**National Cervical Screening Programme: Changing the primary laboratory test**

Public consultation submission summary

February 2016

# Contents

[Contents 2](#_Toc444612699)

[Summary 3](#_Toc444612700)

[Background 3](#_Toc444612701)

[Guiding principles 4](#_Toc444612702)

[Key themes from submissions 4](#_Toc444612703)

[Feedback from submissions 5](#_Toc444612704)

[Cervical screening coverage 5](#_Toc444612705)

[Proposed screening pathway 8](#_Toc444612706)

[Increasing screening intervals 12](#_Toc444612707)

[Changing the starting age for screening 14](#_Toc444612708)

[Introducing exit screening 16](#_Toc444612709)

[Workforce impact 17](#_Toc444612710)

[NCSP Register 19](#_Toc444612711)

[Next steps 20](#_Toc444612712)

# Summary

## Background

The National Screening Unit (NSU) within the Ministry of Health’s National Health Board is responsible for the development, management and monitoring of population-based screening in New Zealand. The National Cervical Screening Programme (NCSP) is one of its screening programmes.

New Zealand has one of the most successful cervical screening programmes in the world. The NCSP 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. The number of women who die from cervical cancer in New Zealand has fallen by 60 percent since the NCSP began in 1990. However, the benefits of cervical screening 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 three core features of an effective cervical cancer prevention programme are primary prevention (human papillomavirus (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 through HPV immunisation. The second line of defence is to conduct cervical screening so that cell changes can be identified before they become cancer. Currently cervical screening involves an examination of the cells from the cervix (cytology), with HPV testing to follow in some clinical situations.

Cervical cancer is the fourth most common cancer for women. Around, 266,000 women worldwide die from cervical cancer each year (IARC 2013). Exposure to high-risk types of HPV (hrHPV) causes cervical cell changes. HPV is a common virus that frequently clears up by itself. However, in some cases, the infection persists, and if the associated cell changes are not treated, they can lead to cancer of the cervix.

The NCSP aims to reduce the number of New Zealand women who develop cervical cancer. Changing the primary laboratory test to one that identifies whether or not a woman has HPV is a natural step forward to improve the quality, safety and effectiveness of the programme. International research has found this approach, called primary HPV screening, is accurate and detects more women at risk of developing abnormal cell changes than the current testing method using cytology. Compared to the current screening programme it is predicted that:

* new cases of cervical cancer will reduce by a further 15% in unvaccinated women and 12% in vaccinated women
* deaths from cervical cancer will be reduced by a further 16% in unvaccinated women and 12% in vaccinated women.

The potential benefits of adopting primary HPV screening include:

* decrease in cervical cancer incidence and mortality
* better detection of risk of precancerous cervical cell changes
* providing a more effective test both, for women who have had the HPV vaccine and those who have not
* safe but less frequent screening (every five years rather than every three).

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 NSU has commissioned modelling work on the implications of moving to primary HPV screening. The modelling work has identified a particular pathway that could work well for New Zealand. The model used has been extensively peer reviewed.

In September 2015 the NCSP released a public consultation document on changing the primary cervical cancer screening test. In October 2015, thirteen consultation meetings, hui and fono were held with members of the public, community based organisations and health professional groups. Individuals and organisations were invited to make a submission in response to the proposed changes, and the NCSP received 87 submissions. This document summarises the feedback from the public consultation.

The consultation feedback has resulted in refinements to the proposed change to primary HPV screening.

## Guiding principles

Guiding principles for the change to primary HPV screening 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
* 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.

## Key themes from submissions

There were consistent key themes in the submissions about the:

* number of women getting a three-yearly cervical screen and varying rates amongst different ethnicities and population groups (cervical screening coverage)
* different steps in the cervical screening journey depending on the outcome of test results and other assessments (proposed screening pathway)
* change from having a cytology test every three years to a HPV test every five years (increasing screening intervals)
* possibility of increasing the age when cervical screening is available from 20 years to 25 years (changing the starting age for screening)
* possibility of women having a final HPV test between the age of 69 and 74 (five years after their last HPV test) before they leave the cervical screening programme (introducing exit screening)
* consequences for the laboratory workforce of the change to primary HPV screening (workforce impact)
* ways the cervical screening register will support the change to primary HPV screening (NCSP Register).

