Behavioural Donor Deferral Criteria Review

Final Report to the New Zealand Blood Service

April 2008

Preface

This report was first distributed in draft form for consultation in October 2007. A wide range of groups and individuals commented on the draft. The consultation raised a number of very important issues which have now been addressed, as far as possible, in the final version. The particular issues which were raised and how they have been addressed are described below. It is important to note that the review was constrained by the terms of reference to focus mainly on deferral on the basis of sexual behaviour, and hence on the most severe sexually transmitted transfusion transmissible infection: HIV. Nevertheless, other infectious agents transmitted sexually and by injecting drug use were also considered, and we have attempted to ensure, as far as possible, that they have been addressed in a consistent manner.

1. The recommendation to continue any deferral of men who have had sex with men received the most attention. It is acknowledged that the draft report was not fully sensitive to the way in which, for gay men more than any other group, it could appear that deferral was on the basis of identity not behaviour. We have now clarified that it is not identity but specific behaviours (in the context of high prevalence of infection among their partners) which are the subject of deferral.

2. There was a perception that, if only behaviours mattered, then deferral should apply equally to men who have had sex with men (MSM) and to heterosexuals. The reason this is not so is because what matters (as well as behaviour) is the prevalence of HIV among sexual partners. It needs to be emphasised that the prevalence of HIV infection is 40 times greater among MSM than heterosexuals in New Zealand. A deferral period is specifically recommended for those whose partners are at higher risk, in order to exclude very recently infected donors whose infection may not be detected by available tests. These groups are MSM, women who have had sex with a bisexual man, and people who have had sex with someone from a country with high HIV prevalence. A one-year deferral period will substantially reduce the risk of transfusion transmission in these situations. In fact the

average window period (when HIV will not be detected) is much shorter, but a one-year deferral is simple and takes into account the fact that there is some variation in the window period.

3. The reason for a proposed longer deferral period for MSM than the other groups was a source of concern and some confusion. A longer-than-one-year deferral period is used around the world in order to prevent donors with longer standing infection (prevalent cases) from donating. These infections should be able to be detected by current systems, but if there are errors or system failures, they may still be present in blood that is transfused. The groups in New Zealand with higher rates of prevalent infection are MSM and people from high HIV prevalence countries (but not their sexual partners if they do not belong to those groups). The other reason for a longer deferral period is that some groups are more likely to have unknown or untested for sexually transmitted, transfusion transmissible infections (TTIs).

4. Some people recognised the reason we gave for a longer deferral period for MSM but rejected it on the basis that the risk of errors and system failures is so low it can be discounted. We have sought more information on the likelihood of such errors, and conclude that although very small, these risks cannot be discounted. Hence we have recommended a deferral period of five years. See pages 60-63.

5. A criticism was made that the deferral period for heterosexuals from a high prevalence country should be consistent with the deferral period for MSM. We agree with this criticism. In general, in both situations there is a higher rate of prevalent infection and hence a similar deferral period is warranted. See pages 63-65.

6. There were two issues raised in relation to sex work. There was concern that sex workers from high prevalence countries may be reluctant to acknowledge sex work. Hence we agree it would be appropriate to have the same deferral period for all heterosexuals from high prevalence countries. Secondly, it was questioned whether recommendations for sex workers from outside New

Zealand should apply to those from countries such as Sweden or Australia. Unfortunately it is not possible to make recommendations that require detailed information about the patterns of HIV and other sexually transmitted infections among sex workers in many different countries. See pages 65-66.

7. The lack of evidence provided to justify the lifetime deferral of injecting drug users was criticised. We have now included more information to explain the reasons for these recommendations. See pages 33-35.

8. There was concern that in questioning potential donors about broad behavioural risks, many individuals would be deferred despite being at little risk. This is an inevitable consequence of the use of simple questions. We have considered whether more detailed questioning could be used, as it is in sexual health clinics or family planning clinics. The introduction of more specific questioning about sexual behaviours is dependent on prior research showing that such questions can distinguish people at higher risk from those at little increased risk. At present it is standard across the world to have broad based deferral categories. The exception is Italy, because an individualised approach is used there. However, Italy has a high rate of HIV infection in both new and repeat donors, illustrating that further research needs to be undertaken to improve this method of questioning (see Table 5).

9. The context in which deferral policies operate was not made sufficiently clear in the draft document. In the order of 12 percent of potential donors are deferred either on account of their own health or possible risk to transfusion recipients. For instance people who have had a surgical operation, a blood transfusion, been tattooed, or had body or ear-piercing are not allowed to donate for periods up to one year.

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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 and drug using 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 was independent of the NZBS. Dr Peter Flanagan, Medical Director NZBS, provided expert input into the review, but did not participate in the decision making.

The principal task of the review group was to review the ongoing appropriateness of exclusion of donors on the basis of current and/or past behaviour to ensure the safety of blood and blood products in New Zealand. Particular emphasis was put on: (a) the appropriateness of ongoing exclusion of men who have had sex with men (MSM), (b) possible approaches to the risks associated with heterosexual activity in relation to geographic areas of high prevalence, (c) sex work and (d) advice on the development of effective communication tools.

Relevant issues

The NZBS was established in 1998 by the Health Amendment Act. 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. Regular reviews are required because of changes in the operation of the NZBS and in the external environment. In addition, questions have been raised about the justification for the current donor deferral criteria.

There are four 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 will 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 are carried out on

the donated blood, and (for manufactured plasma products) the use of physical and/or chemical methods to inactivate infectious agents.

The reason for asking a potential donor not to donate at this time ("donor deferral") is to further reduce the risk that an infectious agent will be transmitted in a blood donation. The specific reasons are: (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 infections pose a potential risk of transmission. People who have shared injecting drug use equipment also have a higher prevalence of other transfusion transmissible viruses. The major risk behaviour for hepatitis C in New Zealand is injecting drug use. For hepatitis B, the main risk relates to new window period infections and hence recent sexual or injecting drug using behaviour is relevant. For HIV (which is the most severe disease), the risks of transfusion relate to both new window period infections ("incident infections") and established infections ("prevalent infections"). The risk for the latter arises because of potential errors in testing or in the quality system. Hence behaviours that place individuals at risk of both incident and prevalent infections are relevant.

Deferral for other reasons apart from sexual or drug using behaviour is already in place in New Zealand. For instance, because of a theoretical risk of variant Creutzfeldt-Jakob Disease (vCJD) and the lack of a blood test for the infectious agent, people who resided in the 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. Overall approximately 12% of all people who present to donate blood are deferred.

The epidemiology of HIV in New Zealand shows that new diagnoses have increased since 2002, and that this increase is equally among homosexually and heterosexually acquired infections. Most heterosexual infections were acquired overseas. Incident infections in New Zealand – as judged from new diagnoses – were mostly acquired through male-to-male sex (82% for 2003-2006). For prevalent infections the only information is from people attending sexual health clinics. Among this group, in 2005/6, the prevalence of undiagnosed HIV infections was 40 times higher among MSM (20.1 per 1000) than among heterosexuals (0.5 per 1000). Prevalence will also be relatively high amongst people who have migrated to New Zealand from countries with generalized HIV epidemics, though no measure is available.

The current behavioural deferral criteria are that MSM are deferred for 10 years since last male-to-male sexual contact. This is shorter than the UK, US and Canada (lifetime or from 1977) but longer than Australia (one year). Detailed evaluations of deferral periods have been reviewed. There is no published evaluation from Australia. The evaluations show that adherence to deferral is high and that the current risks of transmission of HIV by transfusion are extremely low. Modelling approaches suggest that shortening the deferral period to one year (from lifetime) would increase the already very low risk slightly (in the range of 8 to 66%). There is evidence that a five-year deferral period is as safe as a 10-year deferral period. This comes from data on the very small residual risk of HIV transfusion estimated from current deferral criteria (and hence any hypothetical safety margin will be immeasurably small); secondly from the indirect evidence about HIV prevalence in current US donors who didn't self defer (that men who had abstained from male to male sex for longer than five years did not have raised HIV prevalence); and thirdly that five years is estimated by experts to be long enough to detect novel pathogens.

Similar issues arise for any population in which there is a high prevalence of HIV infection (>1 percent). A short deferral period (for example, one year) will eliminate the risk of "window period" infections, but a longer deferral period will reduce the small risk of not detecting a "prevalent" infection. This applies to MSM and to heterosexuals from countries with high HIV prevalence.

The legal matters which are relevant include the Code of Health and Disability Services Consumers' Rights Regulations 1996 and the New Zealand Bill of Rights Act 1990. The policy approach taken in this report is to determine whether deferral criteria are justified on health and safety grounds. In particular, if there is to be different treatment of a group on behavioural grounds, these must be justified and proportionate and not able to be met reliably in any less restrictive way. Ethical principles were used to consider whether a change in policy would represent an overall improvement, taking both harms and benefits into consideration. It is appropriate to give significant priority to non-maleficence (doing no harm) because recipients face involuntary risks from blood products. Policy and practice concerning blood donation should not impose levels of risk on recipients of the blood supply that alternative policy and practice would not impose. Strictly speaking, donor deferral does not restrict offers to donate, only acceptance of such offers, and the view that there is no right to donate follows from this. Even so, donating blood is a valued social activity. Policies of donor deferral are thus restrictive practices because they generate a form of social exclusion and potentially add to stigma. Therefore, the central question, both legally and ethically, is whether the extent of the restriction is proportionate to the health and safety objective.

Recommendations

(a) The deferral criteria for people who have injected themselves with drugs not prescribed by a doctor should remain (lifetime deferral).

(b) The current ten-year deferral period for men who have had male-to-male sex should be shortened to five years. The grounds are that a change to a five-year deferral will 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 aims to attain the least restrictive method of maintaining the safety of the blood supply.

The wording of the question on the "Donor Questionnaire" (see Appendix One) for MSM should be changed to improve clarity around the use of the

word “sex”. This should be changed to: “…you have had oral or anal sex with or without a condom.”

It is not practicable at present to further define specific sexual activities among MSM that should result in exclusion from donation. Lower-risk activities than unprotected anal intercourse, for example, anal intercourse with a condom or oral sex, are still associated with small risks of HIV transmission, and the absolute risk of transmission depends also on the prevalence of HIV among sexual partners, which is considerably higher for MSM than for heterosexuals. Nevertheless, it is the activities not sexual orientation that is the central issue.

(c) The deferral criteria for heterosexuals who have lived in, or who come from, specified countries should be modified. The list of countries and map should change to better reflect the areas with generalized heterosexual HIV epidemics: i.e. an estimated prevalence of HIV of >1% in the population. Such lists and maps are available through UNAIDS (see Appendix Two). As the geographical criteria now clearly define countries with a higher prevalence of HIV, a deferral period of five years from leaving a high prevalence country is recommended.

(d) A one year deferral should remain for a woman who has had sex with a bisexual man, and for those 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.

(e) The current deferral criteria for sex workers should be amended. People who have worked as sex workers only in New Zealand should not give blood for one year. People who have worked as sex workers in any other country should not give blood for five years.

(f) The NZBS Collection Standards should be amended in the light of this review.

(g) Effective communication tools are required to improve overall understanding of and adherence to behavioural donor criteria. Public information is required to increase self-deferral. The NZBS should work with other relevant bodies (for example, the New Zealand AIDS Foundation) to produce information explaining the reasons for behavioural deferral criteria.

The donor questionnaire will need to be revised in the light of Recommendations (a) – (e). At that time it should be reviewed for clarity and ease of understanding. The "three box" layout for Special Questions 1 of the health questionnaire was raised in the consultation process as a cause of potential stigma for those in certain risk categories. Altering the layout to a "single box" format (if this is feasible without losing effectiveness) and asking once whether any of the above apply might be a way of overcoming the issue. For donors who are deferred at the blood service, a clear explanation needs to be provided as to the reasons why. There should be written information, but ways of enabling potential donors to discuss the issues with someone with sufficient expertise should be explored.

(h) There should be a review of these recommendations in five years. In the future the epidemiology of TTIs including HIV may change in New Zealand. Detailed data from Australia on the effects of a one-year deferral should by that time become available. Viral inactivation techniques for whole blood may be developed and implemented, and validated ways of questioning about specific sexual behaviours may have been developed.

1. Background

Review process

The New Zealand Blood Service (NZBS) has asked a group to review the current criteria for the deferral of people from blood donation based on behaviour. This relates to sexual and drug using behaviour which 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 such people donated blood. The review group is independent of the NZBS but Dr Peter Flanagan, Medical Director NZBS, has provided expert input into the review. He was not present when the recommendations were developed. The names of review group members are in Appendix Three.

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 contributes to the decision by the NZBS to undertake a further review now.

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 required consideration. In particular the concerns were about the justification for different deferral periods for men who have sex with men (MSM) and heterosexuals, and about the rationale for broad deferral categories based on behaviour rather than on specific risk activities.

The process of this review is based on the terms of reference (see Appendix Four). The review group had expert legal advice from Professor Paul Rishworth, Dean,

Faculty of Law, University of Auckland. Specific expertise within the group were provided in the areas of ethics (Associate Professor Andrew Moore, Department of Philosophy, University of Otago) and HIV/AIDS epidemiology by Dr Nigel Dickson (AIDS Epidemiology Group, University of Otago). All members of the review group brought expertise to the work. The review group secretariat/researcher was Dr Gabrielle McDonald.

The group has reviewed New Zealand and international evidence and published reports and met on two occasions to formulate the draft report. The draft report was distributed to a range of stakeholders and interested parties, and was available for public comment. Review Group members also attended some consultation meetings, on invitation of stakeholder groups. The review group met a third time following this consultation to finalise the report. See Appendix Five for a list of those specifically consulted and Appendix Six for a list of respondents.

This report has two main parts. The first describes the NZBS and the international situation with respect to behavioural donor criteria, the current situation in New Zealand, evidence about the effectiveness of donor deferral to prevent transmission of TTIs, and legal and ethical considerations (Sections 1-4). The second part describes the recommendations on behavioural donor deferral and makes some proposals for the development of effective communication tools in relation to these recommendations.

