Section 2: HPV Primary Screening

Screening age and interval

HPV Primary Screening is recommended for those in Aotearoa New Zealand who have a cervix and are aged between the ages of 25 - 69.

Participants should be encouraged to participate in the NCSP if they are a person/whānau with a cervix, aged 25 to 69, who:

- Has ever had intimate skin-to-skin contact or any sexual activity (even if they haven't been sexually active for decades)
- Has only had non-penetrative sex (i.e. Oral sex)
- Is straight, gay, lesbian, bisexual, or queer
- Is transgender, gender diverse, or non-binary and has a cervix
- Has only been with one sexual partner
- Has had the HPV vaccination or not
- Is pregnant or has had a baby
- Has been through menopause

All potential participants are notified at 25 years of age when they are eligible for screening, based on information held on the NHI population database. The notification of eligibility for screening is centrally generated by the NCSP Register. Where a primary/community care provider is not recorded for an individual, information regarding alternative places where screening is available locally can be found will be provided to participants.

Screening for participants under the age of 25

Cervical screening is **not recommended** for people aged less than 25 years, even when they have experienced early sexual contact. There is no evidence to support screening participants under the age of 25 as the harms outweigh the benefits of screening for participants in this age group.

Participants under 25 years of age who have commenced screening should be recalled when they are next due for screening.

For young participants who are sexually active, and who have been immune deficient for more than five years, a single HPV test between 20 and 24 years of age could be considered on an individual basis (regardless of HPV vaccination status).

It is important to encourage participants to engage with cervical screening from the age of 25.

Exit testing for participants aged 65 to 74

Older people who are unscreened or under-screened remain at risk of cervical cancer because of potential undetected cervical lesions. [1,2] It is therefore important to have adequate cervical screening prior to ceasing screening at age 69. People aged between 65 and 74 years who have not met the exit criteria should have HPV test.

Participants between the ages of 65 and 74 do not need an exit test if either of the following exit criteria have been met:

- They have had two consecutive negative cytology samples after the age of 62, in the cytology-based programme (one of which was over the age of 65)
- They have had an HPV not detected result after age 65 years (or age 67 if immune deficient)

If a participant requires an HPV exit test and the result is HPV not detected the participant can cease screening. If HPV is detected they should follow these management guidelines, as a new primary screening test result.

An HPV test **is not required** for participants who were previously unenrolled in the cytology screening programme because they had completed the exit requirements of the cytology programme.

Participants over the age of 65 who continue to have an HPV detected result should not exit the programme until they have an HPV not detected test result. [3] However, in some circumstances the exit criteria may not be met and the decision to continue management in participants aged 70 years and older with HPV detected (any type) and negative, ASC-US or LSIL cytology should be based on a discussion between the patient and their health care provider.

Consideration should be given to the participant's previous cervical screening history when making decisions regarding ongoing management and risk of cancer. The decision to exit screening may be determined by the participant's overall wellness and medical co-morbidities which may mean that their life expectancy or

quality of life is not enhanced by ongoing testing and intervention.

Screening for participants aged 75+ years

The NCSP **does not recommend** cervical screening in asymptomatic people over the age of 75 years. People over the age of 75 years will be unenrolled from the programme, unless they are in follow-up after a previous abnormality.

For unenrolled participants, management is the responsibility of the clinician ordering the test. If HPV or cytology testing does occur after unenrolment because of age, the results will be recorded by the NCSP Register but will not be tracked so reminder letters will not be sent to the participant.

RECOMMENDATIONS – EXIT TESTING FOR PARTICIPANTS AGED 65-74	
R2.01 Participants aged 65-74 exit testing	**Consensus-based recommendation** Participants between the ages of 65 and 74 who have not met the exit criteria should be invited to have an HPV exit test.
R2.02 Participants aged 65-74 years with a test result of HPV not detected (exit testing)	**Evidence-based recommendation** Participants aged 65-74 years who have an HPV not detected screening test result can cease screening and will be unenrolled from the NCSP.
R2.03 Participants aged 65-74 years with a test result of HPV detected	**Consensus-based recommendation** Participants aged 65-74 years who have an HPV detected (any type) screening test result should follow the clinical practice guidelines for managing participants after HPV testing.
R2.04 Screening for asymptomatic people aged 75+ years	**Practice point** Screening is **not recommended** for asymptomatic people aged 75+ years of age who have already been unenrolled from the NCSP. Management the responsibility of the ordering clinician. If HPV or cytology testing does occur after unenrolment because of age, the results will be recorded by the NCSP Register but will not be tracked and reminder letters to the participant will not be issued.