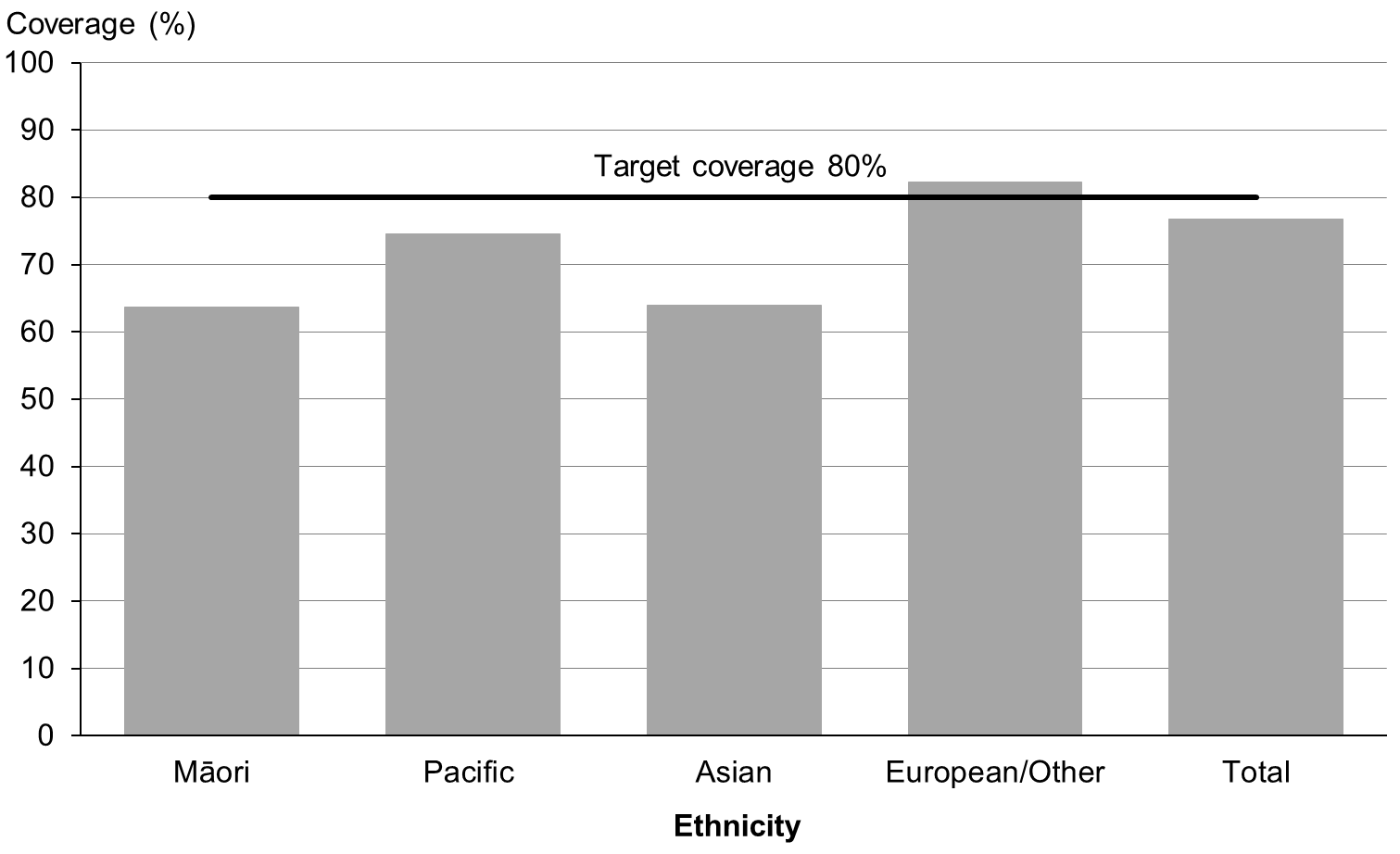
# Feedback from submissions

Below is a summary of the comments raised in the submissions as well as the 13 meetings that took place across New Zealand. The submissions raised similar themes and issues.

## Cervical screening coverage

Since the National Cervical Screening Programme (NCSP) was set up in 1990, the number of new cases of cancer has decreased by around 50 per cent and the number of women who die from cervical cancer has declined by about 60 per cent. The percentage of women participating in cervical screening has slowly risen, although gaps in coverage can be seen in Figure 1 below.

