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National Cervical Screening Programme: Changing the primary laboratory test

2015

Public consultation paper

National Screening Unit

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How to have your say

This consultation document seeks your feedback on proposals to change the National Cervical Screening Programme (NCSP). Decisions will be made using your feedback, as well as the results of further research, and expert and consumer advice from technical and governance groups.

Your submission may be requested under the Official Information Act 1982. If this happens, it will normally be released to the person who requested it. If you think there are good reasons why your submission should not be released, please indicate those reasons in your submission.

Please provide your feedback to the National Screening Unit by:

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Submissions close on 23 October 2015 at 5 pm.

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Introduction

This consultation document seeks your feedback on proposals to change the National Cervical Screening Programme (NCSP). Decisions will be made using your feedback, as well as the results of further research, and expert and consumer advice from technical and governance groups.

Background

Cervical cancer is the fourth most common cancer for women. Around, 266,000 women worldwide die from cervical cancer each year (IARC 2013). Usually when a woman's cervical cells change, it is because she has been exposed to high-risk types of human papilloma virus (hrHPV). If these changes are not treated, they can lead to cancer of the cervix.

The three core features of an effective cervical cancer programme are primary prevention (HPV immunisation), secondary prevention (screening and early treatment) and tertiary services (treatment and palliative care) (WHO 2014). This means that the first line of defence against cervical cancer is to prevent it by HPV immunisation. The second line of defence is to conduct cervical screening so that cell changes can be identified before they become cancer.

New Zealand has one of the most successful cervical screening programmes in the world. The National Cervical Screening Programme provides a robust framework for cervical cancer screening: it consists of quality standards, audit, a common pathway and centralised recording of data. Over 73 percent of eligible women aged between 20 and 69 years have regular smear tests within recommended timeframes and the number of women who die from cervical cancer in New Zealand has fallen by 66 percent since the NCSP began in 1990. However, the benefits of the scheme are not spread equally across all population groups. In particular, Māori, Pacific and Asian women are less likely to get screened and they have a higher cervical cancer rate than the overall population of New Zealand women.

The NCSP aims to continue to reduce the number of New Zealand women who develop cervical cancer. It is well established that hrHPV can cause cervical cancer. Changing the primary laboratory test to one that identifies whether or not a woman has hrHPV is a natural step forward to improve the quality, safety and effectiveness of the programme. This approach, called primary HPV screening, is recognised as a more sensitive test. It is better at detecting pre-cancerous changes and reducing death from cervical cancer than the current cytology-based test.

An independent 2015 Parliamentary Review of the NCSP recommended that New Zealand give priority to reviewing evidence and developing recommendations to change over to primary HPV screening. The National Screening Unit (NSU) has commissioned modelling work on the implications of moving to HPV testing. The modelling work has identified a particular pathway that could work well for New Zealand. The model used has been extensively peer reviewed. The Australian cervical screening programme has also used it as the basis for its own renewal.

This consultation paper discusses the implications of moving to that pathway. For a technical analysis of the modelling work and relevant international research, see the companion paper, *National Cervical Screening Programme: Changing the primary laboratory test: Technical appendix to the public consultation paper* (Technical Appendix).

Guiding principles for this project are that the final approach should:

- deliver a best-practice national cervical screening programme
- make access to screening more equitable for women in all population groups
- be acceptable to women
- maintain and improve safety and quality of screening for enrolled women
- maintain a skilled and competent workforce to deliver the national programme
- have been established after consulting with a wide range of stakeholders so that there is a smooth transition to the new primary screening pathway
- maintain and improve the NCSP-Register's capability to support the programme.

Decisions will not be made in isolation: it is vital to engage the public and the health sector so that any changes are successful. Potential changes are being carefully thought through and are based on the best available evidence. To support this project, the NSU has asked for input from a wide range of New Zealand and Australian experts in epidemiology, cancer modelling, colposcopy, pathology, cytology, microbiology and primary care, as well as from Māori and Pacific community members. This input will continue throughout the project.

Decisions on future changes

A significant amount of work must be done before final decisions are made about changes to the New Zealand cervical screening programme. Programme changes must be safe, effective and acceptable to women. They must also support programme aims to eliminate equity gaps and improve coverage rates.

We seek your advice on the best way to refresh our screening pathway so that it:

- is fit for purpose in light of developments in testing technologies
- best meets the needs of New Zealand women.