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HPV testing options for participants

The primary HPV screening programme provides participants with a choice of how their screening test is performed. **It is important screen takers** discuss the options available to participants so they can make an informed decision about which test is most suitable for their individual circumstances. Table 1 provides guidance for screen takers when discussing these options with participants.

A meta-analysis assessing the accuracy of HPV testing on self-collected vaginal samples versus clinician collected samples has reported HPV vaginal swab samples are as accurate as a clinician taken cervical sample when using PCR with DNA-based HPV testing.[1,2] All HPV testing systems used in New Zealand laboratories for processing and reporting HPV results from vaginal swab samples, are required by the NCSP to use PCR DNA-based HPV testing methods.

Māori, Pacific and Asian people have experienced lower cervical screening coverage rates compared to people of other ethnicities. Cervical screening rates have been declining for Māori and Pacific people since 2017.[1,2] The barriers to cervical screening are multifactorial and complex and the option of vaginal swab self-testing could improve cervical screening coverage among under and unscreened participants.[3-8] HPV self-sampling studies in Aotearoa New Zealand have shown high levels of acceptability of the test among Māori, Pacific and Asian participants. Studies have demonstrated high rates of Follow-up following an HPV detected

result on a vaginal swab for either a repeat cervical sample or colposcopy. It was reported some participants required additional support to be provided to engage with follow-up cervical cytology and colposcopy.[4-7]

Participants have the option of an HPV vaginal swab sample (self-test or clinician assisted) or a clinician taken cervical sample using LBC taken during a speculum examination.

Cervical sample for HPV testing

A cervical sample is a clinician taken sample which is placed in a Liquid Based Cytology (LBC) vial to test for HPV. If HPV is detected, reflex cytology will be performed to assist with determining the next step in the screening pathway. Reflex cytology means that the laboratory will automatically add on a cytology test using the same LBC sample. If the HPV result is not detected, reflex cytology will not be performed.

Vaginal swab sample for HPV testing

A vaginal swab sample can be collected as a self-sample or clinician assisted sample when the participant is unable to perform the swab of the lower vagina, or requests assistance, for example, if they are not confident about taking the vaginal swab adequately. If HPV Other is detected using a vaginal swab sample, a clinician taken cervical sample for cytology is recommended.

A vaginal swab **is not recommended** for participants who have signs or symptoms suggestive of cervical cancer, including persistent post coital, intermenstrual or post-menopausal bleeding or unexplained persistent vaginal discharge. It is important that these participants have a clinical assessment and a co-test for both HPV testing and cytology performed.

Co-test sample for HPV testing with cytology

A co-test requires a clinician taken cervical sample where both HPV and cytology are reported. This **is recommended** in specific clinical situations. Participants requiring a co-test include those:

- With symptoms suggestive of cervical cancer (e.g. Have unexplained postcoital bleeding or persistent intermenstrual bleeding, postmenopausal bleeding or unexplained persistent vaginal discharge)

- Undergoing Test of Cure co-test following treatment of HPV detected adenocarcinoma in-situ (AIS)
- Treated for adenocarcinoma in-situ (AIS), where the HPV status prior to treatment was HPV not detected or unknown.
- Treated for a HPV not detected high grade squamous abnormality

Co-testing is not required for breakthrough or irregular bleeding due to hormonal contraception or a sexually transmitted infection, recurrent vaginal infections such as bacterial vaginosis or candida, heavy menstrual bleeding, pelvic pain or contact bleeding at the time of obtaining a cervical sample for a primary HPV screening.