*Figure 1 – NCSP coverage (%) by ethnicity for women aged 25-69 years in the three years ending 31 December 2015*



**Key points**

1. There is a particular need to focus on improving coverage rates for Māori women (as a Treaty Partner). Māori women are still twice as likely as non-Māori women to develop and die from cervical cancer.
2. Access for Pacific women also needs to improve as they are screened less often and have a higher mortality rate than European / other women.
3. There are other groups of women who have never been screened or who are not screened every three years. These women may:

* have limited health literacy i.e. understanding of the existence of cervical screening or how to access the service
* live with a disability or other health conditions (such as obesity)
* not have a good relationship with their general practice (for example, if they owe money)
* be part of a low socio-economic groups and unemployed
* be Asian, migrant, or refugee women
* live in a remote rural area
* have experienced sexual abuse
* be older
* be afraid or anxious needing extra support
* not engaged with health services or society
* have had difficult experiences (with the health system).

1. The system may not provide an appropriate service for some women to access.

* The cost of screens and limited availability outside of general practice or health clinics is a barrier.
* The health service is challenging for women who have experienced discrimination and socio-economic hardship.
* Women only go to the doctor when they are sick (cervical screening is not seen as a priority).
* Practices are busy. This is one of many services they offer. The clinical environment is a barrier, and also the psycho-social environment within it.
* Barriers from general practice in referring to other services who could provide alternative options.

1. Inequality in access to screening is the greatest challenge for the NSU to address and the success of any change needs to be measured in terms of reducing and eliminating inequalities.

**Submission feedback**

Consultation submissions provided ideas for removing barriers that prevent women from participating in the cervical screening programme. Some of the ideas put forward are highlighted in Table 1.

*Table 1 - Cervical screening coverage submissions*

| Theme | Submitters’ feedback |
| --- | --- |
| Cost | * Ensure the free and low cost options are accessible and well-advertised. * Make cervical screens free for everyone. |
| Support services | * Improve availability of culturally specific support services for priority group women. * Have more Māori women trained to deliver cervical screening to women. * Have non-Pacific women as an option for delivering cervical screens to Pacific women. |
| Services nine to five | * Have after-hours services on evenings and/or weekends. * Mobile screening units that operate within and outside normal business hours. * Offer option for self-collected samples. |
| Clinical atmosphere | * Provide training for receptionists/front desks. * Ensure cultural competency, sensitivity, and skill of the screener. * Have flexible appointments. * Have culturally appropriate methods for invitation and recall for screenings. * Improve training and materials for staff to better support women. |
| Communication | * Improve health literacy materials and availability, including being specific to people and their locality. * Promote positive messages about the necessity of cervical screens to normalise them and remove the taboo. * Focus should also include informed consent and what to do if a woman is experiencing symptoms. * Ensure women are aware of the options, and that alternative options are freely available. * Make information available that targets men as they can be influential in supporting women to get screened. * Increase training for health professionals and practitioners to educate women about their bodies, health, and the need for cervical screens. |
| Whakamā or fear | * Establish a trusting relationship. * Cultural competence of services and smear taker is essential. * Provide timely and effective information. * The gender and the ethnicity of the smear taker can be important. * Offer option for self-collected samples. |
| Only go to the doctor when sick | * Promote cervical screening as wellness checks. * Include as part of sexual health exams. |
| Transportation and childcare issues | * Provide support with transport for screening. * Mobile screening units. * Offer option for self-collected samples. |

**NSU approach**

1. The NSU has prioritised several strategies for improving women’s access to cervical screens which will be key to supporting women following any programme change. These strategies include:
   * re-scoping the Screening Support Services contracts to provide more targeted support for women to access screening
   * providing free cervical screens for priority group women[[1]](#footnote-1)
   * identifying the geographical areas in New Zealand with the highest level of need.
2. The NSU has commissioned research on the feasibility of self-sampling as a way to reduce inequalities. Self-sampling would involve a woman taking her own vaginal sample to test for HPV. One study is currently underway in Christchurch to research the acceptability of self-sampling using a tampon. Other research groups are seeking to run pilots on self-sampling for Māori women. The results of these studies, coupled with the increasing availability and quality of self-sample kits, will inform further recommendations around self-sampling. The NSU is aware of the need for alternative options for sampling, however any self-sampling options for women need to be as effective and safe as a sample taken by a smear taker.