Preventing cervical cancer: an overview

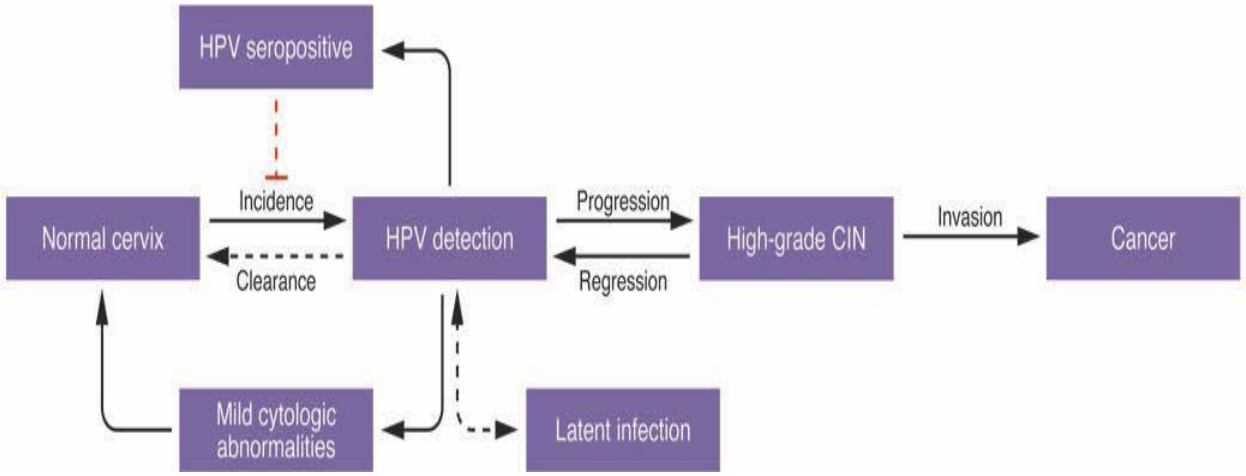
Cervical cancer is a preventable disease. Almost all cases (99 percent) of squamous cell cervical cancer and more than 90 percent of cervical glandular cancers are caused by persistent infection by hrHPV types. This section gives an overview of this cause of infection and the approaches that can be taken to preventing it from developing into cervical cancer.

What is HPV?

Human papillomavirus (HPV) is a very common virus that is easily spread between people; most women will have it at some point in their lives. There are over 100 different types of HPV and more than 40 of these can affect the genital area.

HPV is passed from one person to another through sexual contact. One study found that even women who have had only one sexual partner have a 46 percent risk of getting cervical HPV infection at three years after having sex (Collins et al 2002). Often the body's immune system will clear the infection before the woman notices any symptoms. However, for a small number of women, persistent hrHPV infection can lead to cervical cell changes; if these changes are not treated, they may cause cancer (see Figure 1).

Figure 1: Natural history of HPV infection and cervical cancer



Primary prevention: HPV immunisation

HPV immunisation is our first line of defence to reduce cervical cancer and other HPV-related infections. The HPV vaccine currently funded in New Zealand protects women against four types of HPV. Two of these types (6 and 11) are the main cause of genital warts, and types 16 and 18 are closely linked with a higher risk of developing cancer of the cervix, vagina, vulva, anus or throat (oropharyngeal). Other, less common types of hrHPV can cause cancer and are not currently included in the vaccine so it is still important that vaccinated women continue to have regular cervical screening.

Since 2008, HPV immunisation, along with regular cervical screening, has provided a foundation for preventing cervical cancer. A three-dose course of HPV immunisation, which protects against the four strains of HPV noted above, is offered free to all eligible girls aged 12–20 years. As the Ministry of Health constantly monitors newer HPV vaccines being developed, it is possible that vaccines that protect women against more hrHPV could be introduced in the future.

Overall, 55 percent of young women have been vaccinated against HPV. More Māori, Pacific and Asian girls have been vaccinated than young women of other ethnicities (for girls turning 12 in 2014, HPV immunisation rates are 63 percent for Māori, 72 percent for Pacific, 65 percent for Asian and 55 percent for other). The goal is to achieve herd immunity, when enough people in a population are immunised to protect people who are not immunised. New Zealand would need a vaccination coverage rate of around 75–80 percent to achieve herd immunity against HPV. To increase vaccination coverage rates so that we can work towards this goal, the national HPV immunisation programme is revitalising its immunisation campaign.

Evidence shows that the current liquid based cytology screening pathway is less effective at screening HPV-immunised women for cervical cancer than primary HPV screening (Technical Appendix, p 20).

Decisions about the new pathway need to consider changing HPV vaccination coverage rates and the HPV impact on cervical screening outcomes. The NCSP and HPV immunisation team work closely together to ensure that New Zealand women can access high-quality programmes to prevent cervical cancer.

Secondary prevention: cervical screening

The current programme

Cervical screening is the second line of defence against cervical cancer. Screening aims to detect abnormal cell changes early on so they can be treated before they progress to cervical cancer. For most women, the recommended time between smear tests is three years. This screening interval is shorter for some women who have had cell changes detected previously.

Smear testing

In a smear test, a smear taker (a nurse or doctor) opens the vagina with a metal or plastic instrument (speculum), which allows them to see the cervix and easily access it to collect cervical cells. The smear taker uses a thin broom or brush to take cells from the cervix; they then put the cells into liquid and send them to the laboratory for testing.

Liquid based cytology

The NCSP has evolved over time to keep pace with new developments in medical science and technology. The main laboratory test is liquid based cytology (LBC). LBC is a method of preparing cervical samples for the laboratory to examine. The cells taken by the smear taker are added to a vial containing preservative, and sent to the laboratory for processing and staining.

New Zealand is technologically advanced in that almost all laboratories that do this work for the NCSP have a semi-automated process for screening these samples. In addition to the automated technology, specialist laboratory scientists, technicians and doctors visually grade any suspicious-looking cell samples using a microscope and provide advice on whether a woman needs further investigation or monitoring.