The New Zealand Blood Service

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 system, the most vulnerable people are the blood recipients. Decisions around blood safety need to be made with the best interests of the recipients in mind. Blood recipients face an "imposed risk" around safety and find themselves in a position of having to trust decisions on blood safety made by others, as they frequently have no alternatives other than transfusion. 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.[1]

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 20 years have chronic hepatitis C.[2] In Canada in 1997 a Commission of Inquiry on the Blood System[3] 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 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 Krever:

- 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.
- Preventative 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 is encapsulated in the second and third statements above, has been adopted by internationally recognised blood services.

The New Zealand Blood Service (NZBS) was established in 1998 by the Health Amendment Act, following a review of the multiple blood services in New Zealand. Prior to this, blood centres operated at a regional level with variable practices and variable deferral criteria. The NZBS is a Crown Entity (Statutory Corporation) with specific responsibility for the collection, manufacture and distribution of blood

[1] Centres for Disease Control and Prevention. Antiretroviral postexposure prophylaxis after sexual, injection-drug use, or other nonoccupational exposure to HIV in the United States. Morbidity and Mortality Weekly Report. January 21, 2005; 54: no RR-2.
[2] Faed J. Haemophilia treatment: where to from here? Have the risks increased? NZMJ 2003; (116) 1180. Available from URL: http://www.nzma.org.nz/journal/116-1180/559/
[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.

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 sperm[4] 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.

Regulation of blood services in New Zealand

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 currently 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. The NZBS maintains Collection and Manufacturing Standards that broadly align to the requirements of the *CoE Guide*. Changes to these standards require review and

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

endorsement by Medsafe. Donor selection criteria, including the behavioural donor criteria, are included in the Collection Standards.

    - CSL Bioplasma, the company that manufactures New Zealand plasma into a number of products, is required to meet European Pharmacopoeial requirements and also European Medicines Evaluation Agency Guidance on manufacture.

- Good Manufacturing Practice
    - Medsafe inspects the NZBS manufacturing sites on an annual basis. Manufacturing licences are issued on the basis of the inspection.

The current regulatory environment is expected to change. The governments of New Zealand and Australia committed to the development of a joint medicines regulatory system in early 2000. This was to be achieved by the establishment of the Australia New Zealand Therapeutic Products Authority (ANZTPA). The Therapeutic Products and Medicines Bill is the proposed enabling legislation in New Zealand to support the establishment of ANZTPA. The Bill was under consideration by Parliament, but has currently been put on hold. If ANZTPA is established there is an expectation that the NZBS and Australian Red Cross Blood Service will harmonise standards over time. Nevertheless, it is expected that New Zealand will retain the ability to set its own criteria for donor selection.

International behavioural donor deferral criteria

Over the years most countries have established deferral criteria after concerns about transfusion transmissible infections. The main infections implicated are HIV, hepatitis B and hepatitis C. These infections are all easily transmitted by injecting drug use, and HIV and hepatitis B are commonly sexually transmitted. Hence behavioural donor criteria relate to injecting drug use and sexual behaviours.

Table 1 shows current deferral criteria in place internationally for men who have sex with men.

Table 1 Current deferral periods for men who have sex with men

Country	Current Deferral	Comment
ASIA PACIFIC		
Australia	Deferred for 12 months	Complaint being considered by the Human Rights Commission
Hong Kong	Deferred for an indefinite period	
Japan	Deferred for 12 months	
Singapore	Permanently deferred	
NORTH AMERICA		
United States	MSM since 1977 permanently deferred	The USFDA has recently reaffirmed its position. In doing so it indicated 'a willingness to consider new approaches to donor screening and testing, provided those approaches assure that blood recipients are not placed at increased risk of HIV of other transfusion transmitted disease.'
Canada	MSM since 1977 permanently deferred	Canadian Blood Services recently reviewed their exclusion and remained with the permanent deferral of MSM from 1977.
EUROPE		
Austria	Permanently deferred	
Belgium	Permanently deferred	
Denmark	Permanently deferred	
Finland	Permanently deferred	
France	Permanently deferred	The ABC newsletter published 8 September 2006 indicated that the French Minister of Health announced that 'the blanket prohibition on blood donation by gay men will end soon.' However, there is no evidence on either the EFS or AFSSAPS websites of any change in policy.
Germany	Permanently deferred	
Ireland	MSM ever having oral or anal sex (even with a condom) permanently deferred	
Italy	National policy is to exclude on basis of 'risky behaviour'	All donors are interviewed by a doctor. The interpretation of 'risky behaviour' is unclear and inconsistently applied. At least some centres continue to exclude MSM.
Netherlands	Permanently deferred	
Norway	Permanently deferred	
Portugal	Permanently deferred	
Spain	No specific exclusion of MSM	In the late 1990's a move was made from excluding homosexual men to excluding people with promiscuous sexual behaviour from donating blood. A 12 month exclusion exists for anyone who has had more than a sexual partner in the last 12 months.
Sweden	Permanently deferred	During 2006 the Swedish National Board of Health and Welfare considered a proposal to reduce the deferral period to 6 months. Following consultation they decided to leave the permanent deferral in place.
Switzerland	MSM since 1977 deferred	
United Kingdom	MSM ever having oral or anal sex (even with a condom) permanently deferred	The United Kingdom Blood Transfusion Services have recently reviewed their behavioural exclusion criteria and have remained with permanent deferral following analysis of infections detected in blood donors over the period 1995-2006.
AFRICA		
South Africa	MSM deferral for 6 months (oral or anal sex with or without a condom)	

2. Current situation in New Zealand

Current behavioural donor criteria

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

There are four 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 will 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 three tier combination approach to safety. This involves:

(1) A questionnaire that screens potential donors prior to donation. This is based on lifestyle factors or behaviours that place them at increased risk of acquiring blood borne infections. While crude, this has been shown to be an effective way of reducing TTIs. The questionnaire is followed by an interview with a registered nurse which provides a further level of detail (see below).

(2) Tests that are highly sensitive (reliably have a positive result when the disease being tested for is present) and specific (tests that are reliably negative when the disease is not present) are carried out on donated blood to identify prospective donors who are infected with a TTI.

(3) The use of physical and/or chemical methods 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.

The general approach used by the NZBS to assess donors is similar to that adopted by other major international blood services. Donor selection involves two main steps:

(1) 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, which provides information on blood borne viruses and the reason for exclusion of 'high risk' donors.
  - *Donor Information* leaflet, which provides information on the process and adverse events associated with donation.

(2) The Donor Interview.

- All donors undergo a confidential interview with a Registered Nurse.
- The interview focuses on responses in the questionnaire and also reinforces the key safety criteria through the use of standardised questions. The Collection Standards document is used to determine eligibility.
- Donors sign the declaration on the DSR at the end of the interview.

The behavioural exclusion criteria were determined in 1999 and have remained the same since. They are as follows:

You should <u>NEVER</u> give blood if:

- You, or any of your current (or past) sexual partners have (has) 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 clotting factor concentrates at any time.
- You think you need an HIV or Hepatitis test.

You should not give blood for <u>TEN YEARS</u> following any occasion in which:

- You have had sex with another man, even 'safer sex' using a condom (if you are a male).
- You have worked as a sex worker (prostitute) or accepted money or drugs in exchange for sex.

You should not give blood for <u>ONE YEAR</u> after sex with:

- A man who has had sex with another man (if you are female).
- Anyone whom you know carries the Hepatitis B or C virus.
- Anyone who has ever injected themselves with drugs not prescribed by a Doctor.
- A sex worker (prostitute).
- Anyone with haemophilia or a related clotting disorder who has received clotting factor concentrates at anytime.
- Anyone who lives in or comes from a country considered to be high risk for HIV infection. (See map Appendix Seven).

For a copy of the donor questionnaire, see Appendix Two.

Epidemiology of HIV/AIDS

Mode of transmission

HIV can be transmitted through sexual intercourse, infected blood or blood products, from mother to baby, and through contaminated needles. Different sexual acts have different risks of HIV transmission to a non-HIV infected partner. The estimates of relative risk range from one for receptive oral sex, 10 for receptive vaginal sex and 50 for receptive anal sex[5].

Condom use is known to reduce the risk of transmission. The degree to which it does this is difficult to accurately determine. Davis and Weller performed a meta-analysis of 25 published studies and estimate that consistent condom use reduces the risk of HIV transmission by about 87%, compared to no condom use[6]. A further meta-

[5] Centres for Disease Control and Prevention. Antiretroviral postexposure prophylaxis after sexual, injection-drug use, or other nonoccupational exposure to HIV in the United States. Morbidity and Mortality Weekly Report. January 21, 2005; 54: no RR-2.
[6] Davis KR, Weller SC. The effectiveness of condoms in reducing heterosexual transmission of HIV. Family Planning Perspectives 1999; 31(6): 272-9.

analysis found that consistent condom use reduced the transmission of HIV in heterosexual couples by approximately 80%[7]. The range of effectiveness was estimated as 35 – 94%.

Epidemiology of HIV/AIDS in New Zealand

National data on HIV/AIDS is recorded as coded information and is collected by the AIDS Epidemiology Group. Information is recorded for people who are diagnosed with HIV and people who meet criteria for AIDS, the late stage of the spectrum of disease caused by HIV. This information includes likely means of infection, likely place of infection and ethnicity.

By the end of June 2007 a total of 2782 people had been diagnosed with HIV and 913 people had been notified with AIDS.

AIDS

The number of people with AIDS rose steadily in the late 1980s, was relatively stable in the early 1990s, subsequently dropped, and has continued at a lower level over the last decade (Figure 1). The main cause of the drop in the number of cases of AIDS since 1996 is the successful use of antiretroviral treatment that reduces the progression of immunosuppression in people infected with HIV. Currently, the majority of people who progress to AIDS have not previously been diagnosed with HIV, that is, they are diagnosed late in the course of their illness.

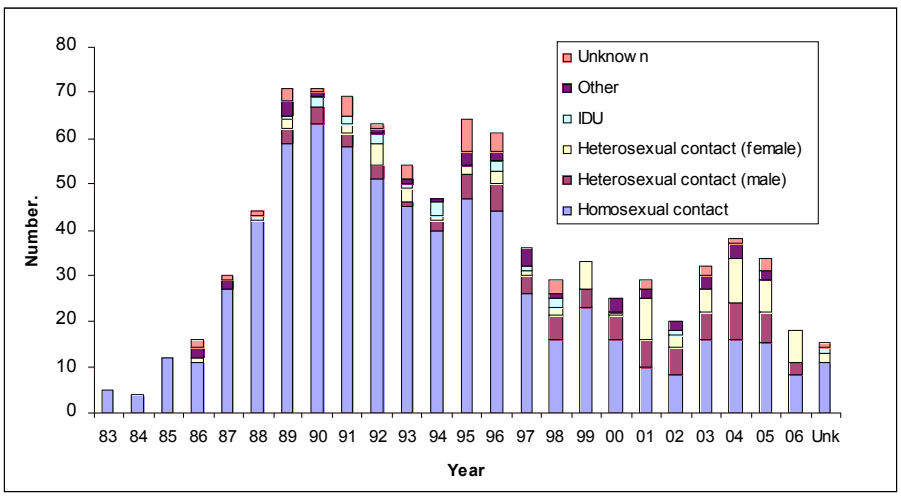

Figure 1 Number of AIDS notification by year of diagnosis and means of infection

[7] Weller SC, Davis-Beaty K. Condom effectiveness in reducing heterosexual HIV transmission (review). The Cochrane Library 2007, Issue 3.

HIV diagnoses

The numbers of people with diagnosed HIV according to means of infection and year of diagnosis are shown in Figure 2. It is important to appreciate that the infection might have occurred many years before the diagnosis was made. Of note, since 2002 there has been a marked increase in new diagnoses.

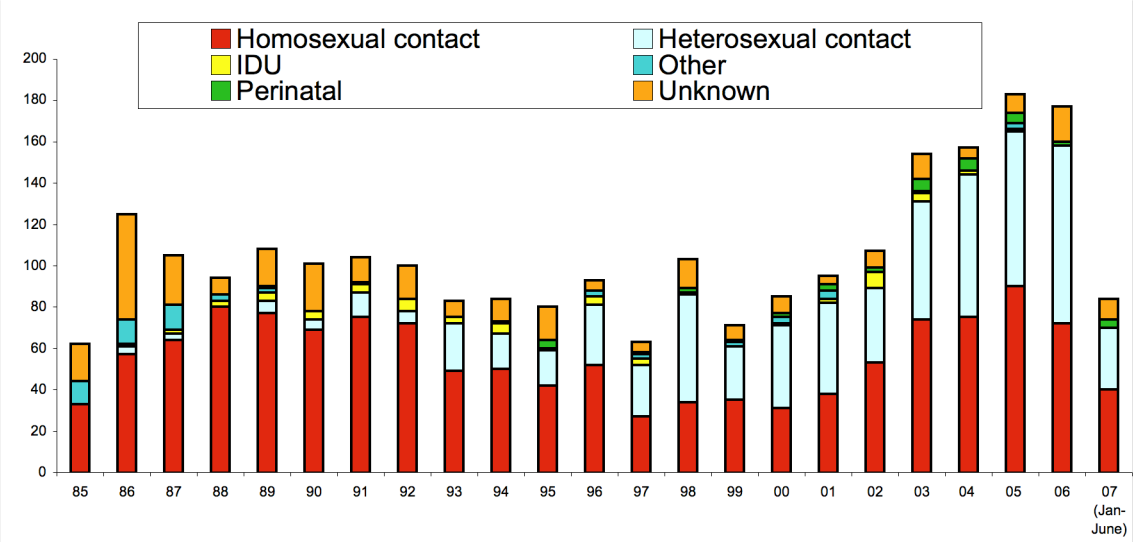

Figure 2 Annual number of diagnosed HIV infections by year of diagnosis and likely means of infection

In the last few years, the two main means of infection have been homosexual and heterosexual contact. While the ethnic distribution of the MSM diagnosed with HIV is similar to the adult New Zealand population, those diagnosed with heterosexually-acquired HIV were more likely to be of African or Asian ethnicity. The increase in diagnoses since 2002 among MSM has been due to men infected in New Zealand; the parallel rise among the heterosexually infected has been due to people infected overseas, mainly in Sub-Saharan Africa and Asia. Figure 3 shows the annual number of infections acquired in New Zealand according to means of infection since 1996. From 2003 to 2006, MSM made up 82% (220/270) of all such diagnoses.