## Proposed screening pathway

The following describes the proposed routine cervical screening pathway for women. This pathway is intended to prevent cervical cancer in healthy women and in “special clinical circumstances” the pathway may vary, for example, women with reduced immunity may follow a different pathway to others.

*Figure 2 – Proposed screening pathway*

The primary test

* The first test performed on a woman’s sample will be an HPV test with partial genotyping. Partial genotyping means that the HPV test used will be able to tell whether the high-risk type of HPV present is type 16 or 18 or another high-risk HPV (hrHPV). These results determine the next steps in the pathway.

Women testing negative for hrHPV

* Women who test negative for hrHPV types will be advised to continue with routine 5-yearly screening.

Women testing positive for hrHPV types 16 or 18

* Women with a positive test result for hrHPV 16 or 18 will be referred directly for colposcopy[[2]](#footnote-2) assessment.
* The laboratory will automatically add on a cytology test (adjunct test), and the results of this will help the colposcopist make assessment and treatment decisions.

Women testing positive for other types of hrHPV (not 16 or 18)

* Women with a positive test result for other types of hrHPV (not 16 or 18) will have a cytology test automatically added on by the laboratory (reflex test). The results of this test will determine what happens next:
* If the cytology test shows that a woman has high grade changes, she will be referred directly to colposcopy.
* If there are no changes detected or changes are low grade, the woman will be asked to have another HPV test in 12 months’ time.
* If, 12 months later, she tests positive for any type of hrHPV, she will be referred to colposcopy and a cytology test will be done to help the colposcopist make assessment and treatment decisions.
* If, 12 months later, hrHPV tests are negative, the woman will be advised to return to routine 5-yearly screening.

Colposcopy pathway

* The pathway for women following colposcopy assessment is still being reviewed, and will be included in public consultation as part of the process of developing new programme guidelines for primary HPV screening.

What if a woman experiences symptoms?

* If a woman is concerned about symptoms she should see her doctor as soon as possible. The doctor may take a cervical smear and refer for further assessment by a specialist gynaecologist.
* Symptoms to watch for include unusual bleeding between periods, an unpleasant smelly vaginal discharge and/or discomfort, pain, or bleeding during or after sex.

**Key points**

1. The collection of cells from the cervix will be the same for women with primary HPV screening and will continue to be taken via a smear test.[[3]](#footnote-3)
2. The HPV test will be the first (primary) test performed on the cells.
3. If the HPV test is positive cytology[[4]](#footnote-4) will be used to help determine what kind of follow-up a women needs (adjunct test).
4. Women with test results that indicate they are at high risk of developing abnormal cell changes that may lead to cervical cancer will be referred to colposcopy for further assessment and/or treatment.
5. International research has found the primary HPV screening is accurate and detects more women at risk of developing abnormal cell changes than the current testing method using cytology.

**Submission feedback**

Most submitters generally supported moving to HPV primary testing as it is a more sensitive test to detect whether a woman is at risk for developing cervical cancer. Some submitters had reservations about the modelling research that the proposed changes are based on, as well as the quality of the HPV laboratory tests that would be used. Submissions about the pathway are summarised in Table 2.

*Table 2 - Proposed pathway submissions*

|  |  |
| --- | --- |
| Theme | Submitters’ feedback |
| Modelling | * The model may underestimate the sensitivity of automation assisted cytology and overestimate the sensitivity of HPV testing. * The model has not evaluated the impact of the proposed change on high risk populations such as Māori, Pacific and Asian women. * There is an over-reliance on international data and the model may not be applicable to the New Zealand situation. |
| Co-testing | * The NCSP should consider co-testing (using both HPV and cytology to test samples) at 5 yearly intervals to: * provide even greater specificity than HPV testing alone. * reduce the number of referrals to colposcopy. * provide greater assurance to stakeholders about the safety and effectiveness of moving to primary HPV testing. |
| Implementation | * The proposed change should be piloted before a national roll-out. * The NCSP should wait until more evidence is available from similar countries making this change. |
| Cytology testing | * Cytology test results should be available to triage women for colposcopy services and to inform clinical management at colposcopy. * Women testing HPV 16/18 positive and with low grade cell changes may be able to be managed with 12 monthly monitoring to reduce the number of referrals to colposcopy. * A cytology based pathway has the collateral benefit of detecting less common cancers such as endometrial, uterine and adenocarcinomas. |
| Quality of HPV tests | * Quality of HPV tests used by laboratories must be high. |

**NSU approach**

1. Modelling performed to date has incorporated New Zealand specific data and reflects how the proposed change will impact women in the New Zealand context. These outcomes are consistent with outcomes for other countries such as Australia and the United Kingdom.