Participants with post coital bleeding with an HPV not detected and negative, ASC-US or LSIL cytology do not routinely require colposcopy. [10-12] If there is macroscopic suspicion of cervical cancer on clinical examination referral to colposcopy clinic should occur urgently. **It is important** participants with post coital bleeding are managed as per the local health pathways and appropriate clinical examination is undertaken.

Participants with HPV not detected and negative, ASC-US or LSIL cytology will be recommended to have a repeat HPV test in 5 years as management of symptoms is not part of the cervical screening programme.

Participants with abnormal vaginal bleeding should be managed as per local health pathways as they require full investigation as clinically indicated.

Table 1: National Cervical Screening Programme Clinical Guidelines Cervical Screening: Supporting your patients to make the choice

	Clinician taken cervical sample	HPV vaginal swab sample
Are both sampling types accurate?	Both methods have equivalent sensitivity for the detection of HPV and CIN2+/AIS[12]	
Do they Identify HPV infection?	Yes	Yes
Is reflex cytology and co-testing possible?	Yes	No
Indicated for those: • Those who are eligible for cervical screening, including during pregnancy • Follow-up in the pathway where an HPV test is required • Those undergoing Test of Cure HPV test following treatment for an HPV detected HSIL, following regression of CIN2 or discordance with ASC-H and HSIL cytology and not confirmed histologically	Yes	Yes
• Patients who have signs and symptoms of cervical cancer such as unexplained postcoital or intermenstrual bleeding, post-menopausal bleeding, unexplained persistent abnormal vaginal discharge – see footnote [3] • Those undergoing Test of Cure co-test for HPV detected AIS, following atypical glandular cytology not confirmed histologically and HPV not detected HSIL • Those undertaking annual co-testing after treatment for HPV not detected or unknown HPV status adenocarcinoma-in-situ	Yes	No
Management of participants in whom HPV is not detected. Approximately 90% of participants having an HPV screening test	Return in 5 years Return in 3 years if immune deficient	Return in 5 years Return in 3 years if immune deficient
Management of participants in whom HPV Other is detected Approximately 8.0% of participants having an HPV screening test	Reflex cytology will be performed on using the original sample; no need for a further sample to be taken	Return for clinician-collected cervical sample for cytology within 6 weeks. The incidence of HPV detected Other is age dependent. Approximately 5% of participants will have high grade cytology.
Management of participants in whom HPV 16 or 18 is detected Approximately 2% of participants having an HPV screening test	Refer to colposcopy	Refer to colposcopy
Management of an invalid or unsuitable HPV test	If cytology has been reported, offer vaginal swab within 4 weeks.	Repeat within 4 weeks

[1] Arbyn et al, detecting cervical precancer and reaching underscreening women by using HPV testing on self samples updated meta-analyses BNJ 2018 363 :k4823

[2] Saville et al, Analytical performance of HPV assays on vaginal self-collected vs practitioner-collected cervial samples: the SCoPE study, Journal of Clinical Virology 2020, doi: https//doi.org/10.1016/j.jcv.2020.104375

[3] Contesting is not required for breakthrough or irregular bleeding due to hormonal contraception or a sexually transmitted infection, heavy menstrual bleeding, or contact bleeding at time of obtaining a routine cervical screening test sample

RECOMMENDATIONS – HPV PRIMARY SCREENING	
R2.05 An HPV test replaces the cytology screening test	**Practice point** Participants have the choice of sampling methods for taking their primary HPV screening test.
R2.06 Clinical consultation prior to HPV screening	**Practice point** All participants require a consultation with clinical history and informed consent history prior to HPV testing
R2.07 Informed choice for participants about screening options	**Practice point** When deciding whether to choose a vaginal swab or clinician collected cervical sample, people must be given clear information by screen takers about the likelihood that HPV may be detected and, if so, the follow-up tests that will be required. If a participant / whānau chooses a vaginal swab the screen taker must provide information about how to collect the sample and how they will receive the test results. Among those attending for a regular screening test, approximately 2% will have HPV detected 16 or 18 and approximately 8% will have HPV detected Other although the proportion of those with HPV detected Other varies by age. Participants also have the option of having a clinician taken cervical sample for HPV screening. Some participants will require a co-test, and this will be determined by their screen taker, based on the participants clinical and screening history.
R2.08 Ensure participants and whānau are provided with information about HPV and cervical screening	**Practice point** Participants and whānau should be provided with advice and information regarding HPV testing and cervical screening. It is important to discuss the role of the NCSP and gain informed consent. Provide NCSP resources to participants and whānau where appropriate, at time of screening and when notified of results.

