else

⁵⁰ Davison KL, Brant LJ, Presanis AM, et al. A re-evaluation of the risk of transfusion-transmitted HIV prevented by the exclusion of men who have sex with men from blood donation in England and Wales, 2005-2007. *Vox Sanguinis* 2011;101:291-302.

detected but inadvertently released for clinical use. The problems may occur if the test system (1) fails to detect infection even though a marker is present (extremely unlikely); (2) fails to detect a rare form of the virus (a theoretical possibility with test systems for HIV-1 given its high mutation rate); and (3) detects infection but the Blood Service fails to remove it. This last type of error, called ‘quarantine’ or ‘release’ error, is now very unlikely because of the automated IT system, Progesa, used by both the manufacturing centres and the hospital blood banks. This provides, in international terms, a unique opportunity to control the release of individual blood components across the whole national blood network. The latest system (e-Progesa) was implemented in New Zealand in mid-2012.

Estimates of residual risk for HIV and HCV transfusion transmission have reduced in New Zealand since the time of the last review, though the confidence intervals are very wide. Table 8 shows current estimates, which take NAT testing into account, based on a model by Schreiber et al.⁵¹

Table 8 Estimates of residual risk of HCV and HIV transfusion transmission

	Risk of window period donation per 10 ⁶ donations	Rate of window period donations	95% confidence interval for rate
HCV	0.5	1: 2,150,480	1: 305,067-15,159,221
HIV	0.2	1: 5,145,855	1: 358,547-73,853,322

These advances in donation testing and handling imply that the already extremely low risk of failing to detect the relevant infections, except during the window period, may have declined further. This suggests that a shorter deferral period might be appropriate.

(c) New modelling studies of risk of HIV transmission: incident or prevalent infection?

At the time of the last review two studies had been published which estimated risk of HIV transmission with different deferral criteria for MSM,^{52, 53} and there was also a third then unpublished report.⁵⁴ Since that time, there have been two more modelling studies from the UK.^{50, 55} Davison et al evaluated the change in risk from lifetime exclusion of MSM to a 5-year deferral or no deferral. The underlying risk of HIV transmission (with lifetime deferral of MSM and 12 month deferral of heterosexuals from Sub-Saharan Africa) was estimated to be 1 per 4.41 million donations. The estimated increase in risk in moving to 5 years was between 0.4% and 7% (depending on compliance with the deferral), and in moving to no

⁵¹ Schreiber GB, Busch MP, Kleinman SH et al. The risk of transfusion-transmitted viral infections. *New England Journal of Medicine* 1996;334(26):1685-1690.

⁵² Soldan K, Sinka K. Evaluation of the de-selection of men who have had sex with men from blood donation in England. *Vox Sanguinis* 2003;84:265-73.

⁵³ Germain M, Remis RS, Delage G. The risks and benefits of accepting men who have sex with men as blood donors. *Transfusion* 2003;43:25-33.

⁵⁴ Leiss W, Tyshenko M, Krewski D. Men having sex with men donor deferral risk assessment: an analysis using risk management principles. *Transfusion Medicine Reviews* 2008;22:35-7.

⁵⁵ Davison KL, Conti S, Brailsford SR. The risk of transfusion-transmitted HIV from blood donations of men who have sex with men, 12 months after last sex with a man: 2005-2007 estimates from England and Wales. *Vox Sanguinis* 2013;105:85-88.

deferral was 26.5% (i.e. to a risk of 1 per 3.49 million). Most risk (94.8%) was estimated to be from window period donations, with 2.7% attributable to assay sensitivity and 2.5% to quarantine or release errors. The authors concluded that if compliance with deferral remained the same, the only increase in risk would come from the higher prevalence of HIV infection, and that this effect would be expected to be negligible (0.4%).⁵⁰ A follow-up study by Davison et al estimated the risk of moving from lifetime to a 12-month deferral for MSM and concluded, again if there was no effect on compliance, the increase in risk would be negligible (0.5%, compared with 0.4% for a 5 year deferral) or one extra HIV transmission every 455 years in England and Wales.⁵⁵ Hence, moving from 5 years to 12 months would change risk by even less, 0.1%, that is less than one extra transmission every 455 years.

It is clear from these modelling studies, based on data from England and Wales, that most of the very small risk of transmission, if there was no deferral, now comes from incident or window period donations. The risk from prevalent HIV infection is negligible under current testing and handling regimes. Conversely, a modelling study from the US demonstrates that quarantine release errors in hospitals in the US are still the most significant preventable sources of risk.⁵⁶ The New Zealand testing and handling arrangements effectively exclude the risk of quarantine release type errors seen in hospital-based blood services in the US, and are as good as or possibly better than those in England and Wales.

These models imply that moving to a 12 month deferral would not increase risk to the blood supply, because almost all the source of risk currently in New Zealand comes from incident/window period infections (and 12 months would cover all window period infections). Compliance has a larger effect on risk, so this lack of increase in risk would only be true if compliance did not get worse as a result of shortening the deferral period.

(d) Changes in epidemiology of HIV and other relevant TTIs and of sexual behaviour in New Zealand

Since the previous decision about donor deferral in 2008, the annual number of new HIV infections diagnosed among MSM has been relatively constant, though at a higher level than in the middle 1990s. This can be considered to reflect a relatively stable incidence.

The prevalence of HIV among MSM has risen since then as more people have been infected – and diagnosed – than have died (or gone overseas). While this increased prevalence sets up the possibility of an increase in incidence, this may be offset by the reduction in infectivity among people on treatment for HIV.

Importantly, people are more infectious soon after being infected, so it is new incident infections that are most like to drive any increase in incidence. Hence as well as prevalence, changes in when infected people are diagnosed (itself a reflection of testing), when and how they are treated, and changes in how all MSM behave will impact on the risk of new

⁵⁶ Anderson SA, Yang H, Gallagher LM, et al. Quantitative estimate of the risks and benefits of possible alternative blood donor deferral strategies for men who have had sex with men. *Transfusion* 2009;49:1102-114.

infections occurring. From 2002 to 2011, five repeat cross-sectional behavioural surveillance surveys were conducted among MSM at community locations in Auckland (n=6091). Participation was anonymous and surveys were self-completed. Recruitment methods were consistent at each round.

In these surveys, HIV testing in the 12 months prior to each survey increased among MSM, in particular rising from 40.0% in 2008 to 50.4% in 2011.⁵⁷ Condom use was dependent on the type of partner sexual contact occurred with, and was higher during anal intercourse with a casual sexual partner (81% had always or almost always used condoms in the six months prior to survey) than with a steady partner (34% had always or almost always used condoms). Trends in condom use were generally stable, with a small decrease reported in 2011 in the context of casual sex.

Successive surveys found a reduction in sexual contact with high numbers of male partners (more than 20) in the six months prior to survey. This was somewhat counterbalanced by anal intercourse becoming more common. The combination of these behavioural trends meant that while most MSM reported protective practices, including high and sustained levels of condom use, the changes witnessed in partnering and practices resulted in a slightly greater overall proportion over time being potentially exposed to HIV transmission risk. For example, in 2002 15.1% of all respondents had engaged in any unprotected casual sex, in 2011 this had risen to 19.9%. It is not yet known whether the increase seen in HIV testing behaviours has offset this risk and reduced the prevalence of undiagnosed incident HIV infections circulating in the MSM population.