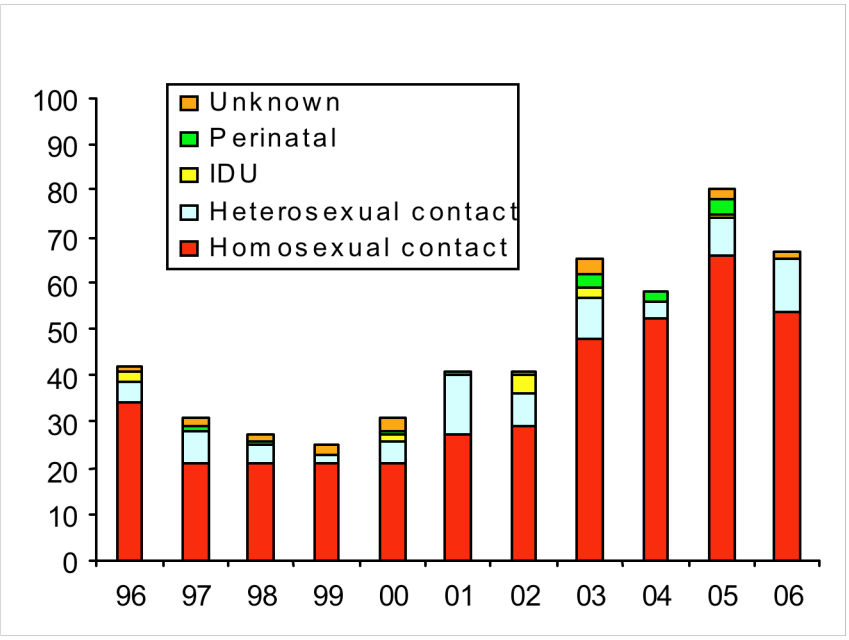

Figure 3 Annual number of diagnosed HIV infections by year of diagnosis and likely means of infection that occurred in New Zealand, 1996-2006

The rise in diagnoses among MSM, similar to that found in many developed countries, is likely to be due to an increase in incidence, as other explanations such as there being more testing seem unlikely. This is probably a reflection of a number of factors: a rise in prevalence due to increased survival of people with HIV driving incidence; a relaxation of safer sex practices among some MSM compared to the mid-1990s; possible changes in patterns of sexual mixing such as more partners meeting through the internet; and also a possible increase in prevalence of other Sexually Transmitted Infections (STIs) that increase infectivity of, and susceptibility to, HIV.

Unlinked anonymous HIV prevalence among sexual health clinic attenders 2005/6

In 2005/6 the AIDS Epidemiology Survey Group undertook an unlinked anonymous study of HIV prevalence among attenders at Sexual Health Clinics who were having blood tested for syphilis and/or hepatitis B. The main findings on prevalence (Table 2) confirm that, in this sentinel population at increased risk of STIs, HIV is concentrated among MSM, with relatively little spread among heterosexual men and women. Among MSM there was a higher prevalence in Auckland than elsewhere, with the highest prevalence among men aged 30-49 years. While the prevalence of HIV among heterosexual men and women in this population was low, all the major ethnic groups in New Zealand were represented. Importantly, in this population the

prevalence of previously undiagnosed HIV among MSM (20.1 per 1000) was 40 times higher than that among heterosexual men and women (0.5 per 1000).

Table 2 Unlinked anonymous HIV prevalence among sexual health clinic attenders 2005/6

		Overall			Previously undiagnosed		
		No.	per 1000	95% CI	No.	Per 1000	95% CI
Men	Heterosexual	6/4795	1.2	0.5-2.7	2/4791	0.4	0.05-1.5
	MSM	36/817	44.1	31.0-60.5	16/797	20.1	11.5-32.4
Women	Heterosexual	5/3639	1.4	0.5-3.2	2/3635	0.6	0.07-2.0
	WSW*	0/146	0.0	0.0-24.9	0/146	0.0	0.0-24.9
Transsexual		0/26	0.0		0/26	0.0	
Unknown		0/16	0.0		0/16	0.0	
Total		47/9439	4.98	3.66-6.62	20/9223	2.12	

* Women who have sex with women

Gay Auckland Periodic Sex Surveys

The Gay Auckland Periodic Sex Surveys (GAPSS) have been undertaken among MSM in Auckland in 2002, 2004 and 2006. In 2006, 1228 men were enrolled from the Big Gay Out fair day (70%), gay bars (12%) and sex on site venues or gay saunas (18%). While HIV testing was not undertaken, participants were asked about whether they were HIV positive and about HIV testing (Table 3).

Table 3 Proportion of all GAPSS participants reporting HIV test and current HIV status

	2002	2004	2006
HIV test ever	71.1%	72.5%	72.2%
HIV test in previous 6 months	23.9%	25.9%	25.8%
Reported to be HIV positive	4.7%	4.3%	3.3%

In the 2006 survey, nearly two-thirds (63%) reported sex with a casual partner in the previous six months of whom about three-quarters (73%) had had anal sex. Of these, about a third (35%) had not used a condom on at least one occasion. These proportions were similar to those found in the 2002 and 2004 surveys. Of the participants in the 2006 survey, 8% reported having had an STI in the previous year.

Surveillance of HIV/AIDS in New Zealand suggests:

- There is ongoing spread of HIV among MSM in New Zealand, probably at a rate higher than in the late 1990s. The incidence of HIV (i.e. new infections in New Zealand) is much higher among MSM compared to heterosexuals.
- Improved survival of people with HIV and ongoing spread means that the prevalence (i.e. the number of people living with HIV) is increasing.
- Behaviours that put people at risk of HIV acquisition continue among MSM.
- Some people infected with HIV are not currently diagnosed, as evidenced by the facts that (a) some people with HIV are not being diagnosed until they meet criteria for AIDS, and (b) not all previously undiagnosed infected people enrolled in the sexual health clinic study were tested at that visit.
- The prevalence of HIV among heterosexual men and women is very low relative to MSM.
- Most new diagnoses among heterosexuals are among people who have been infected in countries with generalised HIV epidemics (i.e. countries with an estimated prevalence of >% in the adult population).

HIV among blood donors

In New Zealand from 2000-2006 there have been 12 donors identified with HIV infections. All were male. The means of infection and whether the donation was from a first time or repeat donor is shown in Table 4. The proportion of donors for whom the means of infection was never ascertained was higher than that for all people diagnosed with HIV.

Table 4 Number of HIV diagnoses among first time and repeat blood donors in New Zealand 2000-2006

	First time donors	Repeat donors	Total
MSM	0	3	3
Heterosexual	2	1	3
Other/Unknown	3	3	6
Total	5	7	12

Over this seven-year period there were 1,119,202 donations; 203,412 by first time donors and 988,790 by repeat donors. Therefore, the proportion of donors found to be infected with HIV was 1.1 per 100,000 donations. The proportion of first time donors infected with HIV was 2.5 per 100,000 donations and of repeat donors 0.7 per 100,000 donations.

In comparison, in Western Europe, in which many of the countries have a similar pattern of HIV epidemic to New Zealand, in 2004 (or the latest year available in the 2000-2004 period) the overall rate was 1.7 per 100,000. This ranged from 0.0 to 10.4 in specific countries.[8] As shown in Table 5 the proportion in Western Europe among first time donors was 5.0 per 100,000 (ranging from 0.0 to 18.1 per 100,000) and among repeat donors 0.8 per 100,000 (ranging from 0.0 to 1.8 per 100,000). In Australia the overall proportion for the period 2000-2005 was 0.35 per 100,000.[9]

Therefore, while there are some differences in the prevalence of HIV among donors internationally, the magnitude of the problem in New Zealand is similar to that in Australia and Western Europe.

Table 5 Proportion of blood donations from first-time donors, number of HIV donations and HIV prevalence among donations from first-time and repeat donors in 2004 (or latest year available).

Geographic area and country	Year	Proportion of donations from first-time donors (%)	Donations from first-time donors		Donations from repeat donors	
			No. HIV	HIV+/100 000	No. HIV	HIV+/100 000
West						
Belgium	2004	7	1	1.9	2	0.3
Denmark	2004	9	1	2.8	2	0.6
Finland	2004	6	0	0.0	0	0.0
France	2004	15	15	4.0	20	0.9
Germany	2004	8	25	4.8	52	0.9
Greece[a]	2002	19	19	18.1	2	1.0
Italy	2003	12	24	9.4	33	1.8
Ireland	2004	12	1	5.5	0	0.0
Luxembourg	2004	4	0	0.0	0	0.0
Malta	2002	20	0	0.0	0	0.0
Monaco	2001	8	0	0.0	0	0.0
Netherlands	2004	5	0	0.0	4	0.5
Sweden	2004	6	0	0.0	2	0.3
Switzerland	2004	5	0	0.0	5	1.4
United Kingdom	2004	11	7	2.3	11	0.4
Total West		10		5.0		0.8
Centre						
Croatia[b]	2003	12	2	11.0	4	2.8
Poland	2004	16	15	9.1	2	0.2
Romania	2001	19	26	36.8	9	3.1
Serbia & Montenegro[c]	2002	2	1	18.0	1	11.4
Slovenia	2001	13	0	0.0	0	0.0
Total Centre		15		16.3		1.2
Total WHO European Region				6.5		0.9

[8] Likatavicius G, Hamers F, Downs AM, Alix J, Nardone A. Trends in HIV prevalence in blood donations in Europe, 1990–2004. AIDS 2007; 21:1011–8.

[9] National Centre in HIV Epidemiology and Clinical Research. HIV/AIDS, viral hepatitis and sexually transmissible infections in Australia Annual Surveillance Report 2006. National Centre in HIV Epidemiology and Clinical Research, The University of New South Wales, Sydney, NSW; Australian Institute of Health and Welfare, Canberra, ACT. 2006.

Current epidemiology of hepatitis B and C

Hepatitis B

Hepatitis B Virus (HBV) is transmitted through the exchange of body fluids during sexual activity or by infected blood. This may occur through blood transfusion, haemodialysis, acupuncture, intravenous drug use, accidental needle stick injuries, from tattooing, from mother to baby or from close contact amongst small children.

It is estimated that over 70,000 people in New Zealand are carriers of HBV, i.e. a prevalence of approximately 1.7%. Many carriers are not aware that they have the virus.[10] It is carriers of the virus who pose a risk of transfusion transmission.

Certain groups have a high prevalence of hepatitis B, such as Injecting Drug Users (IDU), MSM and those from certain countries. A national study examining the prevalence of hepatitis in IDU found that 14% of IDU using a needle exchange had been infected with HBV in the past. None were carriers of HBV.[11] A national survey of MSM found 8% had ever had hepatitis B.[12] Of asylum seekers screened during 1999-2000, 16.5% were Anti-HBs positive, indicating either past vaccination or infection. Nearly 3% of the asylum seekers were HBsAg positive, indicating either recent infection (within six months), or a state of chronic carriage.[13] There are also ethnic groups with a higher prevalence of hepatitis B. Of relevance to the New Zealand population, is that these include Māori, Pacific Islanders and those of Asian ethnicity.[14]

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[10] 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.

[11] 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.

[12] 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

[13] Hobbs M, Moor C, Wansbrough T, et al. The health status of asylum seekers screened by public health in 1999 and 2000. New Zealand Medical Journal; 2002: 115 (1160). Available at URL;http//:www.nzma.org.nz/journal/

[14] World Health Organisation. Western Pacific Regional Plan to improve hepatitis B control through immunisation. Manila: World Health Organisation. 2003.

Those who are infected with HBV early in life are more likely to become chronic carriers of the virus. This is seen particularly in some ethnic groups which have had historically high rates of mother to child transmission.

The risks of transfusion transmission of HBV relate to either seroconversion (which will be recent infection in adults and hence likely to be either sexual or IDU transmission) or to chronic carriage. Chronic carriage will usually be detected by current HBsAg tests unless the person has occult HBV, with loss of HBsAg. This latter group has been a source of transfusion transmission, but the risk of occult HBV will be reduced by hepatitis B virus nucleic acid testing introduced in September 2007.

The implications of these observations are first that behavioural risks (sexual, IDU) relate to seroconversion and hence donor deferral should reduce risk, and second that risks of undetected chronic infections will be substantially reduced by hepatitis B virus nucleic acid testing. Deferral on the basis of likelihood of chronic infection might further reduce this risk, but it would entail deferral of ethnic groups that make up a significant minority (28%)[15] of the New Zealand population. This could threaten the supply of blood.

Hepatitis C

Hepatitis C Virus (HCV) is a blood borne virus. Transmission may occur through blood transfusion, haemodialysis, acupuncture, injecting drug use, accidental needle stick injuries, from tattooing or from mother to baby and rarely sexually.[16]

At risk groups for infection include IDU, recipients of unscreened blood products and some immigrant groups. Of those infected with HCV, 50-70% go on to become chronic carriers.[16] A national study examining the prevalence of hepatitis in current IDU found that 70% of IDU using a needle exchange were HCV antibody positive.[11] In asylum seekers from 1999-2000, 1.1% tested positive for HCV antibody, indicating current infection or a state of chronic carriage. Those of African origin were significantly more likely to be HCV antibody positive than those from other regions.[13]

[15] Statistics New Zealand Website. URL: www.stats.govt.nz Accessed 27.11.07.
[16] *Harrison's principles of internal medicine*. 16th edition. Kasper, DL, Fauci, AS, Longo, DL et al, editors, New York: McGraw-Hill. 2005.