The NSU has commissioned the Cancer Council of New South Wales (CCNSW) to conduct modelling that analyses the impact of the proposed change on Māori, Pacific and Asian women.

1. The NSU is not considering using a pilot as part of implementing the change to HPV primary screening in New Zealand. The International Agency for Research on Cancer and the World Health Organisation have endorsed HPV testing as the primary method for cervical screening. Pilot studies have been undertaken in other countries and findings show that primary HPV screening is safe and more sensitive than cytology.
2. Co-testing means testing all cervical screen samples using an HPV test as well as looking for cell changes with a cytology test. Evidence indicates there is minimal benefit with respect to reducing cervical cancer incidence and mortality rates compared with the proposed pathway of using primary HPV screening followed by cytology for those women who are positive for high-risk types of HPV.

## Increasing screening intervals

There was a high level of support for the proposed five yearly screening interval. Many agreed that less testing was beneficial and that primary HPV screening was safe and effective with longer intervals.

**Key points**

1. International evidence and research commissioned by the NSU has found that primary HPV screening every five years is accurate and detects more women at risk of developing abnormal cell changes than the current testing method using cytology every three years. Women with a negative HPV test are less likely to develop abnormal cell changes in the next few years than women with the negative cytology test. The clinical evidence supports the sensitivity and accuracy of primary HPV screening being safe and effective at five-yearly intervals.
2. Clinical evidence indicates that the sensitivity and accuracy of primary HPV screening is safe over a longer period than five years. Not all women will have their screen within the five-yearly recommended interval and this was considered internationally when determining the screening interval.
3. Based on evidence and best practice other countries are changing to primary HPV screening, including England, Australia and the Netherlands.
4. A woman will have a reduced number of screens across her lifetime, which will reduce the harm of screening in terms of stress and anxiety.

**Submission feedback**

With the 5-yearly interval some concern was expressed about the ability to make sure women did not fall through the gaps and were properly supported so they access their screens on time.

Submissions about the screening interval can be found in Table 3.

*Table 3 - Screening interval submissions*

|  |  |
| --- | --- |
| Theme | Submitters’ feedback |
| Women may take longer | * Women may turn up late for screening (maybe seven to ten years). * They may be difficult to track down because they have moved or changed contact details. * Women may think screens are less important if they occur less frequently. * They may forget because it’s been so long. * They may not have a good relationship with their health professional because of decreased visits. |
| Increased inequalities | * Longer screening intervals may widen gaps among Māori and Pacific women. * It may mean priority group women experience higher mortality because they don’t get screened often enough. * Under-screened and never screened women may need additional support services. |
| Safety of test | * Women may lose confidence if safety of test only done every five years. * They may feel that that less screenings will result in later detection. |
| Need for shorter intervals with some women | * Immunosuppressed women (such as women who are HIV positive, have undergone chemotherapy, or who have received organ transplants). * Women with multiple sexual partners, who commence sexual activity at a young age, or other high risk sexual behaviours. * Survivors of sexual abuse. * Women who have not been vaccinated against HPV. |
| Need for longer intervals for other women | * Older women. * Women in monogamous relationships. * Vaccinated women. * Other low risk women. |
| Not getting follow up care | * Women may be nervous or scared to follow up with treatment. * They may feel it isn’t as important or urgent. |

**NSU approach**

1. Screening coverage rates will remain a priority of the NSU and the impact of any change on screening behaviours will be closely monitored to ensure women do not move to a screening interval longer than the recommended five years.
2. Mitigation strategies will be put in place to support women in getting screened regularly.

* Improving invitation and recall services for women to get screened will be necessary. This will include changes to the cervical screening register so that health professionals can improve contact with women who are due for screening as well as have better access to women’s records.
* Ensuring support for follow up care will be important.
* Communication strategies and materials will also be developed to educate health professionals as well as women about primary HPV screening and the safety of the HPV test. Additional training may be necessary as well.

## Changing the starting age for screening

In the current pathway, cervical screening begins at age 20. The consultation document outlined a proposed starting age of 25. Raising the starting age for cervical screening elicited the most discussion in the submissions and consultation meetings.