Since 2007, there has been no evidence of change in the rate of diagnosed heterosexually acquired HIV in New Zealand. A policy of offering all pregnant women an HIV test was introduced in 2006, and is now in place throughout the country with a high uptake in most areas. Very few pregnant women (two in each of the past two years) have been diagnosed among over 60,000 being tested each year (prevalence 0.03 per 1000). No heterosexually acquired HIV has been identified among first time and repeat blood donors since 2006. So overall there is no evidence of an increased incidence of heterosexually acquired HIV infection in New Zealand since the last consideration of donor deferral criteria. There has been a decline in diagnoses of HIV heterosexually acquired overseas.

Notifications of HBV and HCV infections have declined since 2007 and the detection of HBV and HCV among blood donors has also declined. Diagnoses of infectious syphilis in sexual health clinics increased in the 2000s, and markedly from 2008 to 2009.²⁷ Most diagnoses have been among MSM. Among blood donors, from 2003 to 2007 there were 10 people with RPR titre of 1:4 or less and 13 in the period 2008 to 2012, with only a slight male excess. These data are hard to interpret but suggest no increase among donors and that compliance with deferral among MSM is responsible for the lack of an appreciable male excess.

⁵⁷ Saxton P, Dickson N, Hughes A. Location-based HIV behavioural surveillance among MSM in Auckland, New Zealand 2002-2011: Condom use stable and more HIV testing. *Sexually Transmitted Infections* 2013, online first doi: 10.1136/sextrans-2013-051160.

These data and analyses imply that incidence of HIV among MSM has remained at a similar level in the last five years. In the same period, prevalence of HIV among MSM has increased and there has been a small increase in risk behaviour, and an increase in HIV testing, so any change in occurrence of undiagnosed HIV infection is uncertain. Syphilis among MSM has also increased. These data also show that MSM remain at much higher absolute risk of having undiagnosed incident HIV infection than heterosexuals.

(e) Emerging TTIs

In 2008, the possibility of emergence of unknown TTIs (uTTIs) formed part of the rationale for a five-year deferral period for MSM and sex workers from outside New Zealand. It is important to keep in mind that donor deferral based on sexual behaviour to reduce risk of uTTI is based on modelling, expert opinion and, most importantly, past experience.

Over recent years various pathogens have emerged, re-emerged, or increased in prevalence requiring careful consideration by blood services internationally. These include West Nile Virus (causes encephalitis transmitted by mosquitoes); Lyssavirus (causes rabies and similar illnesses usually transmitted by bites from infected animals); Hepatitis E virus (causes hepatitis transmitted by the faecal-oral route); and variant Creutzfeldt–Jakob disease (vCJD; causes rapidly fatal dementia and never shown to be transmitted sexually). In the case of vCJD, risk of transfusion related transmission is reduced by exclusion of donors who were resident in UK, Ireland or France between 1980 and 1996. Past exposure to Hepatitis E was more commonly identified among MSM in UK;⁵⁸ however, outbreaks of illness have occurred only in developing world settings and have not been associated with sexual transmission. Thus, many recent uTTIs are not associated with sexual behaviour.

There is no recent evidence to suggest that sexually transmitted uTTIs are emerging problems, and thus no new evidence to support a prolonged deferral period on this basis.

(f) Evidence from Australia following reduction in deferral period for MSM

Australia reduced its deferral period for MSM (from lifetime or 5 years, depending on the state) to 12 months between 1996 and 2000 and an evaluation of this policy was published in 2010.⁵⁹ The number of HIV positive donations in the five-year period before the policy change was the same as the number in the five years following, and the proportions that were MSM were not significantly different. All the men with HIV who later disclosed sex with men would have been deferred by the 12-month exclusion if they had complied with it. The authors concluded that there was no evidence that the reduced deferral time had

⁵⁸ Payne BAI, Medhi M, Ijaz S, Valappil M, Savage EJ, Gill ON, et al. Hepatitis E virus seroprevalence among men who have sex with men, United Kingdom [letter]. *Emerging Infectious Diseases* [Internet]. 2013 Feb [cited 30.10.2013]. <http://dx.doi.org/10.3201/eid1902.121174>

⁵⁹ Seed CR, Kiely P, Law M, Keller AJ. No evidence of a significant increased risk of transfusion-transmitted HIV infection in Australia subsequent to implementing a 12-month deferral for men who have sex with men. *Transfusion* 2010;50:2722-30.

increased recipient risk and that compliance with deferral was the most important modifier of risk. A further study has examined TTIs among Australian blood donors from 2005 to 2010,⁶⁰ and concluded that prevalence was substantially lower than among the general population, reflecting the effectiveness of donor education and donor selection. Since that time, Australia has had a review of donor deferral related to sexual activity and has concluded that the deferral period for MSM and sex workers could be reduced to six months.⁶¹ The Australian Red Cross Blood Service accepted this recommendation, but the regulator (the TGA) has rejected it and a 12 month deferral will be retained.

The implications of these data are that reducing the deferral period to 12 months for MSM will not increase risk over the current deferral period.

(g) Further consideration of ethical issues

The following analysis appeals just to ethical considerations invoked in previous advisory work to blood services^{62, 63, 61} or in consensus documents on blood donation issues⁶⁴, and it focuses on the ethics of retaining or changing current New Zealand policy and practice.

Those responsible for blood services have obligations of beneficence to ensure that the supply of blood and blood products that donors provide is sufficient to meet need. They also have obligations of non-maleficence not to put already vulnerable patients who need blood or blood products at preventable risk of harm. This obliges them to ensure that the blood supply in their care is as safe as it is reasonably practicable for them to make it, including preventing donation of blood that is infected with HIV, HBV, HCV or other blood-borne TTIs. Further, recipients of blood are often very ill and may even be unable to give informed consent. Hence there may be imposed risks on the recipient. Some recipients also require multiple transfusions of blood or blood products.

Those responsible for blood services also have obligations to potential donors. One such obligation is not to exclude potential donors on any discriminatory ground. This obligation is grounded in potential donors' moral rights against discrimination, not in any alleged 'right to donate'. Blood services are also obliged, as far as practicable, not to cause exclusion-related harm such as stigma to potential donors. Relatedly, they are also obliged to avoid the unfairness or injustice that would arise if different individuals or groups are treated differently without a proportionate difference in risk that would be presented by accepting their respective offers to donate.

⁶⁰ Lucky TTA, Seed CR, Keller A, et al. Trends in transfusion-transmissible infections among Australian blood donors from 2005 to 2010. *Transfusion* 2013;doi:10.1111/trf.12144.