A national survey of MSM found 1.8% had ever had hepatitis C, but this risk was considerably higher in men with a past history of injecting drug use.[12] These data show the critical risk behaviour for hepatitis C in New Zealand is injecting drug use.

Even short term injecting drug use is associated with high rates of incident infection. Because of the high prevalence of hepatitis C in the IDU community there is rapid acquisition of the virus by new users through sharing needles or drug preparation equipment.[17] For example, a study in Baltimore in 1988 to 1989 found that intravenous drug users were exposed to the virus very quickly, with 65% becoming infected within one year of the initiation of injecting.[18] Furthermore, in many countries, particularly the former Soviet Union, IDU is an increasingly important source of HIV infection. This alone suggests that a prolonged deferral is appropriate.

In addition to hepatitis C and HIV, injecting drug use is a potent mode of transmission of other blood borne viruses. This point is evidenced by the increased prevalence of various infections in people with a history of IDU. Indeed the prevalence of viral markers in IDU is often used to assess whether a particular blood borne agent is or is not easily transmitted by blood.

In recent years a number of viruses have been detected by molecular research. Often these are of uncertain or no pathogenic significance. In each case however the prevalence of the infectious agent is significantly higher than that seen in blood donors. Examples are shown in Table 6 below.

Table 6 Prevalence of selected viruses in blood donors and IDU

Virus	Prevalence in Blood Donors	Prevalence in IDU
Sen V	2%	23-54%
GBV-C	1-3%	71%

Current and recent IDU are deferred because of the risk of incident infection. The data above combined with the prevalence of HCV infection in New Zealand IDU, supports an extended deferral for people with a history of injecting drug use. This is

[17] Hagan H, Thiede H, Weiss NS, et al. Sharing of drug preparation equipment as a risk factor for hepatitis C. American Journal of Public Health 2001; 91(1): 42-46.
[18] Garfein RS, Vlhov D, Galai N et al. Viral infections in short-term injection drug users: the prevalence of the hepatitis C, hepatitis B, human immunodeficiency, and human T-lymphotropic viruses. American Journal of Public Health 1996; 86(5): 655-661.

in keeping with international best practice, which is very consistent with a lifetime deferral for IDU (see Table 7 below).

Table 7 International deferral periods for intravenous drug users

Country	Intravenous Drug Use
New Zealand	Permanent deferral
Australia	Have you **ever** used drugs by injection or been injected even once with drugs not prescribed by a doctor or dentist?
United States (AABB)	Have you **ever** used needles to take drugs, steroids, or anything not prescribed by your doctor?
Canada	Have you **ever** taken illegal drugs or illegal steroids with a needle even one time?
Singapore	Have you **ever** taken or injected addictive drugs?
Council of Europe	Have you **ever** injected any drugs?
United Kingdom	You must never donate if you have **ever** injected, or been injected with, drugs; even a long time ago or only once. This includes body-building drugs.
Netherlands	Permanent exclusion
France	Permanent exclusion if you have **ever** injected drugs
South Africa	Have you **ever** injected yourself, or been injected, with illegal or non-prescribed drugs; even a long time ago or only once?

Blood donation testing

The NZBS tests each and every blood donation for a range of infectious diseases. The current infections tested for on all donations are HIV, hepatitis B, hepatitis C and syphilis. HTLV I/II is tested for on new donors and cytomegalovirus on selected donations. 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.

Two different, but complimentary, types of tests are used.

The first involves detecting the body's immune response to the infectious agent. This involves the detection of antibodies. This type of testing has been the mainstay of blood donation testing for many years. Testing for HIV antibodies was introduced in 1985 and for hepatitis C antibodies in 1992.

The second type of test detects the presence of the virus itself. This approach has been used for many years to detect the presence of hepatitis B where the target of the test was the viral coat (hepatitis B surface antigen). More recently tests have been

developed that detect the presence of virus nucleic acid (so called Nucleic Acid Tests). The level of viral nucleic acid in infected donors is very low and amplification techniques are needed to detect them. The NZBS introduced Nucleic Acid Testing (NAT) in 2000 using the Chiron Procleix assay. This assay detects both HIV-1 and HCV nucleic acids. Testing was initially undertaken using semi-automated systems using donation samples in small pools of up to 16 donations. In September 2007 a fully automated system was introduced that enables testing of individual donations. This system also allows detection of hepatitis B virus nucleic acid.

The window period

The test systems utilised by the NZBS are highly sensitive and are able to detect most, if not all, cases of established infection. However, no test is perfect 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 so called "window period". Considerable research has been undertaken to improve understanding of the early phases of infection with major blood borne viruses. Following infection the virus enters susceptible host cells. It then begins to replicate and small amounts of viral nucleic acid will become detectable in the blood stream. This situation may exist for several days or weeks at which point the individual may become unwell and exhibit symptoms and signs of the early disease. This phase is normally associated with the development of antibodies to the virus. The antibodies may not however be protective and the virus and antibody may co-exist for many months or years. The window period is the time between acquiring the infection and the development of detectable infectious markers. The length of the window period has reduced significantly in recent years as more sensitive tests have become available. The availability of nucleic acid tests has significantly reduced the length of the window period.

Figure 4 shows a schematic representation of the early period of infection including the presence of the window period.

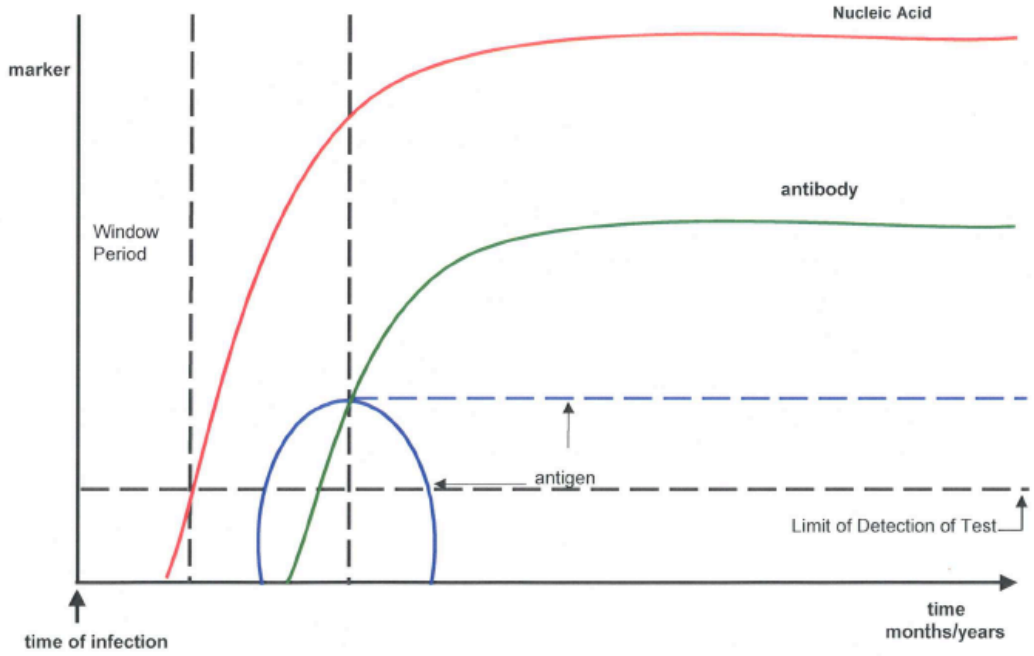


Figure 4 Diagnostic markers during early phase of infection.

Table 8 provides an indication of the average window period for the major blood borne viruses when single donation nucleic acid testing is in place. It should be noted that the quoted window period is an average only. Atypical cases of HIV and hepatitis C can occur. Affected individuals may not have the usual pattern of infection and therefore may not produce positive test results at the expected points in time. This may occur in individuals with unusual genetic makeup or who have an altered immune response to infection.

Table 8 Estimated average window periods for selected viruses

Virus	Estimated Average Window Period
HIV	11 days
Hepatitis B	26 days
Hepatitis C	10 days

The window period has important implications for blood transfusion. Blood donations given by infected donors during this period may not be detectable by current test systems. 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. The frequency of window period transmission has reduced significantly with the introduction of nucleic acid testing. Nonetheless transmission continues to occur and has been reported for both HIV-1 and HCV in the recent international literature. To date, no window period transmissions for HIV or HCV have been documented in New Zealand since screening for these viruses commenced.

Incident and prevalent infections

The implications of recent (incident) infections and established (prevalent) infections for the NZBS are different.

Incident infections are those that may be missed because of the window period. This type of infection is usually identified because a regular blood donor who has previously been tested and found to be negative donates again and is then found to have a positive result. This is called a "seroconversion". This happens in a few cases each year. The implications for the NZBS are very significant. Firstly, the possibility exists that the most recent negative donation might have been given during the window period. The NZBS needs to follow up the recipients of this donation in order to determine whether infection has been transmitted. The risk of this increases as the time between donations becomes shorter and is a particular concern with regular plateletpheresis donors. An illustrative case is shown below.

In early 2006 a regular plateletpheresis donor was found to be HIV positive. ESR results showed a pattern consistent with recent seroconversion. The donation was discarded and a "look back" investigation initiated. The donor had been donating platelets on a monthly basis. The two previous donations were given 38 and 77 days prior to the index donation. Retesting of the stored samples from the previous donations confirmed negative results in both HIV antibody and single donation NAT tests.

The recipients (three in total) of the previous two donations were contacted and testing arranged. One of the recipients was a three-year-old child who received the platelets during cardiac surgery. Fortunately all recipients were negative for HIV infection.

The look back process was particularly stressful. Based on the available data this was a near miss event. There was a real possibility that had the donor presented a week earlier that transmission might have occurred.

Incident type infections also impact on the NZBS plasma fractionation programme. This involves large pools of plasma being used to manufacture blood products such as Factor VIII, used in treatment of people with haemophilia, and Intravenous Immunoglobulin, used in the management of a number of diseases. Incident type infections can impact on the safety of the products manufactured from the plasma pool and also potentially impact on supply of the products to patients. The NZBS is required to undertake look back investigations when a blood donor seroconverts for a major infection. An example is shown below.

In April 2003 a regular donor was identified to be HIV positive. The donation was discarded and a look back investigation initiated. The donor had previously donated in January 2003. The retained specimen from this donation was retrieved and tested. Negative results were obtained in both HIV antibody and single donation NAT tests. The donor was recalled and retested.

Plasma from the January donation had been sent to CSL and included in a fractionation pool. Product from the pooling was quarantined pending a full investigation. As part of the investigation, the Australian Therapeutics Goods Agency set up an expert panel to review the case. The panel concluded that whilst accepting no HIV could be detected in the January donation that they could not exclude an early infection. Utilising the precautionary principle they therefore recommended that product manufactured from the pool should not be used. The financial value of the product was $4 million. The product withdrawal resulted in a temporary shortage of Factor VIII supplies. Surgery in people with haemophilia was postponed pending the availability of additional product.

The impact of established or prevalent type infections is very different. These infections should be identified by the NZBS test systems. However, no system is perfect and the possibility, albeit rare, that an infected donation might either not be detected by testing, or else be detected but inadvertently released for clinical use must be considered. Such incidents have not yet occurred in New Zealand. However, occurrences have been described in the international literature and thus it is important that the NZBS aims to minimise the risk that this might occur. This type of occurrence 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 the NZBS includes systems to detect this type of error. The risk is further reduced because the NZBS now undertakes two independent tests for each major virus. The likelihood that both tests will fail for any single donation is very low.

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

   The 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. Occasionally however, new forms of the virus emerge. These are called variant viruses. 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, the so called HIV subtype O. Whilst the number of cases of this form of HIV was low, many test systems initially failed to detect them. Blood services, including the NZBS, now use HIV antibody tests specifically designed to detect this subtype.

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 low. The NZBS uses a fully integrated IT system to track the results of testing and to prevent the release of blood components manufactured from infected donations. Indeed the IT system used by the NZBS, Progesa, probably means that the risk of this type of error is lower than in many other international blood services. This is because Progesa is utilised in both the 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.

Residual risk

Transmission of major blood borne viruses is now very rare indeed. The frequency of such events is so low that it is not feasible to measure even with very large studies. Blood services have therefore developed models to assess the level of risk of transmission occurring. These models are used by blood services internationally to assess the overall risk within the system. The residual risk of transmission is the likelihood that, in statistical terms, an infection will be transmitted when blood donations are fully tested for the infectious agent. The residual risk model use data on the rate of incident and prevalent infections in blood donors to estimate the risk. The models incorporate risk levels for window period donations, test errors and quarantine/release type errors. The calculated residual risks for developed blood services are very low and the range of uncertainty around these estimates (the confidence interval (CI)) is often very large. Table 9 below provides estimates, developed by the NZBS, on the residual risk associated with tested blood in New Zealand.

Table 9 Residual risk of transmission for HIV and HCV

Virus	Residual risk of transmission	Estimated frequency of transmission in years
HIV	1: 2,254,241 donations (95% CI 1,215,945 - 6,832,080)	1 every 11 years (1 every 6 to 34 years)
HCV	1: 1,906,260 (95% CI 1: 1,072,919 - 4,514,646)	1 every 9.5 years (1 every 5 to 23 years)

The estimated risks of transmission of HIV and HCV are very low. No transmissions have been documented in New Zealand since routine testing was introduced for these viruses. This suggests that the low residual risk figures are reasonable estimates. It must however be remembered that the low levels of risk are achieved by a combination of measures and are not solely due to the effect of blood donation testing.

Estimating the risk of hepatitis B transmission is more problematic because of the natural history of the infection. The NZBS estimates that the overall risk of transmission for this agent is in the order of 1 in 100,000 donations. Occasional transmissions of hepatitis B by tested blood are seen in New Zealand suggesting that the estimated risk is reasonably accurate.

