

HIV Screening in Pregnancy

*identification
invitation
information
testing
treatment
evaluation*



A Report to the New Zealand Minister of Health

OCTOBER 2004

NATIONAL
HEALTH
COMMITTEE

NATIONAL ADVISORY COMMITTEE
ON HEALTH AND DISABILITY
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Incorporating the Public Health Advisory Committee
Te Rōpū Tohutohu i te Hauora Tūmatanui

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The National Advisory Committee on Health and Disability (National Health Committee or NHC) is an independent committee appointed by, and reporting directly to, the New Zealand Minister of Health.

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(National Health Committee)
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ⁱ The members of the Scientific Advisory Group were Dr Helen Moriarty, Norma Campbell, Dr Nigel Dickson, Dr Alec Ekeroma, Dr Jane MacDonald, Assoc.Professor Charlotte Paul, Dr Sally Roberts, Dr Bryan Schroeder, Dr Lesley Voss, Dr Lucille Wilkinson, Ann Yates and Professor Linda Holloway (Chair and NHC member).

Foreword

HIV screening in pregnancy is an important and contentious issue in which there is much interest. The National Health Committee (NHC) has applied its screening assessment criteria to evaluate antenatal HIV screening in New Zealand.

Although New Zealand's estimated prevalence of antenatal HIV is low, the implications of HIV are significant, both for individual women, their families, and society. The overall incidence of HIV is rising in this country, and over time further increases in HIV among women are likely. HIV incidence is increasing in our neighbouring Pacific region, as well as further afield, which will contribute to New Zealand's prevalence of HIV. The estimated prevalence of antenatal HIV is higher than that of some conditions already screened for in New Zealand babies, such as cystic fibrosis.

Effective interventions that reduce the risk of pregnant women transmitting HIV to their infants have led to a greater emphasis on antenatal HIV screening worldwide. It is estimated that if women with HIV are identified during pregnancy and use a combination of interventions, the risk of mother-to-child transmission can be reduced from as high as 31.5 percent to less than 2 percent.

There is considerable debate about the benefits and harms of HIV screening in pregnancy and the best way to offer screening – universally or selectively. The current policy in New Zealand is a selective policy based on risk assessment. Evidence suggests that this policy is not being implemented properly.

Those with a particular interest in antenatal HIV screening include midwives, doctors and nurses caring for pregnant women, paediatricians and other specialists, women's organisations, women in the community, people working with HIV/AIDS and policy-makers.

The NHC acknowledges the diverse range of views and values that various interest groups bring to the issue, and that social and cultural beliefs around HIV may vary. It is important to respect the full range of views. Debate on screening in pregnancy can be emotive, as it involves considerations around the future health of babies and children. It is important that children's rights are considered, and essential to respect the rights and preferences of women.

The NHC has undertaken a comprehensive investigation of this issue, assisted by a scientific advisory group and consultation with the health sector. It has considered evidence from overseas and New Zealand. While some other countries have moved to a universal offer of screening, the NHC believes that caution should be used in applying overseas evidence and experience to New Zealand. Our context is unique, with a low prevalence of HIV and a maternity care system that differs from those in other countries.

The NHC believes that there is currently insufficient evidence to recommend a policy change to a universal offer of antenatal HIV screening across New Zealand. However, it is recommending a pilot study to trial universal screening in the Auckland area. Evaluation of that study will be crucial in assessing feasibility, cost, acceptability to women and providers, and effectiveness in reducing mortality and morbidity.

In addition, the NHC recommends that the current antenatal HIV screening policy be properly implemented. Ways to improve implementation include updating the risk assessment guidance, a training and education programme for maternity care providers, promoting the policy to pregnant women and maternity care providers, as well as monitoring and evaluation.

New Zealand lacks a national policy on antenatal screening in general, which leads to a wide variation in practice. The NHC recommends that the Ministry of Health undertake a review of the full range of antenatal screening practices in New Zealand.



Robert Logan Chair



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Executive Summary

Greater emphasis on HIV screening in pregnancy has emerged during the past decade due to effective interventions that can reduce the risk of pregnant women transmitting HIV to their infants.

The National Health Committee (NHC) has considered whether New Zealand should move to a universal offer of antenatal HIV screening or retain the current policy (a selective offer based on risk assessment). The committee has drawn on advice from a scientific advisory group, a consultation process, and evidence from New Zealand and overseas.

The NHC's screening assessment criteria were used to examine the issue of antenatal HIV screening, and to consider how best to offer screening. A summary of the application of the screening criteria can be found on page 6 (Table 1).

This report considers three potential policy options for antenatal HIV screening in New Zealand:

- A current policy properly implemented**
- B new policy of universal offer of screening (opt-in)**
- C new policy of universal offer of screening (opt-out).**

There is evidence that the current guidelines are not being implemented in New Zealand.¹ Submissions to the NHC expressed concern that the policy has not been promoted or supported. There has been a lack of training for maternity care providers about HIV and antenatal HIV screening. It is the NHC's view that it would be preferable to improve implementation of the policy, rather than reject the policy at this stage. A selective approach may be more cost-effective than a universal offer, as only those women deemed at higher risk are screened.

The NHC's advice on these options includes two main recommendations to be carried out concurrently.

Firstly, the NHC recommends that a study be carried out to trial a universal offer of screening (Option C) in order to assess the potential feasibility, costs, acceptability and effectiveness of this approach in New Zealand. A pilot study is needed to gain further information on a range of important issues. These include:

- practical issues in implementing a universal offer
- the financial costs of implementing a universal offer policy in New Zealandⁱⁱ
- acceptability to health professionals
- acceptability to pregnant women
- effectiveness of a universal offer policy compared with proper implementation of a selective policy.

ⁱⁱ There has been an incremental cost-benefit study done by Bramley and colleagues (Bramley D, Graves N and Walker D. 2003. The cost-effectiveness of universal antenatal screening for HIV in New Zealand. *AIDS* 2003 17:741-748) but the resulting costs would vary considerably depending on different prevalence estimates and the time taken for pre-test discussion, delivery of results and post-test counselling.

Secondly, the NHC advises strengthening the implementation of the current policy on antenatal HIV screening across New Zealand (Option A). Specific ways to improve implementation are suggested on page 20 but include:

- national coordination, monitoring and evaluation
- updating the risk assessment guidance
- a training programme for maternity care providers
- promoting the policy to pregnant women and providers.

The decision to recommend Options A and C is based on the need to ensure that practical and ethical considerations are met (criteria 5 to 8), rather than on the availability of evidence for the effectiveness of screening programmes (criterion 4).

The NHC has chosen to recommend a pilot study of Option C rather than recommending a policy change across New Zealand for the following reasons:

- 1) several key areas of uncertainty remain – including practical issues, costs and acceptability – which could be examined through a pilot study
- 2) the Scientific Advisory Group to the NHC recommended caution in applying overseas findings on antenatal HIV screening to New Zealand
- 3) the potential impact of a recent immigration policy change to screen all migrants for HIV in terms of reducing cost-effectiveness of universal screening in the future, and
- 4) submissions to the NHC supported a pilot approach.

Many submissions to the NHC supported a pilot because it would identify the best way to provide a national service and help assess acceptability to pregnant women and providers. Any practical issues in introducing a universal offer of HIV screening could be addressed, as well as resourcing and system capacity. Finally, the amount of information and support needed by providers could be assessed.

The NHC suggests that the pilot study should be in the Auckland area, due to the higher prevalence of HIV and the numbers of migrants from high-prevalence countries.

The NHC believes that it is crucial to retain a high-quality process for HIV screening. It is important to ensure that the move to pilot a universal offer in Auckland does not reduce the quality of the screening process or encourage a superficial ‘tick the box’ approach. The NHC recommends that all maternity care providers be trained in dealing with HIV issues. It also recommends that the current funding for the first antenatal visit be reviewed in light of the need to undertake proper risk assessment and discussion of HIV screening and its implications. It is also critical to retain a genuine informed consent process. The NHC recommends that informed consent processes for all antenatal screening are reviewed, and that written consent be recorded (either in electronic or paper form).

The NHC recommends that a comprehensive review of all antenatal screening be undertaken in order to improve oversight and implementation of the wide range of screening of pregnant women.

In giving this advice, the NHC believes that the issue must be seen in the wider context of HIV prevention, and prevention of other sexually transmitted infections. The World Health Organisation has emphasised the importance of primary prevention in preventing transmission of HIV to infants:

The most effective approach to preventing vertically acquired HIV infection in children is through primary prevention among women of childbearing age, and secondarily through the prevention of unwanted pregnancies among HIV-infected women and of MTCT [mother-to-child transmission].²





While antenatal screening for HIV can be effective in identifying women with HIV, and preventing mother-to-child-transmission (MTCT), this is only a secondary prevention. The NHC suggests that more emphasis should be placed on primary prevention of HIV.



A more accurate indication of prevalence of HIV among pregnant women is also required. The NHC recommends that a prevalence study be undertaken to achieve this.

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TABLE 1

Summary of antenatal HIV screening against the NHC screening assessment criteria

National Health Committee Screening Assessment Criteria		Does antenatal HIV screening meet the criteria?
	Criterion 1 The condition is a suitable candidate for screening	The NHC considers that this criterion is met. Although there is a low prevalence of HIV among pregnant women, it has significant implications. There is also evidence of rising numbers of people with HIV in New Zealand, including women, and these increases are likely to continue in the future. Screening is already done for some conditions that are less prevalent than HIV, eg, cystic fibrosis.
	Criterion 2 There is a suitable test	The NHC considers that this criterion is met. The test for HIV is simple and safe, as well as being extremely sensitive and specific. It is acknowledged that a small number of women will require a second test one month after screening, which is likely to cause anxiety. In addition, the 'window period' can produce false negative results. The possibility of false negatives and false positives must be discussed with women prior to screening.
	Criterion 3 There is an effective and accessible treatment or intervention for the condition identified through early detection	The NHC considers that this criterion is met. Effective interventions are available for the prevention of mother-to-child transmission of HIV. There is evidence that early treatment leads to better outcomes.
	Criterion 4 There is high quality evidence, ideally from randomised controlled trials, that a screening programme is effective in reducing mortality or morbidity	Option A - Proper implementation of current policy The NHC believes there is insufficient evidence to support or reject this policy option against Criterion 4. There is some evidence suggesting that the current policy is not effective, because it is not being implemented. There has been insufficient promotion of the policy and a lack of training for providers. There is little provision in the current maternity care system in terms of time for the Lead Maternity Carer (LMC) to discuss HIV testing and its implications to women. Some overseas studies have suggested that targeted testing fails to identify a substantial proportion of HIV-positive women. The potential effectiveness of proper implementation of New Zealand's current policy is unknown. An evaluation of Norway's screening programme concluded that for a very low prevalence population, selective screening might be feasible.
		Option B - Universal offer – opt-in The NHC believes there is insufficient evidence to support or reject this policy option against Criterion 4. Evidence suggests that this option is not as effective as a more routine approach where women 'opt out'. Research has estimated that moving from this approach to an 'opt-out' policy can double the uptake of screening.

		<p>Option C - Universal offer – opt-out</p> <p>The NHC believes there is insufficient evidence to support or reject this policy option against Criterion 4. Overseas evidence indicates that a universal offer of screening results in high uptake and identification of most HIV-positive women.</p> <p>However, the evidence is from observational studies and trials of uptake in countries that have different maternity care systems to New Zealand. The Scientific Advisory Group to the NHC cautioned against extrapolating overseas experience to New Zealand. It is also not clear from the literature how much of the overseas reductions in perinatal transmission were due to shifting to a universal policy or to the increased effectiveness and use of interventions to reduce mother-to-child transmission.</p>
	<p>Criterion 5</p> <p>The potential benefit from the screening programme should outweigh the potential physical and psychological harm (caused by the test, diagnostic procedures and treatment)</p>	<p>This criterion requires the potential benefits of screening to be maximised, and harms minimised. With any screening, there is a need to balance the benefits against potential harms, at both individual and population levels.</p> <p>Two very important benefits are gained from antenatal HIV screening, irrespective of the approach. These are the opportunity to prevent mother-to-child transmission and to gain early intervention for women found to be infected. The Scientific Advisory Group to the NHC found that knowledge of the possible harms of antenatal HIV screening and treatment is incomplete, so a cautionary approach should be taken. Potential harms include anxiety from false positive results, and false reassurance for false negative results.</p> <p>The NHC believes that further information is needed to compare the practical issues and acceptability associated with Options A and C (which would be gained through a pilot study). Once this information is gained, a more accurate indication of the balance between benefits and harms could be made.</p>
	<p>Criterion 6</p> <p>The health care system will be capable of supporting all necessary elements of the screening pathway, including diagnosis, follow-up and programme evaluation</p>	<p>In order for this criterion to be met (for all three options), national oversight of antenatal HIV screening would need to be established and specific resources allocated. Training is required to ensure that all those offering screening have the latest information and are supported to offer pre/post test discussion.</p> <p>The NHC believes there are some uncertainties in comparing the three options against this criterion. It is not clear which option would require the most change in terms of improving the health care system's capability to support the screening pathway. Comparing Options A and C would help to identify which option would require the most resources in order to improve capability.</p>

	<p>Criterion 7 There is consideration of social and ethical issues</p>	<p>The NHC considers that this criterion is met for all three approaches, as long as fundamental ethical requirements are followed. Irrespective of the approach, crucial elements of informed consent, adequate information and pre/post-test discussion and counselling must be integral to the policy.</p> <p>Social and ethical issues arise with each of the options. There is uncertainty around the acceptability of a universal offer to women (Options B and C), particularly those from parts of Africa and Asia where HIV prevalence is high. On the other hand, a small study in the South Island found that some women preferred a universal offer.</p> <p>A universal approach may be more acceptable to health professionals, as they would not need to ask women personal questions about their risk status (as in Option A).</p> <p>The NHC believes that antenatal HIV screening should be voluntary and undertaken only with a written record of informed consent (there should be a record of written consent for all antenatal screening including HIV, either in paper or electronic form). All pregnant women must be provided with at least a minimum set of information about HIV screening in pregnancy, both written and oral. All pregnant women who are HIV-positive should be offered specific HIV counselling.</p>
	<p>Criterion 8 There is consideration of cost-benefit issues</p>	<p>The NHC has examined cost-benefit issues in relation to antenatal HIV screening and considers that this criterion is met. Although there is no study in New Zealand comparing the cost-benefit of antenatal screening with other health care interventions, there is a study that looks at the incremental costs and benefits associated with moving from the current system to a universal offer of HIV screening.³ This study estimates the total incremental cost of moving from the current system to a universal offer to be \$723,607. Such a programme would detect 5 HIV exposed babies and avoid 1.15 cases of HIV infection in babies annually.</p> <p>The results of the study compare favourably (for the base case analysis) with findings overseas where universal screening has been adopted. However, a key problem is that the true prevalence rate of HIV infection is not known and this may lead to variations in costs.</p> <p>As there are remaining areas of uncertainty associated with cost-benefit issues, including prevalence, the NHC is recommending implementing Option A and undertaking a pilot study of Option C in Auckland. A pilot study will provide evidence as to whether the current best estimate of costs can be confirmed as being within an acceptable range.</p>

Recommendations

The National Health Committee (NHC) recommends to the Minister that the Ministry of Health (in conjunction with District Health Boards and relevant professional colleges):

- 1 develop and conduct a pilot study to assess the potential feasibility, costs, acceptability and effectiveness of a universal (opt-out) offer of antenatal HIV screening. The results of the study will allow an informed, evidence-based decision to be made on any move towards a universal offer in the near future.

The NHC suggests that this pilot study is:

- undertaken in Auckland
 - carried out for two years
 - independently monitored and evaluated
- 2 ensure that the current policy for antenatal HIV screening is properly implemented in all areas of New Zealandⁱⁱⁱ (excluding the site of the pilot study which will trial a universal offer)
 - 3 promote the antenatal HIV screening policy across New Zealand, both for the pilot study and proper implementation of the current policy, to all maternity care providers and pregnant women, and offer training for providers
 - 4 fund a national prevalence study, using anonymous unlinked testing of neonatal bloodspots, to more accurately determine the true prevalence of antenatal HIV in New Zealand
 - 5 monitor the impact of the Government's immigration health screening policy change to screen all migrants for HIV, for its effect on HIV prevalence in New Zealand
 - 6 review the funding for the first antenatal visit so that proper risk assessment is undertaken and HIV screening and its implications are adequately discussed with pregnant women
 - 7 ensure that the National Screening Unit's framework for quality improvement is applied to antenatal HIV screening
 - 8 undertake a comprehensive review of the full range of antenatal tests and protocols for screening, as a key step in improving oversight and implementation of all antenatal screening including HIV.

The NHC suggests that this review of wider antenatal screening cover:

- the consent process^{iv}
- provision of information on antenatal screening to women and providers
- training of providers, and the reporting of test results to women.

ⁱⁱⁱ Suggestions for strengthening the implementation of the current policy are detailed on page 20 and include updating the risk assessment guidance, better promotion of the policy, training for providers, information for providers and women, and monitoring of the policy, including economic analysis.

