



**Submission on The proposed changes to the National Cervical Screening Programme (NCSP)
National Screening Unit**

PO Box 5013

Lambton Quay

Wellington 6145

Email primaryhpv@moh.govt.nz

Compiled on behalf of Women's Health Action Trust.

By Dr Sandy Hall and Holly Coulter

Contact:

sandy@womens-health.org.nz

Po Box 9947 Newmarket

Auckland 1149

64 9 5205295

Women's Health Action

Women's Health Action is a women's health promotion, information and consumer advisory service. We are a non-government organisation that works with health professionals, policy makers and other not for profit organisations to inform government policy and service delivery for women. Women's Health Action is in its 31st year of operation and remains on the forefront of women's health in Aotearoa New Zealand.

We provide evidence-based analysis and advice to health providers, NGOs and DHBs, the Ministry of Health, and other public agencies on women's health (including screening), public health and gender and consumer issues with a focus on reducing inequalities. We have a special focus on breastfeeding promotion and support, women's sexual and reproductive health and rights and body image.

Introduction:

The World Health Organisation (WHO) developed six principles which underpin cervical screening programmes, including our own. They include the overall benefits of screening outweighing the harm, the programmes being people centred, provide equity and access, have informed consent as a priority and respect autonomy and confidentiality, be monitored and evaluated regularly and have continuous quality improvement¹. Women's Health Action would expect any changes to screening programmes in Aotearoa New Zealand to be made in this context. Consequently our submission is made with these principles in mind.

In general, we support the move to use the HPV testing but only as part of the primary screening test being initially undertaken in tandem with continued smear testing and that the use of HPV testing as the primary test needs to be thoroughly investigated in the New Zealand context using independent researchers.

We believe both the ATHENA study and the incomplete COMPASS study in Australia do not completely demonstrate the safety of converting completely to HPV testing, particularly for women under 30 who are not immunised. The levels of immunisation uptake in Aotearoa New Zealand have been relatively low and certainly differ from Australia. We believe that concerted efforts need to be made to improve the HPV immunisation programme in New Zealand alongside any changes to the cervical screening programme.

We also believe that the differences in health system access and costs must be taken into account, particularly in terms of the provision of acceptable free services in a timely manner to ensure equitable outcomes. We are also concerned about the possibility of skill loss in regards to cytology and histology services as well as their capacity to cope with a short term rise in demand.

Independent, New Zealand based research needs to be done before making a decision about changing screening age or interval as there is currently a lack of sufficient research to establish what the impact of these changes would be.

¹ Andermann, A., Blancquaert, I., Beauchamp, S. and Dery, V. *Revisiting Wilson and Jungner in the genomic age: a review of screening criteria over the past 40 years*. Bull World Health Organ. 2008 April; 86(4): 317–319.
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2647421/>

1. The modelling work done to date supports the preferred pathway as the one likely to achieve the greatest benefits. However, are there any other options that you believe the NCSP should investigate further?

We are not sure which modelling or research you are referring to. However, we believe there is not enough independent evidence to support a complete move away from current testing models to solely HPV testing. We are also concerned that the research is not completely independent and there has been considerable lobbying by immunisation and test manufacturers around changes to our screening programme. We suggest more consumer involvement is required, both as advisors, and to provide feedback about the proposals and that changes should not be made in haste. We therefore suggest testing should be done in tandem for a period of evaluation and research. This would also allow time for education around HPV and the tests themselves.

The rapid roll-out of the proposed new pathway would result in the loss of much of New Zealand's skilled cytology workforce, and mean that if the new pathway proved unsuitable for New Zealand women, there would be a significantly reduced capacity to meet demand of cytology services.

Further, if HPV-testing is shown to be unacceptable to New Zealand women, a switch to offering HPV-testing only could lead to a drop in screening uptake, which could potentially have serious negative consequences for women. Independent research is needed not only into the efficacy of HPV testing, but also its acceptability to women in Aotearoa New Zealand, before a change is made to offer HPV-testing as the primary screening tool and eliminate the current pathway.

2. What further evidence and/or research should the NCSP consider to gain a comprehensive understanding of the impacts of proposed changes to the screening pathway?