HPV triage

HPV testing is already part of the cervical screening pathway. It is currently used to help work out what further monitoring or assessment a woman needs if any low-grade cell changes are detected from the LBC test (this process of collecting evidence through several different methods is called triaging). New Zealand laboratories currently use two commercial hrHPV tests: the Roche Cobas 4800 and Abbott Real Time. Both of these tests can detect type 16 and 18 individually and 12 other hrHPV subtypes collectively (meaning that it shows a woman has one of these subtypes but does not identify which one).

Colposcopy

If laboratory testing detects cell changes, women needing closer investigation are referred to a specialist gynaecologist or colposcopist. The specialist conducts an examination using a special microscope for looking at the cervix and surrounding tissue (colposcopy). If needed, they also take a sample of tissue (biopsy) from the cervix and send it to the laboratory for further testing (histology). Colposcopy can also involve a range of treatments to remove cells showing pre-cancerous changes.

For more information on the current NCSP pathway, go to: www.nsu.govt.nz/health-professionals/national-cervical-screening-programme/cervical-screening-guidelines

Primary HPV testing

International evidence shows convincingly that introducing testing for hrHPV types as the first test (primary HPV testing) in the screening pathway is the most effective way to prevent cervical cancer. The World Health Organization (WHO) endorses this approach (WHO 2014).

Compared with cytology, HPV testing further reduces the risk of cervical cancer. HPV testing is a more sensitive test than cytology. It is less prone to human error from interpreting the slides, as the test is fully automated. Because the test is more sensitive, it may be possible to increase the time between screening from three to five years.

Some of the potential benefits of adopting primary HPV testing are that it could:

- reduce cervical cancer cases and deaths
- improve our ability to detect risk of pre-cancerous cervical cell changes
- provide an effective test both for women who have had the HPV vaccine and those who have not

- provide safe but less frequent screening (every five years rather than every three)
- allow a more independent assessment as test results are either positive or negative, in contrast to the more subjective laboratory interpretation that is needed to identify cell changes with LBC
- open up the possibility of introducing the option of HPV self-sampling for women who currently find it difficult to access screening services
- keep the New Zealand programme in line with internationally recognised best practice
- potentially be more cost-effective than the current programme.

One of the main drivers for changing the cervical screening pathway is that, since the HPV vaccination has been introduced, the number of women who are HPV vaccinated is increasing. Evidence shows that HPV screening is more effective than LBC for screening HPV-immunised women. By detecting the virus, a health provider can identify women at higher risk of developing cervical cancer and can treat any pre-cancerous changes before they become cervical cancer (Elfstrom et al 2014).

Other countries, such as the Netherlands, United Kingdom and Australia, are introducing primary HPV screening. The NCSP is monitoring the process of transition to primary HPV testing in these countries. As New Zealand already uses LBC sampling and HPV triage, we are well placed to consider a move to HPV primary screening.

Modelling work

The NSU commissioned extensive modelling work from the Cancer Council New South Wales to identify the risks, benefits and opportunities of changing to HPV primary testing. This work evaluated the lifetime effects and costs of a range of strategies compared with current cervical screening practice, in both vaccinated and unvaccinated cohorts, based on current vaccination rates in New Zealand. It concluded that a range of potential screening strategies were predicted to do more to reduce cervical cancer cases and deaths than the current programme. All of these strategies involved a move to primary HPV screening. Four main HPV pathways were considered as part of the modelling process.

The next section sets out the pathway identified as offering the greatest benefits, based on this modelling work. For detailed information on the modelling evaluation, see the Technical Appendix (pages 15-18).

A new pathway for cervical screening

Based on modelling work (see the previous section), primary HPV testing with partial genotyping was identified as the pathway with the potential to have the most favourable outcomes for women aged 25–69 years. Under this proposed pathway:

- hrHPV testing with partial genotyping is conducted
- women who test positive for HPV 16 or 18 are referred straight to colposcopy for further assessment
- women whose samples test positive for 'other' cancer-causing (oncogenic) hrHPV types are triaged using LBC. Where high-grade cell changes are found, women are referred to colposcopy. Women with no cell changes or with low-grade changes are given a further HPV test in 12 months.

Table 1 compares this proposed approach with the features of the current pathway. Figure 2 presents a flowchart showing the proposed approach in more detail.

Table 1: Comparison of the features of the current and proposed pathways

	Current pathway	Proposed pathway
Primary screening test	Liquid based cytology with automation assisted screening	hrHPV testing with partial genotyping
Age range	Women aged 20–69 years	Women aged 25–69 years
Interval between screenings	3 years	5 years
Triage options	ASCUS/LSIL result + reflex hrHPV DNA testing (in women age 30+)	HPV positive result HPV 16/18 positive women referred straight to colposcopy Women positive for other oncogenic HPV have a further LBC test (LBC reflex testing)
Exit strategy	LBC test at age 69 years	HPV test at age 69 years (or an exit test between 69 and 74 years – ie, five years after the last screening event)
Self-collection	N/A	Yes (specified circumstances)

The proposed pathway achieves the optimal balance between detecting pre-cancerous lesions and limiting the potential harms of screening, such as unnecessary anxiety caused to women and the risk of over-treatment of a condition that may not progress to cancer.