^{iv} Written record of informed consent should be required for all antenatal screening including HIV but this may be in either electronic or paper form.

In making these recommendations the NHC highlights the following:

- Evidence relating to the full financial implications of the options considered for antenatal HIV screening is not available.
- The prevalence of HIV infection within the Pacific region is increasing and the profile of HIV within New Zealand may be very different in the future. Increases in heterosexual transmission will produce changes in the distribution of HIV, with higher numbers of women and babies affected.

Accordingly the NHC is making recommendations that place New Zealand in the best position to make an informed judgement on an uncertain future. The NHC gives particular weight to recommendations 1 and 2 being carried out concurrently.

Facts and figures

- An estimated 56,000 women give birth in New Zealand each year.
- In 2003, five children were diagnosed with HIV in New Zealand. This was the largest number in any year to date.
- The risk of transmission from a mother with HIV to her baby can be reduced from as high as 31.5 percent to less than two percent if the mother uses a combination of interventions and treatment.^{4, 5}
- If a universal offer of antenatal screening was the policy in New Zealand, then on an annual basis approximately 55 000 pregnant women would be tested for HIV (based on live births rather than total number of pregnancies). Nearly all pregnant women with HIV infection would be detected by the first test.
- If all infected pregnant women were detected through antenatal screening:
 - an additional 4 -18 women would be diagnosed with HIV annually
 - if interventions to prevent transmission were taken up by all of these women, it is estimated that on average 1 - 4 perinatal infections could be prevented annually.⁶
- The incidence of HIV is rising in New Zealand. There were 136 new cases of HIV in New Zealand in 2002, and in 2003 there were 188 new HIV cases – this was a 44% rise in the number of new infections in those two years.
- HIV is increasingly affecting women. Between 1996 and 2002, 24% of newly diagnosed infections in New Zealand were in females.
- The women diagnosed with HIV in New Zealand are disproportionately from parts of the world where heterosexual transmission is relatively common, with 74% percent of HIV cases among women in New Zealand since 1996 acquired overseas – 44% in Africa and 17% in Asia.
- Each HIV test costs \$14.70 but there are associated costs to run an effective screening programme.



Introduction

Both internationally and in New Zealand, there is debate about the benefits and harms of HIV screening in pregnancy and the best approach to this screening. The increased emphasis on HIV screening in pregnancy has emerged over the past decade due to the availability of effective anti-retroviral and other interventions that can reduce the risk of pregnant women transmitting HIV to their infants.

There is debate on how screening should be offered – universally to all women as part of routine practice, selectively (for those with recognised risk factors), or on a ‘request only’ basis. Another question is whether the test should be offered with comprehensive information and discussion, or alongside other antenatal blood tests with at least a minimum of information.

Studies indicate that New Zealand’s current policy of HIV screening in pregnancy (selective offer based on risk assessment) is not being implemented by maternity care providers, and that a systematic reassessment and implementation of a workable strategy needs to be undertaken.¹

The NHC has examined whether New Zealand should continue with the current policy of HIV screening in pregnancy with initiatives to improve its implementation or to move to a universal offer of screening. The committee’s advice and recommendations to the Minister of Health are presented in this report.

National Health Committee

The National Advisory Committee on Health and Disability (National Health Committee, NHC) provides the Minister of Health with independent advice on the kinds, and relative priorities, of public health services, personal health services, and disability support services that should, in the committee’s opinion, be publicly funded. The committee has previously provided advice on screening for colorectal cancer and prostate cancer.

Process for this project

The issue of whether New Zealand should move from the current antenatal HIV screening policy to a universal offer of screening was brought to the attention of the NHC in 2002. Mounting debate on the issue in the health sector was an impetus for the work. Women’s Health Action ran a seminar to encourage dialogue on the issue in July 2002. It attracted 100 people from a range of health professions, policy settings and the community. The seminar’s purpose was to inform the debate and encourage discussion, rather than attempting to come to a consensus about whether screening should take place. A report was produced with transcripts of the presentations and a summary of the discussion.⁷ The report highlights that there was no consensus among participants as to the best way forward with antenatal HIV screening.

In April 2003, the NHC released the report *“Screening to Improve Health in New Zealand: Criteria to assess screening programmes in New Zealand.”*⁸ The criteria that were developed are shown in Table 2 and form the framework for this report.

TABLE 2

Criteria for assessing screening programmes

- 1 The condition is a suitable candidate for screening.
- 2 There is a suitable test.
- 3 There is an effective and accessible treatment or intervention for the condition identified through early detection.
- 4 There is high quality evidence, ideally from randomised controlled trials, that a screening programme is effective in reducing mortality or morbidity.
- 5 The potential benefit from the screening programme should outweigh the potential physical and psychological harm (caused by the test, diagnostic procedures and treatment).
- 6 The health care system will be capable of supporting all necessary elements of the screening pathway, including diagnosis, follow-up and programme evaluation.
- 7 There is consideration of social and ethical issues.
- 8 There is consideration of cost-benefit issues.

The committee convened a scientific advisory group^v to examine the evidence on antenatal HIV screening in relation to the first five criteria listed above. A separate consultation process was used to assess the issue against the last three criteria (6 to 8), where individuals and groups responded to a discussion document. Both documents are available on request from the NHC and provide details of the evidence that underlies this report. The advisory group's report is also on the NHC website.^{vi}

In forming its recommendations the committee has drawn on the report by the advisory group, feedback from the discussion document, and other studies and background documents including the report on the Women's Health Action seminar.

^v See page ii for names

^{vi} www.nhc.govt.nz

Background

HIV (Human Immunodeficiency Virus) is a virus that causes a lifelong infection that damages the body's immune system.⁹ AIDS (Acquired Immune Deficiency Syndrome) is a late consequence of HIV infection. Without treatment, about half of those with HIV will progress to AIDS over an average of ten years. HIV is transmitted through the exchange of body fluids such as blood and semen. Around the world, HIV has most commonly been transmitted through unsafe sex or shared drug-injecting equipment, or passed on from an infected mother to her baby. Heterosexual transmission of HIV is increasing worldwide.

HIV in New Zealand

The number of people living with HIV in New Zealand is increasing, as each year more people are diagnosed with HIV than die from AIDS.¹⁰ The number of new diagnoses of HIV is also rising.

In 2003 the number of new cases of HIV reported in New Zealand was the highest since the epidemic began in the 1980s – 188 compared with 136 new cases in 2002.^{11,vii} This is an increase of 44%. Five children were diagnosed with HIV in 2003, which is the largest number in any year to date. The latest figures released by the AIDS Epidemiology Group point to further increases. During the first half of 2004, 67 people were diagnosed in New Zealand with HIV.¹² These increases are consistent with trends in other countries.

The overall number of men reported with HIV since 1985 is significantly higher than the number of women, but more recently women are making up a greater proportion of the annual numbers diagnosed.⁹ Heterosexual transmission of HIV occurs mainly from contact in or from high prevalence regions outside New Zealand (such as parts of Africa and Asia). There is an escalating rate of HIV in the Pacific region, which is likely to affect New Zealand's rate as people move back and forth between New Zealand and the Pacific. With increasing heterosexual spread of HIV and the likelihood of this continuing, there have been calls for New Zealand to follow other countries where HIV screening is offered and recommended to all pregnant women.

In 2003 the Ministry of Health produced an HIV/AIDS Action Plan for New Zealand.⁹ The document promotes a long-term public health approach to the HIV epidemic with primary prevention at its centre. New Zealand is a signatory to the United Nations General Assembly Special Session on HIV/AIDS (UNGASS), which includes a target to reduce the proportion of infants infected with HIV by 20% by 2005 and 50% by 2010. It also aims to ensure that 80% of pregnant women accessing antenatal care have information, counselling and other HIV prevention services available to them.

The Action Plan identifies four target groups who are more likely to practise high-risk behaviours – men who have sex with men, refugees and migrants from high-prevalence countries, injecting drug users and sex workers. While women are not identified as a target group, the Action Plan notes that trends overseas suggest that women, especially young women, should also receive HIV awareness and prevention.

The World Health Organization has emphasised the importance of primary prevention and control of sexually transmitted infections (STIs) including HIV. For countries with low prevalence of HIV, the primary biomedical intervention to prevent HIV transmission more generally is the control of STIs.¹³ The issue of antenatal HIV screening should be seen within the context of the HIV/AIDS Action Plan and the World Health Organization's advice.

^{vii} Note that this figure includes people who were diagnosed overseas but moved to live in New Zealand

Antenatal screening in New Zealand

A wide range of antenatal screening currently takes place in New Zealand. For instance, women may receive tests for anaemia, gestational diabetes, hepatitis B, rubella and syphilis.

Antenatal screening, including for HIV, is currently opportunistic in nature as opposed to an organised screening programme. The NHC suggests the following definitions for opportunistic screening and screening programmes:

Opportunistic screening occurs without quality assurance processes, monitoring or evaluation. However, it may be organised to a greater or lesser degree.

Screening programmes screen entire populations or an identifiable group within the population. Resources are committed to the development, implementation, monitoring and evaluation of all aspects of the programme.

Although antenatal screening is currently applied to a specific population (which is a feature of screening programmes), there is no formal programme oversight or national information system for collating data.

There is no prescriptive set of antenatal tests or consistent approach to antenatal screening practices across the board. Antenatal screening is often undertaken without any consent, or with consent of a limited nature. New Zealand lacks a national policy on antenatal screening and this leads to a wide variation in practice.

The NHC recognises that it is difficult to have adequate quality processes outside an organised screening programme, but stresses that the quality of current antenatal screening could be improved by having appropriate professional audit, and routinely collecting and analysing monitoring data.

The committee believes that further assessment needs to be undertaken on the whole antenatal screening landscape in New Zealand. This should involve a review of all antenatal tests currently being done, as well as development of a consistent approach to antenatal screening throughout the country. There should be consumer involvement in this review. The review should also address whether information provided to women on antenatal screening in general is adequate, and address the training requirements of providers of antenatal screening.

The NHC recommends that:

The Ministry of Health (in conjunction with District Health Boards and relevant professional colleges) undertake a comprehensive review of the full range of antenatal tests and protocols for screening, as a key step in improving oversight and implementation of all antenatal screening including HIV.

Antenatal HIV screening

Although HIV screening clearly occurs in a broader context of antenatal screening, this document focuses on antenatal HIV screening in particular. It considers New Zealand's current policy for antenatal HIV screening (which is opportunistic), as well as two proposed options for screening programmes involving a universal offer.

Effectiveness of HIV interventions in pregnancy

In the mid-nineties it became known that anti-retroviral drugs are effective both in treating maternal HIV and in preventing transmission of HIV from a mother to her child. Other interventions can also reduce the chance of mother-to-child transmission, such as delivery by Caesarean section and avoidance of breastfeeding. As only women who know their HIV status before delivery can benefit from these interventions, there is a mounting emphasis on antenatal screening.

If women with HIV are identified during pregnancy and use a combination of interventions, the estimates are that risk of perinatal transmission can be reduced from as high as 31.5 percent⁴ to less than two percent.⁵

Screening in pregnancy aims to identify women who are HIV-positive in order:

- a) that they may receive optimal medical treatment and psychosocial care for themselves
- b) to decrease the incidence of mother-to-child HIV transmission
- c) to identify HIV-positive infants as early as possible, where mother-to-child transmission occurs, so they may benefit from optimal medical treatment.¹⁴

Primary maternity care in New Zealand is provided by Lead Maternity Carers (LMCs) who work under Section 88 of the New Zealand Public Health and Disability Act 2000. LMCs take responsibility for the care provided to women throughout pregnancy and the postpartum period including the management of labour and birth.

The majority of pregnant women (73%) choose midwives as their LMC, while the rest have General Practitioners (GPs) or obstetricians.¹⁵ However, it may be either a midwife or a GP who undertakes the initial antenatal screening in the first trimester of pregnancy. Women are registered with an LMC in the second trimester of pregnancy, but they may see a midwife or a GP prior to being registered. At registration LMCs are responsible for finding out from women whether they have been screened, and to initiate this process if screening has not occurred.

The Scientific Advisory Group to the NHC advised that HIV should be part of the first antenatal screen, as it is preferable to detect HIV earlier rather than later in pregnancy. Early detection enables consideration of various options, including termination of pregnancy if desired, and allows time to plan interventions to prevent transmission of HIV (both to the baby and to sexual partners).

Other HIV screening in New Zealand

HIV screening of migrants^{viii}

A recent policy change means that, from April 2005, the Department of Labour (Immigration Services) will screen all new migrants for HIV, as part of a comprehensive medical examination.^{ix} This policy will also apply to all foreign students, workers and visitors coming to New Zealand for 12 months or more (excluding Australian citizens and permanent residents).

This change is relevant to the issue of antenatal HIV screening as the majority of women in New Zealand with diagnosed HIV were infected overseas. Seventy four percent of HIV diagnoses among women in New Zealand since 1996 were acquired overseas – 44% in Africa and 17% in Asia.¹⁶

In general, the number of people being routinely screened for HIV prior to residence approval will increase from very few people to everyone from age 11 years.

The policy change could reduce the future cost-effectiveness of undertaking a universal offer of HIV screening in pregnancy, as there should be increased detection of HIV at an earlier stage among migrants and refugees from high prevalence countries.

^{viii} This section was written with input from the Department of Labour (Immigration Services).

^{ix} Previously only adult Quota refugees were screened for HIV, and that screening took place after arrival in New Zealand. This meant that other migrants, asylum seekers and family reunification refugees were not required to undergo mandatory HIV testing.

The new policy may not necessarily lower the incidence of HIV, as the consequence of an HIV-positive result at the border is not exclusion, but the triggering of a protocol to weigh up the pros and cons of allowing the person into New Zealand. Cabinet has agreed to accept up to 20 HIV-positive Quota refugees per year. It should also be noted that extended screening of migrants would not identify HIV cases among New Zealand citizens and residents returning from visits or living overseas, or among Australian citizens or residents.

The NHC recommends that:
The Ministry of Health (in conjunction with District Health Boards and relevant professional colleges) monitor the impact of the Government’s immigration health screening policy change to screen all migrants for HIV, for its effect on HIV prevalence in New Zealand.

HIV screening of blood donations

The New Zealand Blood Service screens all blood donations for HIV and other infectious diseases such as hepatitis B and C. There are around 40,000 blood donations per year. Potential blood donors are required at each visit to complete a confidential questionnaire on their health history, lifestyle and recent travel. Medical staff members are available to help complete the form and it is emphasised that no judgements are made about activities of potential donors.

While the screening process used by the Blood Service has some relevance to antenatal HIV screening, it takes place in a very different context. The expected level of service provided by a maternity carer is different to that of a health professional involved in blood donations. People who give blood donations are choosing to come forward and donate their time and blood, whereas pregnant women are seeking health care and support throughout pregnancy.

Approaches to HIV screening in pregnancy

There are several potential approaches to antenatal HIV screening as shown in Figure 1.

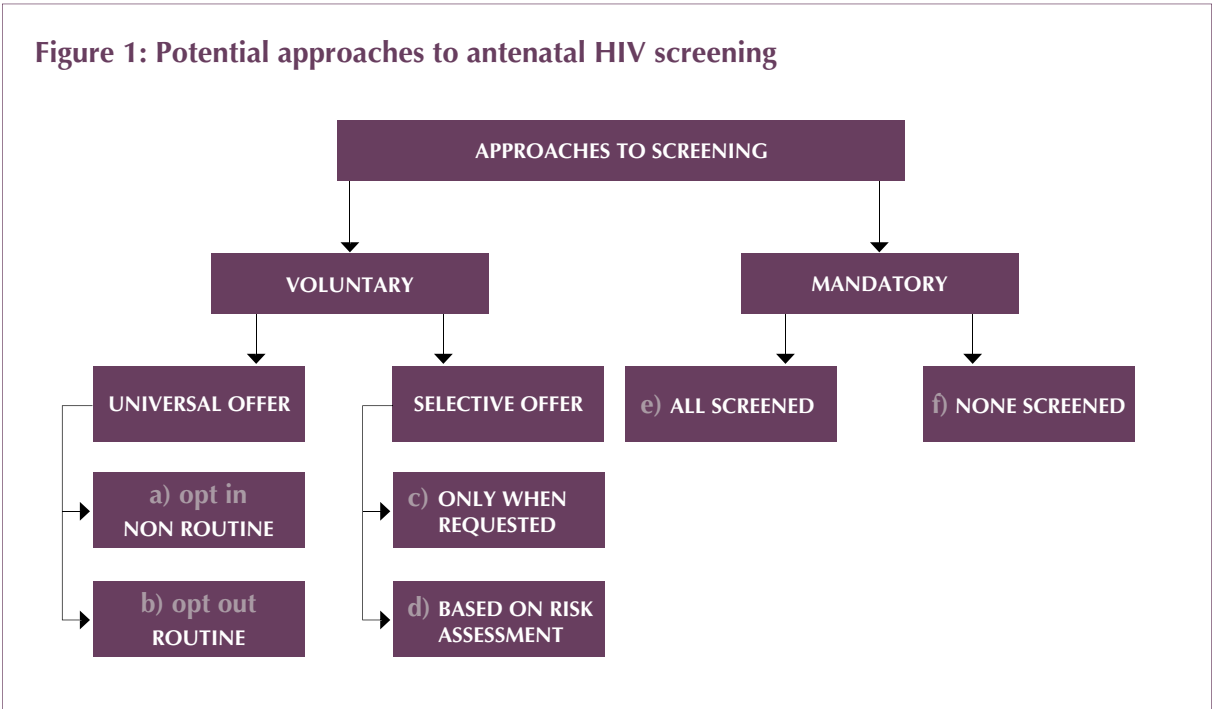


Table 3 describes each of these six approaches to screening. Three options are highlighted for more detailed consideration in this document.