Many submitters expressed concern that raising the starting age of screening may have a negative impact on the health of young women.

**Key points**

1. HPV infection and the cell changes associated with it are common in women (approximately one in three) under the age of 25, particularly those who have not been immunised against HPV. In younger women, these infections commonly disappear on their own without treatment. Screening women under the age of 25 could lead to over diagnosis and over treatment.
2. Cervical cancer in the under-25 age group is rare and not usually detected through a screening programme.
3. Cervical screening identifies abnormalities that if left untreated might develop into cancer. An abnormal screening test leads to further investigation. If an abnormality is identified on the cervix, then part of the cervix may be removed to treat the abnormal area. This treatment can increase the risk of premature births for women who become pregnant after their treatment.
4. There is New Zealand and international evidence that cervical screening for women under 25 is not effective at reducing the number of women in this age group who get cervical cancer. It also does not reduce the number of cervical cancer deaths in women under 25 years of age. This is why countries such as England, Australia, and the Netherlands are changing the commencement age for their screening programmes to 25 years of age or older.

**Submission Feedback**

The majority of comments raised concern about increasing the starting age from 20 to 25 years, only a minority support the proposal:

*Table 4 – Screening starting age submissions*

|  |  |
| --- | --- |
| Theme | Submitters’ feedback |
| Alternative ideas | * Maintain cytology testing for a trial period, having at least one screening test before the age of 25. * Having earlier start dates for screening women with a higher risk of developing cervical cancer. |
| Late identification | * Harms from delayed detection and/or treatment. * Increased number of deaths. |
| Higher risk | * Young women may have higher risk of developing cervical cancer because of: * an earlier age of commencing sexual activity * having multiple sexual partners * lower vaccination rates than other countries * being survivors of sexual abuse. |
| Lack of engagement | * Delays contact with a health provider. * Young women don’t accept the importance of health screening. * Vaccinated women think don’t need to be screened. |
| Equality | * Increase inequalities among Māori, Pacific, and under-screened women. |
| Supportive | * Risk for vaccinated women low. * Cancers often not detected through screening. * HPV infections commonly disappear without treatment. * Treatment can increase risk of premature births. |

**NSU approach**

1. Before making a final decision about whether the starting age will remain at 20 years or change to 25 years additional analysis will be undertaken to:

* look at the number of cases and patterning of cervical cancer in New Zealand women
* assess the impact of New Zealand’s HPV vaccination levels on the number of cases of cell abnormalities in the 20-24 year age group
* assess the impact of the New Zealand’s HPV vaccination levels on the accuracy of cytology testing.

1. The starting age for screening and the process for the 20-24 year age group will be confirmed later in 2016.

## Introducing exit screening

In the current screening pathway, women have a cytology test at the age of 69. In the proposed pathway for primary HPV screening, women will either have an HPV test at the age of 69 or they may have an exit HPV test between the ages of 69 and 74 (ie five years after their last screening).

**Key points**

1. In NSU commissioned modelling an exit test in women aged 69-74 years is predicted to reduce the number of cancer cases and deaths from cancer by a further four to seven percent.

**Submission feedback**

The majority of submitters supported an exit cervical screening for women aged 69 to 74. Many felt longer life expectancy coupled with longer periods of sexual activity made an exit screen necessary.

Submissions about the introduction of an exit cervical test may be found in Table five.

*Table 5 – Introducing exit screening submissions*

|  |  |
| --- | --- |
| Theme | Submitters’ feedback |
| Increased risk for HPV because of additional sexual partners | * Relationship breakdowns and new sexual partners later in life may result in longer periods of sexual activity. * Research has found a slight increase in development of HPV infections in women over 40. * There has been a documented rise in sexually transmitted infections in rest homes, which may also leave older women susceptible to HPV infections. |
| Additional safety | * Women are generally living longer so a longer screening programme with a later exit screen may be safer. |
| May decrease cervical cancer mortality | * International research shows up to a 5% reduction in cervical cancer mortality if screening is extended to older women. |
| Post-menopausal women | * Concern about the level of discomfort or pain post-menopausal women may experience. |
| Benefits | * Need additional evidence to prove that it is beneficial for women over the age of 69 to have an exit screen. |

**NSU Approach**

1. The NSU will work with health professionals to ensure proper guidance and training for providing exit screens to women over the age of 69, including how to support women in this age group who test positive for an HPV infection.
2. The NSU will also monitor the impact of the change to ensure the safety and effectiveness of an exit screening.