The modelling predicts that HPV primary screening is the way to achieve the greatest reduction in cervical cancer cases and deaths in both vaccinated and non-vaccinated women. It is also cost-effective.

For further information on clinical safety and effectiveness, see the Technical Appendix (pages 20-42).

From a woman's perspective, most women would notice no change to the actual cervical screening procedure. The main differences relate to the test used in the laboratory and the subsequent referral pathway. The key differences from a woman's perspective are that the starting age for screening may rise to 25 years, and screening would happen less often: every five years instead of every three.

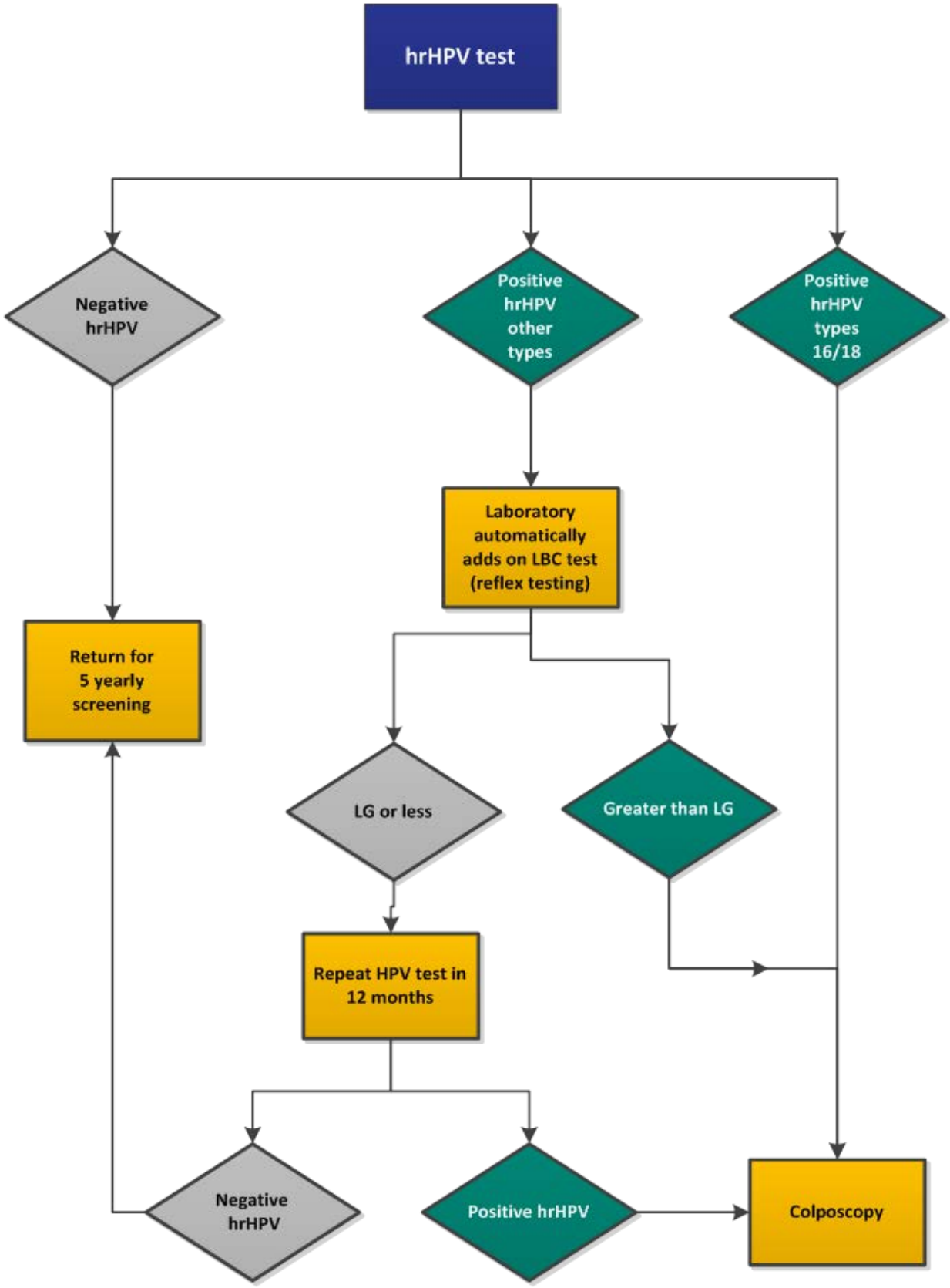
Further research is being commissioned to help address the questions of:

- whether the starting age for screening can be safely raised to 25 years
- how changes to vaccination coverage would affect the programme
- whether self-sampling HPV is a feasible option for some groups of women.