TABLE 3 Description of potential approaches to screening			
Type of approach	Description	Relevance to New Zealand	Consider further?
VOLUNTARY APPROACHES			
a) Universal offer – non-routine, opt-in	Screening would be offered to all women, but would not be presented as routine – they would need to ‘opt-in’ to screening by choosing to accept it.		Yes
b) Universal offer – routine, opt-out (with a recommendation of screening)	Screening would be offered to all women, and presented as routine (as another test alongside other antenatal blood tests). Women could ‘opt out’ of screening by choosing to decline it.		Yes
c) Selective offer only when requested	Women would not be offered screening, but would be screened if they requested it.	This approach alone does not meet the requirements of the current antenatal HIV policy in NZ.	No
d) Selective offer based on risk assessment	All women would be assessed for their risk of HIV, and those considered to be at risk would be offered screening.	This is the current policy in NZ.	Yes
MANDATORY APPROACHES			
e) All screened	All women would be screened, regardless of their wishes.	This is not feasible for NZ, as it is unethical and would contravene the Code of Health and Disability Services Consumers’ Rights.	No
f) None screened	No screening would be undertaken, even if women requested it.	This is not feasible for NZ for the reasons given above.	No

The remainder of this section looks at the three options identified in Table 3 for further consideration:

- A selective offer of HIV screening (based on risk assessment)**
- B universal offer of HIV screening (non-routine, ‘opt-in’)**
- C universal offer of HIV screening (routine, ‘opt-out’).**

Option A - Selective offer of HIV screening based on risk assessment

(New Zealand's current policy)

The current policy in New Zealand recommends assessment of all pregnant women for their risk of HIV and that "where risk factors are identified or are not clear, counselling and voluntary testing be offered".¹⁷ This policy has been in place since 1997. The guidelines state that testing only those women with identified risks for infection will not pick up all cases of HIV so where there is doubt it is better to offer counselling and testing. Therefore, all women who are of the 'uncertain risk' category should be offered HIV screening. The policy is attached in Appendix Three.

This policy is selective in that only the women assessed as being at high or uncertain risk are offered screening, however the risk assessment process is universal as all women should be assessed. If most women are assessed as 'uncertain risk', then it could become a 'de facto' universal offer of screening.

Australia also has a selective offer policy in some states – South Australia, Western Australia and Victoria.¹⁸

See Appendix One for further details of arguments for and against the current policy.

Effective implementation of current policy

The NHC believes the current policy should be properly implemented. The following suggestions could assist in strengthening implementation. Potential changes would need to be considered in more detail by the Ministry of Health, in conjunction with District Health Boards and relevant professional colleges.

- Develop a national, coordinated approach to antenatal HIV screening in the context of wider antenatal screening.
- Update the risk assessment guidance. The New Zealand Blood Service tool could be used as a model. As is the case currently, health providers could choose between using a written tool or a set of verbal questions. In addition, the latest checklist for pre-test discussion and post-test counselling should replace the 1997 one.⁵⁷ The written assessment tool would need to be produced in several languages – Māori, Pacific, and major African and Asian languages.
- Promote the policy more effectively to maternity care providers. Establish a coordinated education and training programme for providers on the policy and on dealing with sensitive issues, including HIV. Training for professionals should include information on HIV and the latest trends in HIV epidemiology, prevention and management. It should also include specific training on working with people from migrant communities and countries with high prevalence of HIV.
- Provision of a public health education programme for women about the antenatal screening policy, HIV, and other STIs to encourage both primary prevention and early identification of risk/early screening, ideally before they become pregnant.
- Increase education to the wider population about heterosexual transmission of HIV.
- Improve referral systems and awareness by LMCs of community resources including HIV counsellors, migrant and refugee support services and community support services.
- Provision of culturally responsible programmes of support for communities most affected by HIV. Provision of specific resources for migrants and refugees regarding HIV prevention and support.
- Introduce monitoring and evaluation of antenatal HIV screening, including economic analysis.

See Appendix One for arguments for and against proper implementation of the current policy.

Option B - Universal offer of HIV screening (non-routine, 'opt-in')

Under this approach, the health professional offers HIV screening to all pregnant women, asking them if they want to be screened ('opt-in'). HIV screening is presented as being 'non-routine', in that it is not part of standard antenatal tests.

This was the previous policy in the United Kingdom (UK) and some provinces of Canada. In the UK the policy changed to an 'opt-out' universal offer in 1998, while in Canada provinces including British Columbia, Ontario and Quebec have retained the opt-in approach (other Canadian provinces have shifted to an 'opt-out' approach).

See Appendix One for arguments for and against the opt-in approach.

Option C - Universal offer of HIV screening (routine, 'opt-out')

Under this approach, the health professional offers HIV screening to all pregnant women in a context where screening is viewed as routine. HIV screening would be presented as just one of a range of standard antenatal tests. Women are asked if they want to decline the offer of screening ('opt-out'). Screening would still be voluntary, with women given the option to decline screening.

Countries with this policy include the UK, United States (US), some Canadian provinces including Alberta, Nova Scotia and Newfoundland, and some Australian states including the Northern Territory, New South Wales and Queensland.

See Appendix One for arguments for and against this approach.

Summary

This section has outlined three distinct approaches to antenatal HIV screening:

- A selective offer of HIV screening (based on risk assessment)**
- B universal offer of HIV screening (non-routine, 'opt-in')**
- C universal offer of HIV screening (routine, 'opt-out').**

Some arguments for and against each option are provided in Appendix One.

No screening approach will be able to identify all HIV cases. Irrespective of the screening option, it is possible that the highest risk women may decline to be screened. In particular, health professionals working with refugees and new migrants have expressed concern that African women may refuse screening.⁷ This is due to a fear that their husbands may leave them if they were found to be HIV-positive. In addition, not all women access antenatal care, and those who do not may be at a higher risk of HIV.

The following section sets out the application of the NHC's screening assessment criteria to antenatal HIV screening.



Application of the NHC's assessment criteria

This section examines antenatal HIV screening using the eight screening assessment criteria developed by the NHC (Table 2). The Scientific Advisory Group considered the first five criteria, while the NHC examined the final three criteria (6 to 8) using a consultation process. The first three criteria are applied to the general issue of antenatal HIV screening, as they relate to the condition and test, irrespective of the approach to screening. Criteria 4 to 8 are considered in relation to each of the three options for screening:

- A selective offer of HIV screening (based on risk assessment)
– proper implementation of current policy**
- B universal offer of HIV screening ('opt-in')**
- C universal offer of HIV screening ('opt-out').**

The criteria are not intended to be absolute, as no existing or potential screening programme fulfils every criterion entirely. At the end of each section the NHC gives its view as to whether each criterion is met.

Criterion 1 The condition is a suitable candidate for screening.

The condition should be an important health problem. This criterion is best viewed as a combination of disease incidence and prognosis, and should be considered from both an individual and a community perspective.

The epidemiology and natural history of the condition, including development from latent to declared disease, should be adequately understood and there should be a detectable risk factor or disease marker, and a latent period or pre-symptomatic stage.

The burden of the condition on all sectors of our community should be considered, including specifically for Māori.

Is antenatal HIV an important health problem?

HIV is a serious health problem, both for individuals and for society as a whole. Without treatment the majority of infected children and adults develop progressive loss of immune function, and consequently suffer serious opportunistic infections and early death.¹⁶ HIV infection leads to progressive loss of the body's ability to combat infections, although there is much variation in the rate of progression of HIV. While the available treatment improves the prognosis,¹⁹ this involves considerable hardship to the individual and their family and friends, and significant cost to the health system.

Overall the number and proportion of HIV infections diagnosed among females in New Zealand has been increasing since the early 1990s. Between 1996 and 2002, 24% of newly diagnosed infections in New Zealand were in females.¹⁶

The women diagnosed with HIV in New Zealand are disproportionately from parts of the world where heterosexual transmission is relatively common, with half of the women diagnosed with HIV between 1998-2001 from Africa or Asia. Seventy four percent of HIV cases among women in New Zealand since 1996 were acquired overseas – 44% in Africa and 17% in Asia. Most people with HIV reside in the north and central areas of New Zealand.¹⁶

Nonetheless, HIV infection appears to be a rare condition among pregnant women in New Zealand. Although the actual prevalence of HIV among women giving birth is unknown, estimates can be made from reports of known births to HIV-positive women and the number of infected children born in New Zealand who have developed AIDS. Currently it is estimated that between 1.5 and 4 per 10,000 pregnant women have HIV, with 45–80 percent estimated to be undiagnosed at the time of delivery.^{x,16} This prevalence estimate is higher than the prevalence of some conditions already screened for among babies in New Zealand. For instance, we screen for the following three conditions, with prevalence rates in brackets – congenital hypothyroidism (1 in 4,800), phenylketonuria (1 in 20,500), and galactosemia (1 in 128,000).²⁰

Up to June 2003, a total of 21 children had been identified as infected with HIV by mother-to-child transmission in New Zealand.²¹ Five children were diagnosed with HIV during 2003, which is the highest number for any year.¹¹

Summary of prevalence of antenatal HIV

Based on these figures, and the fact that there are approximately 55,000 births in New Zealand each year, if all infected pregnant women were detected:

- an additional 4 - 18 women would be diagnosed with HIV per year
- if interventions to prevent perinatal transmission were taken up by all of these women, it is estimated that on average 1 - 4 perinatal infections could be prevented annually.⁶

While HIV infection among pregnant women is likely to increase, the extent will depend on the number of people coming to New Zealand from parts of the world where heterosexual spread of HIV is common, the number of New Zealanders who have sexual contact with people in or from such areas, and the extent of heterosexual spread within this country.¹⁶ In addition, transmission will depend largely on people's sexual behaviour, in particular condom use and rates of partner change.²² While there is no evidence of a heterosexual epidemic of HIV in New Zealand, studies into young people's sexual behaviour suggest this cannot be ruled out in the future.²³ Incidence of STIs is rising, and New Zealand has a relatively high teenage pregnancy rate.

To summarise, the impact of HIV on individuals and society is significant and numbers of new diagnoses are rising, however there is currently a low prevalence of antenatal HIV in New Zealand.

Natural history of HIV

The natural history of HIV infection is adequately understood.¹⁶ There is generally a latent stage when those with HIV are either asymptomatic or have symptoms that are not necessarily due to HIV infection. This stage commonly lasts around ten years. Moreover, the HIV antibody test is an effective disease marker. Except for the very early weeks after infection before HIV antibodies are detectable (the 'window period'), HIV infection is detectable through an antibody test.

^x Based on reports of known births to HIV-infected women during 1998-2001 and the number of HIV-infected children born in New Zealand.

Burden of HIV

While the greatest burden of HIV among women in New Zealand is borne by those women from parts of the world where heterosexual transmission is relatively common, Māori, Pacific and Pakeha women have also been infected. Information on women with diagnosed HIV during pregnancy shows that between 1998 and 2001, half were from Africa or Asia. It is of concern that of the remaining nine women (not from Africa or Asia), five were Māori.¹⁶ The relatively high proportion of Māori may be due to the small numbers, but should be watched in future.

Consideration of a national prevalence study

As raised earlier, the true prevalence of antenatal HIV is unknown. A study to determine the prevalence of HIV amongst pregnant women would be useful, as it would enable more precise local epidemiological data to inform decision-making.

The actual prevalence of HIV among women giving birth could be determined by testing all newborn blood samples that are already taken for metabolic screening. This is because HIV antibodies cross the placenta and can be detected in newborns of infected mothers, even though they may not be infected themselves. In many countries this has been used to monitor the HIV epidemic and in the UK this data is linked to information on the number of pregnant women with diagnosed HIV, in order to determine the proportion of infected women diagnosed.¹⁶

Some submissions to the NHC argued that a prevalence study is unnecessary as there are considerable ethical problems they believe such a study would raise. However, a recent change to Right 7(10) of the Code of Health and Disability Services Consumers' Rights, approved by Cabinet, means that the anonymous unlinked testing of neonatal blood spots, would not infringe the Code. Submissions also stated there are doubts over whether it would provide new information which would significantly change the parameters of the debate, and a study of this type may delay potential improvements to antenatal HIV screening. Other submissions supported the notion of a prevalence study. The NHC believes that a prevalence study could be undertaken at the same time as improving the current policy and implementing a pilot study.

The NHC recommends that:

The Ministry of Health (in conjunction with District Health Boards and relevant professional colleges) fund a national prevalence study, using anonymous unlinked testing of neonatal bloodspots, to more accurately determine the true prevalence of antenatal HIV in New Zealand.

Conclusion

The NHC considers that Criterion 1 is met. HIV is a serious condition for those affected and for their families and communities. The natural history of the disease is understood and there is generally a latent period where an asymptomatic mother could infect her infant. HIV infection is detectable through antibody testing.

Despite the low prevalence of undiagnosed HIV among pregnant women, the significant implications of HIV for the individual, family and community justify it being classed as an important health problem. Furthermore, there are increasing numbers of new diagnoses of HIV in New Zealand, and it is likely this trend will continue into the future.

As the actual prevalence of antenatal HIV is not known, the NHC recommends that a prevalence study be undertaken to determine this.

Criterion 2 There is a suitable test.

There should be a suitable screening test. Specific consideration needs to be given to the following test characteristics.

Safe: *harm is kept to a minimum.*

Simple: *a test should be easy to perform, to interpret, and capable of use by paramedical and other personnel where possible.*

Reliable: *the test should give consistent results.*

Accurate/valid: *a test must give a true measurement of the condition or symptom under investigation.*

Highly sensitive: *high probability of giving a positive finding when the person being screened has the condition being sought. Sensitivity should be sufficient to lead to a substantial impact on the disease from a population perspective.*

Highly specific: *high probability of giving a negative finding when the person being screened does not have the condition being sought. Specificity should be sufficiently high that a positive test is reasonably predictive of the target condition. This is important because of harms that result from false positive screening tests.*

Pre-implementation issues

The distribution of test values in the target population should be known and a suitable cut-off level defined and agreed. The cut-off level determines whether someone is classified as having a positive or negative screening test.

There should be an agreed policy on the further diagnostic investigation of individuals with a positive test result and on the choices available to those individuals.

From the perspective of the person being tested, the HIV test is simple and safe.¹⁶ The current use of enzyme immuno-assay (EIA) testing with confirmatory Western Blot (WB) is extremely sensitive (100%) and specific (99.9%) and has been used successfully internationally for many years to screen blood donations.^{16,xi}

Potential numbers of women for screening

- If a universal offer of antenatal screening was the policy in New Zealand, then on an annual basis approximately 55,000 pregnant women would be tested for HIV (based on live births rather than total number of pregnancies).
- Nearly all pregnant women with HIV infection would be detected by the first test.¹⁶

False positive tests

Under the current protocol of testing, about 1 in every 1,000 uninfected women may require retesting within one month of the initial screen to get a confirmed negative result. Although virtually all those who require repeat HIV testing will not be infected,¹⁶ it is acknowledged that they will be subjected to considerable anxiety and stress. It is crucial that women are informed of the possibility of false positive results before testing takes place.

^{xi} Note that these levels of sensitivity and specificity are from the combination of both tests (EIA testing with Western Blot)

Around 55 women each year would require retesting under a universal offer policy. The estimated combined false positive rate of repeat EIA reactivity and Western Blot positivity in a low prevalence population is 1 per 250,000.¹⁶

False negative tests

There is some concern about universally offering HIV testing when there is a chance of a false negative result due to the 'window period'. There are three possible approaches to addressing this concern. Firstly, when a negative test is received it is assumed that a woman does not have HIV, even though a very small proportion will in fact turn out to be positive. A second option may be to repeat testing, in say three months. A third option may be moving the HIV test close to the time of delivery. This would mean the woman would be tested so close to delivery time that a false negative result would not occur during the window period.

It could be argued that the first option is ethically unacceptable, as there is a small chance of not detecting HIV due to the window period. However, this position assumes that it is only acceptable to have no false negative tests whatsoever, which is not a realistic standard. The NHC believes it should be assumed there would be some false negatives from HIV testing, but that it is crucial that maternity providers advise women of this reality.

The second option would require developing a practical protocol for repeat testing and resources to fund this. There are some problems with this option, as it would require repeat testing of all pregnant women and substantial resources, in order to detect a very small proportion of women who were infected after the first test, or whose infection was not detected at the first test (because of the window period). A study of antenatal HIV screening in Norway found that of 961,000 eligible women who were tested, two who seroconverted after the screening were not diagnosed before childbirth and had children infected with HIV.⁵¹ The authors argue that two occurrences in more than 12 years do not justify introducing a second test in pregnancy.