R2.09 Assistance with vaginal swab collection	**Practice point** Participants who have difficulty collecting a lower vaginal sample by themselves can be assisted to do so by the provider. The provider can collect the vaginal sample using a self-collection swab without using a speculum.
R2.10 Settings where self-testing can be performed	**Practice point** Vaginal swabs can be obtained from a range of health care settings. Swabs can be performed in community settings or the home.
R2.11 Support for cervical screening	**Practice point** Ask all participants/whānau whether they require assistance or support to attend cervical screening. Consider transport, cultural support and where appropriate, offer referral to Support to Screening Services.
R2.12 Use of topical estrogen before clinician taken cervical samples	**Practice point** A short course of vaginal estrogen therapy is recommended in post-menopausal participants. It may also be useful for participants with vaginal atrophy associated with progestogen contraception or people using testosterone therapy. The recommended course of vaginal estrogen treatment is nightly for 3 weeks and should be stopped 2 nights prior to a cervical sample being taken. The reason for the use of vaginal estrogen should be explained to participants. (to reduce discomfort from the speculum and to improve the diagnostic accuracy of cytology).
R2.13 Use of endocervical brush for sampling in participants aged 50 and over	**Practice point** When taking a cervical sample or co-test an endocervical brush should routinely be used in participants aged 50 and over to ensure adequate sampling of the endocervical canal. As participants age the transformation zone extends into the endocervical canal. It is important for participants use vaginal estrogen prior to cervical sampling if post-menopausal.

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Transitioning into the HPV screening programme

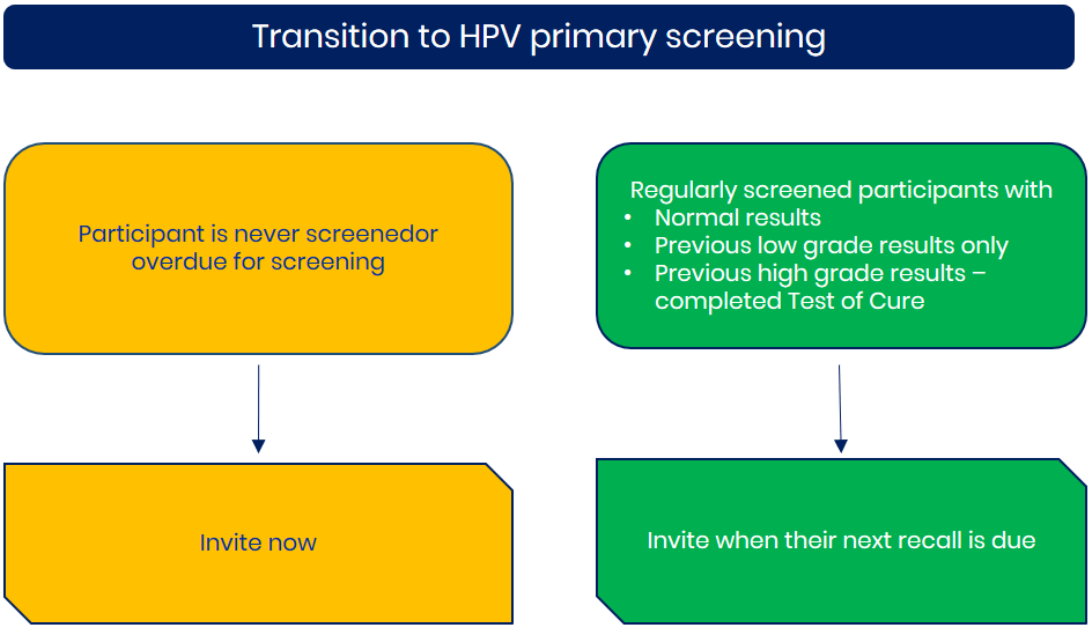
Participants transitioning from the previous cytology screening programme are at different points on the screening pathway and need to be transitioned safely into the new HPV primary screening programme. These transition recommendations differ from the primary screening recommendations and are to be used only when participants are transitioning into the HPV screening pathway for the first time.