Key points

1. Informed consent and information about the harms and benefits of screening are still as important as ever.
2. The HPV vaccine does not protect against all the types of HPV that cause cervical cancer, so women who have been vaccinated against HPV still require cervical screening.
3. Primary HPV screening is a slightly different way of testing the cervical cell sample and women would not notice this change.
4. Primary HPV testing is safer and more effective than current LBC primary testing, and women do not need to be screened as often. In addition, a potential option is to introduce self-sampling for women who are less likely to have a smear test, which could help engage more Māori, Pacific and Asian women in cervical screening.
5. The age range for screening may change from the current **20–69** years to **25–69** years. An exit screening test could be introduced between the ages of 69 and 74 years.
6. Women would be routinely screened every **five years**. Those who have a higher risk of developing cervical cancer and require closer monitoring would be screened more frequently.
7. Samples taken by smear test can be used for both the hrHPV test and for LBC testing to look at cell changes if this is needed.
8. Women found to have hrHPV types 16 or 18 would be referred directly to colposcopy.
9. Women who test positive for other hrHPV types would be assessed using LBC and their testing and/or treatment pathway would depend on the outcome of this test.
10. Laboratories already have well-established mechanisms and processes for hrHPV testing. Moving to primary HPV testing would increase the volume of hrHPV tests for laboratories and reduce the number of LBC tests to process.

Figure 2: The proposed pathway



LG = low grade

Invitation to comment on the proposed pathway

We are asking for your feedback on the proposed pathway, the impact of any proposed changes and any further specific issues that you think we should work through as part of any strategy for making these changes to the NCSP.

Proposed pathway: HPV testing with partial genotyping

Under the proposed strategy, HPV 16/18 positive women are sent to colposcopy for further assessment, and samples testing positive for 'other' hrHPV types are then triaged using LBC. Women with high-grade cell changes are sent for colposcopy and those with low-grade or no cell changes repeat the HPV test in 12 months.

Question 1

Although the modelling work to date supports the proposed pathway as the one likely to achieve the greatest benefits, are there any other options that you believe the NCSP should investigate further?

Further research

The project team is working through a detailed analysis of the modelling work and waiting for modelling for specific ethnic groups. It is commissioning further research to help address the questions of whether the starting age for screening can be safely raised to 25 years, how changes in vaccination coverage would affect the programme and whether self-sampling HPV is a feasible option for some groups of women.

Question 2

What further evidence and/or research do you think that the NCSP may need to consider to gain a comprehensive understanding of the impacts of proposed changes to the screening pathway? Please submit any relevant papers or references that you believe the NCSP should consider.

Screening interval

Currently women are screened every three years if their test result is negative. Because HPV testing is a more sensitive test, it may be possible to increase the time between screening to five years for women who test negative to hrHPV.

Question 3

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

Age range

The modelling work suggests that, with the proposed pathway, the starting age for cervical screening could be raised to 25 years. It predicted that this approach would reduce cervical cancer cases and mortality by 3–15 percent in both vaccinated and unvaccinated women, compared with LBC. Australian data has shown that cervical screening of women aged 20–24 years had no effect on the rate of cervical cancer cases.

The project team has reviewed cancer cases in the under-25 age group. Between 2008 and 2013, a total of 23 women aged 20–24 years were diagnosed with cervical cancer. Among these women, 74 percent of the 19 squamous cancers were micro-invasive carcinomas, which can be conservatively treated by cone biopsy. The NSU has commissioned expert advice to evaluate the clinical safety of raising the screening starting age to 25 years.

The NSU is asking for feedback on the merits, risks and benefits of including an 'exit test' for women aged between 69 and 74 years – that is, five years after the last screening event. For further information, see the Technical Appendix (pages 33-35).

Question 4

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?

Subsequent clinical management

The modelling work considered three different HPV testing strategies.

- **Option one:** The cell sample taken during a smear test can be routinely tested for both hrHPV and LBC at the same time (co-testing).
- **Option two:** The cell sample can be tested using LBC (LBC reflex testing) to triage women for referral to colposcopy or for another hrHPV test in 12 months.
- **Option three:** The type of hrHPV a woman has determines how it will be managed. Women testing positive for hrHPV types 16 and 18 are sent straight to colposcopy for further assessment. Women with other types of HPV that are linked with a lower risk for developing cancer would have an LBC test and, depending on that result, could be sent to colposcopy.

The NCSP considered these options against background questions about the relative risks of under-diagnosis and over-treatment, clinical safety and effectiveness, and value for money. For further information, see the Technical Appendix (pages 20-65).

Option three presents the optimal balance between detecting pre-cancerous lesions and limiting the potential harms of screening (such as causing unnecessary anxiety, detecting transient HPV infection that may clear itself or over-treating a condition that may not develop into cancer). The modelling predicts that, under this option, colposcopy referrals would increase by 1 percent for vaccinated women and 15 percent for unvaccinated women, while treatment for pre-cancer would fall by 2–7 percent (Technical Appendix, page 41).

As the first cohort of women who have been immunised against HPV enters the programme from 2016, and as HPV immunisation rates increase, the modelling predicts that the number of referrals to colposcopy will fall.

Question 5

If the number of referrals to colposcopy increased temporarily, how would it impact on 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?

Equitable access and outcomes for all New Zealanders

Although New Zealand's cervical screening programme is among the best in the world, providing equitable access to the programme for all groups of women remains a challenge (Table 2). Māori, Pacific and Asian women are particularly over-represented among those women who develop and die from cervical cancer, compared with other ethnic groups. Reducing and ultimately eliminating equity gaps by improving access to cervical screening is one of the main measures of success for the programme and will be a continued focus for the NCSP.