The third approach is not an option, as this would remove the woman's option of terminating the pregnancy if she was found to be HIV-positive and would allow less time for consideration of treatment options.

With a low prevalence of undiagnosed HIV, it is unlikely that many women would be missed due to the window period. Estimating from the figures in the Norway study, which involves a low prevalence population, it would be expected that one woman in New Zealand would be missed every 8.7 years due to the window period.

The NHC believes that the preferred option for dealing with false negatives due to the window period is to assume that negative results are in fact negative (the first option above). It is imperative, however, that the possibility of false negative results due to the window period is clearly communicated to women, as well as the very small numbers of such cases.

Conclusion

The NHC considers that this criterion is met. The HIV antibody test is simple and safe, as well as being extremely sensitive and specific.

Two areas of potential concern are acknowledged. Some women will require a second test in a month's time after the first screen, which can cause significant anxiety. In addition, the 'window period' can produce false negative results. The NHC believes the possibility of false negatives due to the window period must be discussed with women, but a universal offer of repeat testing during pregnancy is not feasible.

Criterion 3 There is an effective and accessible treatment or intervention identified for the condition through early detection.

There should be evidence that early treatment leads to better outcomes than late treatment.

Pre-implementation issues

There should be agreed evidence-based policies outlining which individuals should be offered treatment and the appropriate treatment to be offered.

Clinical management of the condition and patient outcomes should be optimised, as far as practical, by all health care providers prior to participation in a screening programme.

Effective interventions are available for prevention of perinatal HIV transmission, including anti-retroviral therapy, delivery by Caesarean section, and avoidance of breastfeeding. There is also effective treatment for HIV-infected mothers and infants.

Detection of the HIV-positive pregnant woman early rather than later in pregnancy is advantageous for the woman, the child and the maternity team as it facilitates options (including termination of pregnancy if desired) and allows time for planning of intervention(s).¹⁶ The early diagnosis of HIV in the mother enables assessment of her own need for anti-retroviral treatment, which may increase her life expectancy, and for awareness of other people's risk. In the event of prophylaxis failure, early treatment of the HIV-infected child with anti-retroviral therapy improves both morbidity and short-term mortality.^{24, 25, 26, 27}

The evidence on effectiveness of perinatal prophylaxis is derived from cohort studies, and from RCTs with untreated persons in control groups. Meta-analysis and systematic review, including Cochrane Review, has demonstrated the benefit of these interventions.¹⁶

Access to treatments is not likely to be a barrier for HIV-infected women in New Zealand. Although anti-retroviral treatments require specialist endorsement, they are available nationwide. Transport may be a barrier for some women, but alternative options such as treatment supervision by telephone, e-mail or videoconferencing can be considered. In the past Māori and Pacific women have had the lowest usage of antenatal services, but access appears to be improving.¹⁶

Conclusion

The NHC considers that this criterion is met. Effective interventions are available for the prevention of mother-to-child transmission. There is evidence that early treatment leads to better outcomes.

Criterion 4 There is high quality evidence, ideally from randomised controlled trials, that the screening programme is effective in reducing mortality or morbidity.

A high standard of evidence is essential because screening is actively promoted to healthy populations and has potential for causing harm. The best level of evidence comes from randomised controlled trials (RCTs). Well controlled RCTs deal effectively with critical potential biases, including length, lead-time, over-diagnosis and selection bias.

Internationally, there have not been any randomised trials where pregnant women are randomly allocated to be offered or not offered screening, and the infant morbidity and mortality outcomes of the two groups compared.

Other countries have introduced a universal offer of antenatal HIV screening without an RCT, relying instead on evidence from randomised trials on methods of offering screening and observational data on the impact of screening programmes.

As antenatal HIV screening can decrease incidence of HIV, rather than just detecting it at an earlier stage, potential biases (such as lead-time, length and over-diagnosis bias) in observational studies are less relevant. For instance, lead-time and length biases occur because diseases identified by screening are likely to be picked up earlier (lead-time bias), and are more likely to grow slowly (length bias) than disease detected without screening. Any comparison of survival among people with screen-detected disease versus clinically presenting disease will show that those in the screen-detected groups survive longest.

This problem does not occur when screening prevents the disease. For HIV screening among pregnant women, although screening does detect the disease at an earlier stage in the women affected, it actually prevents the disease in their children. Observational studies can provide evidence of effectiveness of screening programmes by examining changes in disease incidence following the introduction of screening.¹⁶

This section will consider all three options against Criterion 4.

Option A - Selective offer of HIV screening (based on risk assessment) – proper implementation of current policy

Observational evidence, as well as submissions to the NHC, suggests that New Zealand's current policy is not being implemented. Research has indicated that most women are not questioned about HIV risk and not all pregnant women with HIV are identified. A study assessing attitudes and practice toward antenatal HIV screening among midwives, GPs and obstetricians found that respondents assessed HIV risk in less than 10% of patients.¹ The majority of providers ignored the current New Zealand guidelines with 65% 'never' or 'rarely' performing routine risk assessment. The authors concluded that the current policy of routine HIV risk assessment was not working among respondents.

Respondents to the study identified a range of barriers to risk assessment and discussion of HIV screening, including the personal nature of questions, the risk of increasing women's anxiety, the low prevalence of HIV in the community, and privacy issues. Additional barriers were limited time, skills and experience, as well as cost and the need for consent.

Only 25% of respondents to the study supported the current policy of HIV risk assessment, while the majority of respondents supported a universal offer of HIV screening, either for all pregnant women (39%) or for those in areas of higher prevalence only (27%). The study also highlighted that many providers had not received useful information about HIV infection in the previous five years.

This study covered the upper half of the South Island^{xii}, which comprises 20% of New Zealand's population, and was consistent with earlier findings in Dunedin (1998) and Wellington (1999).^{28, 29} For instance, 62% of providers in the Wellington study rarely or never raised the subject of HIV in pregnancy. However, the applicability of these findings to the rest of New Zealand, particularly Auckland, may be questionable as there are likely to be fewer immigrants from high-prevalence countries in the South Island. Maternity providers in Auckland may be more likely to undertake HIV risk assessment of pregnant women, as there may be greater awareness of HIV and higher risk populations.

Overseas experience indicates that, in general, risk assessment approaches to antenatal HIV screening have not been successful. For instance, before the UK moved to a universal offer of screening, providers were not adhering to the previous risk assessment policy and over 75% of maternal infections remained undiagnosed at birth.³⁰ A key reason for the introduction of routine testing in other countries was the poor implementation of risk assessment policies.

Overseas studies suggest that only a small percentage of HIV-positive women have been identified using a risk assessment approach. National surveillance from 1988 to 1996 in the UK showed that there was no change over time in detection rates. In 1996 only 15% of previously undetected HIV infections were diagnosed in the antenatal period.³¹ The authors expressed concern at the limited impact of selective antenatal testing policies. It should be noted, though, that the groundbreaking evidence for the effectiveness of anti-retroviral treatments to reduce mother-to-child transmission of HIV was produced in 1994, so prior to this time there would have been less incentive for health practitioners to assess women for HIV risk.

A study in 1996 comparing universal, selective and 'request only' policies in London's maternity units found that only 22 of an estimated 322 previously undiagnosed women were identified in 1993 and 1994 – 2 out of 126 in units with selective or request policies and 20 out of 196 in units with a universal policy. In most of the units the uptake of HIV screening was low – less than 10% in units with universal policies and not exceeding 1.5% in units with other policies.³²

A Canadian review found that targeted testing of those at high risk failed to identify a substantial proportion of HIV-positive pregnant women.¹⁴ The authors stated this was due either to unknown risk factors or an unwillingness to be identified as having a risk factor. They reviewed evidence from 1985 to 1997 and concluded that there was a 'fair' level of evidence to recommend against targeted testing from cohort and case-control studies. They also found a 'fair' level of evidence to recommend a universal offer of screening to the general population, based on cohort and case-control studies that showed identification of increased proportions of HIV-positive women.

In summary, there is some evidence from overseas and New Zealand indicating that selective approaches have not been effective in identifying women with HIV. Research in New Zealand has been mostly from the South Island, however, and may not be applicable to Auckland and central New Zealand, which is where most women with HIV live. Countries such as the UK, US and Canada have rejected risk assessment approaches on the grounds that they have not detected a high proportion of women with HIV, and cannot therefore be effective in reducing transmission, mortality and morbidity.

Most developed countries have moved from a risk assessment policy to a universal offer (either opt-in or opt-out).⁷ Some overseas research indicates that a universal offer identifies a higher proportion of HIV-positive women.

^{xii} Canterbury, South Canterbury, West Coast, Nelson and Marlborough

Option B - Universal offer of HIV screening – opt-in

It should be noted that most studies comparing opt-in/opt-out screening have been from areas with a higher prevalence of HIV than New Zealand.

A number of studies have suggested that the opt-in voluntary approach is associated with lower testing rates than the opt-out approach.^{33, 34, 35, 36, 37, 38} Most countries with a universal offer have chosen the opt-out approach, including the UK, Ireland³⁹ and Hong Kong⁴⁰, which do have similar prevalence to New Zealand (excluding London and some other large cities such as Edinburgh). The opt-out method has been endorsed in provinces of Canada⁴¹, parts of the USA⁴² and by the Institute of Medicine, the American Paediatric Society and the American Medical Association.⁴³

A large RCT in Edinburgh (a high prevalence area) found that a universal offer of antenatal HIV screening, using an 'opt-in' approach, resulted in a higher uptake of screening than when screening was available only on request. It compared four different methods of a universal offer of voluntary antenatal HIV (four combinations of written and verbal communication, followed by the direct offer of a test). The control group did not receive any information or a test offer, although testing was available if requested.⁴⁴

The study showed that a test offer resulted in significantly higher uptake than the control group for whom the test was available on request (35% compared with 6%). Neither the leaflet style nor the length of pre-test discussion had an effect on uptake of screening. However, significant independent predictors of uptake were a direct test offer, the midwife seen, and being younger, unmarried or previously tested. Uptake depended more on the midwife than the method of offering the test, which underlines the importance of health practitioner training and further research in this area. This study recommended a universal offer policy, but only for areas with high prevalence of HIV.

During the nineties in Britain, an 'opt-in' approach resulted in around half of eligible women being screened, identifying only one fifth of infected women. In one British hospital, only one in seven pregnant women chose to be screened for HIV with an 'opt-in' approach.⁴⁵

In some locations where the opt-in approach has been used, for example Edinburgh and some areas of the US, the proportion of women agreeing to undergo HIV testing has been reported to range from 36 percent to 86 percent.^{44, 46}

However, evidence suggests that this option is not as effective as a more routine approach where women 'opt out'. A randomised controlled trial in Edinburgh compared the uptake of HIV screening between an opt-in universal offer in 1998, with an opt-out approach in 1999.³⁵ Both approaches had similar requirements for information and consent, but with a change in emphasis in that testing was routine unless the woman declined. The study found that uptake of HIV screening with a routine, opt-out approach more than doubled compared to the opt-in approach (88% compared with 35%). Some women in the 1998 study were uncomfortable with the 'opt-in' approach, feeling that it implied high-risk behaviour.

In Canadian provinces and territories that have used the opt-in approach, screening rates have ranged from 50 to 60%, whereas rates are higher in the areas that have adopted the opt-out approach.

Option C - Universal offer of HIV screening – opt-out

As raised above, an observational study in Edinburgh found the uptake for an opt-out routine offer was 88%, which was more than double the rate from a previous study using an opt-in approach (35%).³⁵ Researchers concluded that the opt-out method was more effective, was not time-consuming, did not require extra staff, and was supported by most women. Other studies have shown that universal, opt-out screening is socially acceptable and identifies a greater proportion of those infected.⁴⁷

Figures from Britain show that perinatal transmission rates before and after introduction of anti-retroviral treatment in 1995 fell from 19.6% to 2.2% in 1998. It is not clear from the literature how much of these reductions are due to the universal offer itself, or how much is due to the greater effectiveness and use of interventions to reduce mother-to-child transmission. The UK policy changed in 1999 from a universal offer in high prevalence areas to a universal offer, irrespective of prevalence, throughout the UK.

In the UK some hospitals have shown that when an offer and recommendation of voluntary HIV screening is made routine as part of standard antenatal care, uptake is higher than 80%.⁴⁸

In Sweden, which has a low prevalence of HIV and a tradition of strong measures to control sexually-transmitted infections, a policy recommending antenatal screening for all women has achieved testing rates above 95% and identified most HIV-positive women.⁴⁹

Health practitioners in France are legally required to offer HIV testing at the first antenatal visit. In 1992 in the south east of France, 93% of HIV infections in pregnant women were identified.⁴⁹

In the US, mother-to-child transmission of HIV has decreased through increased testing (with a universal offer) and use of anti-retroviral treatment.⁴⁹ There was a substantial decline in the number of infected infants during the nineties, from 1000 - 2000 per year in the early nineties to 280-370 per year in the late nineties. The proportion of mothers who were tested for HIV before birth increased from 70 to 94% from 1993 to 1997.¹⁶

Some studies have shown that a barrier to women being screened is a perception that health providers did not recommend screening, which would lend support to an opt-out approach. Acceptance of antenatal HIV screening is associated with it being viewed as routine.¹⁶

Some studies have suggested that a universal offer of HIV screening even in areas of low to moderate prevalence reduces the rate of maternal-foetal transmission, is widely accepted by pregnant women and compares favourably with other expenditures in preventative and acute medicine in terms of cost-effectiveness.⁵⁰

In contrast, there has been limited absolute impact of antenatal HIV screening in Norway, even with a very high uptake, due to a low prevalence of HIV. A study assessed the impact of screening in Norway between 1987 and 1999, comparing the actual number of children born with HIV to the number that would be expected without a screening programme. The absolute impact of the screening programme was low (1.3 infected children prevented in 100,000 women screened, or nine prevented cases of HIV infection in children over the 12 years of the programme).

The study concluded that the limited impact of screening was due to the very low prevalence of undetected HIV infection among pregnant women in Norway. HIV cases are usually detected before pregnancy, leaving only a few cases to be detected by a screening programme. The authors suggest that given the limited impact of screening among a low prevalence population, an alternative policy of offering HIV screening only to selected women may be acceptable in Norway.⁵¹ While the prevalence of HIV among pregnant women in New Zealand is not as low as in Norway, it is relatively low internationally.

There is evidence for reduction in MTCT (and therefore reduction in mortality and morbidity) from opt-out strategies, but it is often hard to disentangle the effects of the introduction of effective interventions with the effects of the introduction of a universal offer. An opt-out approach seems to be more effective than opt-in.

Comparison of screening strategies

A 1998 study surveyed all 265 maternity units in the UK to determine how screening strategy related to uptake of screening and detection rates.⁵² Uptake of screening was over 10% in only 8 units, all of which had a universal strategy, and in 76% of selective units it was below 0.1%. Detection rates were 14.7% in universal units, 7.8% in selective units, and 7.7% in 'request only' units. The authors concluded that all antenatal HIV screening strategies failed to identify most infected women.

The study suggested that universal offer strategies were failing due to low uptake of screening (less than 10% in 65% of units). Reasons for the failure of selective approaches were an inability to target high-risk groups and a minimal uptake in the groups that are targeted. The authors identified several barriers to high uptake of screening, including a perceived need to manage HIV screening differently from other conditions, and anxiety over informed consent or offering pre-test discussion.

Application to New Zealand

The Scientific Advisory Group to the NHC cautioned that overseas findings could not necessarily be extrapolated to the New Zealand context, as our maternity care system differs from countries that have introduced a universal offer of screening. Screening in the first trimester of pregnancy often occurs before women have been referred to midwife care, so may be done by either a GP or a midwife. The follow-up of test results may be disrupted. New Zealand also has a relatively low prevalence of HIV, as well as a small population.

The Advisory Group concluded that any change in screening policy should be implemented using a pilot approach, with evaluation of test uptake, as evidence from overseas countries cannot be directly applied. The NHC is also advising this approach. As New Zealand has an estimated low prevalence of HIV among pregnant women, the impact of a universal offer of screening on a population basis is likely to be small.

Conclusion

The NHC considers that there is insufficient evidence to support or reject this criterion for Options A, B and C.

The potential effectiveness of proper implementation of New Zealand's current policy is unknown, and overseas studies suggest that targeted testing fails to identify a substantial proportion of HIV-positive women. However, an evaluation of Norway's screening programme concluded that for a very low prevalence population, selective screening might be feasible.

There is evidence from overseas on the effectiveness of a universal, opt-out offer of antenatal HIV screening (Option C), although this is not from RCTs and is generally from countries with higher prevalence of HIV than New Zealand. Because antenatal testing has the potential to reduce the incidence of HIV in infants, studies of the effectiveness of HIV antenatal screening will be less vulnerable to biases (such as lead-time bias, length bias, over diagnosis bias). Therefore it is reasonable to consider evidence from observational studies of antenatal HIV screening that show a decrease in the incidence of HIV in babies.