⁶¹ Review of Australian blood donor deferrals relating to sexual activity. An independent review commissioned by the Australian Red Cross Blood Service. 2012. Available at:

<http://www.transfusion.com.au/sites/default/files/Blood%20Review%20Report.pdf> accessed 30.10.2013

⁶² Behavioural donor deferral criteria review. Final report to the New Zealand Blood Service. 2008. Available at: <http://nzblood.co.nz/Give-blood/Donating/Am-I-eligible/Review-of-donor-criteria> Accessed 30.10.2013

⁶³ SaBTO Advisory Committee on the Safety of Blood, Tissues and Organs. Donor Selection Criteria Review. 2011

⁶⁴ King SM, AuBuchon J, Barrowman N, et al. Consensus statement from the consensus conference on blood-borne human immunodeficiency virus and hepatitis: Optimising the donor-selection process. *Vox Sanguinis* 2002;83:188-93.

When ethical considerations are plural and diverse, particular care is needed in the process and substance of coming to reasonable overall decisions. Especially significant in the present setting is the need to do justice to both recipients' and donors' key rights and interests; and more specifically, to non-maleficence and safety for blood recipients, and to rights of potential donors against discriminatory exclusion from donation.

Two sorts of case merit emphasis. First, if retaining or changing current policy and practice were to be a gain in terms of one ethical factor and *not a loss* in the other, this would be an overall ethical improvement. For example, if reducing deferral of MSM from 5 years to 1 year were to generate no loss of safety, then this would be an overall ethical improvement. Second, if retaining or changing current policy and practice were to be a gain in one ethical factor but a small loss in the other, (e.g. if reducing deferral of MSM from 5 years to no deferral were to increase recipient risk by one extra HIV transmission in every 3 million donations from one in every 4 million), then extra care would be needed to determine which of these two conflicting considerations would be most material.

One widely held view in ethics is that rights have sufficient importance that breaching them can be justified only by especially large favourable differences that doing so would make to interests (e.g. harms or benefits) of others. Applied to the present case, this view would imply that breach of donors' rights against discriminatory exclusion could be justified only by especially large favourable differences that doing so would make to recipient safety. Much ethical thinking about blood services tends, however, to take the opposite approach that even very small favourable differences in recipient safety can justify breaches in donor's rights against discriminatory exclusion.

Part of a justification for the widespread tendency of ethical thinking about blood services to reverse the usual order of priority between rights and interests involves making appeal to history and its ethical significance. In particular, as noted above (Section 1), there have been past failures in the safety of the blood supply that have seriously harmed some recipients. Such history intensifies the obligations of those responsible for the blood supply to take all reasonable and practicable steps to secure safety, and thereby to continue to earn and retain the public's trust.

The ethical considerations, together with the evidence stated elsewhere in the present report, suggest that reduction of MSM deferral from 5 years to 12 months would be an improvement in terms of the rights and interests of potential donors, would generate no increase in risk to recipients (if compliance remained the same) and would thus be an ethical improvement overall.

(h) Opinions of MSM on deferral and issues of compliance

Opinions on deferral

A few countries, but not New Zealand, have surveyed populations for their opinions on

deferral of MSM. In Britain, Grenfell et al⁶⁵ surveyed a population-based sample of men who reported any sexual contact with a man. Only 25% of such men knew about the then lifetime deferral of MSM, knowledge about the reasons for deferral was poor, and most men considered that testing of blood would eliminate all risk. When questioned in qualitative interviews about alternatives to the lifetime deferral, an individual risk assessment approach was favoured but the disadvantages of in-depth questioning were acknowledged, and a 12 month deferral was viewed as a “generally acceptable, equitable, and sufficiently cautious alternative”.

In Canada, a report on surveys of the public, blood donors, students, and gay men concluded that about 50% of the general public were aware of the then lifetime deferral of MSM, and awareness among the other groups was higher. There was strong support for a change to a five-to-ten year deferral as a step in the right direction, especially among MSM and student groups. About 20% of donors and the public were concerned that a change could be detrimental to blood safety. Trust in the Canadian Blood Services was high and the expected policy change would make little difference to this, though the implication is that trust would lift among MSM.⁶⁶

Compliance

In Britain, non-compliance with lifetime deferral was reported by 10.6% of MSM. Ineligible donation was less common in those who reported male-to-male sex in the previous 12 months, as was ineligible donation in the previous 12 months. In the qualitative interviews, reasons given for donation despite deferral were: discounting the experience because it was long ago, practising safer sex, a belief in the infallibility of the blood screening, and feelings of resentment at perceived unfairness.⁶⁵ In Australia, a survey of donors found that 0.23% had not complied with the 12 month deferral for MSM at time of last donation.⁶⁷ Note that this is a survey of donors, not MSM, so the proportions cannot be directly compared. In fact, if the prevalence of male homosexual behaviour is assumed to be 1.9%,⁴¹ the proportion of MSM who did not comply would be 12.1%, similar to the UK survey which was based on non-compliance with lifetime deferral. Non-compliance was associated with older, less educated donors with multiple sexual partners; those perceiving the questions as too personal and not wanting to raise issues with assessors; and history of injecting drug use.⁵⁹ In the US, a survey of MSM in San Francisco found that at least 6% had not complied with the deferral of male-to-male sex since 1977.⁶⁸

The general implications of these data are that 1 year or 5 year deferral periods are more acceptable than longer periods, to both MSM and the general public. Second, compliance by

⁶⁵ Grenfell P, Nutland W, McManus, et al. Views and experiences of men who have sex with men on the ban on blood donation: a cross sectional survey with qualitative interviews. *BMJ* 2011;343:d5604 doi:10.1136/bmj.d5604.

⁶⁶ Ipsos Reid survey for Canadian Blood Services. 2012. Available at: [http://www.blood.ca/CentreApps/Internet/UW_V502_MainEngine.nsf/resources/MSM/\\$file/2012-Ipsos-Reid-Survey-Results.pdf](http://www.blood.ca/CentreApps/Internet/UW_V502_MainEngine.nsf/resources/MSM/$file/2012-Ipsos-Reid-Survey-Results.pdf) Accessed 30.10.2013.

⁶⁷ Seed CR, Lucky TT, Waller D, et al. Compliance with the current 12-month deferral for male-to-male sex in Australia. *Vox Sanguinis* 2013; DOI:10.1111/vox. 12093.

⁶⁸ Belanger GA, McFarland W, Raymond HF, et al. If the permanent deferral were lifted would men who have sex with men want to donate blood, and if so, who would be eligible? *Transfusion* 2013;doi:10.1111/trf.12124.

MSM to deferral is high, but is no higher, and may be lower, in Australia (which has had the shortest deferral period) than in the UK.

(i) Framing the deferral question for MSM: oral and anal sex

Blood Services that defer MSM on the basis of particular sexual behaviours specify oral or anal sex with or without a condom (e.g., Australia, UK, Ireland, South Africa). Canada and the US specify 'sexual contact' in their information to donors as oral (mouth or tongue on someone's ...penis, or anus) or anal.^{69 70}

Nevertheless oral sex carries a low risk of HIV transmission and whether it should continue to be a basis for deferral must be considered.

A reason to consider this change seriously is that it is potentially discriminatory to prevent MSM who exclusively practice lower risk activities from donating if their risk of acquiring and hence transmitting a TTI is of the same order as heterosexuals who are not deferred. Such a change would also satisfy the ethical imperative to remove discriminatory exclusion of donors if inclusion would produce no meaningful increase in recipient risk. Assessment of such a change depends on whether or not it would increase potential infection risk to recipients. The present section considers this issue.