3. Evidence about the effectiveness of donor deferral criteria to prevent transfusion transmitted infections

Reasons for behavioural donor criteria

People with behaviours that place them at increased risk of TTIs, have been requested to defer from donating blood. These behaviours include injecting drug use, male to male sex, sex work or exchange of money or drugs for sex, sex with someone who carries a TTI, with an injecting drug user, or with a sex worker, or with someone who lives in or comes from a country in which there is a generalized epidemic of HIV.

Advice to potential male donors not to give blood if they had had sex with another man was first given in the 1980s to protect the blood supply from the infectious agent for AIDS, before a test for the causative virus, HIV, was available.[19] Since 1985, when a test became available, the accuracy of testing procedures has improved such that the average window period is now reduced to about 11 days, the sensitivity of the test is at least 99.9%, and errors are minimised by advances in IT systems and quality control.

Deferral from donating blood for men who have sex with men (MSM) has also been justified on the basis that it will reduce the risk of other presently unknown, or known but untested for, TTIs (for example, Human Herpes Virus 8[20]) which may be expected to be higher among certain groups at known higher risk of HIV.

All these behaviours only show *on average* that the person is more likely to have a TTI. Some of these people will be at low risk. For instance, it is clear that men who use condoms for anal sex, or have only oral sex with another man, have a lower (though not no) risk of infection.

If it were practicable to do so reliably, it would be more accurate to estimate individual risks rather than group risks. However, group risks of TTIs are used in

[19] 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.
[20] Hladik W, Dollard SC, Mermin J. Transmission of Human Herpesvirus 8 by blood transfusion. New England Journal of Medicine 2006; 355: 1331-1338.

deferral criteria. This means that the deferral categories are broad, but there have been a number of reasons for this. The *Health Questions* sheet must be simple and easy to understand. The NZBS is entirely reliant on volunteer donors. They need to make sure that enough donors attend in order to ensure the collection of sufficient blood to meet the demand from hospitals across New Zealand. Blood donor sessions can be extremely busy with large numbers of donors attending on any given day. Detailed and potentially intrusive questioning about an individual's sexual behaviour has not been considered appropriate, nor feasible, in the context of assessment of blood donor eligibility. The introduction of more specific questioning about sexual behaviours is dependent on prior research showing that such questions can distinguish people at higher risk from those at little increased risk. Research validating this approach is not available. For these reasons, broad deferral categories have been used both in New Zealand and internationally.

Deferral for other reasons apart from behaviour is also practiced. For instance, because of a theoretical risk of variant Creutzfeldt-Jakob Disease (vCJD) people who resided in the UK during the time of the epidemic of Bovine Spongiform Encephalitis (BSE) are requested to defer from donating blood, even if they are vegetarian.

The following section relates specifically to sexual behaviour in relation to the risks of HIV transmission because this is the area where there has been the most uncertainty. There is general agreement that people who have injected drugs outside a health care setting are at considerably higher risk of hepatitis C infection and other TTIs and hence a prolonged deferral period is warranted.

Issues to consider in interpreting study data on donor deferral for MSM

Timing of infection

- Very recent infection (incident) among MSM
    - Because of window period – blood donated when infectious but prior to the development of both a positive antibody test and a positive nucleic acid test.

- The window period is now very short due to the introduction of NAT, and estimated to about an 11 day period when an infectious person is unlikely to be undetectable by either test.

- Established infection (prevalent) among MSM
  - Because both antibody and nucleic acid test produce false negative results.
  - If each has a sensitivity of 99.9% and the test are independent this is $(0.001)^2 = 0.000001$ (i.e. there is a one in 1,000,000 chance that both tests fail at the same time and miss an established infection).
  - Or inappropriate release of blood that is tested and found positive (quarantine/release error).
  - Improved computerised tracking has lessened this risk, but this risk may still be higher than the risk of a true false negative using the two tests.

The improvements in testing and tracking have greatly decreased the risk of transfusing HIV infected blood since the deferral criteria were introduced.

Deferral

If either incident or prevalent infections exist, how would a voluntary deferral policy among MSM reduce risk of donation by people with (a) incident or (b) prevalent infections?

- No deferral
  - Some incident and prevalent infections
- 12 month deferral
  - Total adherence
    - No incident infections
    - Some prevalent infections (undiagnosed infections that occurred >12 months earlier)
  - Some non- adherence
    - Some incident infections (depending of level of adherence)
    - Some prevalent infections (both > 12 months earlier and acquired within 12 months but outside window period)
- Five or ten year deferral
  - Total adherence

        - No incident infections
        - Some prevalent infections (infections that occurred >5 years earlier)
    - Some non- adherence
        - Some incident infections (depending of level of adherence)
        - Some prevalent infections (both >5 years earlier and acquired within 5 years but outside window period)
- Ever deferral
    - Total adherence
        - No incident infections
        - No prevalent infections
    - Some non-adherence
        - Some incident infections (depending of level of adherence)
        - Some prevalent infections (infections acquired outside window period)

Studies relevant to behavioural donor criteria

Since the turn of the century a number of investigations have been carried out to explore whether deferral on the basis of sexual behaviour remains justified. These studies, and information about current risks, are described briefly below.

(1) Studies of HIV positive blood donors

In Sao Paulo, Brazil, the characteristics of blood donors with confirmed HIV infection were compared to a control group. (At the time the deferral criteria included ever having male-to-male sex.) A subsequently disclosed history of male-to-male sex was much more common among HIV positive donors (adjusted odds ratio = 26.2). Of all male donors diagnosed with HIV, 28% reported sex with men.[21]

In the UK, the UKBTS/NIBSC Professional Advisory Committee reported that over

[21] Neto CA, McFarland W, Murphy EL et al. Risk factors for human immunodeficiency virus infection among blood donors in Sao Paulo, Brazil, and their relevance to current donor deferral criteria. Transfusion 2007; 47: 608-14.

40% of re-attending donors found to have HIV infection reported male-to-male sex.[22] For most donors who were not MSM, no risk factors in heterosexual partners were known.

In New Zealand, since 2000, there have been 12 donors identified with HIV infection of whom three subsequently reported male-to-male sex, and the mode of infection was unclear for a further two (i.e. at least 25%). Of those who were not known to have had male to male sex, 2/9 (22%) reported having had sex with someone from a high prevalence area. Seven were repeat donors, including all three of the MSM.

In Australia, which has had a one-year deferral period for MSM since 1997 the number of donors identified with HIV infection from 2000 to 2005 was 22. Of these, six (27%) were MSM.[9]

(2) Studies of the risk profile of blood donors

Ana Sanchez and colleagues used an anonymous mail survey of blood donors, which was linked to HIV screening test results, in the US to estimate the (previously undisclosed) risk behaviour of donors.[23] Of the 25,168 male respondents, 2.4% reported male-to-male sex; 1.2% after 1977. Men who reported male-to-male sex within the last five years were about six times more likely to have a positive HIV test result compared to other donors. But men who reported male-to-male sex more than five years ago were not more likely to have an HIV positive test result though they were still two to six times more likely to report other previously unreported deferrable risks, for example used injected drugs, or taken or gave money or drugs for sex.

(3) Modelling studies estimating the effects of changes in deferral criteria

Soldan and Sinka used epidemiological data from England to estimate by how much the existing deferral criteria for MSM in the UK (ever had male-male sex) reduces the risk of donations with HIV entering the blood supply, and compared this with other

[22] Joint UKBTS / NIBSC Professional Advisory Committee. Position Statement No 10: Blood donor selection to minimise risk of transfusion transmissible infectious agents entering the blood supply. May 2007.

[23] Sanchez A, Schreiber GB, Nass CC, et al. The impact of male-to-male sexual experiences in risk profiles of blood donors. Transfusion 2005; 45: 404-13.

deferral strategies.[19] Included in the model were the incidence of HIV infection in repeat donors currently (calculated from observed seroconversions), prevalence of undiagnosed HIV infection among MSM (from unlinked anonymous monitoring), the size of the MSM population, the sensitivity of the tests in use (99.9%), error rate of the testing process (0.5%), and the window period (15 days [22 minus 7 days of non-infectivity immediately after infection]). The adherence with the current deferral criterion was estimated to be 95%.

The modelling showed that, compared to the current baseline, reducing the deferral period to 12 months after male-to-male sex, with current adherence, would increase the risk of HIV entering the blood supply by 66%. Even with greater (complete) adherence and the 12-month deferral criterion the risk would *increase* slightly by 18%. With no deferral risk would increase by about 500%. These are small absolute increases: for a 12-month deferral compared to current, the risk in England would increase from 0.45 infectious donations per year to 0.75 per year, and to 2.5 per year with no deferral. The actual rate would change from the current estimated 1 infectious donation per 5 million to 1 in 3 million for a 12 month deferral and 1 in 1 million with no deferral.

Germain and colleagues used a mathematical model to evaluate the impact of the current (since 1977) deferral policy for MSM in Canada, compared to a 12-month deferral policy.[24] Included in the model were the proportion of MSM who would not have had sex in the last year (50%), prevalence of undiagnosed HIV among MSM, the window period (assuming that 1 in 2000 would have immunosilent (i.e. undetectable) HIV infection at 12 months), rate of laboratory errors, occurrence of other systems failure and 100% adherence with deferral criteria.

The results showed that the increase in risk of HIV entering the blood supply with a one-year deferral period compared to the since 1977 deferral was only 8% (1 in 925,000 compared to 1 in 1,000,000 units). The authors described the increase as "very low but not zero".

[24] 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.

Conclusions from the published reports

In places like New Zealand and Australia, where MSM account for the highest proportion of people who become infected with HIV in the country, MSM are over-represented among HIV positive blood donors – despite current deferral criteria. Nevertheless, in New Zealand MSM still account for only a minority of infected blood donors. This shows that current deferral criteria are working, and adherence may be in the order of 95% as calculated for England. It can be assumed that only a small number of MSM are continuing to donate with the current 10-year deferral criterion. Surprisingly in Australia, with a one-year deferral for MSM, though MSM are still over represented, the prevalence of HIV is only 4 per million donations, less than in New Zealand (11 per million donations). This suggests that there is either greater adherence to deferral criteria in Australia, or a higher rate of clinical HIV testing and therefore fewer undiagnosed infections, or the figures from Australia are incomplete.

The other studies are helpful in elucidating the likely effects of changes in this deferral period. The two modelling studies address the change from a lengthy deferral period (ever or since 1977) for male-to-male sex to a one-year deferral period. Both indicate that reducing the deferral period to one year would slightly decrease the safety of the blood supply. The Canadian study appears to assume complete adherence to the deferral policy so the source of infections is from an assumed long window period tail, plus an increase in the prevalence of undiagnosed HIV infections which are missed because of test or laboratory error. The English study included the calculated current adherence of 95% and also a change to 100% adherence. The reason for the larger increase in risk in the English study (66%) versus the Canadian one (8%) is unclear. Overall, the increases in risk are very small for a one-year deferral period versus a prolonged deferral period, but are considerably larger if there was no deferral period. The increase in the proportion of the population who would become eligible for donation is also small (1% in England, 2% in Canada).

The study of the risk profile of blood donors from the US confirms that adherence is not 100% in the US either, but it found that the increased risk of HIV infection was confined to those who reported male-to-male sex in the last five years (not just the

past one year, nor longer ago). Hence, from this evidence a period of deferral longer than one year would reduce risk of prevalent infections more than a period of one year only; but a period longer than five years would not reduce risk further.

In conclusion, the increases in risk to the blood supply from moving to a one-year deferral period are primarily from a very small increase in HIV infected donations entering the blood supply undetected because of (a) incident infections: an increase in window period donations (if there is a rare immunosilent period of over a year) and (b) prevalent infections: because of a higher prevalence of undetected HIV infections among men who had sex with men longer than one year ago – leading to more infected donations because of testing, laboratory or system errors. These very small increases in risk appear to arise with deferral periods of one year and possibly up to five years. A five-year deferral period appears to be safer because it is known from the study of men who didn't adhere to self-deferral, that they have more risk behaviour (multiple partners) and HIV infections if they had sex with a man in the last five years versus longer ago. Safety is also enhanced by close adherence to self-deferral. The secondary argument for deferral of MSM is that such men are on average at higher risk of other known blood borne infections, and hence are likely to be at higher risk of unknown sexually transmitted TTIs. Deferral also reduces these potential risks.

Additional information from unpublished reports

The report by Leiss and colleagues[25] on MSM donor deferral risk assessment for the Canadian Blood Services (2007) uses the published sources plus some information from the 2006 FDA hearings to assess risk. This report discusses one, five, and 10 year deferral options. It concludes that a one-year option would almost certainly give rise to an incremental risk of transfusion transmitted infections over existing levels of risk with lifetime deferral. It concludes that risk may not be raised by moving to a five-year or 10-year deferral, although they concluded that a 10-year period would provide an additional safety margin.

[25] Leiss W, Tyshenko M, Krewski D. MSM donor deferral risk assessment: an analysis using risk management principles; a report for Canadian Blood Services. McLaughlin Centre for Population Health Risk Assessment, University of Ottawa. 2007. [Now published as: 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.]

In the transcripts of the 2006 FDA hearings, Andrew Dayton of the US FDA Office of Blood Research and Review reported on another model used in the US to estimate the risks for HIV entering the blood supply. Moving from before 1977 to a five year exclusion period would result in a 25% increase in risk, and a one-year exclusion in a 40% increase in risk. Sensitivity analyses showed that the most important parameters were the prevalence of undiagnosed infection and quarantine/release errors, not false negative errors which were estimated to be less than 3 per million (p252 and following). Celso Bianco reported an update of the Germain study[24] for the US, using lower false negative errors and reported a lower rate of HIV entering the blood supply (p328).

This additional information provides the only estimates of five-year versus one-year deferral periods, suggesting a small increase in safety at five years versus one year.