Caution should be exercised in applying these findings to New Zealand, as we have a unique maternity care system and low prevalence of HIV. The NHC advises that Option A be implemented and Option C be evaluated using a pilot study.

Criterion 5 The potential benefit from the screening programme should outweigh the potential physical and psychological harm (caused by the test, diagnostic procedures and treatment).

The screening programme should ensure that the benefit is maximised and the harm minimised.

If a clear benefit of screening is demonstrable in RCTs, the physical and psychological harms of screening need to be weighed against the benefit and an assessment made of whether there is both a net benefit to the population, and that individual participants can reasonably expect more benefit than harm from screening.

The primary benefits of antenatal HIV screening are to prevent perinatal transmission of HIV infection and to enable early treatment of women. There are additional benefits to women, and their family and community. The Scientific Advisory Group to the NHC stated that knowledge of the possible harms of antenatal HIV screening and treatment is still incomplete.¹⁶ It is also important to balance the desire to identify all HIV-positive women and to prevent transmission with the appropriateness and expense of doing so. Potential benefits and harms are outlined below.

TABLE 4 Summary of potential benefits and harms from antenatal HIV screening	
For women found to be HIV-positive	
BENEFITS	HARMS
Earlier diagnosis allows for assessment of a pregnant woman’s HIV infection and the need for anti-retroviral treatment that will improve her general health and prognosis. (this is a major benefit)	Possible complications from interventions to reduce MTCT, for instance, adverse drug reactions affecting the mother and/or the foetus/newborn and the development of viral resistance and its impact on future treatment options for the mother. However, the World Health Organization has concluded that the benefits of these drugs outweigh any potential adverse effects. There is no research yet on the long-term effects of anti-retroviral treatment on babies/children – as it is relatively new.
Reduction in mother-to-child transmission (MTCT) of HIV infection. (this is a major benefit)	Avoidance of breastfeeding (as a way to reduce MTCT) could be associated with harms to the bonding relationship between mother and child, the health benefits of breastfeeding for children would not be gained, and avoiding breastfeeding may have other social implications in some cultures.
Opportunity for informed choice on continuation of their pregnancy and for planning for future pregnancies. ¹⁶	Some women found to be infected with HIV may choose to terminate the pregnancy, involving anxiety and stress. ¹⁶

For women found to be HIV-positive	
BENEFITS	HARMS
The woman's sexual partners and previous children can have the opportunity to be screened for HIV infection.	
Opportunity to be assessed for personal health complications of HIV infection, such as cervical cancer, and behaviours that may put the woman or others at risk.	
For women found to be HIV-negative	
BENEFITS	HARMS
Knowledge of HIV status.	Increased anxiety while waiting for results.
	Women who require repeat testing could experience significant anxiety and stress. This will occur in approximately 1 in 1000 women. ¹⁶
	Risk that knowledge of a negative result may reinforce or encourage future risk-taking, as women may feel they have 'got away with' previous risk-taking behaviour. ⁵³
	Potential effect on accessing health insurance, as some insurance companies ask if people have been tested for HIV (this would have a lesser impact under a universal offer policy, as insurance companies could not assume increased risk).
For society	
BENEFITS	HARMS
Increased public awareness of HIV and the role of screening, HIV-specific education and health promotion including 'safer sex' messages.	Cost associated with the screening.
Opportunity for contact tracing when women are found to be positive.	The false reassurance that the screening programme will detect all pregnant women infected with HIV and thus prevent all cases of MTCT.
Public health benefits of screening, eg, reduced burden of disease.	Further 'medicalisation' of pregnancy. ¹⁶

A summary of the potential benefits and harms against the three options can be found in Appendix One.

Harm reduction

The key ways that potential harms can be minimised are by ensuring that:

- all women, health professionals and the community are aware of the reasons for HIV screening
- the appropriate time is taken to inform women of this during antenatal care
- the community is knowledgeable about HIV/AIDS and infected people are supported by their community
- health professionals are aware of (a) how to correctly interpret HIV test results and (b) who to contact regarding women found to be infected or where the initial test is inconclusive
- timely response from specialists is available
- confidentiality of people found to be infected with HIV is maintained
- monitoring is undertaken at the introduction of the programme. This should include (a) collection of information on process issues such as acceptability to women and LMCs, and the number of HIV tests performed and (b) outcomes such as the number of HIV infected.¹⁶
- a 'watching brief' is kept on future evidence of the longer-term effects of anti-retroviral treatment on both pregnant women and babies/children.

Conclusion

This criterion requires the potential benefits of screening to be maximised, and harms minimised. With any screening, there is a need to balance the benefits against potential harms, at both individual and population levels.

Two very important benefits are gained from antenatal HIV screening, irrespective of the approach. These are the opportunity to prevent mother-to-child transmission and to gain early intervention for women found to be infected. The Scientific Advisory Group to the NHC found that knowledge of the possible harms of antenatal HIV screening and treatment is incomplete, so a cautionary approach should be taken. Potential harms include anxiety from false positive results, and false reassurance for false negative results.

The NHC believes that further information is needed to compare the practical issues and acceptability associated with Options A and C (which would be gained through a pilot study). Once this information is gained, a more accurate indication of the balance between benefits and harms could be made.

Criterion 6 The health care system will be capable of supporting all necessary elements of the screening pathway, including diagnosis, follow-up and programme evaluation.

To use RCT evidence of efficacy to justify a screening programme, essential programme elements must be in place to ensure screening in practice will match the quality standards of the RCT. The programme elements will include population recruitment, systematic recall, linkage to follow-up assessment, dedicated assessment centres and continuous monitoring and evaluation.

The screening programme should be integrated with existing health services, as far as practicable, with specific goals for Māori participation.

Pre-implementation issues

There must be a plan for managing, monitoring and systematically evaluating the screening programme, a nationally agreed information system for collating data, and an agreed set of quality assurance standards. A quality assurance/quality improvement framework needs to be established from the beginning.

Adequate training for all key personnel, adequate staffing and facilities for testing, delivery of results, diagnosis, treatment and programme management should be made available prior to the commencement of the screening programme.

The screening programme needs to reach all those likely to benefit from it, which may require specific initiatives to reach particular population groups. There is a special imperative to ensure that this is so for Māori.

Essential elements must be in place to ensure the benefits of antenatal HIV screening are maximised and the harms minimised. Some screening tests in New Zealand have been introduced without all the necessary elements in place, which has led to these tests being applied in an unsatisfactory way.

The health care system is currently not capable of supporting adequate implementation of any of the three HIV screening policy options. Dedicated additional resources are needed to either improve the current policy or introduce a new approach.

Nonetheless, a strong infrastructure already exists in New Zealand. There is a workforce of skilled health practitioners who with some additional training would be well placed to implement antenatal HIV screening, irrespective of the approach. The majority of respondents to the NHC's discussion document agreed the health system could become capable of supporting all the necessary elements of antenatal HIV screening, for the following reasons:

- the number of new infections detected by antenatal HIV screening, irrespective of the approach, is likely to be small
- integrated HIV care networks and support systems already exist in most areas (eg, HIV support groups such as Positive Women, New Zealand Prostitutes Collective)
- there are experts in HIV medicine throughout New Zealand, in major centres and secondary hospital settings

- all major centres have the facilities to care for an HIV-positive woman in pregnancy
- interventions for the treatment of the mother and child are available in hospitals in New Zealand that provide tertiary and secondary level care for pregnant women with additional support and guidance from specialists if necessary¹⁶
- there are clear international guidelines for the management of HIV-positive pregnancies that are applicable in New Zealand, and all management options are available. National referral guidelines exist for obstetric practice in New Zealand
- the anti-retroviral agents require specialist endorsement, but are available nationwide, and no particular specialised equipment is required to administer these
- Lead Maternity Carers are experienced in referring women to specialist services for other conditions in pregnancy requiring specialist supervision¹⁶
- the laboratory system for HIV testing is already well established, and should be able to cope with any increased number of tests and implement a consistent approach to reporting results.⁵⁴

With dedicated extra funding for training, support and development of systems such as quality improvement, the health care system would be capable of supporting screening.

Training, staffing and referral

Irrespective of the approach to screening, increased training for health professionals on antenatal HIV, and in dealing with sensitive issues more generally, is essential.

A key reason why the current policy has not been adequately implemented is the limited training and education available to health professionals. Many providers in the South Island study had not received useful information about HIV in the last five years (45% of midwives, 47% of GPs and 29% of obstetricians). The main sources of information used were from professional organisations, conferences, medical journals and the Ministry of Health. Some respondents expressed significant discomfort at doing post-test discussion and some discomfort in interpreting test results.¹

There have been recent improvements in the knowledge of HIV in pregnancy and in ways to reduce transmission to the baby. Education and up-skilling of health professionals is vital to ensuring that there is adequate knowledge about HIV screening in pregnancy and also about antenatal screening in general. Informing and educating providers should be an ongoing process and consumer involvement is essential.

It is important to distinguish between 'discussion' and 'counselling' in terms of the time spent with women prior to, and following, HIV screening. The NHC believes that irrespective of the policy option chosen, it is not feasible to involve a trained counsellor for every pre/post test discussion. However, it is crucial to involve a counsellor when a woman is found to be HIV-positive. The health care practitioner, usually either a GP or a midwife, will be the one who is responsible for facilitating adequate pre- and post-test discussion with women. It is important that they are equipped and supported to do this.

It should be recognised that practitioners may feel intimidated by the issue of HIV, and feel they do not know how to cope with positive results. There may be a need for specific support and referral systems for health practitioners in dealing with positive results.

If HIV were to be added to the current list of antenatal tests (Option C), this would be more feasible than having it separate. However, there would still be a need for a specific consent process – for all antenatal tests including HIV.

There are implications of requiring written informed consent for all antenatal screening (see Criterion 7), as this is not generally done at present. The majority of general practices in New Zealand are now 'paperless', so the introduction of a written requirement may not be easily integrated into current systems.

The NHC believes that informed consent should be recorded, but this could be done either in paper or electronic form.

Option A would require additional training in risk assessment, while the other two options would not require this.

A comparison of the three policy options in terms of requirements for training, staffing, referral and facilities is in Appendix One.

Programme oversight, monitoring and evaluation

There is currently no formal programme oversight, monitoring, evaluation or quality assessment of antenatal HIV screening. A quality assurance/quality improvement framework should be developed at the beginning of any screening programme's establishment. The National Screening Unit is producing a quality improvement framework which should be used for antenatal HIV screening.

A summary of the three options in terms of programme oversight, monitoring and evaluation can be found in Appendix One.

The NHC recommends that:

The Ministry of Health (in conjunction with District Health Boards and relevant professional colleges) undertake a comprehensive review of the full range of antenatal tests and protocols for screening, as a key step in improving oversight and implementation of all antenatal screening including HIV.

Specific initiatives to reach particular groups

Given the high proportion of migrant groups with HIV, it would be important to introduce specific initiatives to ensure that refugee and migrant populations are appropriately engaged with in regard to screening, and to maximise screening uptake among groups most at risk of HIV. There is an HIV/AIDS Refugee Health Education Programme in Auckland and guidance for health professionals on refugee health.⁵⁵

Health educators working with African migrant communities have advised that it is best to screen couples together rather than individually, as the one who tests positive first tends to be blamed for the infection.⁷

Previous experience with screening programmes has found low Māori and Pacific participation in screening (for example, screening for breast cancer, cervical cancer and Hep B carriers). There is a need for specific initiatives to reach Māori and Pacific populations. Option C could be viewed as a specific initiative to reach Māori and Pacific populations through a universal offer, as Māori and Pacific are under-represented in other screening programmes at present.

As some women at high risk of HIV may not be confident with English language, there is a need to consider resources in languages other than English, and use of interpreters where necessary.

Conclusion

Currently this criterion is not met for opportunistic HIV screening, although there is an adequate infrastructure for supporting women with HIV including a skilled workforce.

In order for this criterion to be met (for all three options), national oversight of antenatal HIV screening would need to be established and specific resources allocated. Training is required to ensure that all those offering screening have the latest information and are supported to offer pre/post test discussion. With some extra funding and support, this criterion could be met for each of the three options.

The NHC believes there are some uncertainties in comparing the three options against this criterion. It is not clear which option would require the most change in terms of improving the health care system's capability to support the screening pathway. Comparing options A and C through a pilot study will help to identify which option would require the most resources in order to improve capability.

Criterion 7 There should be consideration of social and ethical issues.

There should be evidence that the complete screening programme (identification and invitation, test, diagnostic procedures, treatment/ intervention) is clinically, socially and ethically understood and acceptable to health professionals and the wider public.

Potential participants in the screening programme should be given information that allows them to weigh up the probable benefit and harms, using their own values and preferences. Culturally appropriate, evidence-based information should be available for people offered screening to assist them in making an informed decision. This information should also explain the consequences of testing, the possibility and importance of false-negatives and false-positives, investigation and treatment.

Pre-implementation issues

The screening programme should be planned, monitored, delivered and evaluated in partnership with the population group offered screening.

The screening programme should continue to reduce inequalities; in particular the programme should address Māori health as a priority.

The screening programme should be delivered within a framework that is responsive to Māori (attending to Treaty of Waitangi, workforce and information ownership issues).

There are important social, cultural, psychosocial and ethical issues to consider in relation to antenatal HIV screening.³⁴ A woman who receives a positive HIV test may be faced with significant discrimination associated with the diagnosis. It may result in rejection or violence by her partner or isolation from her community.⁴¹ Irrespective of the approach to antenatal HIV screening, health professionals must be certain that women understand the objectives, risks and benefits of screening, and that they can refuse the offer.⁴¹

A table considering the social, cultural and ethical acceptability of each of the three options is in Appendix One.

The following sections set out some general cultural and ethical issues that are relevant, irrespective of the screening approach.

Cultural issues

Cultural contexts around HIV are especially important to consider in New Zealand. In some communities, there are strong beliefs about being HIV-positive. For instance, women from some African communities may refuse HIV testing out of fear that their husbands would leave them if they were found to be HIV-positive. In a workshop on antenatal HIV screening, the HIV/AIDS Refugee Health Education Programme highlighted that there is a high degree of stigma associated with HIV and limited knowledge about HIV among African communities.⁷ It was emphasised that it is important to talk with couples about HIV/AIDS and to screen both partners at the same time.

The NHC believes it is crucial that all maternity carers and others working with pregnant women consider cultural issues.

Given the pattern of HIV spread both globally and in New Zealand, it is crucial to consider the needs and views of migrants and refugees, especially those from Africa, Asia, and increasingly, the Pacific. It will be important to consult with these groups and find out the best way to ensure high uptake and acceptability of the offer of an HIV test.

Any policy on antenatal HIV screening should ensure that it is effective in reaching those most at risk. There should be plans to monitor the introduction of antenatal HIV screening to see that it is effective in reaching those most at risk.

All antenatal care should take account of the principles of the Treaty of Waitangi. Māori participation is essential in implementing a universal offer of HIV screening in pregnancy. There needs to be consideration of possible initiatives to reach particular population groups, including Māori.

Informed consent

Informed consent for screening means that the person being offered a test understands:

- that they have a choice whether or not to take the test
- the purpose of screening and what it involves
- the potential benefits, risks, and uncertainties of the screening, including implications for other family/whānau members
- any significant medical, social or financial implications of the condition for which the screening is done
- follow up plans, including availability of counselling and support services.

In New Zealand health care consumers have a legal right to receive appropriate information in order to give informed consent.^{xiii} Two rights under the Code of Health and Disability Services Consumers' Rights are particularly important in considering screening – Right 6 (the right to be fully informed) and Right 7 (the right to make an informed choice and give informed consent).

Informed consent is a process rather than a single event, and is achieved after a range of information on potential harms and benefits of the test have been provided and understood. The process includes pre-test discussion, a decision to accept or reject the test, and post-test counselling if consent has been given. Informed consent must be specifically invited rather than assumed.

The broader concept of informed choice is crucial. People must have accurate information to enable them to weigh up benefits and risks of screening alongside their own values. It is important for health professionals to find appropriate ways to communicate and give information, especially for people with conditions that may impede access to information (eg, literacy level, deafness or blindness), or people for whom English is not their first language.

Informed consent for antenatal HIV screening

The effect of a diagnosis of HIV infection is profound as it has implications for an individual's future health, personal relationships, and experiences of discrimination. This obliges practitioners to provide sufficient information for a person to make an informed decision. It is important that women feel able to refuse testing. Women should be informed that there would not be any negative consequences for them if they decline a test.

The committee believes it is crucial that antenatal HIV testing be voluntary and undertaken only with the informed consent of those being tested (which is what is required under the current policy). The Health and Disability Commissioner suggests that in light of the significant risk of adverse psychological effects to a patient of a positive HIV test, consent should be obtained in writing under Right 7(6)(d)^{ix}. The committee's position is that a written record of consent should be gained, either electronically or in paper form.