People who have never been screened and those who are overdue for screening should be invited now, as the HPV primary screening programme has already commenced. People who are up to date with screening with no previous abnormal results (i.e., those regularly screened as well as those previously under-screened participants who have still had at least one negative cytology screening test within the last three years) should have a primary screening HPV test when their recall is next due (Figure 1).

Participants under 25 years of age who have commenced screening will be recalled when they are next due for screening.

Participants with a previous cytology abnormality who have been returned to regular three-yearly cytology screening should have a primary HPV screening test when they are next due for screening. This includes participants who have successfully completed a Test of Cure following a previous high-grade abnormality.

Figure 1: Transition to HPV primary screening



Participants with previous ASC-US or LSIL cytology results taken in the cytology screening programme.

Participants with ASC-US or LSIL who were not returned to regular three-yearly cytology screening in the cytology screening programme, should have an HPV test when their recall is next due. If the HPV result is not detected, the participant can return to regular interval HPV screening and will be recalled in 5 years for their next HPV screening test (or in 3 years if immune deficient). This includes participants who had previous ASC-US or LSIL cytology with HPV not detected results previously, and had already been recalled for 12-month follow-up testing in the cytology screening programme.

For those with previous ASC-US or LSIL who were not already returned to regular interval screening by having sufficient follow-up negative tests in the cytology programme, should follow these guidelines depending on the result of their first HPV screening test:

1. Participants with an HPV not detected test result can return to regular interval screening.

2. Participants with HPV detected Other on vaginal swab should be recalled for cytology. If cervical sample reflex or follow up cytology is negative, ASC-US or LSIL cytology the participant should be recalled for a repeat HPV test in 12 months. If the cytology is reported as high grade the participant should be referred to colposcopy.
3. Participants with a test result of HPV detected 16 or 18 should be referred to colposcopy with any cytology result, including unsatisfactory cytology. If the HPV test was a vaginal swab collected sample and a cytology result is not available, cytology will be taken at the colposcopy visit.