A new screening pathway will not necessarily improve outcomes equally across different groups of women and we need to ensure it does not widen existing equity gaps. The NSU has commissioned the Cancer Council New South Wales to provide further modelling that will help to understand the impact of the new screening pathway on Māori, Pacific, and Asian women, particularly given that rates of immunisation are higher in the Māori and Pacific communities.

Primary HPV screening may help address some of the existing equity gaps experienced by Māori, Pacific, Asian, and under- and unscreened women if the time between routine cervical smears is increased, which would reduce the cost of screening to women. HPV primary testing may also provide an option for some groups of women to collect the HPV sample themselves (self-sample).

Table 2: Coverage by ethnicity – women aged 25–69 years screened before 30 June 2014, hysterectomy adjusted

Ethnicity	% of women screened	
	In the last 5 years	In the last 3 years
Māori	78.7	62.6
Pacific	91.9	72.8
Asian	62.6	62.6
European/Other	96.5	82.2
Total	**90.6**	**76.3**

HPV vaccination and equity

HPV vaccination rates and changes to the way immunisation is provided will continue to be monitored to identify potential impacts on the screening pathway. It is important to consider differences in immunisation uptake among ethnic groups when identifying how changes in the screening pathway may impact on equity in outcomes for cervical screening (see 'Primary prevention: HPV immunisation' section for further details).

While the rates of Māori, Pacific and Asian women screened for cervical cancer are lower than the rate for women of other ethnicities, the opposite is true for HPV immunisation. The higher rates of HPV immunisation among Māori, Pacific and Asian girls may counteract the lower screening rates in these groups and positively impact on equity gaps in cervical cancer outcomes in the future.

Cost to women

Any initiatives to improve access to screening will consider what the direct costs to participants are, as cost is a known barrier to cervical screening for many women. The NCSP currently offers some free smears to women in priority groups, but most women accessing cervical screening services have to pay for their consultation. At present there is no plan to change the current arrangements where women generally pay the cost of their smear and some women in priority groups have free smears to reduce inequalities.

Reducing the number of tests over a woman's lifetime

Under the proposed pathway, a woman would start screening at a later age and would have more time (five years instead of three) between screenings. Most women would therefore need fewer routine screens and the cost (and effort) of having cervical smears would be lower for them. If screening detected no abnormalities, the number of screens recommended over a woman's lifetime would fall from 18 to 10 smears.

Attending a cervical screening appointment also has indirect costs such as those of travel, child care and time off work. While the barriers to attending each appointment remain the same, reducing the frequency may make it easier for women to keep up to date with screening.

More cultural diversity in health service providers

If women feel out of place or not understood in a health care setting, they are less likely to access health care. Work is needed to engage more Māori and Pacific students in training to become health professionals. The NCSP will continue to work with Health Workforce New Zealand to highlight the need for a new generation of Māori and Pacific students to enter health professional training.

Rural women

Changing to HPV primary testing is unlikely to disadvantage rural women. Women in rural areas participate in cervical screening at similar rates and have similar levels of access to general practitioners, compared with urban women. The rates for different ethnic groups are likewise not significantly different from those across New Zealand (Brewer 2012).

Question 6

Please comment on suggested strategies for eliminating inequalities in screening.

Self-sampling for HPV test samples

Adopting primary HPV testing allows for the option of self-sampling. It has not been possible with LBC testing because, with this method, cells must be taken directly from the woman's cervix.

Data from overseas studies indicates that a woman's HPV self-testing is as effective as clinician-collected samples. New data on self-sampling will continue to be assessed throughout the project.

Self-sampling has the potential to reach women, particularly those from priority groups, who see standard testing by a clinician as less acceptable. At this stage the NCSP is looking at whether to make self-sampling available to women who are not currently engaged with or accessing screening through traditional health services. Women with disabilities for whom cervical sampling is physically challenging could also benefit.

One matter to consider in making this decision is how to manage women in a self-sampling pathway if they are identified as hrHPV positive, as they may need a smear test as part of their subsequent management.

While self-sampling may improve cervical screening equity, the programme is also committed to making standard HPV screening accessible for all populations. The NSU is commissioning research to gain more information about whether and how self-sampling could be included in the new pathway. Key considerations include:

- who to offer self-sampling to and the best way for women to test themselves (eg, at home or at a clinic)
- whether self-sampling is acceptable to women
- how likely it is that women who have a positive result will then agree to a follow-up cytology test, as they will probably need to have a speculum examination with a clinician
- what the cost would be for women who also need an LBC test after self-sampling
- how to reduce cost and access barriers for women in priority groups.

Question 7

Who should self-sampling be offered to?

What is the best way for women to test themselves (eg, 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?

NCSP-Register

One task of the primary HPV screening project is to look at what shape the NCSP-Register (NCSP-R) should take in the future. The NCSP-R is one of the essential components of the screening programme. It is a database containing secure cervical screening information for more than 1.4 million women. This information is used to provide:

- screening histories to support smear takers, laboratories and colposcopists in providing screening services to women
- a back-up service for women by generating overdue screening test letters and screening test result letters
- statistical data that can be used to monitor and evaluate the NCSP.