^{xiii}Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996

^{ix} Submission from the Health and Disability Commissioner to the NHC's discussion document on antenatal HIV screening

At present in New Zealand, informed consent (written or verbal) is not routinely obtained for other antenatal blood tests, such as for syphilis or hepatitis B. The NHC believes that written informed consent for HIV screening should be sought in the context of consent for wider antenatal screening, which implies a new requirement of written consent for all antenatal tests. This would not have to be an onerous requirement, as one form could be used for all tests.

The vast majority of participants in the South Island study favoured routinely obtaining informed consent prior to HIV screening, but were divided on the level of consent. Some felt that consent for HIV should be the same as for other tests, while others believed a higher level of consent should be required.¹

The NHC recommends that:

A written record of informed consent is required for all antenatal screening, including HIV (this may be gained either electronically or in paper form).

Pre-test discussion

A thread that runs through each of the policy options is the question of how much discussion and/or counselling should be held with women prior to screening. There is much debate about this in the literature and amongst the health community. Requiring that there be at least a minimum level of discussion is cheaper, easier to manage in time-limited consultations, and may be more likely to achieve higher uptake of screening. This allows a more comprehensive level of pre-test discussion in some cases, as determined by particular women and their health professionals, on a case-by-case basis.

However, HIV experts argue that there is a certain level of discussion needed for HIV screening, given the serious implications of the disease. A more comprehensive level of pre-test discussion will facilitate more informed choice, but may result in higher costs in terms of health professionals' time and increased anxiety for women.

As raised earlier, there is a distinction between discussion and counselling.^{xv} It is appropriate that maternity health practitioners have discussion with women, but they are not qualified as counsellors, and it would not be cost-effective or feasible to employ counsellors for all pre- and post-test discussion. The exception to this is when women are found to be HIV-positive. Discussion on HIV uses skills that health professionals already have, but there is also a need for some specific training.

Improvement is needed in the pre-test discussion for all antenatal tests, including HIV, as often women are not given any information about the specific tests that are done. The discussion on HIV, Hepatitis B and C, rubella and syphilis should be combined. This would include information about these infections being transmissible to babies during and after pregnancy, along with information about the interventions available to prevent or treat these infections.

Submissions on the NHC's discussion document held diverse opinions about the appropriate nature and extent of communication between health service provider and a pregnant woman preceding a decision being made about an HIV test. The estimated amount of time thought to be required for pre-test discussion ranged from two to 45 minutes.

^{xv} The UK's Department of Health guidelines have used the word 'discussion' since 1996

A randomised controlled trial in Edinburgh comparing minimal with comprehensive pre-test discussion at an antenatal clinic found that there were no differences in anxiety or satisfaction with the consultation depending on the length of the pre-test discussion. A universal offer of testing did not appear to be intrusive or cause anxiety, nor was it inappropriately time-consuming. The average time taken for comprehensive pre-test discussion was 7 minutes 40 seconds, while minimal discussion took an average of 4 and a half minutes.³⁵ Another trial using an 'opt-out' approach in the same region found that the mean time taken to offer the test was 2 minutes 34 seconds.³⁵

Other studies have indicated that the quality and quantity of discussion before and after testing has correlated with test acceptability rates and level of satisfaction.⁵⁶ A study in 1998 suggests that pre-test discussion of pregnant women has led to higher acceptance rates of testing, increased knowledge of HIV transmission and the increased use of condoms and contraceptives. Experience with African settings, where a large number of clients test positive, has suggested that effective pre-test discussion in this setting is crucial and has a significant impact on clients' response to their diagnosis.

The Ministry of Health guidelines on general HIV/AIDS management (not specifically for pregnancy) set out specific issues that should be covered in the course of pre-test discussion, depending on their applicability or relevance to the individual.^{57, xvi} A copy of the checklist for HIV testing is provided in Appendix 2.

Confidentiality is particularly important in the case of HIV screening because of stigma and discrimination that can be faced by people at high risk or living with HIV/AIDS.⁵⁸ Adequate discussion and counselling is also crucial as HIV/AIDS is highly emotionally charged, and discrimination still occurs, not just against those who are HIV-positive, but also against people who have been tested.

The NHC believes that pre-test discussion should be sufficiently detailed to cover the basic set of areas, but does not recommend any particular length of time as the length of discussion needed will depend on each individual situation. The time taken for pre-test discussion should be left to the judgement of the maternity care provider.

The NHC recommends that

the Ministry of Health (in conjunction with District Health Boards and relevant professional colleges) promote the antenatal HIV screening policy across New Zealand, both for the pilot study and proper implementation of the current policy, to all maternity care providers and women, and offer training for providers.

Information for women

Pre-test information should be provided in both a written and oral format, and should be easily understandable and culturally appropriate. Advice about sources of further information should also be provided, such as relevant websites.

An updated pamphlet specific to HIV in pregnancy should be developed. The development and review of information would need to involve all relevant stakeholders, including women, Māori, groups at higher risk of HIV and people for whom English is not their first language.

^{xvi}The current Ministry of Health guidelines on HIV screening in pregnancy (1997 – attached as Appendix Three) also list similar points that should be covered as part of pre-test discussion. These are earlier than the general guidelines, so the later ones are referred to here.

Post-test counselling

Test results should be discussed with women face-to-face, rather than by telephone. It is imperative that those with confirmed positive tests receive specific HIV counselling, including discussion of the risk for perinatal HIV transmission, ways to reduce this risk, and the prognosis for infants who become infected. It is important to address the psychological and emotional wellbeing of women.

Most respondents in the South Island study felt either 'comfortable' or 'mostly comfortable' in providing pre-test discussion, but 44% expressed significant discomfort about providing post-test counselling.¹ Health-care providers are encouraged to obtain referral for specialty care from providers who are knowledgeable in this area, such as counsellors or psychologists. Good referral pathways should be in place prior to undertaking screening.

The Ministry of Health guidelines on HIV/AIDS management set out the specific issues that should be considered in the course of post-test counselling.^{xvii} Appendix Three includes a copy of the checklist for post-test counselling.

Conclusion

The NHC considers that this criterion is met for all three approaches, as long as fundamental ethical requirements are followed. Irrespective of the policy option chosen, crucial elements of informed consent, adequate information and pre/post-test discussion and counselling must be integral to the policy.

Social and ethical issues arise with each of the options. There is uncertainty around the acceptability of a universal offer to women (Options B and C), particularly those from parts of Africa and Asia where HIV prevalence is high. On the other hand, a small study in the South Island found that some women preferred a universal offer.

A universal approach may be more socially acceptable to health professionals, as they would not need to ask women personal questions about their risk status (as in Option A).

The NHC believes that antenatal HIV screening should be voluntary and undertaken only with a written record of informed consent of women being tested (there should be a written record of consent for all antenatal screening including HIV, either in electronic or paper form). All pregnant women must be provided with at least a minimum set of information about HIV screening in pregnancy, both written and oral. All women who are HIV-positive should be offered specific HIV counselling.

^{xvii} The Ministry of Health's 1997 guidelines for HIV screening in pregnancy also outline similar points that need to be canvassed with women when delivering the outcome of testing.

Criterion 8 There should be consideration of cost-benefit issues.

As for other health care interventions, there needs to be scrutiny of the cost-benefit of screening programmes, as they are resource intensive. Careful cost-benefit (including cost-effectiveness) analysis is important so that the screening programme can be compared with other health care interventions.

Cost-benefit analysis should consider the opportunity cost of the screening programme compared with other health care interventions. Other options for minimising the morbidity and mortality of the condition should be considered to ensure screening is the most cost-effective way of obtaining health gains.

Primary prevention interventions, which may be more cost-effective than the proposed screening programme, should have been implemented as far as practicable.

Economic evaluations are carried out to ensure that the best use, in terms of health gain, is achieved by investing resources into one area as opposed to investment in an alternative area. In this case a cost-benefit analysis would compare the costs and benefits that accrue to society from carrying out an antenatal screening programme for HIV. Such an analysis would provide a monetary value that could then be compared to other potential uses of money.

There are no comprehensive cost-benefit studies to compare HIV screening with other potential uses of resources available for New Zealand. There are a number of problems inherent in carrying out such a study in this area, such as the difficulty of assessing the personal costs to a woman, her partner and her family of a potentially preventable HIV diagnosis in their newborn child. A second issue is the very small number of cases that are being seen, as this is likely to lead to large differences in marginal cost associated with small variations.

While cost-benefit analysis is usually undertaken to help decide whether to introduce an intervention compared with other interventions, cost-effectiveness studies are used to compare the different ways of providing the intervention – for example in this case whether universal or selective screening should be introduced.

In 2003 a study (referred to as the Bramley study)³ assessed the costs and benefits associated with moving from the current risk assessment policy to a universal antenatal HIV screening policy in New Zealand. This study was rigorous and extensively peer reviewed by international experts.

In looking at the benefits of introducing universal screening the authors considered the benefits, in terms of net discounted life years to:

- babies who do not get HIV due to appropriate interventions
- babies who still get HIV but who can be treated from birth, and
- mothers who can be identified as HIV-positive and then treated.

The key costs that were considered were:

- pre-test discussion
- HIV antibody test
- consultation to receive results
- test costs associated with true and false positives
- counselling for true positives
- treatment.

It should be noted that the study did not include costs associated with the establishment and implementation of a screening programme, or associated costs such as monitoring, quality assurance and evaluation (as looked at under criterion 6).

The Bramley study found that the total incremental cost of introducing universal HIV screening would be \$723,607 per year and would lead to the identification of an additional 6.25 true positive women per year. Of these 6.25 women, 1.25 would choose to terminate the pregnancy thus leaving 5 babies found to be exposed to HIV as a result of universal screening. Of these 5 babies, with appropriate treatment 1.15 cases of HIV infection would be avoided. This result implies an incremental cost per HIV case avoided of \$629,669. The authors then calculate the cost per discounted life year gained and find this to be \$17,241. It should be noted that these figures would be over and above the costs of the current policy, as the study is focused on incremental costs rather than the total costs.

The figures in the previous paragraph are based upon the 'base-case' scenario. The study also looked at favourable and unfavourable assumptions across a wide range of variables. The most sensitive variable was found to be that for prevalence of HIV. The base case scenario used a prevalence rate of 0.03% that resulted in the figure of \$17,241. By varying prevalence to 0.02% and 0.04% the figure varied between \$10,433 and \$53,554. In addition the base case assumed pre test counselling of 2.4 minutes. The sensitivity analysis varied this to 1.2 minutes and 20 minutes and produced costs of \$15,968 and \$32,090 respectively. As a comparison, the pharmaceutical agency PHARMAC has a figure of \$20,000 per quality-adjusted life year (QALY) as an indicative benchmark for guiding decisions on pharmaceutical funding.

The final figure of the cost per discounted life year gained is a concept commonly used to compare different interventions. The crucial thing to remember, however, is that it needs to be compared with the value that society puts upon a discounted life year saved. If society values these at \$50,000 per year then clearly a cost of \$17,241 would be very cost-effective. In reality we do not know society's valuation of a life year although we do have estimates of the cost per discounted life year saved for a range of other interventions, thus we are able to see what society currently pays to gain an extra discounted life year. Studies suggest that these can vary markedly – reflecting value judgements made in the introduction of different programmes.

A number of respondents to the NHC's discussion document commented upon this area. Some felt that the costs associated with the current system are likely to be higher than a universal screening system because of its uncoordinated nature. They felt that the current system was likely to result in more HIV-positive children than a universal offer, and that in the longer term this would prove more expensive.

Alternatively, other respondents commented that given the very small number of cases seen in New Zealand, it was unethical to put money into this area.

There have been studies carried out internationally to look at the cost-effectiveness of screening programmes. The base case scenarios found in the Bramley study compare well with those of other studies overseas where universal screening has been adopted. Of particular interest is a study from the UK that recommended a move to universal screening from the previous policy (a universal offer for high prevalence areas, with a risk assessment policy elsewhere).⁵⁹ The policy was changed in 1999 to offer screening to all women irrespective of prevalence levels. This was deemed to be cost-effective as long as the costs of the test itself are kept low, and there is high uptake among women. It found that screening was cost-effective within London under a very wide range of varying assumptions. It found differences outside London but concluded that screening was cost-effective if an uptake rate of 90% was maintained, with 3.5 minutes of pre test discussion and an HIV antibody test cost of 0.6GBP. This may mirror the New Zealand experience with different findings for Auckland when compared with the rest of the country. New Zealand is thought to have a similar prevalence of HIV to the UK (excluding London and Edinburgh).¹

A recent Australian study estimated that universal antenatal HIV screening would be cost-effective at a very low prevalence of undiagnosed HIV (greater than 0.004372%). The authors stated that more accurate statistics on the true prevalence of HIV in Australia are required.⁶⁰

There are important differences, however, between New Zealand and countries that have introduced a universal offer of antenatal HIV screening. As well as having a relatively low prevalence of HIV, New Zealand has a smaller population compared with countries with a universal offer of screening. Economies of scale mean that the cost of the testing process is probably higher in New Zealand than in countries with larger populations.

Conclusion

The NHC has examined cost benefit issues in relation to antenatal HIV screening and considers that this criterion is met. Although there is no cost benefit study in New Zealand comparing the cost benefit of antenatal screening with other health care interventions, there is a study that looks at the incremental costs and benefits associated with moving from the current system to a universal offer of HIV screening. This study estimates the total incremental cost of moving from the current system to a universal offer to be \$723,607. Such a programme would detect 5 HIV exposed babies (after terminations) and avoid 1.15 cases of HIV infection in babies.

The results of the study compare favourably (for the base case analysis) with findings overseas where universal screening has been adopted. However, the key problem with the study is that the true prevalence rate of HIV infection is not known and this may lead to variations in costs.

As there are remaining areas of uncertainty associated with cost-benefit issues, including prevalence, the NHC is recommending implementing Option A across New Zealand and undertaking a pilot study of Option C in Auckland. A pilot study will provide evidence as to whether the current best estimate of costs can be confirmed as being within an acceptable range.

Glossary

Acquired immunodeficiency syndrome (AIDS) the most severe manifestation of a clinical syndrome of illness caused by infection with human immunodeficiency virus (HIV – see below). The syndrome is defined by the development of serious opportunistic infections, neoplasms, or other life-threatening manifestations resulting from progressive HIV-induced immunosuppression.

Anti-retroviral therapy (ART) and (HAART) drugs with activity against the HIV-1 virus belong to one of three classes of anti-retroviral drugs (ART). These are named by the site of action in the virus; nucleoside reverse transcriptase inhibitors (zidovudine, lamivudine, didanosine, stavudine and abacavir), non-nucleoside reverse transcriptase inhibitors (nevirapine and efavirenz) and protease inhibitors (ritonavir, indinavir, saquinavir, nelfinavir and lopinavir). The combined use of these agents reduces the viral load and increases longevity. The use of combination therapy is termed HAART (highly active anti-retroviral therapy).

Enzyme immunoassay (EIA) a method for detecting antibody specific for various viruses and bacteria. This method can be automated.

Human immunodeficiency virus (HIV) there are two major groupings of HIV viruses termed HIV-1 and HIV-2. They are members of the Lentivirinae subfamily of retroviruses. HIV-1 is now established as the primary cause of AIDS.

HIV viral load there are several methods for quantifying the number of HIV virions in the plasma of individuals infected with HIV. The amount of HIV RNA is reported as virus copies per ml of plasma. The viral load is a means of following response to therapy and disease progression.

Lead maternity carer (LMC) the health professional that has undertaken to hold primary responsibility for the coordination of clinical case management during antenatal and postnatal care for any individual pregnant woman.

Mother-to-child transmission (MTCT) HIV may be transmitted antenatally, intrapartum or postpartum. MTCT of HIV is also termed 'vertical transmission'.

Randomised controlled trial (RCT) A form of research in which subjects in a population are randomly allocated into groups, usually called study and control groups, to receive or not to receive an experimental preventive or therapeutic procedure, manoeuvre or intervention. Randomised controlled trials are generally regarded as the most rigorous method of hypothesis testing available.

Western blot (WB) a method for transferring proteins, separated by electrophoresis, to a nitrocellulose membrane. The isolated, immobilised proteins can then be used for the detection of specific antibodies. This technique allows very specific assessment of antibody reactivity to the HIV virus because re-activities to a range of separate HIV proteins can be assessed independently. It is used to confirm HIV infection in people with a persistent reactive EIA test.

Window period very early weeks after infection before HIV antibodies are detectable.



