Goodfellow Webinar September 2022

Questions and Answers

National Cervical Screening Programme

Questions	Answers
1. Why start in July 2023? A lot of our patients especially under-screened or unscreened are very keen now.	We recognise that many people are keen for this programme to start. Introducing HPV primary screening requires significant changes to clinical guidelines, reorganisation of laboratories and the build of a new Register that can support the clinical pathway, and critical monitoring the ensures participants are safely managed through the screening pathway. This also allows time for training staff and developing resources to support participants choices . The funding for HPV primary screening was announced in mid-2021, and this intervening time is necessary to get the new systems functional for the go-live date in July 2023.
2. Is self-testing allowed, what choices are available and why is clinical oversight necessary?	Self-testing will be available in primary health care and community settings from July 2023. It is one of three choices for the participant. They can choose between a self-test, having a swab sample taken by a clinician, or having a clinician take a Liquid-Based Cytology (LBC) sample (using a speculum) that can be used for HPV testing as well as cytology if needed. "Self-testing" is a test taken by the participant in any setting acceptable to them, including at home, with the health provider providing clinical oversight. Clinical oversight means that the health professional is responsible for giving advice and getting the informed consent of the participant; providing the test kit to the participant; coordinating and receiving the test back; ensuring the necessary Quality Assurance requirements are met (labelling/date etc); ensuring the correct lab request information is completed; ensuring the participant is told of the test result; and ensuring the result is followed up and the next steps/referrals are completed as appropriate
3. How is the self-test done?	The swab is inserted into the vagina and gently moved around the vaginal walls. The participant does not need to find the cervix.

4. If people self-test at home, is it time sensitive to get it to the lab?	The timing isn't critical as DNA survives very well even on a dry swab. Specific time frames will be announced next year. Delays in samples being sent to laboratories can result in other problems so timely transport is still encouraged.
5. How will the self-test swabs get to participants?	Self-test swabs will be available from healthcare providers or at community events. A self-test can be completed at the location or taken home and returned later in agreement with the healthcare provider. Outreach services may deliver them to the participant's home. The initial implementation of HPV testing does not include a centralised mailout of the self-test kits.
6. Will the new HPV screening replace current cervical screen-taking eventually?	HPV testing will replace cytology as the primary screening test. Cytology will remain an important part of the screening pathway if a participant test positive. This secondary test provides additional information to determine if further management, follow-up or early preventative treatment is needed.
7. What training will be provided for nurses and support staff?	There will be a range of training and education available in the lead-up to July 2023 (and following). This will be offered in a blended learning approach, using a variety of media, including online learning modules, educational videos and online information and resources.
8. How will there be an increase in participation rates?	Transition to HPV testing as the primary screening test, plus the option of self-testing, is expected to reduce barriers considerably. The NSU is working on best options to encourage participant engagement with screening services. We expect the option to self-test will support approaches in both primary health care and community settings to enable improved access to services. Alongside the initial HPV implementation change in July , the programme has commissioned • three implementation research projects specifically focused on equitable participation • co-design of service delivery models with BSA. This research and co-design work alongside the Parliamentary Review findings will inform changes to the future delivery of services after the foundation changes are in place.
9. If HPV 16 and 18 is detected, are they referred directly to colposcopy?	Participants with HPV 16/18 will all be referred to colposcopy but will have a choice of returning first for clinical examination and LBC cytology. Colposcopy is more accurate if the cytology is known prior to the appointment. Direct referral will be preferable where there are barriers to returning to primary healthcare for cytology first or where non-attendance at colposcopy might result if direct referral wasn't an option.

10. Is there anything in a patient's past history that would indicate liquid-based cytology (LBC) would be beneficial for them?	Those with a history of prior abnormalities are recommended to have an LBC sample as the likelihood of needing cytology is higher than for those having a primary screening test. Those having follow up tests after treatment should have a speculum LBC sample taken for the same reason. Cytology cannot be performed on a vaginal swab sample.
11. Are over-70-year-olds who present with a dormant virus activating, as their immune systems age, potentially wise to self-test?	Older participants who are HPV positive are at risk of developing cervical abnormalities and potentially cancer, so need to be identified and followed up. Having a self-test is just as sensitive for detecting HPV DNA as having a clinician-taken sample, at any age. Having a speculum examination can be more uncomfortable for older participants because of epithelial atrophy and vaginal dryness so a self-test may be more acceptable for this age group.
12. How will clinicians keep up their 30 screens per year to maintain their practice when we change to HPV testing in July 2023?	The annual minimum number of speculum-taken samples requirement for sample-takers will be reviewed prior to go live.
13. If you have had the same sexual partner all your life or are not sexually active, should you test for HPV?	Anyone with a cervix who is or has been sexually active should screen. HPV can be passed on in a previous relationship either by yourself or your partner, sometimes many years before, and can lie dormant for years. This also applies to people who are no longer sexually active, for women in same-sex relationships and also those who are post-menopausal or transgender. The invitation to commence screening will go to all 25-year-olds with no reference to sexual activity, as the Register will not be able to distinguish who is and isn't sexually active.
14. Are there different colposcopic findings for different strains of HPV?	No.
15. Would recommended use of Ovestin cream three weeks prior to a screen be under the scope of any screen-taker or only for doctors?	A doctor, nurse practitioner or prescriber nurse can prescribe the required oestrogen cream if this is clinically indicated as is current practice. Primary care nurse prescribers can prescribe oestrogen cream. Community nurse prescribers cannot. Other nurses can request a prescriber colleague to support them.
16. I currently do a comprehensive history / questions, with participants prior to their screen, are you recommending that this is still best practice?	The current practice of consent process and history taking remains important. The required symptom questions must be answered on the laboratory request form.