Epidemiological evidence for HIV transmission

The epidemiological evidence for transmission of HIV by oral sex is sparse. A systematic review has concluded that there are insufficient data to estimate precisely the risk but that the risk is low though not zero.⁷¹ One problem with the studies is that the risk may be over-estimated because men are less likely to disclose anal sex than oral sex because of social desirability bias or recall bias. In one such study 20 men initially denied anal sex in written questionnaires but 11 subsequently disclosed it in interviews.

To compare the risk of an HIV infected donation from a heterosexual practicing vaginal sex with an MSM practicing oral sex, the prevalence of HIV in the respective populations and the infectivity of HIV by vaginal sex and oral sex are relevant. In New Zealand the prevalence of HIV is in the order of 40 to more than 100 times higher among MSM than among heterosexuals who are not deferred. The latter figure is based on an estimated prevalence of HIV among pregnant women in New Zealand who are not from high prevalence countries of 1/10,000. Hence the comparative infectivity would have to be at least 40 times lower for oral sex to make the risks comparable. This is plausible, given the estimates of infectivity from oral sex from individual studies, but uncertain because of the paucity of reliable information.

⁶⁹ FDA Blood donor education materials. Available at: <http://www.fda.gov/downloads/BiologicsBloodVaccines/BloodBloodProducts/QuestionsaboutBlood/UCM273092.pdf>. Accessed 27.01.2014

⁷⁰ O'Brien SF, Ram SS, Yi Q-L, et al. Donor's understanding of the definition of sex as applied to predonation screening questions. *Vox Sanguinis* 2008;94:329-33.

⁷¹ Baggaley R, White R, Boily MC. Systematic review of HIV-1 orogenital transmission probabilities. *International Journal of Epidemiology* 2008;37:1255-65.

Hence, the epidemiological evidence suggests it is possible that MSM who have only had oral sex have a similar risk of transmission of HIV as heterosexuals who are not deferred.

Compliance

Compliance with deferral criteria might be higher if men perceive that the criteria are scientifically based and in accord with current safe sex guidelines for MSM. There is also the concern that, by extension, the entire deferral criteria might be seen as discriminatory and hence some men might not comply with any part of the deferral.

On the other hand, compliance depends in part on the framing of the question. Although some MSM have no difficulty answering very specific questions about their behaviour, and want to do so, the epidemiological studies mentioned above suggest that other MSM will be more reluctant to acknowledge anal sex than oral sex in a questionnaire. For exactly this reason, to frame the question to include both oral and anal sex (with or without a condom) may increase compliance with the anal sex deferral, and will preserve more privacy for the potential donor.

A further issue, as described by Leiss and colleagues⁵⁴ is that there might be special problems for Blood Services when sexual behaviour changes over time. Compliance might be more difficult for regular donors if behaviour changes. A donor may be eligible because he has had only oral sex in the last 12 months and then he may become a regular donor. Each time he presents to donate blood, he is asked again about anal sex. If his behaviour changes, will it be more difficult to acknowledge anal sex when he has become a regular donor? The answer to this question is unclear but is likely to be more of an issue with shorter compared to longer deferral periods, and for MSM compared to heterosexuals because of greater likelihood of change in the relevant behaviours.

Risk of other STIs

Oral-genital sex is associated with transmission of other STIs, for instance syphilis,⁷² and oral-anal sex with transmission of both hepatitis B and hepatitis A.⁷³ Removing the deferral for oral sex among MSM could lead to an increase in identified syphilis and hepatitis B among potential donors and to window period infections. In practice transmission of syphilis by transfusion is extremely unlikely because donations are tested and the agent is rapidly destroyed by refrigeration.

Effect on prevalence of HIV among presenting donors

Because sexual behaviours change over time, some men who have only had oral sex in the last 12 months will have had anal sex in the preceding period and may have acquired HIV that has not been diagnosed. This will be a prevalent infection and as such should be identified by the Blood Service and removed. However one result of a change to allow MSM who have had oral sex in the last 12 months to donate is that more HIV infections might be diagnosed. At present one way of monitoring the safety of deferral criteria is to measure the

⁷² Edwards S, Carne C. Oral sex and the transmission of non-viral STIs. *Sexually Transmitted Infections* 1998;74:95-100.

⁷³ Edwards S, Carne C. Oral sex and the transmission of viral STIs. *Sexually Transmitted Infections* 1998;74:6-10.

occurrence of HIV among donors. This would not be reliable if the change was made. Nevertheless, prevalence could also rise with a shorter deferral period, though this was not seen in Australia with the reduction to 12 months.

Other considerations

The protection of the blood supply is a very conservative endeavour. Maintaining public confidence in the safety of the blood supply is also critically important. At present all countries that specify the type of male-to-male sex that should lead to deferral include both oral and anal sex, with or without condoms. To recommend that New Zealand make a world first step in relaxing the current deferral criteria arguably should require more detailed and robust information than available at present to compare the relative risks for HIV, to evaluate the risks for other STIs, and to determine how compliance would be affected.

Although the information is limited, removing the oral sex deferral appears more likely to increase the risk of TTI transmission than to reduce it. A precautionary or conservative approach to blood safety would argue for staying with the oral sex deferral.

(j) Context of human rights law

The New Zealand Bill of Rights Act 1990 ('BORA') applies to government and non-government bodies that perform public functions (s 3(b)). NZBS is a Crown Entity with public functions that include managing the donation and supply of blood and blood products (New Zealand Public Health and Disability Act 2000 (NZPHDA), ss 54-55). In its performance of these public functions, NZBS is required to observe all relevant BORA rights and freedoms.

The BORA states its rights and freedoms broadly (e.g. "freedom from discrimination"). These require specification in particular contexts, here in the context of determining blood donation criteria. They are also subject (s 5) to such "reasonable limits" as are "demonstrably justified in a free and democratic society". BORA s 19(1) provides:

Freedom from discrimination

(1) Everyone has the right to freedom from discrimination on the grounds of discrimination in the Human Rights Act 1993 (HRA).

The grounds of discrimination are stated in the HRA s 21 and include "sexual orientation". The courts have held that BORA s 19 precludes both direct and indirect discrimination, the latter occurring when no prohibited ground of discrimination is directly employed but the effect is that people are treated differently by reason of such a ground. In particular in the present setting, blood donation deferral conditions as to MSM may have the effect of treating persons differently by reason of the HRA s 19 characteristic of "sexual orientation". The distinguishing behavioural characteristic (men having sex with men) is so closely aligned with gay male sexual orientation that it might fall under the rubric of "indirect discrimination" if the other features of the test for discrimination exist.⁷⁴ Such deferral

⁷⁴ In *Northland Regional Health Authority v Human Rights Commission* [1998] 2 NZLR 218, it was determined

conditions would have the effect of deferring MSM from the opportunity to donate blood.