4. Legal and ethical considerations

Legal considerations

The statutory functions of the NZBS are outlined in Section 1, above. Particularly relevant to the current review of Behavioural Donor Criteria is the expectation that the NZBS should take all reasonable precautions to ensure that the blood it supplies is safe.

Consumers of blood transfusion services have rights, including those expressed in the Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996. In particular, Right 4 is the right to services of an appropriate standard; and Right 2 is the right to freedom from discrimination, coercion, harassment and exploitation. NZBS is required deliver its services to an appropriate standard, and in a non-discriminatory way.

The rest of this section, below, focuses on broad health and safety aspects of 'services of an appropriate standard', and on matters of discrimination.

New Zealand Bill of Rights Act 1990

The NZBS is a Crown Entity and performs a public function. It therefore falls within the scope of s 3(b) of the New Zealand Bill of Rights Act 1990. It follows that the NZBS is required to observe the rights and freedoms expressed in that enactment. One such right, of particular relevance in the present context, is the s 19 right against discrimination, which reads:

> **Freedom from discrimination**
>
> (1) Everyone has the right to freedom from discrimination including on the grounds of sexual orientation, in the Human Rights Act 1993.

The three key questions to ask when assessing whether discrimination exists, in terms of section 19, are:

1. Does the policy or legislation draw a distinction based on one of the prohibited grounds of discrimination?
2. Does this distinction involve disadvantage to the person or group?
3. If the answer to both these questions is "yes", then consideration needs to be given to whether the limit on the right to be free from discrimination is reasonable, in terms of section 5 of the Bill of Rights Act. If it is, then the policy or practice does not amount to discrimination. The policy or practice infringes section 19(1) only where it cannot be demonstrably justified.

Addressing question one:

The NZBS Behavioural Blood Donor Criteria distinguish groups (MSM) on grounds of behaviour, not sexual orientation as such. But the distinguishing behavioural characteristic (men having sex with men) is so closely aligned with the group of gay men that it would fall under the rubric of "indirect discrimination", if other features of the test for discrimination, discussed below, exist.[26]

Addressing question two:

It might be said that the Behavioural Blood Donor Criteria cause no disadvantage to those deferred from donating, because there is no "right" to donate blood. Nothing, it might be said, is really lost. But even if there is no right to donate blood, disadvantage might still be caused. For example, it might be considered a disadvantage to be excluded from a valued social practice of donation, and also a disadvantage to face associated stigma for being men who have sex with men. This *might* be enough to contravene s 19 in a "prima facie" sense. Whether, in the end, s 19 is contravened depends on the answer to question 3; that is, whether there is justification for the practice.

Addressing question three:

This is a central question. Section 5 of the Bill of Rights states that:

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

> 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.

This concept of "reasonable limits", or some closely related concept, is common to all countries that have an applicable bill of rights. It is generally taken to resolve itself into the following two broad considerations[27]:

First, whether the infringing provision, policy, practice, or service in question serves an important objective; and

Second, whether there is a rational and proportionate connection between that objective and the infringing provision, policy, practice, or service; or whether the objective may instead be achieved in another way which interferes less with the right or freedom affected.

In the present context, the objective that lies behind behavioural deferral criteria – safety of the blood supply – is manifestly pressing and important. The next questions are all to be answered in the context of epidemiological and other relevant evidence.

(a) Is the means of attaining the objective – the exclusion of groups whose activities are associated with higher risks of infection – rational?

(b) Is that means proportionate?

(c) Might there be some other way of attaining the objective that is rational and proportionate but also preserves more of the relevant right [against discrimination]?

The overall point is that an activity will count as prohibited discrimination if the different treatment is not "demonstrably justified", with the concept of justification turning on matters of evidence considered in the light of the general test set out above.

[27] See *Quilter v Attorney General* [1998] 1 NZLR 523 (CA); and *R v Hansen* [2007] 3 NZLR 1, incorporating the Canadian approach to this issue from *R v Oakes* [1986] 1 SCR 103.

Ethical issues

Donor selection criteria can be considered in terms of their consistency with applicable ethical principles. A Canadian consensus document[28] proposes these be:

- Trust (including trustworthiness of the trusted party)
- Justice (including fair distribution of burdens and benefits, or risks and rewards)
- Rights and privileges (as applicable)
- Autonomy (including enabling free and informed decisions to be made)
- Non-maleficence (doing no harm)
- Beneficence (doing good wherever possible)
- Accountability (including for performance of the NZBS)
- Privacy and confidentiality

To generate practical guidance, such ethical considerations also need to be brought together in an overall judgement of the matters at issue. One way to express this is in the broad principle that policy and practice should be changed only if such a change would be an overall improvement, taking both harms and benefits into consideration.

To generate practical guidance, ethical considerations must be further specified, and appropriate priorities established. In the context of blood donor criteria, it is appropriate to give significant priority to non-maleficence, and thereby to safety of the blood supply. This can be justified on the grounds that the risks that recipients face from blood products are involuntary (not due to their own choices), whereas the level of risk that blood donation policy and practice imposes on these recipients is somewhat subject to voluntary control. Furthermore, there is some history of recipients suffering harm from blood products in settings where risk to them could have been further reduced.

[28] 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.

In short, policy and practice concerning blood donation should not impose levels of risk on recipients of the blood supply that alternative policy and practice would not impose. The priority of blood safety is reflected also in the terms and conditions the NZBS must observe in carrying out its responsibilities, including the requirement that:

> The NZBS 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 sperm are safe to use.

Even assuming that policy and practice should give significant priority to safety of the blood supply, there are different possible interpretations of this safety objective for any proposed change to blood donor criteria:

That it must *increase* the safety of the blood supply.

That it must at least *maintain* the safety of the blood supply.

That it must *not more-than-minimally reduce* the safety of the blood supply.

Policy proposals can be assessed by answering the following questions: Which safety objective should be adopted? Which donor deferral policies are consistent with which of the above potential safety objectives? Any proposal that would increase the safety of the blood supply would be obviously beneficial. Any proposal that would only maintain the current level of safety would need to demonstrate significant further benefits; and this demand for justification would be more intense still for any proposed change that would even minimally reduce safety of the blood supply.

Strictly speaking, donor deferral criteria do not restrict offers to donate, but instead restrict acceptance of such offers. Relatedly, donation is essentially a two-agent process (donor and recipient), so it is actually not a restriction of liberty or autonomy if the recipient declines to accept some offers (c.f., declining an invitation to tango). The view that there is no right to donate follows from this. Even so, an important effect of any policy to restrict the offers that the NZBS may accept is to exclude some potential donors. Donating blood is a valued social practice. Policies of donor deferral are thus restrictive practices, because they generate a form of social exclusion, and such exclusion also potentially adds to stigma.

In considering any restrictive practices, the Siracusa principles on restrictive measures, as elaborated in a different setting by the National Ethics Advisory Committee[29] provides a way of thinking through the relevant issues. This approach also closely parallels the one outlined above for consideration of legal issues.

NEAC guidance on restrictive measures and respect/manaakitanga states:

- When possible and appropriate, restrictions should be voluntary rather than compulsory. Measures that promote voluntary compliance will reduce the need for compulsory restrictions.
- Restrictive measures should restrict only those rights it is necessary to restrict. Special attention may be needed for people who are subject to restrictions (for example, to their freedom of movement) to ensure their other rights are protected.
- Reciprocal support may be appropriate for people who, in order to protect others, are subject to restrictive measures.
- Restrictive measures can only be justified when all of the narrowly defined circumstances set out in human rights law, known as the Siracusa Principles, are met:
    - the restriction is provided for and carried out in accordance with the law
    - the restriction is in the interest of a legitimate objective of general interest
    - the restriction is strictly necessary in a democratic society to achieve the objective
    - there are no less intrusive and restrictive means available to reach the same objective
    - the restriction is not drafted or imposed arbitrarily, that is, in an unreasonable or otherwise discriminatory manner. [30]

[29] National Ethics Advisory Committee. Getting Through Together: Ethical values for a pandemic. Wellington: Ministry of Health. 2007.

[30] The Siracusa Principles are summarized in World Health Organisation. Questions and Answers on Health and Human Rights. Geneva: World Health Organisation. 2002.

The safety of the blood supply is clearly a “legitimate objective of general interest”. This being so, the key ethical questions can be stated as follows:

Does current policy on blood donor deferral:

- Make maximal use of voluntary measures to maintain safety of the blood supply?

- Use the least restrictive measures consistent with reliably achieving this safety objective?

- Operate in a reasonable manner, with particular reference to those who are subject to restrictive measures?

5. Review of the current exclusion of donors in New Zealand

The following sections specifically address the terms of reference. The principal task of the review group is to review the ongoing appropriateness for exclusion of donors on the basis of current and or past behaviour to ensure the safety of blood and blood products in New Zealand. The areas of emphasis in the terms of reference relate to sexual behaviour, and in particular the appropriateness of the ongoing exclusion of men who have sex with men.

There is no recommended change to the deferral criteria for people who have injected drugs not prescribed by a doctor (lifetime deferral). This is based on the high prevalence of hepatitis C in this population and high risks of other TTIs, some of which may be unidentified, and the early acquisition of hepatitis C in new IDU. There is insufficient information available on the potential consequences of changing the deferral criteria, in part because a lifetime deferral for IDU is practiced very consistently by blood banks internationally. Hence this criterion is not discussed further.

Each of the terms of reference is addressed in turn. In (a), the deferral of MSM is first discussed in relation to consideration of a one-year deferral versus the current 10-year deferral, and then in relation to a five-year deferral. Potential benefits and harms are considered in relation both to safety and supply issues and to social, legal, and ethical issues. Finally, the conclusions are stated. In (b) and (c) on aspects of heterosexual behaviour, the issues the review group considered are described and conclusions drawn. The last section (d) provides advice on the development of effective communication tools.

(a) The appropriateness of ongoing exclusion of men who have had sex with men.

The first question posed by the review group was:

"Given the current 10-year deferral period following male-to-male sex, what are the potential benefits and potential harms of remaining with this deferral period compared with moving to a one-year deferral period?"

The question was posed in this way because it is clear from the literature that removing the deferral period entirely would result in an appreciable risk of HIV entering the blood supply; a life-time deferral would not appreciably reduce the risk compared to 10 years.

Safety and supply issues

There are a number of potential benefits of remaining with a 10-year deferral period. The current criteria, in place since 1999, have not resulted in any documented reports of transfusion transmitted HIV, despite two instances where HIV seroconversion occurred in repeat donors and window-period transmission was possible. A 10-year deferral reduces the risk of transfusion transmission of prevalent HIV infections, compared to one year. In New Zealand the prevalence of undiagnosed infection (from sentinel surveillance) is 40 times higher among MSM (2.0%) versus heterosexuals (0.05%). In addition a 10-year deferral period provides a safety buffer for other un-tested for or unknown sexually transmitted TTIs. These are likely to be more prevalent among men who have had male-to-male sex recently compared to in the more distant past. It is conjectured that most clinically important emerging infections will be identified within five years of first occurrence in a population.

A move from the 10-year deferral to a one-year deferral would increase risk to blood recipients in the order of 8% to 66%. This is, however, still very low in absolute terms. It should also be recognised that some recipients require frequent transfusions over many years and hence a small risk is multiplied. The greater safety afforded by a longer period of deferral is because men who have had male-to-male sex in the last five years have been shown to have a higher prevalence of undiagnosed HIV infection compared to those who have had sex with men only in the more distant past. Although such infections should be detected by testing (and with current testing almost all will be) the possibility that errors can occur at the laboratory and in the distribution of blood i.e. quarantine/release errors has to be recognised. Research

carried out in other countries shows that the actual prevalence of undiagnosed infection and the occurrence of errors are critical issues

There are a number of potential harms to the blood supply of remaining with a 10-year deferral period. These relate to the donor pool and adherence with deferral criteria. The donor pool is reduced by having any deferral criteria. In this case a small proportion of men who are asked not to donate blood now would become eligible to donate if deferral became one year. This has been estimated to be an increase of 1% in England, but will be smaller in New Zealand as the move would be from a 10-year rather than an ever deferral period. If remaining at 10 years led to a reduction in adherence to the deferral criteria for any reason, this could increase incident and prevalent HIV infection in the donor pool.

Social, legal, and ethical issues

There are specific potential benefits of remaining with a 10-year deferral period in social and ethical terms. This period is consistent with, or indeed shorter than, the deferral periods of most other countries. The UK, Sweden, Canada, and the US have recently reviewed their policies and have recommended no change to lifelong (or post 1977) deferral for MSM.

Although a change to a one-year deferral period would increase the risk only slightly, there is an ethical priority to protect recipients of blood because such recipients face this risk involuntarily (not due to their own choices).

There are several potential harms of remaining with a 10-year deferral period. An important harm of deferral is social exclusion from the valuable social practice of blood donation. There is also the related harm of stigma associated with exclusion on the basis of male-to-male sex. The harms would be reduced slightly by reducing the deferral period because fewer men would be excluded. Nevertheless, this harm would remain because a deferral period is recommended specifically for MSM compared to heterosexuals, and all currently sexually active MSM would still be deferred.

The second question posed to the review group was:

Given that a five-year deferral is less restrictive than a 10-year deferral, would a move to a five-year deferral maintain the safety of the blood supply?

The evidence for a five-year versus a 10-year deferral period was reassessed by the Review Group. There are no modelling studies that estimate the risk for five years versus 10 years. There are two pieces of relevant information (as described above) which support a longer-than-one-year deferral, both relating to a five-year deferral. Men who have had male-to-male sex in the last one to five years have been shown to have a higher prevalence of undiagnosed HIV infection than men who have had sex with men only in the more distant past (whose risk is not elevated). Secondly, it has been conjectured that most emerging infections will be identified within five years of first occurrence in a population. Hence moving to a five-year deferral will not reduce the safety of the blood supply.