## Workforce impact

The primary impact on the workforce will be in the laboratory particularly the cytology workforce. In the change to primary HPV screening we also need to keep all of the health sector engaged and aware of the changes and what it means for them.

**Key points**

1. It is very likely that the number of cytology tests undertaken in New Zealand will reduce over time. Skilled cytology staff will still be needed to analyse cytology samples as all women who have a positive HPV test will also have a cytology test (reflex test).
2. As the changes are implemented there may be some temporary increase in volumes for laboratory and gynaecology services.
3. All those involved in cervical screening both women and the health sector will be kept informed about changes to the cervical screening programme with the move to primary HPV screening.

**Submission feedback**

At several of the consultation meetings held around the country, the discussions focused on the impact of the proposed changes on the laboratory workforce. Primary concern was on the ability of cytology staff to maintain current or increased demand for services, although potential pathology and histology staff shortages were also noted.

A few submitters also expressed an interest in keeping primary care, including smear takers, informed about changes associated with the move to primary HPV screening.

*Table 6 – Workforce impact submissions*

| Theme | Submitters’ Feedback |
| --- | --- |
| Change screening pathway | * Use a cytology test to assist colposcopy services in assessment and treatment of women. |
| Loss of skilled staff | * Proposed changes are happening too quickly and there’s too little information. * Uncertainty has caused trained staff to leave. * Will lose staff to overseas or other careers. * Can’t get skilled workforce back once it’s gone. * Cytology staff perform non-gynaecological services as well, so could impact other services. |
| Challenges with recruiting new staff | * Lack of new staff because fearful of job security. * Education training programmes are decreasing. * No new trained staff coming through. * Fearful of job security and/or timelines for changing to primary HPV screening. |
| Handling increased demand for services | * Difficulty maintaining current level of services, reduced staff may exacerbate backlog. * May not be enough pathology staff to support additional histology referrals with primary HPV screening. * Will there be additional resources for colposcopy and other services? * Will timeframes for referrals and reporting be amended? * Need to understand lab and staff requirements soon. |
| Ways to keep staff engaged | * Keep informed and provide regular updates about changes. * Provide support to staff through the transition. * Incentivise retention during transition. * Training for new careers after change to primary HPV screening. * Alternate career pathways (such as cytology staff being re-trained for histology). * Ensure training or re-training is internationally-qualified. * Need certainty of lab contracts. * Lab contracts should include diagnostic support at secondary and tertiary hospitals. * Need predictable lab volumes. |
| Training / communication | * Regular, local training courses for smear takers, but with the same content across the country for consistency. * Create clear, concise educational materials for providers and clients that are focused on informed consent. * Create booklets, flowcharts, cards, etc. about the benefits of the change to primary HPV screening. * National media campaign, including resources and web links with information. * Provide regular updates on the NSU website. |

**NSU approach**

1. The NSU is undertaking research to better understand laboratory and staff requirements leading up to and after changing to primary HPV screening. The NSU will also work closely with laboratories and skilled staff before any changes take place to identify the best ways to support the workforce. These strategies will ensure a smaller, but equally skilled workforce remains in place to meet demand for services.
2. The NSU has made cytology testing a part of the pathway for primary HPV screening. All women who test positive for HPV (whether 16/18 or other) will have a cytology test to support colposcopy referrals and management. This means that a cytology test will be done on the original sample collected for the HPV test in order to determine a woman’s risk and subsequent level of follow up care.
3. The NSU is developing a communication strategy with the dual focus of providing women with detailed information about the changes to the screening programme as well as equipping providers with the knowledge and tools to successfully carry out their roles. Primary care will be engaged throughout the development of new consumer-friendly materials for primary HPV screening.

## NCSP Register

In the current programme, women are invited and recalled for their cervical screening through the general practice they visit. Follow up reminders are then sent by the NCSP Register which monitors when women are due for cervical screens.

**Key points**

1. Introducing primary HPV screening requires the NCSP register to be changed for the different screening pathway.
2. Changes to the register could be big or small.

**Submission feedback**

Submitters largely took this as an opportunity to discuss potential improvements to the NCSP Register. Feedback for who should have responsibility for inviting and recalling overdue women varied considerably.