Because changing to HPV primary testing would substantially change the screening pathway, the NCSP-R would also need to change significantly to continue to be fit for purpose. When deciding what changes to the NCSP-R are needed, matters to consider include:

- clarifying what the role of the NCSP-R should be in a primary HPV screening environment, including the interface between primary care and the NCSP-R
- whether the main responsibility for inviting women into the programme and recalling them at regular intervals should rest with the health care provider or the NCSP-R
- what the new NCSP-R should look like and what functions it needs to perform
- how the NCSP-R aligns with other similar Ministry of Health registers, such as the immunisation register and cancer registers
- how any changes to the NCSP-R would impact on central and regional register teams.

Regardless of which pathway is chosen or what age women are when they join the programme, a systematic and robust way of inviting women to join the programme is needed. At the moment a woman's primary care provider or smear taker responsible for her care invites her onto the scheme and recalls her at three-yearly intervals. The NCSP-R operates as a back-up system, issuing recall notices when a woman is overdue.

Question 8

We seek your feedback on how you believe women would prefer to be invited to join the programme and to be reminded to keep participating in the programme.

What should be taken into account when 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?

The cervical screening workforce

The NCSP workforce is made up of:

- smear takers (usually general practitioners and practice nurses)
- laboratory staff, including pathologists, scientists and technicians
- colposcopy clinic staff, including colposcopists and colposcopy nurses
- staff of district health boards (DHBs), staff of primary care and independent service providers, and NCSP-Register administrators.

Smear takers

New Zealand has around 7500 active smear takers, made up of around 5000 general practitioners and 2500 nurses who are trained to take smears. If women are screened every five years with HPV primary screening, the volume of smears taken and the amount of work related to recalling women for smears would fall. Because smear taking makes up only a small part of the general practice workload, staffing levels in primary care would be unaffected by a change to HPV primary screening.

With primary HPV testing, the process of collecting a specimen from most women would remain the same as it is now. All smear takers would need access to refreshed information on HPV testing, how to interpret HPV results, and how to manage women under new cervical screening guidelines.

Laboratory staff

The staff working within the NCSP laboratory service include:

- pathologists who are medical graduates with specialist qualifications in pathology
- cytoscientists who are medical laboratory science or science graduates with specialised training in cytology
- cytotechnicians who are laboratory trained in cytology and have gained the Qualified Medical Laboratory Technician (QMLT) certificate from the New Zealand Institute of Medical Laboratory Science (NZIMLS)
- histoscientists who are medical laboratory science graduates or science graduates with specialised training in histology
- histotechnicians who are laboratory trained in histology and have gained the NZIMLS's QMLT certificate

- molecular pathology scientists and technicians with expertise in hrHPV testing
- laboratory assistants (unregistered).

Overall, many variables will impact on the numbers of cytology, histology and HPV tests that are processed in an HPV primary screening environment. These variables include HPV vaccination rates in women, the screening age, and the details of the HPV primary testing pathway developed by the Guidelines and Policies and Standards work streams.

Pathologists

Approximately 35 pathologists report gynaecological cytology. Gynaecological cytology currently makes up about 5 percent of most pathologists' total workload.

If HPV primary screening is introduced, the gynaecological cytology workload would fall, while the histology workload is likely to increase. The change to HPV primary testing could make it more difficult to maintain a highly skilled gynaecological cytopathology workforce in the long term.

Cytoscientists and cytotechnicians

If HPV primary screening is introduced, the most significant workforce impacts would be on the cytoscientists and cytotechnicians who specialise in cytology. Currently around 60 cytoscientists and cytotechnicians are employed in seven New Zealand medical laboratories. These staff collectively process and screen around 400,000 smears taken each year, and gynaecological cytology makes up at least 80 percent of their workload.

The impact on cytoscientists and cytotechnicians would be significant because, although cytology would still be needed in an HPV primary testing environment, the volumes will be a lot lower. The Workforce work stream will look at how best to support these important members of the NCSP workforce.

It may be a challenge for New Zealand to retain lower numbers of highly specialised scientific staff to undertake the cytology that will still be required with primary HPV screening, and to maintain their skills. Cytology staff are also needed to process non-gynaecological cytology specimens. It will also be a challenge to encourage new medical laboratory scientists and technicians into cytology, given that a limited number of jobs will be available.

The proposal to implement HPV primary screening is already causing uncertainty for the current cytology workforce. A key risk is that some experienced members of this workforce will look for another career path before the new pathway is introduced, which would put pressure on laboratories to keep up with the current workload.

While more HPV tests will be needed, this work is automated and may not be appealing to the cytology workforce that prefers microscopy. Any increase in the HPV testing workforce is likely to be smaller than the reduction in the required cytology workforce.

Histoscientists and histotechnicians

Overall, HPV primary testing is expected to increase the number of cervical histology specimens to be processed. It is necessary to gain a better understanding of how this would impact on the workforce of histoscientists and histotechnicians.

Molecular pathology scientists and technicians

The volume of HPV tests would increase significantly if the proposed pathway was introduced. Additional staff may be required to process the higher volumes.