Judicial decisions on the meaning of “discrimination” in s 19 of the BORA have established that there is a two part test:

The first step is to ask ‘whether there is differential treatment or effects as between persons or groups in analogous or comparable situations on the basis of a prohibited ground of discrimination’. The second question is whether the treatment ‘viewed in context ... imposes a material disadvantage on the ... group differentiated against’.⁷⁵

The operation of a deferral might be considered “material disadvantage”, due to its being an exclusion from a valuable social practice of donation, and due to associated stigma for being men who have sex with men. We were advised that cases in the courts to date have tended to involve financial disadvantages rather than social stigma. However we have proceeded on the basis that for ethical even if not for legal reasons it is right that the deferral criteria be tailored so far as possible to avoid this stigma.

Next, while it might be said that there is no “right to donate” such that exclusionary criteria do not fall to be justified at all, the better view is that the overall function of NZBS in relation to the blood supply embraces *all* the actions required for it to operate – that is, the recruiting of donors and setting the terms for acceptable donations, as well as processing and providing blood products. In that sense, adopting criteria for donor deferrals is an “act done” in connection with the performance of NZBS’s “public functions”, and so subject to the BORA as a result of s 3(b)⁷⁶. In other words, the issue is not whether there is any “right to donate” but whether the criteria that NZBS adopts in relation to donations are consistent with its obligations under the BORA. There may be no right to donate, but there *is* a right to be free from discrimination on the prohibited grounds.⁷⁷

that the concept of discrimination should be interpreted broadly and purposively and, in particular, that whether discrimination is the intended consequence of policies or actions is immaterial to the question of whether discrimination exists in fact. Both direct and “indirect” discrimination are proscribed by section 19 of the Bill of Rights Act, and the concept is defined in section 65 of the Human Rights Act 1993. 51

⁷⁵ See *Child Poverty Action Group v Attorney-General* [2013] NZCA 402 at para [43], citing from *Ministry of Health v Atkinson* [2012] 3 NZLR 456 (NZCA).

⁷⁶ Section 3(b) provides:

3. Application—This Bill of Rights applies only to acts done—
[...]

(b) By any person or body in the performance of any public function, power, or duty conferred or imposed on that person or body by or pursuant to law.

⁷⁷ See *Cain v Australian Red Cross Society* [2009] TASADT 03. This concerned a complaint under Tasmania’s equivalent of the New Zealand Human Rights Act 1993, which prohibited discrimination on the grounds of “sexual orientation” and “lawful sexual activity” (the latter not being a ground in the New Zealand legislation). The complaint concerned a deferral policy of 12 months for MSM. Application of Tasmania’s legislation turned first on whether the facilities and criteria for blood donations were a “service” offered by the Red Cross, or at least were “in connection with” a service (this being the phrase from the legislation). The Tribunal ruled that the Red Cross’s “service” could readily be conceived as embracing the soliciting of donations on the criteria that it sets, given that collecting blood is integral to its activity. But in any event it was enough to say that the deferral period was imposed “in connection with” the service of producing blood and blood products.

Similar reasoning would apply in New Zealand if the matter fell to be determined under our Human Rights Act. In fact, for reasons already explained, it is the BORA that applies and not the Human Rights Act. Under the BORA there is no equivalent requirement (to establish that there is a “service”). Rather, the issue under BORA is

In sum, the criteria that the NZBS employ for accepting or declining blood donations must be consistent with BORA and HRA rights against discrimination.

The next matter is whether, in terms of BORA s 5, any indirect discrimination that might be present in the specification or application of blood donation criteria can be regarded as “reasonable limits” (on the right against discrimination) that are “demonstrably justified in a free and democratic society”.⁷⁸ The required approach to this question has been established by judicial decisions. The following questions arise:⁷⁹

- (a) does the limiting measure serve a purpose sufficiently important to justify [curtailing the right]?
- (b) (i) is the limiting measure rationally connected with its purpose?
(ii) does the limiting measure impair the right ... no more than is reasonably necessary for sufficient achievement of its purpose [minimal impairment]
(iii) is the limit in due proportion to the importance of the objective [proportionality]?

As to (a), the objective of the limiting measure – ensuring the safety of the blood supply – is manifestly important. The Gazette Notice associated with the NZPHDA states this objective as the requirement that the NZBS shall ensure its functions: “(b)... are carried out safely and to a high level of quality, and shall take all reasonable precautions with a view to ensuring that the blood... [is] safe for use”.

And the “limiting measure” – here the deferral of persons in high risk groups – is rationally related to that objective. Put in terms of the above judicially-developed criteria, steps (a) and (b)(i) can therefore be answered affirmatively.

The relevant issues then become minimal impairment in (b)(ii) and proportionality in (b)(iii). These can be considered together.

One significant matter in any potential change or confirmation of existing blood donation criteria is therefore what difference, if any, it would make to the safety of the blood supply, compared to the most relevant alternative option. The other significant matter is what difference, if any, such change or confirmation of existing blood donation criteria would make to the extent of any breach of the right against discrimination, again compared to the

whether a deferral on the criteria is an “act done ... in the performance of [a] “public function” (s 3(b)). We were advised that a Court is likely to so hold, especially given that the Human Rights Act 1993, which would apply to private sector discrimination in New Zealand, is to substantially similar effect as the Tasmanian legislation involved in the *Cain* case (that is, the Human Rights Act, too, embraces acts “in connection with” the provision of “services”. The scope of the phrase “acts done ... in the performance of a public function” in s 3 of BORA is likely to be held at least as extensive as the equivalent provisions in the Human Rights Act for non-public actors.

⁷⁸ Section 5 of the Bill of Rights provides:

5. **Justified limitations**—Subject to section 4 of this Bill of Rights, the rights and freedoms contained in this Bill of Rights may be subject only to such reasonable limits prescribed by law as can be demonstrably justified in a free and democratic society.

⁷⁹ *Child Poverty Action Group v Attorney-General* [2013] NZCA 402 citing *R v Hansen* [2007] 3 NZLR 1 (SCNZ), adopting the Canadian approach to this issue from *R v Oakes* [1986] 1 SCR 103 (s 5 of BORA was adapted from s 1 of the Canadian Charter of Rights and Freedoms; hence the significance of the Canadian approach).

most relevant alternative option. Finally, considering any such difference to blood safety, and any such difference to the right against discrimination, the overall question would be whether the connection between these two matters is proportionate.

Summary of evidence relevant to a decision on whether to change the deferral criteria

Maintaining the safety of the blood supply, while at the same time interfering as little as possible with the rights and freedoms of potential donors, is the objective of the decision making. Any restrictions must be rational and proportionate.

The evidence points towards shortening the deferral for men who report sex with men to 12 months. In reaching this conclusion we have taken particular account of advances in donation testing and handling, such that errors have now been virtually eliminated from the system; new modelling studies that have identified the current risk of HIV in advanced Blood Services as almost entirely (95%) from window period infections; the reported experience of Australia which has had a 12 month deferral for more than 10 years and no identified transmissions of HIV or other relevant TTIs and indications of no worse compliance; and the apparent high compliance with current deferral criteria in New Zealand.

In addition, the views of MSM gained in other jurisdictions show that knowledge of the rationale for deferral is important and may improve compliance. The rationale for the previous five-year deferral was relatively complex, though it was explained in the previous report, relating to a risk of both window period infections and to prevalent infections through test or quarantine and release errors. The latter can now be considered negligible, and a 12-month deferral – based on the length of the window periods for the relevant infections plus a cautious margin of error – is easier to explain.