The law requires that any deferral for MSM, on the basis of behaviour, must serve an important objective and there must be a rational and proportionate connection between the objective and the restrictive policy. The important objective is the safety of the blood supply. The more-than-one-year deferral is rational because it is based on the much higher prevalence of HIV infection among MSM in New Zealand and the higher risk of other sexually transmitted TTIs. It is not proportional to maintain a ten-year deferral because there is good evidence that a five-year deferral is just as safe.

Conclusion

(i) The current 10-year deferral period for men who have had male-to-male sex should be shortened to five years. The grounds are that a change to a five-year deferral will 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 attempts to attain the least restrictive method of maintaining the safety of the blood supply.

(ii) The wording of the question for MSM on the "Donor Questionnaire" should be changed to improve clarity around the use of the word "sex".

This should be changed to: "…you have had oral or anal sex with or without a condom."

It is not practicable at present to define further specific sexual activities among MSM that should result in exclusion from donation. Lower-risk activities than unprotected anal intercourse, for example, anal intercourse with a condom or oral sex, are still associated with small risks of HIV transmission, and the absolute risk of transmission depends also on the prevalence of HIV among sexual partners, which is higher for MSM than for heterosexuals. Nevertheless, it is the activities not sexual orientation that is the central issue.

(b) Consideration of possible approaches to protect the donated blood supply from the risk 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.

The review group considered the following matters:

- The current deferral period for heterosexuals who have had sex with anyone who lives in or comes from a country considered to be at high risk of HIV infection is one year. There is no specific deferral period for heterosexuals who themselves have lived in or come from these countries.

- Currently the NZBS includes as high risk all countries in any WHO region that contains within them some countries with a high HIV prevalence. In practice, this means that all countries are classed as high risk except Western Europe, Scandinavia, China and Australia. The actual prevalence in these excluded countries is from <1:1000 to >20 percent.

- In New Zealand, most HIV infections among heterosexuals are among people from Sub-Saharan Africa or South-East Asia.

- Among HIV positive blood donors in New Zealand, 22% of those with a likely heterosexual mode of infection were from countries with generalized epidemics.

- A more limited range of countries – those with generalized HIV epidemics (defined here as an HIV prevalence of >1% in the adult population) – is warranted to identify people at higher risk.

- The current one-year deferral period will decrease the risk of incident HIV infections but not prevalent infections.

- A longer period of deferral for heterosexuals who have lived in or come from countries with generalized HIV epidemics would reduce the risk from prevalent HIV infections. The length of deferral should be determined by the period in which there is a higher prevalence of undiagnosed HIV infection. There are no specific data, but it is expected that five years from last sexual contact in the country with a generalized epidemic will substantially reduce risk, because the majority of people with HIV are likely to be diagnosed in that period.

- Although a longer period of deferral would apply widely to populations from Sub-Saharan Africa, this is not expected to cause problems with the blood supply to members of these groups with rare blood types in New Zealand.

Conclusion

(i) The list of countries and map should change to better reflect the areas with generalized heterosexual HIV epidemics: i.e. an estimated prevalence of HIV >1% in the adult population. Such lists and maps are available through UNAIDS. See Appendix Two.

(ii) The deferral criteria for heterosexuals who have lived in or come from specified countries should be modified. As the geographical criteria now clearly define countries with a higher prevalence of HIV, a deferral period of five years from leaving the high prevalence country is recommended.

(iii) The Collection Standards document should be revised to make it consistent with these recommendations.

(c) The appropriateness of excluding current and former sex workers and the appropriate period of any such exclusion

The review group considered the following matters:

- Information on HIV incidence and prevalence among sex workers in New Zealand. There have been only 20 women diagnosed with HIV who were known to be sex workers and three to four men who were reported to be infected by a sex worker in New Zealand. The prevalence among sex workers in the 2005/6 survey of sexual health clinic attenders was 0/343. This is consistent with a population prevalence among female sex workers of up to 12 per 1,000.

- Current sex workers are at potentially higher risk of incident infection because of multiple sexual partners. This risk is much reduced but not eliminated by regular condom use.

- Past sex workers will be at increased risk of prevalent HIV infection if they come from a country with a generalized epidemic. Indeed they are likely to be at higher risk than other people from those countries because sex work has been an important mode of transmission in many such countries (for example, Thailand).

- Past sex workers in some countries without a generalised epidemic, for example, Spain, parts of the former Soviet Union, will also have a high prevalence.
- Past sex workers who have worked only in New Zealand are unlikely to be at increased risk of prevalent HIV infection.
-

Conclusion

(i) The current deferral criteria should be amended.

(ii) People who have worked as sex workers only in New Zealand should not give blood for one year.

(iii) People who have worked as sex workers outside New Zealand should not give blood for five years.

(d) Advise on the development of effective communication tools to improve overall compliance with the behavioural donor criteria and to explain the reason for their ongoing use.

It should be recognised that the donor selection process contributes significantly to the safety of blood components and blood products derived from large plasma pools. The main purpose of the selection process is to ensure that the act of donation will not pose a risk to the donor or to the recipients. It is still necessary to use selective donor screening to minimise the risk of blood donations from donors with prevalent or incident infection slipping through the safety net and being accidentally transfused. This is because, despite advances in laboratory testing and the other elements of the blood service safety net, all have high but not perfect capabilities for achieving blood safety. The deferral of individuals who may have greater risk of having transfusion transmissible infections is an important contributor towards ensuring blood safety.

In relation to the development of effective communication tools to improve overall compliance with the behavioural donor criteria and to explain the reason for their ongoing use, the review group considered the following matters:

(a) The public information regarding donor selection criteria and information needed to better facilitate self -deferral of individuals with risk factors.

(b) The effectiveness and efficiency of the donor questionnaire as an instrument of donor deferral.

(c) The donor interview.

An important aim of the donor selection process is self-deferral.[28] Self-deferral is a process in which individuals elect not to donate blood because they identify themselves as having characteristics that place them at potentially higher risks of carrying transfusion transmissible infections, or because they are aware that the service will defer them if they do not defer themselves. Self-deferral works when all affected people are aware of who should self defer (and why) rather than presenting to the blood service.

At the blood centre potential donors complete a questionnaire, which asks questions about their health and other factors that could pose a risk to their own health by donating or increase their risk of donating infected blood. Screening questions help people, even those who feel well, to identify themselves as potentially at higher risk of TTIs. Individuals whose lifestyle, behaviour or circumstances place them at increased risk of acquiring or having acquired such infections are deferred or excluded through a series of questions in the questionnaire.

The growing length and complexity of the donor questionnaire has been raised as an issue in international literature as possibly being a factor that could lead to jeopardizing the efficacy of the screening process.[24] It has been suggested that if a questionnaire is too long it may discourage eligible persons from donating. Blood services must through necessity be able to process donors within a reasonable time frame and accordingly there is a limit to the number of questions that can realistically be used to achieve throughput of donors in a timely manner.

It has been argued that donors have a right to complete the donor questionnaire and undergo a donor interview.[31] If they are not accepted on that occasion they have the right to expect a clear explanation as to why they have been deferred. Ideally they should be given written information to take away that clearly and simply explains the rationale for their non-acceptance.

The review group notes that recommendations to improve the current donor screening process in Canada have been made.[28] These are:

[31] Franklin IM. Is there a right to donate blood? Patient rights; donor responsibilities. Transfusion Medicine 2007; 17: 161-8.

1. Ongoing evaluation of the public perception of blood donation, including their reasons for donating or not donating, their understanding of the use of donated blood and the safety of donated blood. There should also be ongoing evaluation of donor understanding of the screening process and their satisfaction with the processes.

2. A systematic validation for the current questions. This would lead to justification for the exclusion criteria and may also lead to an improvement in the clarity and complexity of the questions.

3. Ongoing evaluation of methods of communication with the public. This should provide ongoing public and donor education to improve donor understanding of self-selection or self-deferral. Exclusion must be justified and the information should be provided to the public and in particular to the groups who may feel that the exclusion is discriminatory.

Conclusion

The review group considers that the NZBS should look at the possibility of an ongoing systematic programme by which it might develop and evaluate 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. Suggested areas to consider are:

(a) Public information to increase self-deferral

The NZBS should consider establishing an ongoing, systematic programme of public education including making information available to enable potential donors to self-defer prior to presentation at the blood donation centres. Information surrounding the major transfusion transmissible viruses, namely HIV, hepatitis C and hepatitis B should span more evenly across the spectrum of these major transfusion transmissible viruses. Consideration could be given to providing information relating to risk factors for their acquisition while not tending to focus on HIV as is the case with the "Safe Blood Starts With You" leaflet. The NZBS should also consider reviewing its current written information

including offering translated versions, evaluating the reading levels of its current pamphlets and their efficacy in terms of informing potential donors in relation to the major transfusion transmissible infections and those most at risk of infection.

The NZBS could work with the AIDS Foundation to produce a pamphlet that explains the reasons for the behavioural deferral criteria. Use of the NZBS website to facilitate self-deferral should be explored. Information about the availability of clinical testing for HIV and/or hepatitis viruses at other sites should be displayed at blood donor centres.

(b) The donor questionnaire

The effectiveness, reliability and validity of the current questionnaire should be evaluated. Where there is ambiguity with respect to the meaning of a question, this should be rectified. The "three box" layout for Special Questions 1 of the health questionnaire was raised in the consultation process as a cause for potential stigma for those in certain risk categories. Whether it is feasible to alter the layout to a "single box" format (without losing effectiveness) and asking once whether any of the above apply might be a way of overcoming the issue. In addition the question title might be improved by renaming to "Donor Deferral".

The NZBS needs to ensure that adequate explanations are provided to deferred donors. As well as written information, consideration should be given to having at least one person present at each donation centre who has sufficient knowledge to provide a satisfactory explanation for people who are deferred, if they request it. If this is not possible then a suitable person needs to be available by telephone.

(c) The interview

The interviews at the blood donation centres are time consuming and a potential source of frustration to some donors. The NZBS needs to evaluate the reliability and validity of the donor interview in relation to the questionnaire and donor deferral.

Future review

There should be a review of these recommendations in five years. In the future the epidemiology of TTIs including HIV may change in New Zealand. Detailed data from Australia on the effects of a one-year deferral should by that time become available. Viral inactivation techniques for whole blood may be developed and implemented, and

validated ways of questioning about specific sexual behaviours may have been developed.

New Zealand Blood Service
The gift of life

DONOR SESSION RECORD FORM

ID Presented _____
Signature _____

1

If your personal details are printed below ~
(1) Please check the information printed in Box 3
(2) Write any corrections or updates in Box 4
(3) Complete the questionnaire overleaf
(4) Read the declaration overleaf and sign when asked

2

Have you donated blood in the past? If Yes.
Where _____ When _____
Number of previous donations _____

3

TITLE	SURNAME

GIVEN NAMES	DATE OF BIRTH

ETHNIC GROUP	SEX	DONATION COUNT	LAST DONATION

COUNTRY OF BIRTH

POSTAL ADDRESS

STCODE

CONTACT DETAILS

MAIL/MOBILE:
OME TELE: WORK TELE:

4

TITLE	SURNAME

GIVEN NAMES	DATE OF BIRTH

ETHNIC GROUP	SEX	DONATION COUNT	LAST DONATION

COUNTRY OF BIRTH

POSTAL ADDRESS

POSTCODE

CONTACT DETAILS

EMAIL/MOBILE: _____
HOME TELE: _____ WORK TELE: _____

OFFICE USE ONLY

DONOR DETAILS CONFIRMED		DONOR STATUS	ABO / Rh	TYPE	VENUE DETAILS

DONOR NUMBER	DONATION NUMBER	TODAY'S DATE AND TIME	DONOR LINKED SIGNATURE

HB - Capillary	HB - Venous		BP - 1	BP - 2	PULSE	PHLEBOTOMY TYPE	INTERVIEWER SIGNATURE
					Reg / Irreg		

Phlebotomist SIGNATURE	TIME	DURATION	BARCODE REC.	REMOVED BY	DEFERRALS
	START				
	FINISH				

EDICAL AND OTHER COMMENTS

	SIGNED
	SIGNED BY DATE
NKING DEFERRALS	SIGNED
	SIGNED BY DATE
LINKING COMMENTS	SIGNED
	SIGNED BY DATE
ADMINISTRATION AND DONOR MAINTENANCE	SIGNED
	SIGNED BY DATE

HEALTH QUESTIONS

THESE QUESTIONS MUST BE ANSWERED CAREFULLY. They protect you and any patients receiving your blood. A "Yes" answer may not necessarily exclude you from blood donation. **All donors must read the "Safe Blood Starts With You" and the "All About Donating Blood" leaflets.** Thank you very much for your help.

SPECIAL HEALTH QUESTIONS - 1.

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 clotting factor concentrates at any time.
- You think you need an HIV or Hepatitis test.

COULD ANY OF THE ABOVE APPLY TO YOU? Yes ☐ No ☐

You should not give blood for TEN YEARS following any occasion in which:

- You have had sex with another man, even 'safer sex' using a condom (if you are male).
- You have worked as a sex worker (prostitute) or accepted money or drugs in exchange for sex.

COULD ANY OF THE ABOVE APPLY TO YOU? Yes ☐ No ☐

You should not give blood for ONE YEAR after sex with:

- A man who has had sex with another man (if you are a female).
- Anyone whom you know carries the Hepatitis B or C virus.
- Anyone who has ever injected themselves with drugs not prescribed by a Doctor.
- A sex worker (prostitute).
- Anyone with haemophilia or a related blood clotting disorder who has received clotting factor concentrates at anytime.
- Anyone who lives in or comes from a country considered to be high risk for HIV infection. (see map).

COULD ANY OF THE ABOVE APPLY TO YOU? Yes ☐ No ☐

SPECIAL HEALTH QUESTIONS - 2.