Colposcopists and colposcopy nurses

Women with abnormal cervical smear results are currently referred to colposcopy for assessment and diagnosis. The colposcopy workforce includes gynaecologists and nurses with expertise in colposcopy. Colposcopy staff can be employed in DHB colposcopy clinics and/or private practice.

Introducing primary HPV testing would be likely to increase colposcopy referrals in unvaccinated populations. However, this higher demand would be offset by a decrease in referrals in the vaccinated population and a small reduction in colposcopy-directed treatment. The change in workload is not expected to significantly over-burden the DHB colposcopy clinics, but this assumption would need to be tested and monitored during the planning and implementation phases.

The colposcopy workforce would require training in the changes to the screening and treatment pathway for women.

Regional coordination, invitation and recall, and NCSP-Register staff

In addition to the health professionals in the NCSP workforce, staff supporting these health professionals include:

- NCSP-Register staff employed at New Zealand Post and by DHBs
- NCSP regional coordination and invitation and recall staff employed at DHBs, primary health organisations and independent service providers
- kaimahi and health promoters who support women in priority groups to use screening services.

These staff need to understand the NCSP pathway and would need to be upskilled to adapt to the changes resulting from HPV primary screening. Other parts of the NCSP workforce (including health professionals) look to these staff for guidance and support.

Question 9

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 higher number of gynaecological histology specimens?

Regional coordination, and invitation and recall staff

What is the best way to ensure that you are well informed about the changes resulting from HPV primary screening?

Next steps

The National Screening Unit within the Ministry of Health is guided by a range of technical, advisory and governance groups. These include the:

- technical reference group made up of clinical experts and leaders from the gynaecology, laboratory and public health sectors, and Māori and Pacific consumers
- project steering group consisting of clinicians, and Māori and Pacific members
- Māori Monitoring and Equity Group
- NCSP Advisory Group
- National Screening Advisory Committee (NSAC).

After this consultation period, NSAC will consider the consultation feedback and make recommendations to the NSU about whether the programme should introduce HPV primary testing. The NSU will develop advice to the Minister of Health, including NSAC's recommendations. The Minister will then decide whether to direct the NSU to develop policy to implement HPV as the initial test in the screening pathway.

If the Minister advises the Ministry to go ahead with this change, the next step will be to set up work streams involving the health sector and consumers (particularly Māori and Pacific peoples) to look in more depth at the best way to implement HPV primary testing. The work streams will consider:

- guidelines for managing cervical screening in New Zealand
- NCSP Policies and Standards
- information technology (NCSP-Register)
- science, technology and workforce
- funding
- equity
- communications
- research and evaluation.

The NSU aims to ensure that any change to the new pathway is well managed and that cervical screening is accessible and equitable.

References

Brewer, et al. 2012. Travel time and distance to health care only partially account for the ethnic inequalities in cervical cancer state at diagnosis and mortality in New Zealand. *Australian and NZ Journal of Public Health* 36: 335.

Collins, et al. 2002 High incidence of cervical human papillomavirus infection in women during their first sexual relationship. *British Journal Obtetrics and Gynaecology* 109: 96.

Elfstrom KM, Smelov V, Johansson AL, et al. 2014. Long term duration of protective effect for HPV negative women: follow-up of primary HPV screening randomised controlled trial. *British Medical Journal* 348: g130.

International Agency for Research on Cancer. 2013. *Biennial Report 2012–2013*. Lyon. World Health Organization.

WHO. 2014. *Comprehensive Cervical Cancer Control: A guide to essential practice* (2nd edition). Geneva: World Health Organization. URL: http://apps.who.int/iris/bitstream/10665/144785/1/9789241548953_eng.pdf (accessed 9 September 2015).

Submission form

The National Screening Unit (NSU) wants to know what you think about our proposed changes to the National Cervical Screening Programme (NCSP).

The consultation documents can be found here.

Please provide your feedback to the questions below. You can send your response to the NSU by:

- Online submission can be made here.
- Post National Screening Unit
  PO Box 5013
  Lambton Quay
  Wellington 6145
- Email primaryhpv@moh.govt.nz

Submissions close on 23 October 2015 at 5 pm.

General comments

- You may find that some questions are not relevant to you. Feel free to leave those questions blank.
- There is also an opportunity to make a more general submission at the last question.

Submissions may be requested under the Official Information Act 1982

If this happens, your submission will normally be released to the person who requested it. However, if you are submitting as an individual (rather than representing an organisation), you can request that your personal details should not be released by selecting the options below:

1. Answer this question only if you are submitting as a private individual, and you do not want your personal details released or published

☐ I do not want my personal details to be released

☐ I do not want my personal details included in the published summary of submissions

2. Your contact details:

Name:

Organisation (or Private):

Address/ email:

3. 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?

4. 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? Please provide links or references to any documents the NCSP should consider. Email any relevant papers that the NCSP should consider to primaryhpv@moh.govt.nz.

5. 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?

6. 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?

7. 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?

8. Screening equity

Please comment on suggested strategies for eliminating inequalities in screening.

9. Self sampling

- Who should self-sampling be offered to?
- What is the best way for women to test themselves (eg, 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?

10. 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?

11. 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?

12. Do you have any other feedback?

Thank you for your submission.