One of the alternatives we considered was a 6-month deferral, as has recently been recommended in Australia (though it has not been accepted by their regulatory authority, the TGA). We have decided against this largely on the basis that there is neither evidence of how it will work in practice nor evidence from modelling, and there is less margin for error in mis-judging time since last sexual contact. In these circumstances we could not be satisfied that such a move, although slightly less restrictive for MSM, would attain the objective of the deferral criteria.

The other alternative we considered was further specifying the sexual behaviour that should be subject to deferral. In 2008 we rejected this approach as being dependent on there having been research showing that such questions can distinguish people at higher risk from those at little increased risk. Since that time, no such research has been published. In relation to number of partners, modelling studies⁴² show that the risk of *not detecting an HIV infection in donated blood* is substantially greater (in the order of 60 times) for an average MSM who reports himself as monogamous than for an average heterosexual with one new partner, due to the substantially higher risk of an unknown HIV positive partner. In

addition, there are disadvantages to in-depth questioning because it is intrusive, and there is also limited evidence that some MSM who do not comply with donor deferral already find questions about sexual risk too personal.⁵⁹ Furthermore, people are not reliable at assessing their own risk. In New Zealand, most MSM who had undiagnosed HIV infection believed that they were definitely or probably uninfected, and many had had a recent negative HIV test. Again, we could not be satisfied that such a move would be consistent with attaining the overall objective of the donor deferral criteria.

We also considered whether deferral for oral or anal sex should be retained. Though the risk of HIV transmission by oral sex is very low, it is uncertain, and other considerations caution against a change. These are uncertainty about the effects on compliance because of the framing of the question, the risk of other STIs, the precautionary principle, and the conservative nature of Blood Service activities. Although the information is limited, removing the oral sex deferral appears more likely to increase the risk of TTI transmission than to reduce it. In this situation, a precautionary or conservative approach to blood safety argues for staying with the oral sex deferral.

For heterosexuals and sex workers from countries with higher prevalence of HIV, the relevant evidence is similar to that mentioned above in relation to MSM. As there is now a negligible risk from missing established or prevalent infections, a longer deferral period than 12 months cannot be justified. A change to a 12-month deferral for all people who come from, or who have lived in, areas of higher HIV prevalence, and all sex workers, also simplifies the process of donor selection.

In 2008, the possibility of unknown or untested for sexually transmitted TTIs was part of the rationale for a longer deferral period, with expert opinion suggesting novel infections would be diagnosed within 5 years. We have reconsidered this issue in the light of the new infections which have emerged since that time. In addition, a review of new TTIs has noted no consistent pattern to predict emergence and magnitude of threats to blood safety.⁸⁰ These facts, together with the current intensive surveillance for emerging infections and the decisions of Australia and the UK not to base deferral periods for MSM on risks of uTTIs, has led us to decide that keeping a five year deferral period on this basis is not proportional. Nevertheless it is likely that many of the men who would become eligible to donate with a 12 month deferral (i.e. no sex with a man in the last 12 months) will also not have had sex with a man in the preceding few years, so will be less at risk of uTTIs.

⁸⁰ Stramer SL, Dodd RY. Transfusion-transmitted emerging infectious diseases: 30 years of challenges and progress. *Transfusion* 2013;53:2375-83.

7. RECOMMENDATIONS

Recommendations on deferral criteria

The review group makes the following recommendations, based on the evidence discussed in the present report.

- (a) Men who have sex with men
It is appropriate to have ongoing exclusion based on the specific sexual behaviour. The current deferral period for men after having had sex with a man should be shortened to 12 months. The stipulation that this applies to oral or anal sex, with or without a condom, should be retained.
- (b) Heterosexuals from geographical areas with a high prevalence of HIV
The deferral of heterosexuals who have lived in or come from an area with a generalized epidemic of HIV should continue but should be shortened to 12 months.
- (c) Sex workers
The deferral of current sex workers should continue. The deferral period for people who have engaged in sex work in New Zealand should remain at 12 months, and for those who have engaged in sex work elsewhere, it should be shortened to 12 months.
- (d) Sex with someone at higher risk of STIs, especially HIV
A 12 month deferral should be continued for women who has had sex with a bisexual man, those who have had sex with a person who carries the Hepatitis B or C viruses, or with an injecting drug user, a sex worker, a person with haemophilia or related condition who has received treatment with plasma-derived clotting factors at any time, or with a person who lived in or comes from a country with high HIV prevalence.
- (e) Amendments to one other related deferral criterion is recommended. Question 1 of the Health Questions states “You must never give blood if you or any of your current (**or past**) sexual partners have (had) AIDS or a positive test for HIV”. [emphasis added]. The permanent deferral of people with current sexual partners with HIV is appropriate, but the permanent deferral for people with past sexual partners with HIV should be shortened to 12 months since last sexual contact, in line with the other recommendations. Nevertheless, it should be made clear that anyone who has had sex with someone with HIV and has not been tested subsequently should not donate.

Recommendations on communication with the relevant populations

Advice on effective communication tools to improve overall compliance with the deferral criteria, and to explain the reasons for their ongoing use, was given at the time of the 2008 review.

The review group recommended that the NZBS look at developing and evaluating its mechanisms for informing the public regarding the eligibility criteria for donation, encouraging the act of donation whilst better enabling any individuals affected by any deferral criteria to recognise the fact and self defer. This included advice to: (a) establish an ongoing systematic programme of public education including making information available to enable potential donors to self-defer, including reviewing the 'Safe Blood Starts with You' leaflet, working with the AIDS Foundation on a leaflet, and use of the NZBS website for self-deferral; (b) review the donor questionnaire; and (c) review the interview.

The NZBS has made considerable progress since the last review. Public information to increase self-deferral for MSM has been improved by working with the New Zealand AIDS Foundation to develop a leaflet, implementation of a new 'Frequently Asked Questions' for donors on the website; and importance of self deferral has been emphasised with recruitment teams and included in the revised Donor Coordinators Handbook. HIV awareness courses are run for NZBS nurses by the AIDS Foundation and these have recently been extended to recruitment teams. All donor staff are expected to have an opportunity to participate.

Review of the donor questionnaire for plain English was undertaken in 2009. The main criticism was that there was too much information in too small a document, but this has not yet been modified for practical reasons. The NZBS has identified improvements 'for clarity and understanding' as a major future project. The interview has not been reviewed, though staff training should have improved handling of sensitive issues. Nor has translation of the donor questionnaire been undertaken, though leaflets about blood donation are now translated into relevant languages.

Further recommendations for 2014 are:

- (a) A communication strategy to inform people of the new criteria and to enable self-deferral among MSM, sex workers, and people from geographical areas with high HIV prevalence should be developed, extending the approach already used by NZBS.
- (b) Improvements in the questionnaire for clarity and understanding should proceed.
- (c) The issue of translation of the questionnaire into languages relevant to the increasingly diverse New Zealand population should be considered again. We appreciate that potential donors must be able to be interviewed and that it may be impracticable to have specialist nurses available who can speak the relevant languages. Nevertheless interpreters are used in many other areas of the health system.