1. Did you have any injection of human pituitary extracts such as growth hormone or gonadotrophin (fertility treatment) before 1985? Yes ☐ No ☐
2. Do you suffer from unexplained neurological condition or have had surgery of the brain or spinal cord? Yes ☐ No ☐
3. Have any of your blood relatives had CJD (Creutzfeldt-Jacob Disease)? Yes ☐ No ☐
4. Have you ever received a cell, tissue or organ transplant (cornea, kidney, bone-marrow, liver, etc)? Yes ☐ No ☐

TRAVEL QUESTIONS

5. Have you travelled outside New Zealand or Australia in the last three years ? Yes ☐ No ☐
6. Have you visited or lived in the United Kingdom (England, Scotland, Wales, Northern Ireland, Isle of Man and the Channel Islands) **or** in France **or** in the Republic of Ireland between 1st January 1980 and 31st December 1996 for a total period of 6 months or longer? Yes ☐ No ☐
7. Have you received a blood transfusion in the United Kingdom, France or the Republic of Ireland from 1980 onwards? Yes ☐ No ☐

NZBS Use Only

GENERAL HEALTH QUESTIONS

8. Do you have any health concerns at present ? Yes ☐ No ☐
9. Have you visited a Doctor/Health Clinic in the last 6 months or since your last donation? Yes ☐ No ☐
10. Have you taken any medicines at all in the last two weeks other than the contraceptive pill? Yes ☐ No ☐
11. In the last week have you had dental treatment, a cold sore, cold, cough, sore throat or any other infection? Yes ☐ No ☐
12. In the last 12 weeks have you or any of your household had any diarrhoea, vomiting, stomach pain or upset stomach? Yes ☐ No ☐
13. In the last 6 months have you had any of the following (please tick as appropriate):
    - Vaccinations Yes ☐ No ☐
    - Needle stick injury Yes ☐ No ☐
    - Acupuncture, body/ear piercing, tattooing Yes ☐ No ☐
    - Any medical procedure e.g.endoscopy Yes ☐ No ☐
14. In the last year have you had any of the following (please tick as appropriate):
    - Hepatitis, jaundice Yes ☐ No ☐
    - Surgical operation or blood transfusion Yes ☐ No ☐
15. Women: Are you breast feeding or have you had pregnancy, miscarriage or abortion in the last 12 months? Yes ☐ No ☐
16. In the last three years have you had treatment for acne or psoriasis? Yes ☐ No ☐
17. Have you ever had any of the following (please tick as appropriate):
    - Heart disorder Yes ☐ No ☐
    - Stroke Yes ☐ No ☐
    - Cancer Yes ☐ No ☐
    - Epilepsy Yes ☐ No ☐
    - Malaria Yes ☐ No ☐
    - Severe allergy Yes ☐ No ☐
    - Other serious illness Yes ☐ No ☐
18. Do you wear a medic-alert bracelet? Yes ☐ No ☐
19. Do you have a hazardous occupation or take part in a hazardous hobby e.g. flying, rock climbing? Yes ☐ No ☐

Please read the Declaration below.

- Today I have read and understood the "Safe Blood Starts With You" leaflet and the "All About Donating Blood" leaflet.
- To the best of my knowledge my health information is correct. I am over the age of 16 years.
- I consent to my blood being tested for blood groups and evidence of some infections, including HIV, Hepatitis B & C, Syphilis, HTLV and any other test found necessary for the safety of the recipient. I understand I will be notified if any important abnormalities are found.
- In consenting to give blood, I understand it will be used for the benefit of others and may be used for transfusion and/or teaching and/or diagnostic procedures and/or quality procedures. Samples will be stored for future comparative tests and may need to be sent overseas for any special investigations.

Date: _____

Donor's Signature: _____

Privacy Act The information collected will be used and held by the New Zealand Blood Service to assess your eligibilty to donate blood. You have a right to access and request the correction of the information in accordance with the Health Information Privacy Code and related New Zealand law.

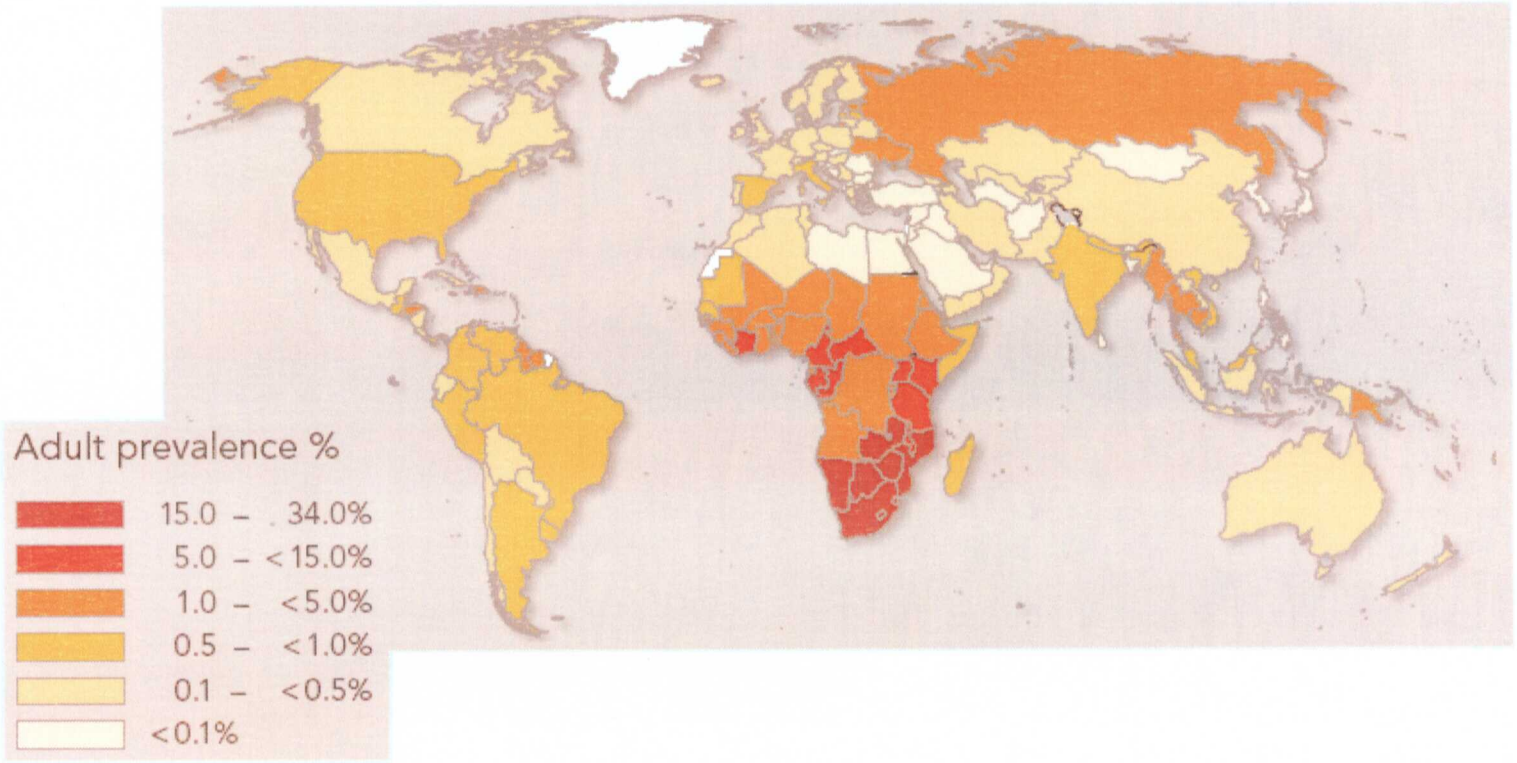
World Health Organization

UNAIDS
JOINT UNITED NATIONS PROGRAMME ON HIV/AIDS

UNHCR UNICEF WFP UNDP UNFPA UNODC ILO UNESCO WHO WORLD

A global view of HIV infection

38.6 million people [33.4–46.0 million] living with HIV, 2005



06/06 e

2006 Report on the global AIDS epidemic
Fig 2.4

Appendix Three

Review Group Members

Chair

Professor Charlotte Paul, Department of Preventive and Social Medicine, University of Otago

Members

Mike Carnahan, ex-President, Haemophilia Foundation of NZ

Dr Nigel Dickson, Director, AIDS Epidemiology Group, University of Otago

Tony Hughes, Research Director, New Zealand AIDS Foundation

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

Dr Paul Parish, NZBS donor representative

Dr Julia Peters, Public Health Physician, Professional/Clinical Director, Auckland Regional Public Health Service

Grant Storey, Principal Technical Specialist (Blood), Communicable Diseases, Public Health Directorate, Ministry of Health

Review Group Advisors

Secretariat/Researcher

Dr Gabrielle McDonald, Public Health Medicine Registrar

In Attendance

Dr Peter Flanagan, Medical Director, New Zealand Blood Service

Legal Advisor

Professor Paul Rishworth, Dean, Faculty of Law, University of Auckland

NZBLOOD
Te Ratonga Toto O Aotearoa

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.

Behavioural donor criteria

1.3 The current behavioural donor criteria utilised by NZBS were developed in 1999, shortly after the NZBS was established, and were designed to achieve national consistency in this area.

1.4 The criteria presently in place 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 clotting factor concentrates at any time.
- You think you need an HIV or Hepatitis test.

You should not give blood for TEN YEARS following any occasion in which:
- You have had sex with another man, even 'safer sex' using a condom (if you are male).
- You have worked as a sex worker (prostitute) or accepted money or drugs in exchange for sex.

You should not give blood for ONE YEAR after sex with:

- A man who has had sex with another man (if you are a female).
- Anyone whom you know carries the Hepatitis B or C virus.
- Anyone who has ever injected themselves with drugs not prescribed by a Doctor.
- A sex worker (prostitute).
- Anyone with haemophilia or a related blood clotting disorder who has received clotting factor concentrates at anytime.
- Anyone who lives in or comes from a country considered to be high risk for HIV infection.

1.5 Significant developments have occurred since the current criteria were developed. These include:

(a) The implementation of a centralised model for processing and testing of all blood donations.

(b) The implementation of a national Blood Management system, (known as Progesa), in all of NZBS sites and also in District Health Board Hospitals.

(c) Improved testing systems for blood borne viruses. All blood donations are now tested directly for HIV and Hepatitis C virus in addition to antibody testing for these agents.

(d) Plans to further improve the security of testing of blood donations by the introduction of single donation Nucleic Acid Testing in the second half of 2007. This testing will enable the detection of viruses to include Hepatitis B virus DNA.

1.6 NZBS is aware of concerns raised both locally and internationally by members of the gay community in relation to the behavioural screening questions, and the criteria that apply to gay blood donors through those questions. A recent complaint to the Human Right Commission reinforces the requirement for a review of these issues in the wider context of the scientific advances that have taken place since 1999.

1.7 Given the above, the NZBS intends to commission a formal independent review of the behavioural screening questions that are used as part of the donor selection process with the aim of ensuring that they remain consistent with best international practice but are appropriate in the local New Zealand environment.

2. PART II: TERMS OF REFERENCE

The Review Group

2.1 A Review Group is to be formed comprised of a group of experts and an independent chair. 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.

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 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 is considered appropriate, to recommend how exclusions from donation ought to 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 sexual activities that should result in exclusion from donation.

(ii) The level of protection afforded by regular condom use and whether this is sufficient in the context of transfusion transmission to avoid exclusion.

(iii) 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.

(iv) 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 excluding 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 about its own operations, including, where relevant a demonstration of the blood donation process that is followed on a day to day basis by NZBS.

2.9 The Ministry of Health may be available to assist in the consultation exercise outlined as Phase Three below.

Expectations

2.10 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: [indicative timing is set out in brackets after the description of each phase].

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. [two months]

Phase Two – review and development of draft discussion paper

3.3 This phase will see the Review Group reviewing the medical and scientific literature and is expected to result in the development of a draft discussion paper with initial recommendations. [10 weeks]

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 who have an interest in the issues at stake. [6 weeks]

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. [one month]

Phase Five – legal

3.7 The position paper will be reviewed by a suitably qualified senior Legal Counsel to assess whether the recommendations are consistent with New Zealand law. Legal Counsel may wish to meet with the Review Group to assist in this process through the earlier Phases. [two weeks]

Phase Six - NZBS consideration and review

3.8 The position paper and recommendations will be provided to NZBS for internal review and consideration by the NZBS Board. [two weeks – to coincide with Board meeting]

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. [depends on nature and extent of recommendations]

PETER FLANAGAN

National Medical Director

New Zealand Blood Service

June 2007

Appendix Five

Organisations Consulted

Auckland Gay Lesbian Welfare Group Inc
Body Positive
Department of Molecular Medicine, University of Auckland
District Health Board Chief Medical Advisors/Medical Directors
Haemophilia Foundation of New Zealand
Hepatitis C Resource Centre
The Hepatitis Foundation of New Zealand
Human Rights Commission
Immune Deficiencies Foundation of New Zealand
Te Kupenga Hauora Māori, School of Population Health, University of Auckland
Leukaemia and Blood Foundation of New Zealand
Ministry of Health
New Zealand AIDS Foundation
New Zealand Centre for Political Debate
New Zealand Prostitutes Collective
New Zealand Rainbow Labour
Te Pai o Maramatanga
Positive Women
Refugee Council of New Zealand
Selected Members of Parliament
Wellington Rainbow Network

Appendix Six

Respondents to discussion document

Name	Organisation
Clive Aspin	Te Pai o Maramatanga
Wayne Baker	
Robyn Brown	Hepatitis C Resource Centre
Dick Bunton	Otago District Health Board
James Faed	Transfusion Medicine Specialist
Susanta Ghosh	Transfusion Medicine Specialist
Rachael Le Mesurier	New Zealand AIDS Foundation
Robert Logan	Hutt Valley District Health Board
Rosslyn Noonan	Human Rights Commission
Marama Pala	
Jim Richardson	
Tony Simpson	Rainbow Wellington
Mark Thomas	Auckland District Health Board
Janice Wilson	Ministry of Health
Deon York	Haemophilia Foundation of New Zealand