We believe independent research must be undertaken in the New Zealand context across a range of issues including:

- Access by different population groups;
- Safety of the vaccines and effectiveness over time;
- Acceptability of the vaccines and the HPV testing to consumers;
- Safety of stopping cervical smear testing and other risks including missed diagnosis or overdiagnosis;
- Workforce issues in cytology and colposcopy services;

- The safety and efficacy of self-tests including the possibility of other health issues not being identified in the absence of doctor - patient contact;
- Acceptability of self-testing to women;
- Access and waiting times for colposcopy;
- Workload of histology services;
- The potential impact of increasing the screening age to 25 for women who become sexually active at a younger age;
- The potential impact of increasing the screening interval to 5 years for women who are under screened or DNA for follow-ups.

Research needs to be Aotearoa New Zealand based and relevant to the diversity of New Zealand women rather than adapting international models as has been used for the current proposal.

3. Screening interval

- Please comment on the proposal to routinely screen women every five years.
- Are there any groups of women who may have a higher risk and require a shorter screening interval?

In theory we think it would be beneficial to have less screening but we believe that this should be done only after further research is completed to ensure there are no risks of harmful outcomes as a result of increasing the screening interval. This will hopefully also identify women who are at higher risk and require additional or more frequent screening.

Given records of high “Did Not Attend” (DNA) rates for colposcopy services, and the amount of time that it can take to follow up on a client who has DNA for an appointment, we have concerns that there may be harmful consequences of increasing the screening interval in cases where there is a long delay between an abnormal result and engaging in follow-up.

4. Age range for screening

- Please comment on the potential change in age range for cervical screening from the current 20–69 years to 25–69 years.
- Should there be an exit test for screening between the ages of 69 and 74 years?

We note that the United States does not recommend hrHPV testing for screening of women aged less than 30 years, as the transient nature of HPV infections in this age group, may mean unnecessary referral to colposcopy² and ³.

We are concerned about making any changes to our current programme before adequate research in the New Zealand context is undertaken. We have a relatively low immunisation uptake and boys have not been offered immunisation. In addition, many New Zealanders become sexually active prior to 15. We would suggest that at least one screening test should be undertaken before the age of 25 unless there is definitive research to prove testing at 25 poses no risks.

We agree there should be an exit test done by a health practitioner in the context of information about the end of testing and any risks.

5. Referrals to colposcopy (for clinicians)

- If the number of referrals to colposcopy increased temporarily, how would it impact on the capacity and timeliness of colposcopy service delivery?
- What would be the best way to limit any such impact?
- How important is it to your clinical practice to have a cytology result for the women you see at colposcopy?

We note this is targeted towards clinicians but suggest it is imperative to get feedback from women. We have serious concerns about the possibility of increased waiting times for colposcopy results and possibly for histology. We also believe this may further could contribute to inequities, with women with lower incomes being less able to access private services in cases of long wait times. We also acknowledge that currently, targets for time interval between receiving an abnormal result and colposcopy are not being met⁴, and that this could be exacerbated by the new pathway.

²“The problem with using HPV testing for screening for cervical cancer is that infection with HPV is very common. In the US, the Centers for Disease Control and Prevention estimates that most sexually-active women will acquire HPV at some point in their lifetime.³ However, only a few infected women will go on to develop cervical cancer. Moreover, HPV infection typically occurs in younger age groups whereas cervical cancer usually develops later in life”. At Wright, T. Expert forum. www.researchreview.co.nz accessed October 12th 2015.

³ In 2012, new US guidelines for cervical cancer screening recommended Pap smear and hrHPV co-testing as the preferred approach in women aged ≥ 30 years. All of the screening studies conducted up to this point had been cross-sectional. However, screening is typically done multiple times in a woman’s lifetime so multiple rounds of screening are necessary in an evaluation setting for the benefits of HPV testing versus cytology to become evident. Wright, T. Expert forum. www.researchreview.co.nz accessed October 12th 2015.

⁴ As discussed at the National Cervical Screening Programme Auckland Public Consultation, 19th October 2015.