Recommendations for future research

(a) Relevant to the acceptability of the deferral criteria

Acceptability and compliance with the deferral criteria are important. While the very small numbers of diagnosed HIV infections amongst donors suggest that compliance is excellent, there are a few instances where donors later acknowledged risk behaviours, showing

compliance is not complete. Compliance depends on understanding the deferral criteria, agreeing with them sufficiently, and feeling comfortable enough to disclose the risk behaviour.

A survey of MSM on knowledge and attitudes to deferral would be valuable. In addition, a survey of blood donors asking about compliance with deferral criteria and reasons for non-compliance would assist in determining whether modifications to the donor questionnaire or interview should be made.

(b) Relevant to assessing sexual risk for TTIs in the population

While excellent information is available for MSM on sexual behaviour and HIV risk, and risk of other STIs, there is a paucity of information on heterosexual behaviour and on sex work. The proposed national survey of sexual and reproductive health should include questions about sex work, for both workers and clients. Though understandably more emphasis has been put on surveys of safety among sex workers, further research should examine issues of condom use and STI occurrence among sex workers who work in different situations (e.g. 'managed' versus street workers).

A repeat study of HIV among sexual health clinic attenders, and among MSM recruited from community settings, would provide updated estimates of relative HIV burden and progress on reducing incident unrecognised infections respectively. The forthcoming national survey of sexual and reproductive health would provide comparative data on sexual behaviours for MSM and heterosexual men and women in the New Zealand population.

Future review of deferral criteria

These criteria should be reviewed again when there is information which might materially affect future decisions.

Appendix 1

Terms of Reference

Proposal for a Review of NZBS Behavioural Donor Criteria

1 PART I: INTRODUCTION AND BACKGROUND

1.1 Internationally Blood Services take steps to reduce the risk of transfusion borne viral infection. Rather than rely on any single step in isolation, scientific evidence demonstrates that a combination approach is a more effective screening method.

1.2 Consistent with this, in New Zealand, a three tier combination approach to safety is currently adopted:

(a) Individuals whose lifestyle or behaviour places them at increased risk of acquiring blood borne infection are excluded through a series of questions asked before donation takes place.

(b) Highly sensitive and specific tests are carried out on donated blood to identify prospective donors who are already infected.

(c) When available physical and/or chemical methods are used to inactivate viruses and other infectious agents (pathogen reduction). Currently these methods are utilised for manufactured plasma products but are not routinely available for blood components.

1.3 The current behavioural donor criteria utilised by NZBS were developed in 2008 by an independent expert review led by Professor Charlotte Paul from the University of Otago. The 2008 review recommended that the criteria should be reviewed again after five years in order to ensure that the criteria remain consistent with developing scientific knowledge and international practice.

1.4 The criteria introduced following the 2008 review are as follows:

You should NEVER give blood if:

- You, or any of your current (or past) sexual partners have (had) AIDS or a positive test for HIV.
- You carry the Hepatitis B or C virus.
- You have ever injected yourself, even once, with drugs not prescribed by a Doctor.
- You have haemophilia or a related clotting disorder and have received treatment with plasma derived clotting factor concentrates at any time.
- You think you need an HIV or Hepatitis test.

You should not give blood for FIVE YEARS :

- Following oral or anal sex with or without a condom with another man (if you are male)
 - After engaging in sex work (prostitution) or accepting payment in exchange for sex in any country other than New Zealand
- After leaving a country in which you have lived and which is considered to be at high risk of HIV infection (includes sub Saharan Africa and parts of Asia. Full list available at blood collection sessions and at www.nzblood.co.nz)

You should not give blood for ONE YEAR

• Following sex with anyone:

- whom you know carries the Hepatitis B or C virus.
- who is a sex worker (prostitute).
- who has ever injected themselves with drugs not prescribed by a Doctor.
- who lives in or comes from a country considered high risk for HIV infection.
- who has haemophilia or a related blood clotting disorder and received treatment with plasma derived clotting factor concentrates at any time.
- After engaging in sex work (prostitution) or accepting payment in exchange for sex in New Zealand.
- If you are a woman, after engaging in sex with a man who has had oral or anal sex with another man.

1.5 Significant developments have occurred both within NZBS and internationally since the review undertaken in 2008. These include:

- (a) Implementation in 2008 of single donation Nucleic Acid Testing (NAT) for HIV, HCV and HBV. This has increased overall sensitivity of the testing systems used by NZBS for these viruses with a consequent reduction in the early 'window period'
- (b) In 2012 NZBS implemented an upgraded blood management system (e-Progesa). This will support the future introduction of an electronic donor questionnaire. No timelines have been established for this.
- (c) The Australian Red Cross Blood Service (ARCBS) commissioned their own review on the topic. The report identified that the deferral for men who have sex with men (MSM) might safely be reduced to 6 months subject to the demonstration that the change will not impact on compliance.
- (d) United Kingdom Blood Services, other than Northern Ireland, moved from a permanent deferral for MSM to a 12 month deferral in 2011.
- (e) Canadian Blood Services moved from a permanent deferral for MSM to a five year one in July 2013.
- (f) Adoption of a resolution by the Council of Europe on sexual behaviours of blood donors that have an impact on transfusion safety Resolution CM/Res (2013)3 in March 2013.

1.6 NZBS continues to be aware of concerns in the gay community, in New Zealand and overseas, in relation to the behavioural screening questions, and the criteria that apply to gay blood donors through those questions. 3 complaints have been received by the Human Rights Commission (HRC) since 2008. These were all dealt with through the HRC mediation process. Rainbow Wellington in particular continues to lobby for change to the current policy.

1.7 Given the above, NZBS intends to commission a further independent review of the behavioural screening questions with the aim of ensuring that they remain consistent with best international practice and continue to be appropriate in the local New Zealand environment. This review will utilise the framework developed for the 2008 review and focus on scientific, regulatory and other relevant information that has become available since the last review.

2. PART II: TERMS OF REFERENCE

The Review Group

- 2.1 The review will be undertaken by an independent expert group. This will be chaired by Emeritus Professor Charlotte Paul. The Review Group will be comprised of suitably qualified experts and will be selected by agreement between the chair person and NZBS from willing and available candidates. Where possible this will include members of the original review group from 2008.

Principal Task of Review Group

- 2.2 To review the ongoing appropriateness for exclusion of donors on the basis of current and/or past behaviour to ensure the on-going safety of blood and blood products provided in New Zealand.
- 2.3 In the event that a form of screening relying on behavioural donor criteria remains appropriate, to recommend how exclusions from donation should be structured.

Process

- 2.4 NZBS does not seek to prescribe what steps the Review Group might consider useful in order for it to carry out its task. NZBS does require that the process follow a particular sequence, and that a focused consultation exercise takes place in the manner stipulated in Part III of this document. Other than that, it is for the Review Group to decide for itself how it will carry out this Terms of Reference and provide to NZBS its report and recommendations.