*Table 7 – NCSP register submissions*

| Theme | Submitters’ Feedback |
| --- | --- |
| How are women invited / recalled | * Variety of methods including letters, emails, texts, phone calls, and face-to-face. * Flexibility for health professionals to use the method that works best for a woman or a group of women. |
| Responsibility for invitation and recall | * General practice should have complete responsibility. * NCSP Register could serve as a safety net which could complement the invitation and recall from general practice. * NCSP Register should be a population-based register with centralised invitation and recall. |
| Linkages | * Link with other registers to provide full access to a woman’s screening and immunisation history. |
| Development | * Include smear takers and health professionals in the re-development of the NCSP Register. * Have the Register available online. * Needs to be more user-friendly and accessible, including direct query by health professional. |

**NSU Approach**

1. The NSU has a work stream specifically for Register development and will consider the core functions and options for improvements. This may include the development of an easier-to-use interface.
2. The health sector will be engaged throughout the process so that any changes improve functionality, especially at the user end.

# Next steps

1. The NCSP will move to implementing, in 2018, cervical screening using a primary HPV test with partial genotyping for HPV 16/18, for women aged 25 to 69 years.

* Adjunct cytology will be done in women who test positive for HPV16/18. These women will have cytology (using the same sample) so that cytology results are available at colposcopy. All women with HPV16/18 will be immediately referred to colposcopy.
* Reflex cytology will be done in women who test positive for other HPV types. These women will have cytology (using the same sample) with referral to colposcopy only if high grade cell changes are found. Women with no cell changes or low grade changes will have a repeat HPV test 12 months later.
* The screening interval will be five years.
* Exit HPV testing of women will be done between 69 and 74 years.

1. The NCSP will undertake further work to:

* assess the harms and benefits of maintaining the screening starting age at 20 years, including additional analyses of:
  + the incidence and patterning of cervical cancer in New Zealand women
  + the impact of New Zealand’s HPV vaccination levels on the incidence of high grade lesions in the 20-24 year age group, and also on cytology test performance.
* assess cytology screening in women aged 20-24 years for a transitional period, depending on the assessment of harms and benefits of screening this age group
* evaluate the test performance and quality of self-collected HPV samples before including self-sampling as a screening pathway
* continue to review any emerging evidence about the clinical merits of co-testing and cost-effectiveness
* continue to engage with the public, community based organisations and health professional groups including those opposed to primary HPV screening.

1. 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 the 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 as we work towards implementing primary HPV screening.

1. Development of guidelines.

* An expert group has been assembled to develop the NCSP clinical guidelines.
* The clinical guidelines will be available for health sector and wider public consultation.
* Once the guidelines have been agreed they will inform the development of the NCSP National Policy and Quality Standards.

1. Workforce modelling.

* Modelling will be undertaken in conjunction with Health Workforce New Zealand to better understand the impact on the workforce involved in cervical screening (not just the laboratory workforce) both during the transition and on-going.
* The workforce modelling will determine next steps.

1. Self-sampling research.

* The Ministry of Health is funding further research about the acceptability and feasibility of self-sampling in New Zealand and the effectiveness of different self-sampling devices.

1. Redeveloping the NCSP Register.

* The NSU has a work stream specifically for Register development and will consider the core functions and options for improvements and ensure the Register is fit for purpose.

1. Priority Group Women includes (a) women aged 20–69 years who are Mâori, Pacific, Asian; or (b) any other woman aged 30–69 years who has never had a cervical smear or has not had a cervical smear for more than five years. [↑](#footnote-ref-1)
2. Colposcopy involves a specialist gynaecologist (colposcopist) examining and/or treating the vagina and cervix with a special microscope known as a colposcope. [↑](#footnote-ref-2)
3. A smear test involves a smear-taker (a nurse or doctor) opening the vagina with a metal or plastic instrument (speculum) which allows visualisation of, and easy access to the cervix for collecting cervical cells. The smear-taker uses a thin broom or brush to take cells from the cervix; cells are then placed into liquid and sent to the laboratory for testing. [↑](#footnote-ref-3)
4. Cytology is the laboratory test used to look at cervical cells under a microscope to see whether there are any abnormalities in the sample. Cell abnormalities are usually graded as low or high and are associated with different levels of risk of developing cervical cancer. [↑](#footnote-ref-4)