Appendix One: Background information

Approaches to HIV screening in pregnancy (from page 20)

Option A: Selective offer of HIV screening based on risk assessment	
Arguments for New Zealand's current policy	Arguments against New Zealand's current policy
<p>May be cost-effective, although there is no actual evidence for this.</p> <p>Targeting high-risk women is appropriate for individuals.</p> <p>Both woman and practitioner more likely to be motivated if targeting those at high-risk.</p> <p>Less chance of false positives and false negatives.</p> <p>Favourable benefit-risk ratio (screening for HIV has risks and costs – the ratio of costs to benefits is better when benefits are larger – women at high risk of HIV are more likely to get significant benefits.)</p>	<p>Written submissions to the NHC and meetings with key informants indicated that the current policy is not well promoted or applied. Respondents to the NHC's discussion document gave the following reasons for ineffectiveness of the guidelines.</p> <ul style="list-style-type: none"> - Risk-based screening does not identify all HIV-positive women. - Health professionals do not consistently offer screening to those at increased risk of HIV infection. If the screening is offered, pre-test discussion is often not provided. - The guidelines require the health professional to ask personal questions of the woman that may cause offence or distress. There may be some anxiety about whether to offer the test, particularly to African women. - Stigmatising significance of 1) even being made the offer (as telling them they are one of the 'high risk' ones) and 2) there are limits to how sensitive risk assessment can be made to be - The Ministry of Health has not given adequate information on antenatal HIV screening to maternity providers.
	Inadequate promotion of the 1997 Ministry of Health guidelines on antenatal HIV screening to GPs and LMCs.
	Most women would meet the criteria for being in the 'uncertain risk' category, and should therefore be offered testing (de facto universal policy if properly implemented).
	Most developed countries have moved to a universal approach.
	Potential resistance by providers unhappy with the current policy.

Arguments for strengthened implementation of current policy (Option A)	Arguments against strengthened implementation of current policy (Option A)
<p>Current policy hasn't been well promoted to providers.</p> <p>May be cost-effective (but no evidence for this).</p> <p>The NZ Blood Service uses a written assessment tool for every potential blood donation – health professionals currently using this (40,000 times per year) – it is acceptable to health professionals and potential donors.</p>	<p>Some submissions to the NHC argued that even if the present guidelines were updated and better promoted they would not be effective in identifying women at risk.</p> <p>A fundamental problem with the risk assessment approach is the difficulty of correctly identifying women at risk of HIV.</p> <p>Cohort and case-control studies have shown that targeted testing to those with identifiable risk factors will identify only 8 to 58% of those who are HIV-positive.¹⁴</p>
<p>Improving how LMCs handle sensitive issues generally would have the advantage of improving HIV risk identification as well as improving screening for other common issues such as domestic violence, abuse, other sexually-transmitted infections, depression, etc.</p>	<p>Risk assessment puts the onus on the health practitioners' communication skills and personal judgement. It also assumes that women have awareness of their own risk status. A study of HIV-positive women found that 90% had no perception of risk before testing positive.⁶¹ Evidence suggests that many women who believe that they are involved in a monogamous relationship are at risk of HIV due to their partner's past or ongoing risk activity.⁶¹ Some women are exposed to risk factors that health care providers may not be aware of.</p> <p>Anecdotal and qualitative evidence suggests that women may be discouraged by health professionals from HIV testing due to a perceived absence of risk factors.⁶²</p>
	<p>Social and cultural issues in performing risk assessment, for instance, difficulties in discussing personal issues.</p> <p>Risk assessment could be discriminatory – as the health practitioner is required to use personal judgement to assess risk, and people may feel stigmatised.</p>
	<p>Potential resistance by providers who are unhappy with the current policy.</p>

Arguments for universal offer – opt-in (Option B)	Arguments against universal offer – opt-in (Option B)
For health providers, a universal offer may be preferable to a risk assessment approach, as they would not have to ask personal questions of women or make a judgement on their behaviour and level of risk.	Evidence suggests there is less uptake of screening with this approach compared with opt-out.
Opportunity for advice on safer sex and other prevention measures to all pregnant women – whole population approach to prevention.	It treats HIV as a ‘special case’, whereas many submissions to the NHC argued against HIV being presented as unique.
The low numbers of women with HIV is an argument for offering a universal test – as the numbers requiring treatment will also be low.	An active choice has to be made to go ahead with the test, which may discourage some women from choosing one.
	This approach could increase feelings of discrimination, as women have to choose to be screened, as opposed to ‘opting out’. It may be easier for women to accept a test that will be routinely performed unless the woman actively declines.
	A requirement for comprehensive discussion would be more costly than less comprehensive discussion. Potential resistance from midwives (the College of Midwives is awaiting NHC’s report).
	Potential resistance from health practitioners in having to offer the test to all women.

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Arguments for universal offer – opt-out (Option C)	Arguments against universal offer – opt-out (Option C)
A universal and routine offer could make it easier for health professionals to raise the issue and women would be less likely to feel judged.	The cost of this approach is likely to be higher than a selective approach, as more women would accept the offer of screening.
This approach could reduce the potential for stigmatisation, as it does not treat HIV as a special case.	A higher rate of screening will require more time, which has cost implications.
If every health professional follows the policy in every situation then all HIV-positive women who receive antenatal care should be given the opportunity to be screened (although those who do not access antenatal care will still be missed).	A higher testing rate will mean that some women are subjected to unnecessary screening, resulting in increased anxiety for these women.
Making screening for HIV a ‘norm’ – easier to do it, behaviourally appropriate, changing norms.	The impact of false negative results on women and families is significant (although there will be few of these – 1 in 1000).
Opportunity for advice on safer sex and other prevention measures to all pregnant women – whole population approach to prevention.	There is also a concern that negative results may reinforce unsafe sexual behaviour in the future, as women could feel they have ‘got away’ with risky practices. ⁵³ A policy of universally offering the test could increase the potential for of promoting a false sense of security.
The low numbers of women with HIV is an argument for offering a universal test – as the numbers requiring treatment will also be low.	Some submissions to the NHC argued that a universal offer would increase the ‘medicalisation’ of pregnancy and birth.
	In practice, the characterisation of screening as universal or routine may create a presumption on the part of both the health professional and the woman concerned that the test will be conducted. This may diminish the importance attached to a full discussion of the risks and benefits of screening. However, the NHC believes that HIV screening could be offered routinely with a universal requirement of informed consent, given that it is already in many countries.
	Potential resistance from health practitioners in having to offer the test to all women, especially from midwives who have expressed concern about further medicalisation of pregnancy.

Criterion 5: Benefits and harms

Summary of potential benefits against the three options (A, B, C)	
For women found to be HIV-positive	
BENEFITS	CONSIDERATION OF THE THREE OPTIONS
Earlier diagnosis allows for assessment of a pregnant woman's HIV infection and the need for anti-retroviral treatment that will improve her general health and prognosis.	Similar effect across the three options.
Reduction in mother-to-child transmission (MTCT) of HIV infection.	There is more evidence from overseas on the success of option C in preventing MTCT, but there is very little assessment of Option A in the literature.
Opportunity to be assessed for personal health complications of HIV infection, such as cervical cancer, and behaviours that may put her or others at risk.	Similar effect across the three options.
Woman's sexual partners and previous children can have the opportunity to be screened for HIV infection.	Similar effect across the three options.
Opportunity for informed choice on continuation of this pregnancy and for planning for future pregnancies ¹⁶	Similar effect across the three options.
For women found to be HIV-negative	
BENEFITS	CONSIDERATION OF THE THREE OPTIONS
Knowledge of HIV status.	Option C would be the most effective in producing this benefit, as more women would be screened so more would know their negative status.
For society	
BENEFITS	CONSIDERATION OF THE THREE OPTIONS
Increased public awareness of HIV and the role of screening, HIV-specific education and health promotion including 'safer sex' messages.	Options B and C would have potential for higher public awareness of HIV as the screening would be offered universally, so there would be more discussion about risk factors and HIV. However Option A could include an information campaign, which might raise public awareness.
Opportunity for contact tracing when women are found to be positive.	Similar effect across the three options.
Public health benefits of screening, eg, reduced burden of disease.	Similar effect across the three options.

Summary of potential harms against the three options	
For women found to be HIV-positive	
HARMS	CONSIDERATION OF THE THREE OPTIONS
<p>Possible complications from interventions to reduce MTCT, for instance, adverse drug reactions affecting the mother and/or the foetus/newborn and the development of viral resistance and its impact on future treatment options for the mother. However, the World Health Organization has concluded that the benefits of these drugs outweigh any potential adverse effects.</p> <p>There is no research yet on the long-term effects of antiviral treatment on babies/ children – as it is so new.</p>	Similar effect across the three options.
<p>Avoidance of breastfeeding (as a way to reduce MTCT) could be associated with harms to the bonding relationship between mother and child, the health benefits of breastfeeding for children would not be gained, and not breastfeeding may have other social implications in some cultures.</p>	Similar effect across the three options.
<p>Some women found to be infected with HIV may choose to terminate the pregnancy.¹⁶</p>	Similar effect across the three options.
For women found to be HIV-negative	
HARMS	CONSIDERATION OF THE THREE OPTIONS
<p>Increased anxiety while waiting for results.</p>	<p>On an individual level, there will be a similar effect across the three options for individual women.</p> <p>On a population level Options B and C would produce more anxiety overall as they will result in higher testing rates than Option A.</p>
<p>Women who require repeat testing could experience significant anxiety and stress.</p> <p>Approximately 1 in 1000 women would require repeat testing in a month's time after the initial test.¹⁶</p>	<p>Again, Option A would produce less false negatives, as there would be less testing. If almost all of the 56,000 pregnant women per year were tested, Option C could require retesting of up to 56,000 women.</p>
<p>Risk that knowledge of a negative result may reinforce or encourage future risk-taking, as women may feel they have 'got away with' previous risk-taking behaviour.</p>	<p>Option A would have the least chance of producing this harm, as there would be less testing overall and relatively less negative results.</p> <p>Option C would have the most chance.</p>

For women found to be HIV-negative	
HARMS	CONSIDERATION OF THE THREE OPTIONS
Potential effect on accessing health insurance, as some insurance companies ask if people have been tested for HIV.	If insurance companies requested disclosure of testing per se (rather than just a positive result) Option A would have the most chance of producing this harm, as those assessed as 'risky' could be discriminated against, whereas under Option C there would be less chance, as all pregnant women would be offered testing (so insurance companies could not assume a higher risk).
For society	
HARMS	CONSIDERATION OF THE THREE OPTIONS
Cost associated with the screening.	Option A would probably have the lowest cost, as there would be less screening overall. Options B and C would be the most expensive. However, universal risk assessment under option A would require more risk assessing – so could also be costly. More information on costs is needed.
The false reassurance that the screening programme will detect all pregnant women infected with HIV and thus prevent all cases of MTCT.	Similar across all three options.
Further 'medicalisation' of pregnancy ¹⁶	Options B and C could involve further medicalisation of pregnancy through screening a higher number of women. (A universal screening offer is more 'medical' than application of risk assessment because it encourages more testing). Risk assessment is more targeted to appropriate people.

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Criterion 6: Capacity of the health care system

Comparison of the three options in terms of requirements for training, staffing, referral and facilities		
Option A	Option B	Option C
Similar need for specific training on antenatal HIV across all options – although Option A would require training in risk assessment for all antenatal health practitioners.		
Similar need for appropriate protocols for referral and management across all options.		
Similar need for counselling services to advise and support women with false positive results.		
Similar need for protocols for how to offer screening, the extent of pre- and post-test discussion or counselling required, management of repeat testing, knowledge of management and referral of the HIV-positive mother to be developed and disseminated to maternity care providers.		
Similar need for extra resources for training health professionals to deal specifically with the situations of migrants and refugees from high prevalence areas.		
Fewer implications for lead maternity carers in terms of the time required to implement the policy – more effective implementation of a risk assessment approach would probably take less time overall than implementing a universal offer, although risk assessment of all women will still be time-consuming.	The Advisory Group to the NHC noted that an area of uncertainty is the considerable implications of a universal offer of screening for lead maternity carers. ¹⁶ A likely increase in testing would mean a greater capacity for training and facilities is needed.	The Advisory Group to the NHC noted that an area of uncertainty is the considerable implications of a universal offer of screening for lead maternity carers ¹⁶ A likely increase (probably even more than option B) in testing would mean a greater capacity for training and facilities is needed.
Practitioners would be able to spend more time per person on quality pre/post test discussion with this option – as they would be focusing on those at highest risk. Less people overall would be screened so could spend relatively more time with each of them. Debates around the appropriate extent of pre/post test discussion would become less relevant with this option.		Concern that routine screening would require longer, more difficult antenatal consultations and change the emphasis of care. Concern about additional time needed, and training resources. ⁷ Extra demands on busy practitioners – to offer screening to all, and to manage an increased level of screening. Potential opportunity costs of spending more clinical time on this – less time to spend on other issues.

Option A	Option B	Option C
Training practitioners to deal with sensitive issues generally, including HIV, would have spin-off effects in other areas such as other sexually-transmitted infections, violence against women, other risk-taking behaviours etc. And may be a better use of resources/skills development than requiring a universal offer.		As the NZ College of Midwives do not currently support routine HIV testing (although, note that this position is a draft consensus statement – they are awaiting NHC’s work to make decision), it could be difficult to implement.
Less likely to have to improve/expand facilities for processing and interpreting tests (such as laboratory testing) - as there would be less screening overall.		Greater capacity required for facilities as higher level of screening.

Summary of programme oversight, monitoring and evaluation (Criterion 6)		
Option A	Option B	Option C
The current policy is opportunistic – so there is no formal programme oversight, national information system, or consistent quality assessment, monitoring or evaluation.	A universal offer of screening would require a plan for managing, monitoring and systematically evaluating the screening programme, a nationally agreed information system for collating data, and an agreed set of quality assurance standards.	
Having appropriate professional audit, and routinely collecting and analysing monitoring data could improve quality.		
National oversight and coordination of the current policy could be introduced, as part of strengthening its implementation.		

Criterion 7: Social and ethical acceptability

This table considers whether each option for antenatal HIV screening is socially and ethically acceptable.

Social, cultural or ethical issues	Option A	Option B	Option C
Cultural issues/ acceptability to all cultures in NZ.		The Scientific Advisory Group to the NHC stated there was uncertainty around the acceptability of a universal offer to women, particularly those from parts of Africa and Asia where HIV prevalence is high.	The Scientific Advisory Group to the NHC stated there was uncertainty around the acceptability of a universal offer to women, particularly those from parts of Africa and Asia where HIV prevalence is high.
Women at the highest risk may be the ones least likely to accept a test because of cultural and social attitudes around being HIV-positive – importance of primary prevention, and working appropriately with communities.			Option C would be helpful for women at high risk who may not ask for testing – research shows that women at risk of being HIV-positive are less likely to request testing in pregnancy.
Language and communication barriers for those women most at risk in NZ – African/Asian migrants.			Generally an issue for all three options.
Acceptability to women generally.		In 2001 a small study was conducted in Christchurch to elicit acceptability of HIV screening during pregnancy in women. ⁶³ All study participants favoured a universal offer of HIV testing during pregnancy and most said they would agree to be tested, if the test was offered and recommended.	

Social, cultural or ethical issues	Option A	Option B	Option C
Potential for stigma and feelings of discrimination.	<p>Women may feel that personal questions about risk factors are inappropriate or discriminatory.</p> <p>There may be discrimination in how the practitioners treats women, how decisions are made about how much depth to go into with questioning.</p>	<p>The onus would be more on women to request screening and to make an active choice to 'opt-in'. There may be greater potential for stigma and feelings of discrimination if women opt-in, as opposed to screening being presented as routine.</p> <p>Women who are unaware of being at risk would not benefit.</p>	Probably less chance for discrimination, as the test is seen as routine and offered to all, with a recommendation of having it.
Acceptability to health professionals.	<p>Strengthened implementation of the current policy may be acceptable to health professionals but would need to communicate and promote it properly, provide good training.</p> <p>Current policy isn't seen as acceptable as it is not being implemented at present.</p>	<p>Universal approaches may not be acceptable to midwives, eg, College of Midwives doesn't currently support a routine approach – awaiting NHC work for final decision.</p> <p>The South Island study suggested a universal approach would be acceptable to health professionals.</p>	
Ethical principles – justice, beneficence.	<p>A more routine approach to antenatal HIV screening could be justified by the ethical principles of justice and beneficence.³⁴ Targeted testing tends to stigmatise groups that are identified as high-risk and making testing routine may reduce stigma and discrimination, as individuals will not be singled out for testing based on perception of risk.³⁴</p> <p>Routine offer of testing would help women who may not be aware of their HIV risk – e g, women who may not know their partner's sexual history, etc.</p> <p>There is an argument that offering HIV screening only to pregnant women suggests that they are a 'problem'. The point was made in the Auckland workshop on HIV screening that there is no suggestion of routinely testing high-risk populations, eg, men who have sex with men or IV drug users.⁷</p>		

Social, cultural or ethical issues	Option A	Option B	Option C
Ethical obligation to protect the child.	While this has been used as an argument for Option C, it could apply to all. Pregnancy differs from other clinical situations of HIV transmission in ethically important ways: “the foetus who is exposed to HIV in utero is in no position to take steps to reduce potential harms”. ³⁴		
Concerns about further ‘medicalising’ pregnancy.		Some submissions to the NHC stated that adding HIV to the routine antenatal tests would further medicalise pregnancy and birth, and discourage a ‘well-women’ approach to pregnancy.	
Personal nature of HIV and risk factors.	Concerns by respondents in research (Chambers et al) that risk assessment requires practitioners to ask women personal questions – discomfort with this.	Less of an issue as HIV test offered to all – but would still require practitioners to undergo pre and post-test discussion with a greater number of people than Option A.	
Concern about provoking anxiety in women.	Less chance of this as targeting the screening to high-risk women.	More chance. But could also argue the other way – there could be more anxiety around being assessed as ‘risky.’	