Areas of emphasis

- 2.5 Particular emphasis should be placed in the following areas:
- (a) The appropriateness of ongoing exclusion on men who have had sex with men and in particular:
 - (i) Whether it is possible to define specific sexual activities that should result in exclusion from donation.
 - (ii) Whether (in the context of routine blood donation operations) it is possible to consistently identify a set of criteria by which individuals might be identified whose risk of acquiring blood borne infections is likely to be higher than that of the wider population.
 - (iii) The appropriate period (if any) of any exclusion.
 - (b) Consideration of possible approaches to protect the donated blood supply from the risks associated with HIV acquired through heterosexual activity, with particular emphasis on risks associated with sexual exposure with people in or from geographic areas of high prevalence.

- (c) The appropriateness of continuing to exclude current and former sex workers and the appropriate period of any such exclusion.
- (d) Advise on the development of effective communication tools to improve overall compliance with the behavioural donor criteria and to explain the reasons for their ongoing use.

Sources to be consulted

- 2.6 In undertaking the review the following sources are **required** by NZBS to be considered by the Review Group (in addition to any other material that the Review Group might consider relevant and helpful to this Terms of Reference):
- (a) Epidemiological and other survey data on the pattern and mechanisms of transmission of HIV infection and other blood borne infections in New Zealand and overseas.
 - (b) Current international practice by major international Blood Services.
 - (c) Data in relation to transfusion transmission of blood borne virus infections and mechanisms whereby this might be reduced.

Assistance and resources

- 2.7 NZBS is available to provide the Review Group with assistance and resources in carrying out its functions. It is not anticipated that the Review Group will need to engage any contractors of its own to assist it in carrying out its review.
- 2.8 NZBS will provide to the Review Group as part of its process:
- (a) A legal briefing at the outset so that the Human Rights issues can be properly appreciated and understood.
 - (b) Information concerning the activities and systems used by NZBS as required by the review group.

Expectations

- 2.9 In developing the recommendations the Review Group is expected to address:
- (a) Compliance with current New Zealand legislation.
 - (b) The over-riding obligation of NZBS to ensure that blood components provided for transfusion to patients are as safe as reasonably achievable.
 - (c) The regulatory obligations of the NZBS including conformance with recognised international standards.
 - (d) Ethical issues in relation to both potential donors and recipients of blood and blood products.

- (e) The practicalities of implementing recommendations in the routine environment of NZBS activities.

3. PART III: THE REVIEW PROCESS

- 3.1 The review is intended to occur in a number of phases, as follows: Phase One – appointment of Review Group
- 3.2 The review will be undertaken by an expert group led by an independent chair. The chair will be appointed by NZBS. Membership of the group will be agreed jointly by the independent chair and the NZBS.

Phase Two – review and development of draft discussion paper

- 3.3 The Review Group reviews the medical and scientific literature and develops of a draft discussion paper with initial recommendations.

Phase Three – consultation

- 3.4 The draft discussion paper and the initial recommendations will be consulted upon with appropriate stakeholders. The mechanism for consultation will be jointly agreed upon by the independent chair and the NZBS. The intention of NZBS is that the expert group will carry out a focused consultation exercise with appropriate and relevant organizations with an interest in the issues at stake.

Phase Four – review and reconsideration

- 3.5 The responses received from consultation will be reviewed by the expert group. The draft discussion paper and the recommendations will be reviewed in the light of the comments and feedback received through the consultation process.
- 3.6 The Review Group will then prepare their draft final report and recommendations.

Phase Five – Scientific peer review

- 3.7 The draft final report and recommendations will be reviewed by an appropriate expert to confirm scientific accuracy and appropriateness of the recommendations.

The comments arising from the scientific review will be reviewed and a definitive report developed for the New Zealand Blood Service.

Phase Six - NZBS consideration and review

- 3.8 The position paper and recommendations will be provided to NZBS for internal review and final sign off by the NZBS Board. NZBS will determine if a formal legal review of the contents and recommendations is appropriate as part of this process.

Phase Seven – implementation and other approvals

- 3.9 This will involve gaining regulatory approval from Medsafe for any changes to current practice, and the implementation of any approved recommendations throughout the NZBS organisation and donor centres.

PETER FLANAGAN
National Medical Director NZBS
September 2013

Appendix 2

Review Group members

Chair

Emeritus Professor Charlotte Paul

Members

Associate Professor Andrew Moore, Department of Philosophy, University of Otago

Associate Professor Nigel Dickson, Director, AIDS Epidemiology Group, University of Otago

Mr Grant Storey, Principal Technical Specialist (Blood), Clinical Leadership, Protection & Regulation, Public Health\Communicable Diseases, Ministry of Health

Dr Julia Peters, Public Health Physician, Auckland Regional Public Health Service, ADHB.

Dr Steve Ritchie, Infectious Disease Physician, Auckland District Health Board and Senior Lecturer, Molecular Medicine and Pathology, School of Medical Sciences, University of Auckland

Dr Peter Saxton, New Zealand AIDS Foundation Fellow, School of Population Health, Faculty of Medical and Health Sciences, University of Auckland

Mr Richard Scott, The Haemophilia Foundation of New Zealand Inc. (HFNZ)

Dr Paul Parish, NZBS donor representative

Review Group Advisors

In attendance

Dr Peter Flanagan, National Medical Director, NZ Blood Service

Legal advisor

Professor Paul Rishworth, Barrister, Auckland

Secretariat/researcher

Dr Gabrielle McDonald, Public Health Physician

Appendix 3

Organisations consulted

NZ Sexual Health Society

Australasian Society for Infectious Diseases, New Zealand branch

OUTLine NZ

Body Positive Inc., Auckland Branch

Body Positive Inc., Wellington Branch

Haemophilia Foundation NZ National Office

Hepatitis C Resource Centre

The Hepatitis Foundation of New Zealand

Immune Deficiencies Foundation of New Zealand

Te Kupenga Hauora Māori, Faculty of Medicine and Health Sciences, The University of Auckland

Leukaemia and Blood Cancer New Zealand

Director General of Health, Ministry of Health

New Zealand AIDS Foundation National Office

New Zealand Prostitutes Collective National Office

Ngā Pae o te Māramatanga, The University of Auckland

Positive Women

Refugee Council of New Zealand

Louisa Wall, MP

Grant Robertson, MP

Kevin Hague, MP

New Zealand Medical Association

Medical Council of New Zealand

Council of Medical Colleges

Rainbow Wellington

University of Auckland LGBTI Network

Rainbow Group, Faculty of Education, The University of Auckland

Rainbow Youth Incorporated

National Haemophilia Management Group

Dr Jim Faed, Transfusion Specialist

INA (Māori, Indigenous and Pacific Island HIV/AIDS Foundation)

Chief Medical Officers of each DHB

Appendix 4

Respondents to consultation document

Dr Don Mackie, Chief Medical Officer, Ministry of Health

Dr Mark Peterson, Chair, New Zealand Medical Association

Tony Hughes, Scientific Director, NZ AIDS Foundation

Phil Camish, Chief Executive, Bay of Plenty DHB

Dr Sally Roberts, Clinical Head of Microbiology, Auckland DHB

Steve Gibbons, Chair, Transfusion Committee, Canterbury DHB

Rainbow Wellington

Jackie Edmond, Chief Executive, NZ Family Planning Association

Dr Edward Coughlan, President, NZ Sexual Health Society