Participants with previous HSIL or Glandular abnormalities

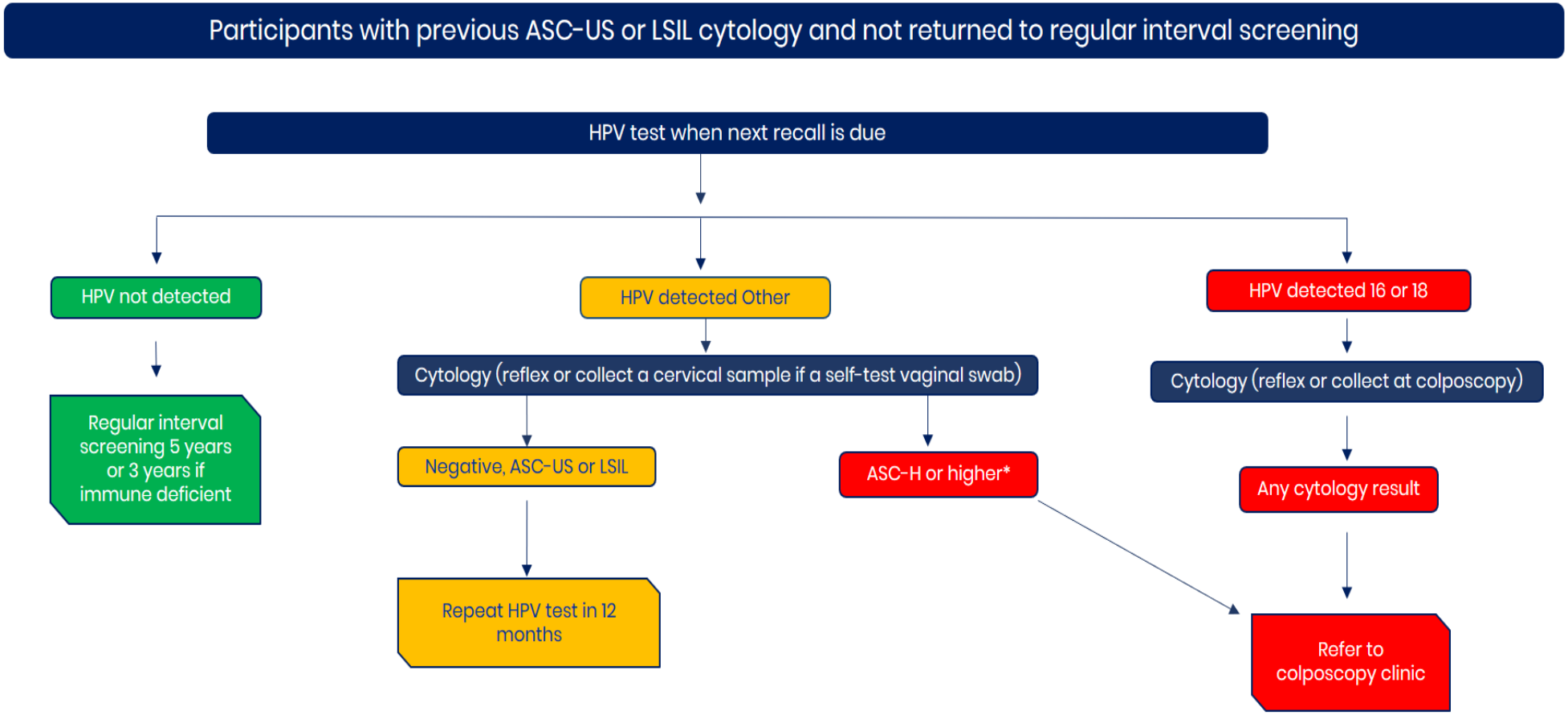
Participants with a previous high grade squamous abnormality or any previous glandular abnormality (excluding HPV negative or unknown HPV status AIS) should complete a Test of Cure before commencing HPV primary screening.

Refer to the new Test of Cure pathway for participants with a previous high grade squamous abnormalities as the Test of Cure testing management has changed (refer to section 8)

A Test or Cure is not required for those who have had cytology reports of atypical endometrial cells because endometrial abnormalities are not caused by HPV infection.

If referral to colposcopy was recommended in the last cytology report and the colposcopy visit has not occurred, the first event in the new programme should be a colposcopy.

Figure 2: Transition to HPV Primary Screening: Participants with previous ASC-US or LSIL cytology and not returned to regular interval (three yearly or one-yearly if immune deficient) screening in the cytology screening programme.



Participants with a previous HPV not detected result

For those who have already had HPV tests in the previous cytology based screening programme:

Those who have had an HPV not detected result using validated HPV test technology and no subsequent abnormal results in the current cytology programme, should be recalled in three years or one year if immune deficient. Participants who had previous ASC-US or LSIL cytology with HPV not detected should be recalled as per the last laboratory recommendation in 12 months.

RECOMMENDATIONS – TRANSITION TO HPV PRIMARY SCREENING	
R2.15 Recall for screening	**Practice point** Those who have participated in the primary cytology screening programme and have not had any previous abnormality or have been returned to regular screening after treatment/follow-up, should be recalled for an HPV screening test when their recall is next due.
R2.16 HPV testing for participants in follow-up after ASC-US or LSIL	**Practice point** Participants with ASC-US or LSIL in the cytology screening programme who had not returned to regular 3-yearly screening on the day of transition (12/9/23) should have an HPV test when their recall is next due. If the HPV result is not detected the participant can return to regular interval screening. Participants with HPV detected Other on vaginal swab should be recalled for cytology. If the repeat or reflex cytology (cervical sample) is negative, ASC-US or LSIL a repeat HPV test should be repeated in 12 months. Participants with high grade cytology should be referred to colposcopy. Participants with a test result of HPV Detected type 16/18 should be referred to colposcopy with any cytology result, including unsatisfactory cytology. If the HPV test was a swab collected sample and a cytology result is not available cytology will be taken at the colposcopy visit.
R2.17 Colposcopic management of prior cytology detected abnormalities should continue	**Practice point** Participants who have been referred for colposcopy following a cytologic abnormality in the cytology screening programme should continue their colposcopic management according to these guidelines.