We have some reservations about the women who test positive for HPV 16, 18 [the HPV types responsible for 70% of cervical cancers] being referred directly to colposcopy, given that it is a relatively invasive procedure. Because HPV testing has less specificity than liquid-based cytology⁵, there is the risk of false-positives, which could lead to women unnecessarily undergoing colposcopy. A better pathway would be to complete liquid-based cytology before colposcopy for women who test positive for HPV 16,18. It is vital that the chance of false-positives is identified, and made clear to women, to ensure they are fully informed and can make an informed choice about whether to undergo colposcopy.

We also believe the sensitivity of the HPV tests may lead to women presenting at colposcopy with smaller lesions that colposcopists have trouble finding or knowing where to look. We believe there must be investigation of the potential impact of alternative pathways including cytology. We should also consider cytology for women > 30 years who may have increased risk. There are implications for the colposcopy workforce with the projected increased demand as well as a record of high DNA rates for attendance at colposcopy clinics.

6. Screening equity

Please comment on suggested strategies for eliminating inequalities in screening.

Women's Health Action strongly recommends that screening be fully funded and free to all women to ensure equitable outcomes. Cost has been consistently identified as a barrier to screening, and it is important to acknowledge both direct and indirect costs such as transport, childcare, and lost income from taking time off work⁶. Reducing the number of tests over a woman's lifetime may reduce the total cost of screening, but will have no impact on women discounting health in favour of more urgent expenditures.

We believe it is important to ensure accurate, detailed information on HPV immunisation, screening, and cervical cancer is made available to all women, and that this needs to be done prior to any changes to the screening programme. Knowledge of the purpose of screening varies greatly across women⁷, and may impact on their decision to participate or not participate. This

⁵ Wright, T. C., Stoler, M. H., Behrens, C. M., Sharma, A., Zhang, G., & Wright, T. L. (2015). Primary cervical cancer screening with human papillomavirus: End of study results from the ATHENA study using HPV as the first-line screening test. *Gynecologic Oncology*, *136*, 89–197.

⁶ Foliaki, S., & Matheson, A. (2015). Barriers to Cervical Screening among Pacific Women in a New Zealand Urban Population. *Asian Pacific Journal of Cancer Prevention*, *16*(4), 1565-1570.

⁷ Lovell, S., Kearns, R. A., & Friesen, W. (2007). Sociocultural barriers to cervical screening in South Auckland, New Zealand. *Social Science & Medicine*, *65*, 158-150.

will be a particularly salient issue if we move to HPV testing as the primary screening method, and it should be an imperative to ensure that women understand that HPV testing is still important even if they have been HPV-immunised, and to ensure any stigma around HPV being associated with sexual activity is addressed.

It is important to ensure that current services are equipped to meet the needs of diverse women in New Zealand. If self-testing becomes an option, it is vital that it is a choice that can be made by women freely and not because of a lack of acceptable services to meet their needs. Those who currently have lower access rates include some refugee and migrant populations, rural women, lesbians and women with disabilities. For example, women with physical disabilities are often met with barriers to screening because of inadequate facilities⁸.

It is also important that screening providers reflect the choices of different women, and are not organised on the basis of what it is expected they would prefer. For example, in a small community, a Pacific smear taker may be seen as inappropriate to Pacific women⁹.

Culturally and linguistically diverse clients should be offered appropriate resources and education and a trained health interpreter if needed. For example, the Asian population in New Zealand has low screening rates and language has been identified as a barrier to screening¹⁰.

7. Self sampling

- Who should self-sampling be offered to?
- What is the best way for women to test themselves (e.g., at home or at a clinic)?
- If a woman tests positive for HPV during self-sampling, she will need either follow-up cytology or referral to colposcopy. What do you think the uptake of follow-up for a positive test would be?
- What issues do you see with self-sampling?

⁸ Peters, K. (2012). Politics and patriarchy: Barriers to health screening for socially disadvantaged women. *Contemporary Nurse*, 42(2), 190-197.

⁹ Foliaki, S., & Matheson, A. (2015). Barriers to Cervical Screening among Pacific Women in a New Zealand Urban Population. *Asian Pacific Journal of Cancer Prevention*, 16(4), 1565-1570.