Appendix Two: Checklist for HIV testing

The following two checklists are from the Ministry of Health's *HIV/AIDS Management Guidelines; Voluntary counselling and testing for diagnosis of HIV infection*.

Checklist for HIV testing and pre-test discussion

Specific consent to be tested for HIV must always be obtained.

It is recommended to consider addressing the following issues in the course of pre-test discussion, depending on their applicability or relevance to the individual. If not addressed in the pre-test discussion, they should be addressed during post-test counselling.

- 1 The test is for HIV infection, not a test for AIDS.
- 2 Significance of the 'window period' in relation to recent risk behaviour and the resulting accuracy of the test result.
- 3 Significance of a positive test with respect to:
 - medical implications (prognosis, treatment)
 - psychological issues (coping, support, relationships)
 - social implications (who needs to know, employment, discrimination implications for insurance)
 - HIV status not being notifiable.
- 4 Explain safeguards regarding preservation of confidentiality ie, anonymous encryption of test form.
- 5 Discuss future prevention measures.
- 6 Safer sexual behaviour.
- 7 Safe drug injecting behaviour.
- 8 How results of test are to be obtained (in person, face to face).
- 9 Any costs that may be involved.

Post-test counselling

- 1 Providing the test result:
 - in person, face to face.
 - not by telephone, message or mail.
- 2 Explain the test result:
 - Discuss need for further testing (repeat/confirmatory test, viral load, CD4 count).
- 3 If negative:
 - Discuss possible significance of 'window period' if recent high risk behaviour and need for repeat test for final confirmation.
 - Reinforce behavioural changes needed to prevent HIV infection in future eg, prescription for condoms, information on needle exchange outlets/services.
 - Refer for specialist sexual health counselling, if required.

4 If positive:

- Schedule adequate time to give positive results.
- Arrange initial psychological support arrangements and follow-up appointment.
- Discuss need for further testing (repeat/confirmatory test, viral load, CD4 count).
- Discuss with an infectious disease consultant including process for partner notification.
- Referral for specialist counselling and support.
- Provide information on HIV and community resources.
- Reinforce safe sex and needle-using behaviours.
- Explain partner notification and other implications of positive diagnosis.

Appendix Three: Current guidelines on antenatal HIV screening

HIV in Pregnancy Risk screening guidelines and information for health professionals

Contributors

This report was prepared and co-ordinated by Glenn Doherty (Ministry of Health) with specialist contributions from Dr R Meech, Dr S Chambers, Prof D Lennon, Prof D Teele and Dr H Liley. The document has also been supported and contributed to by the Royal New Zealand College of General Practitioners, the Royal New Zealand College of Obstetricians & Gynaecologists, the College of Nurses, Aotearoa (N.Z.) Inc and the New Zealand College of Midwives.

Introduction

This information has been prepared by the Ministry of Health and is intended to provide health professionals with current information and general guidelines on issues surrounding mother-to-child transmission of HIV. It is intended to supplement the *1997 Clinical Management Guidelines: HIV/AIDS* produced by the AIDS Medical Technical Advisory Committee (AMTAC).

These risk screening guidelines are an interim approach with a focus on early screening and testing while data are being collected to determine if routine antenatal testing is appropriate or indeed desirable. It is not intended to provide details of management of mothers and infants, or to provide discussion about the adverse effects of any current treatment regimes. Women found to be at risk and who test positive will clearly need the involvement of appropriate specialists in any future management as well as the involvement of their other maternity carers. When a woman is referred for specialist treatment then that would be the appropriate time to explain details of the advantages and disadvantages of treatment.

Concurrent education material for women is planned with the development of appropriate resources that alert women to matters regarding HIV in pregnancy at the time they present for antenatal consultations.

It is envisaged that the book *Your Pregnancy: To Haputanga* (Public Health Commission 1995) and the leaflet *Women and HIV/AIDS* (Public Health Commission 1994) will both be updated to include current information on mother-to-child transmission of HIV. Information alerting midwives and doctors of the need to assess HIV infection risks in pregnant women was included in *Prescriber Update No. 13* published by the Therapeutics Section of the Ministry of Health in October 1996.

Background

Now that effective strategies to interrupt the transmission of HIV infection from an infected mother to her baby are available, the issue of screening and testing for HIV as part of antenatal care has been raised. Strategies available to interrupt transmission from an infected mother to her baby include the administration of zidovudine (ZDV) during pregnancy, labour and in the perinatal period, in addition to the avoidance of breastfeeding (Connor et al 1994).

The AIDS Medical Technical Advisory Committee (AMTAC) recommended in April 1995 that the Ministry of Health recommend to medical practitioners and midwives:

- to screen all pregnant women for risk behaviours that could predispose them to HIV
- to develop screening initiatives to include risk practices of their sexual partner(s)
- for those women whose personal risk status, or whose partner's (or partners') risk status placed them at risk for HIV infection, or whose risk status was unclear or not known then such women should be counseled and offered testing for HIV.

Women who were found to be HIV-positive should be offered treatment with zidovudine (ZDV) therapy to prevent materno-fetal transmission, which has been shown in a clinical trial to reduce transmission by approximately two thirds. Given an effective intervention is now available to reduce neonatal infection, emphasis must be placed on identifying infected women.

The present information has particular emphasis on:

- a summary of the current key research findings in the area of HIV in pregnancy
- approaches to HIV risk assessment of women and their partners
- issues and advice surrounding testing
- details about management of HIV-infected women
- possible future directions in the management of mother-to-child transmission.

This resource is aimed at assisting health professionals with ways of assessing and managing pregnant women, their partner(s) and children who are at risk for HIV transmission during pregnancy. Recommended approaches described in the document are based on current experiences and practices, largely from overseas.

While the focus is on women 'at risk' the Ministry, in conjunction with AMTAC, is considering the cost-effectiveness of introducing routine voluntary testing of all pregnant women. While the policy options are still to be analysed and agreed to, it is imperative that health professionals are equipped at the present time to advise and manage women and their partners who present antenatally and may be at risk.

What are the current research findings?

Maternal-infant transmission is the primary means by which young children become infected with HIV (Newell and Peckham 1993). The World Health Organization estimates that over 1.5 million children worldwide have been infected with HIV through mother-to-child transmission (Bulterys and Goedert 1996). The risk of transmission from an infected mother to her child varies in different series from 15 to 45 percent. This variation may be related to obstetric practices, and/or the extent of breastfeeding in infancy, virus subtype (phenotype), maternal immune status and maternal viral burden. Transmission may occur in utero, intra partum or postnatally through breastfeeding. In spite of a number of studies, current knowledge of the precise timing and mechanism of transmission remains uncertain, but evidence indicates that at least half of perinatally transmitted infection occurs during the third trimester of pregnancy (Mertens and Burton 1996). With respect to breastfeeding, mothers with HIV infection have been advised that given the ready availability of safe and effective alternatives to breast milk in New Zealand, breastfeeding their baby is contraindicated as this increases the risk of HIV transmission by 10–20 percent (United States Public Health Service 1995).

Initial international guidelines on antenatal HIV screening suggested that testing should be offered to those women in whom risk factors have been recognised (Centers for Disease Control 1985). Subsequent research conducted in Great Britain and the United States shows that a substantial number of women underestimate their degree of risk for HIV (Hawken et al 1995; Minkoff et al 1988). Offering HIV testing only to those with recognised risk factors has therefore resulted in the omission of a large proportion of HIV-positive women from testing, and thus more recent policy guidelines recommend HIV counseling and voluntary testing for all pregnant women (United States Public Health Service 1995; Cozen et al 1993; Hawken et al 1995; Lindsay 1993). While this may be highly desirable in New Zealand where the prevalence of HIV infection among women is low, policy is still in the process of being developed.

What is the current situation in New Zealand?

Up to June 1996, a total of six children have been identified as infected with HIV by mother-to-child transmission, four of them in 1995 (none so far in 1996) (AIDS Epidemiology Group 1996a, 1996b). Up to 30 June 1996, 101 women in New Zealand have been reported as infected with HIV and 23 women have been notified as having AIDS, of whom 15 are known to have died and three have left New Zealand. It is estimated that of the women identified with HIV infection still alive, 64 are in the 15 to 40 years age group. The number of women in New Zealand who have been pregnant while infected with HIV is not known but is estimated to be between 13 and 40. Over the past few years the total New Zealand birth rate has varied a little around 60,000 births each year.

What are the issues surrounding testing/screening pregnant women?

Until such time as voluntary testing might be introduced as part of routine pregnancy care, it is recommended that as part of the antenatal discussion, the risk of HIV for both the woman and her partner(s) should be assessed and in cases where risk factors are identified or are not clear, counselling and voluntary testing be offered. While each primary care setting where maternity and related services are offered may use different approaches to assessing and managing pregnant women, it is up to each health professional to use their own clinical style and judgement to elicit and understand answers to antenatal risk assessments.

The questions developed below are focused on achieving a better understanding of a woman's HIV risk with the view to being able to advise on the need for testing as soon as possible; these questions are designed to elicit the minimum information required. The approach can be either written or oral (at the discretion of the health professional). What is important is that screening takes place routinely.

It is suggested the following two approaches (written and oral) be used as a framework for discussing the need for HIV testing.

Screening questions – written

Because women infected with HIV may pass the virus to their baby during pregnancy, childbirth, or breastfeeding and there are now effective measures available to prevent such transmission, we wish to check whether or not you or your partner(s) are at risk of HIV infection. If you are at risk of HIV infection or cannot identify your risk status, we wish to offer further counselling and a blood test for HIV.

Would you please consider the following questions, and indicate whether the answer to any of them is YES for either yourself or your partner(s)/husband. At this stage we do not need to know which of you or your partner(s), or which question(s) is/are responsible for the answer, only whether or not there is a YES answer. At this stage the only information that will be recorded will be that these questions have been considered. We acknowledge that you may not be able to answer or may not know the answer to some questions, particularly as they relate to your partner(s). Please indicate if this is the case. If you have any concerns or need any further information we are happy to discuss these with you.

- 1 Have your partner(s) ever had male-to-male sexual experience in the past (including only a single such experience)?
- 2 Have you or your partner(s) ever injected yourselves, or been injected by others, with drugs that were not prescribed by a doctor or ever shared drug-injecting equipment used by other people?
- 3 Have you or your partner(s) ever had sexual contact with anyone likely to be described as gay or bisexual or who was a known drug user?
- 4 Have you or your partner(s) ever exchanged or received money or drugs for sex at any stage?
- 5 Have you or your partner(s) ever had sexual contact with a person from an overseas country, particularly one where HIV/AIDS is common such as in Africa or Asia?
- 6 Have you or your partner(s) ever received a blood transfusion or clotting factors prior to 1985?
- 7 Do you have any worry or concern that you or your partner(s) may possibly be infected with HIV?
- 8 Have you or your partner(s) ever been diagnosed with a sexually-transmitted disease?

If the answer to any of these questions is YES, or if you are at all uncertain, we will arrange counselling and a blood test for HIV.

Screening questions – oral

'I should like to ask about HIV because effective treatment is available now to prevent the virus passing from a pregnant woman to her unborn child. There is a blood test that checks for HIV which requires counselling for the pregnant woman before and after the test.'

'Do you have any worries about HIV? If yes, would you like a test? Some ways a woman can contract HIV include:

- having had sexual partner(s) who have had unprotected sex with another man
- you or your sexual partner(s) having ever been an injecting drug user and have shared needles
- having had a sexual partner(s) who has had sexual contact overseas particularly where HIV/AIDS is common
- having had a blood transfusion prior to 1985.' 'Do you think any of these may apply to you?'

What are the issues and advice surrounding testing?

If possible at the first antenatal visit, women should be asked about risk behaviours for HIV infection to both themselves and their partner(s), the purpose of which is to identify those women who are pregnant and may be infected with HIV and who should be offered counselling and testing to prevent transmission of HIV to their child. Partners should also be advised to be counselled and tested for HIV if their behaviour places them at personal risk. Testing only those women with identified risks for infection will not, however, identify all cases of HIV. If there are any doubts about a woman's risk status, it is better to offer counselling and testing rather than miss a preventable episode of HIV transmission to the infant. The following points should be covered at the time a test is indicated.

Pretest discussion checklist

Specific consent to be tested for HIV must always be obtained. Discussion should cover:

- 1 what an HIV antibody test means (it is not a test for AIDS)
- 2 the significance of a negative test ('window period' in relation to recent risk behaviour)
- 3 the significance of a positive test with respect to:
 - the unborn child/children
 - zidovudine (ZDV) therapy – reduction of the risk of perinatal transmission
 - termination of pregnancy – abortion
 - medical implications (prognosis, treatment) for the mother
 - psychological issues (coping, support, relationships)
 - notification requirements for AIDS (note: HIV status is not notifiable)
 - social implications (who needs, or does not need, to know, employment, discrimination)
- 4 what are the safeguards with respect to preservation of confidentiality
- 5 future preventive aspects (to be addressed irrespective of the outcome of the test):
 - safer sexual behaviour
 - safer drug-injecting behaviour
- 6 how the test results are to be obtained (in person, face-to-face)
- 7 any costs that may be involved.

Post-test discussion

Delivering the outcome of the testing, whatever the result, is to be conducted personally, face-to-face, and not by telephone or mail.

- 1 Explanation of test results:
 - significance of either a positive or negative test
 - possible significance of the 'window period', especially if there has been recent risk behaviour
 - future preventive aspects (safer sex/drug injecting behaviour)
 - referral to a specialist with experience in HIV medicine
- 2 If negative:
 - possible significance of the 'window period', especially if there has been recent risk behaviour
 - future preventive aspects (safer sexual/drug-injecting behaviour)
- 3 If positive:
 - necessity for repeat and confirmatory testing
 - repeat, confirmatory test organised
 - arrangements for counselling and assessment for anti-retroviral therapy
 - referral to a specialist with experience in HIV medicine (Department of Health 1993).

Counselling persons with recognised risk behaviours for HIV is best done by an experienced person who deals with these situations frequently. If risk behaviours are acknowledged, and you have little experience in dealing with discussion in these areas, you are advised to seek the assistance of an advisor or counselor from a sexual health clinic or a counsellor from the local alcohol and drug clinic as appropriate. In addition, women found to be positive after testing will require a specialist referral. A list of specialists is provided in this resource for advice and referral in the first instance.

What are the management approaches for HIV-positive women during pregnancy

Strategies available to interrupt transmission from an HIV-infected mother to her baby include the administration of zidovudine (ZDV) to the mother during pregnancy and delivery, and to the newborn. A study has demonstrated that using zidovudine from the second trimester onwards, intravenously at the time of parturition, and administered orally to the infant for six weeks post-partum, can reduce the transmission of HIV by approximately two-thirds (United States Public Health Service 1994).

Factors that are associated with materno-fetal transmission include:

- *maternal plasma viral burden* women with higher viral burdens have higher rates of transmission
- *maternal immune status* higher rates of transmission occur with lower CD4+ cell counts
- *viral phenotype* the significance of syncytium including (SI) phenotype is not clear.

Those women found to be HIV-positive should be tested to assess viral burden and CD4+ cell numbers. This may necessitate referral to a physician experienced in managing HIV infection to evaluate the clinical status of the pregnant woman. Women who test positive for HIV should be offered zidovudine (ZDV) to prevent HIV transmission to their baby.

What are the future directions in respect of managing HIV-positive women?

It is known that other anti-retroviral agents (such as stavudine (d4T) and lamivudine (3TC)) can cross the placenta. The role of these agents, and the value of combination therapies (such as AZT and 3TC) in further reducing materno-fetal transmission is being addressed in studies currently underway. Further, the impact of protease inhibitors on materno-fetal transmission is being studied in clinical trials that are just commencing. It is hoped that improved therapies may reduce transmission rates to below 10 percent, but for this to occur it will become necessary to identify all HIVinfected pregnant women. This would necessitate HIV testing to become one of the routine antenatal tests recommended for all pregnant women.

Contact details of specialists

The following are specialists available in the first instance for advice or referral:

HIV specialists

Dr R Meech, Napier Hospital. Ph: (06) 834-1828

Dr R Ellis-Pegler, Auckland Hospital. Ph: (09) 379-7440

Dr M Thomas, Auckland Hospital. Ph: (09) 379-7440

Dr K Romeril, Wellington Hospital. Ph: (04) 385-5999

Dr S Chambers, Christchurch Hospital. Ph: (03) 364-0915

Paediatricians

Prof D Lennon, Middlemore Hospital. Ph: (09) 276-0044

Prof D Teele, Christchurch Hospital. Ph: (03) 364-0747

Obstetrician

Dr MAH Baird, National Women's Hospital. Ph: (09) 638-9919

Further information about HIV in pregnancy

For further information about HIV in pregnancy please contact:

Ministry of Health Ph: (04) 496-2000

Dr Alison Roberts Senior Advisor, Public Health Medicine

Dr Harry Nicholls Senior Advisor, Communicable Diseases

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