RECOMMENDATIONS – TRANSITION TO HPV PRIMARY SCREENING	
R2.18 Prior treatment for HSIL and Test of Cure	**Practice point** Participants treated for HSIL (CIN2/3) in the cytology screening programme and who are undergoing or have not yet started a Test of Cure, should complete a Test of Cure HPV test in accordance with these guidelines. This can be a vaginal or cervical sample. Participants who have HPV detected (any type) during Test of Cure surveillance should be referred to colposcopy.
R2.19 Prior treatment for HPV not detected HSIL and Test of Cure	**Practice point** Participants treated for HPV not detected HSIL (CIN2/3) in the cytology screening programme and who are undergoing or have not yet started a Test of Cure, should complete a Test of Cure co-test in accordance with these guidelines. Please refer to section eight for guidance.
R2.20 HPV testing for those with past cytologic glandular abnormalities, except those with atypical endometrial cells	**Practice point** Participants who were referred to colposcopy because of atypical glandular cells (except atypical endometrial cells) in the cytology programme, and have not attended, should be encouraged to attend colposcopy. Participants with a previous atypical glandular cell cytology result (except atypical endometrial cells) and no subsequent abnormality on histology (diagnostic punch biopsy or treatment) should complete a Test of Cure co-test before commencing HPV primary screening. Those who have not had any histology reported since the atypical glandular cells cytology result (except atypical endometrial cells), should undergo a Test of Cure co-test. This includes those with historic atypical glandular results where colposcopy was not performed.
R2.21 HPV testing for those with a past cytology result of atypical endometrial cells	**Practice point** Participants who have had a previous cytology report of atypical endometrial cells should have a primary screening HPV test when their recall is next due if either of the following applies: • They have already been investigated by specialist services following their report of atypical endometrial cells and discharged back to primary healthcare • The cytology report of atypical endometrial cells was more than three years previously.

	Where neither of these two conditions applies, referral to specialist gynaecology services is recommended. A Test of Cure is not appropriate as endometrial lesions are HPV negative.
R2.22 Prior treatment for HPV detected (any type) Adenocarcinoma in situ (AIS)	**Practice point** Those who have been treated for HPV detected AIS with complete excision in the cytology screening programme can be discharged to primary care for follow-up. They should complete a Test of Cure co-test and can then return to regular interval screening on completion of the Test of Cure. Participants undergoing a Test of Cure co-test who have a test result of HPV detected (any type) should be referred to colposcopy. Participants undergoing a Test of Cure co-test who have a high-grade cytology result (ASC-H, AGC, AIS or higher grade) should be referred to colposcopy, irrespective of the HPV test result. Those with an HPV not detected and low grade cytology should have a repeat co-test in 12 months.
R2.23 Prior treatment for HPV negative or unknown HPV status Adenocarcinoma in situ (AIS)	**Practice point** Those who have been treated for AIS in the cytology screening programme where the HPV status prior to treatment was not detected or is unknown, should have annual co-testing unless they have had a total hysterectomy with negative margins, in which case they can stop screening. Please refer to Section 9: Management of glandular abnormalities for guidance regarding the length of time that annual co-testing should continue after complete local excision of AIS, where the HPV status prior to treatment was not detected or is unknown.
R2.24 Education and awareness for participants and whānau	**Practice point** Guiding participants and whānau through the change and what this means for them is particularly important during the transition to the HPV primary screening programme.