¹⁰ Lovell, S., Kearns, R. A., & Friesen, W. (2007). Sociocultural barriers to cervical screening in South Auckland, New Zealand. *Social Science & Medicine*, 65, 158-150.

There is insufficient research to evidence whether HPV self-sampling will be acceptable to those women who are in the unscreened/under-screened populations. We need to assess this by talking with women.

While the possibility of self-testing may seem to offer the possibility of increased access to screening, we must ensure access to a full range of screening services for all women until there is sufficient evidence to support this hypothesis.

We need to have a clearer understanding of what's involved with self-sampling, the sensitivity and accuracy of self-testing, as well as likely costs for the woman, before we can provide any advice.

We also need to know if there are any possible side effects or potential for injury and in exactly what circumstances have self test kits been tested. We therefore think this requires more investigation but believe that there is a role for self-testing in the context of oversight by a health practitioner and in the context of some women feeling more comfortable with self-testing. Self-testing would need to be a targeted approach, be fully funded, and an option that is provided as an alternative to free, appropriate, and accessible screening through a health practitioner.

We need to evaluate the effects of self-testing removing the opportunity for observation other health issues that is provided when undergoing screening by a health professional, and the a risk of perpetuating disengagement with health services, particularly in groups with currently low access rates.

We believe these and other questions need to be fully investigated with women, in particular those form groups with lower screening rates, to establish whether self-testing is acceptable to them. We also need to evaluate the risks of women testing positive and not pursuing testing.

8. Invitation and recall to screening

- What should be taken into account when re-designing the NCSP-Register for HPV primary screening?
- What is the most reliable way of systematically inviting women into the programme and recalling them at the appropriate time?
- Whose role should it be to invite and recall women into screening?

We recommend there be a separate consultation on the changes to the NCSP-Register once a decision on the primary screening test is made. High quality/accurate information to be provided to women must be developed with consumer involvement

9. Cervical screening workforce

- Smear takers: What information do you need to confidently engage with your patients if HPV primary screening is introduced?
- Cytopathology workforce: How do we retain gynaecological cytopathology professionals (existing cytopathologists, and anatomical pathology registrars) and maintain their expertise in the long term?
- Cytoscientists and cytotechnicians: What can we do to maintain a gynaecological cytology workforce in the period before HPV primary screening is introduced?
- What should we do to ensure New Zealand has an adequate number of expert gynaecological cytology staff in the long term?
- Histology and molecular biology staff: Does the molecular biology workforce have any additional training requirements?
- How much capacity do histology laboratories have to process a 10–30 percent increase in gynaecological histology specimens?
- Regional coordination, and invitation and recall staff: What is the best way to ensure you are well informed about the changes resulting from HPV primary screening?

We wonder whether a survey of this workforce should have been completed separately so public and health practitioner comments could be based on more information. We have serious concerns about the loss of skill and practitioners in this workforce.

10. Further Questions:

We believe the following questions need to be resolved before any permanent changes are made to the current screening programme.

- What will women be told if they test positive – that they are of high risk of cervical cancer; higher risk of cervical cancer; higher risk of pre-cancerous lesions?
- What might ‘high’ and ‘higher’ risk actually mean? How will this be determined? Will it be specific groups or populations?

- If a woman is a 'higher risk' and requires a shorter screening interval, how will you ensure that this does not marginalise communities who are deemed high risk?
- What impact will this have on women?
- Won't there be a large number of women who have been sexually active before the age of 15, who are not immunised who could in theory develop cell changes or even cancer before the age of 25?
- What will be done to ensure women < 25 who do develop symptoms that may be/are cervical cancer are taken seriously, with symptoms investigated and appropriately treated?
- The pilot study¹¹

What are the results of this programme so far?

What is the level of consumer advisory involvement?

Why is it only a service evaluation study?

How will you measure the success of the programme?

Will coverage be the sole measure, or will issues such as informed consent be given priority?

Thank you for the opportunity to provide this feedback.

¹¹ In collaboration with the Australian COMPASS trial organisers, a service evaluation project is being undertaken to trial HPV testing as a primary cervical screening test in New Zealand to test systems and processes to plan for a possible transition to a modified screening programme.