17. I take opportunistic screens while seeing mostly postpartum women for contraception. Am I better to use a brush as opposed to a broom with LBC?	HPV remains the primary screening test with the option of self-testing. HPV testing can be done in the postpartum period without compromising the sample. The postpartum period is not a good time to take a sample for cytology, because the low levels of oestrogen and the reactive change in the cervix after delivery, can make the cytology difficult to interpret. Breastfeeding prolongs the difficulties with cytology interpretation. It is better to take cytology samples during pregnancy, if screening is due, or to wait until at least three months after delivery before taking a sample for cytology. A cytobrush is designed to sample the endocervical canal and should be used in conjunction with a broom sampler, not as a standalone sampler, as it is important to sample the outer part of the cervix as well as the endocervical canal. A cytobrush should not be used during pregnancy.
18. Can the HPV swab be taken if a participant is having periods?	Yes. It is largely a matter of personal preference although a large amount of blood on the swab occasionally interferes with the test and an invalid HPV result may be reported, requiring the sample to be repeated.
19. Can HPV swab be used on anus/penis/throat to pick up virus?	NCSP HPV testing is part of screening for cervical cancer. Testing at other body sites would be part of a clinical assessment outside of the NCSP.
20. If a participant over 60 is negative for HPV, can they leave the screening programme early?	Cervical screening is recommended from the age of 25 to 69. Those who are un/under-screened at age 69, should be offered an exit HPV test up to 74 years of age, to ensure they are HPV negative before exiting screening. In this age group, detection of HPV of any type should trigger referral to colposcopy for assessment.
21. Does it require written or verbal consent or either?	Informed consent is required, which can be confirmed verbally and then documented by the screen-taker.
22. Can HPV testing be done for women who had LSIL?	Yes. Many cases of LSIL identified on cytology are caused by low-risk HPV types that only rarely cause cervical cancer. These people are at very low risk of cancer and will not be identified as HPV positive because the HPV test only looks for high-risk HPV types.

23. If patients are already on annual cx screen recall, do they still need cytology annually or do they go for HPV screening from next year?	Those currently on annual screening are a varied group. • Those having a test of cure require HPV testing and cytology so will need an LBC sample taken. • During the transition phase those with previous LSIL identified on cytology may have been recalled in 12 months and they will have a high-risk HPV test when they are due for their 12-month repeat test. Many previous LSIL cases will be due to infections with low-risk HPV viruses which will not be positive with the high-risk HPV test used. If the HPV test is negative the participants will revert to five-yearly screens. • In the HPV primary screening programme, 12 months recall is part of the follow-up for those testing positive for HPV Other (non-16/18), as long as the cytology is normal or low-grade. An LBC sample is recommended at recall because the likelihood of needing cytology as well as an HPV test, is higher. • Those who are currently having annual screening because they are immune deficient will be screened every three years with an HPV test in the new programme.
24. Will the partner or partners for HPV-positive patients need testing whether they be male or female?	The HPV testing programme is part of routine periodic screening for cervical cancer. A partner's HPV status does not affect their screening schedule. HPV infections are asymptomatic and usually self-resolving, and no treatment is available. The development of any symptoms in any sexual partner (such as penile or anal lesions) should be investigated appropriately. Immunisation, preferably prior to any sexual activity, is highly recommended for all genders as this greatly reduces the risk of acquiring an infection with the seven types of high-risk HPV included in the vaccine. Continuing screening is still very important, because the vaccine covers seven high-risk HPV types, not all 14 high-risk HPV types that are identified by HPV testing
25. If a participant is doing self HPV test and STI self-swab-does it makes a difference which is done first.	No.
26. How do you recommend recalling for HPV testing and arranging scripts for appropriate clients for Ovestin prior to screen?	Participants will be notified when they are due for cervical screening. Practices will develop local protocols to identify and prescribe for participants who require oestrogen treatment before screening. Oestrogen treatment is not required for primary HPV testing, only for cytology testing.

27. What about the coincidental polyps that may be missed?	This issue applies only to participants who are self-testing and who will not have a speculum examination. Coincidental polyps will not be identified in this group. However, symptomatic patients require a clinical assessment in any case. Asymptomatic polyps are low-risk and any risk is offset by the gains of increased participation with self-testing.
28. How are you going to cope with the potential large number of colposcopy requests for patients who are HPV16/18 positive?	Analysis and workforce modelling is in progress with predicted uptake and capacity of increase for colposcopy across the country. Early indications from the updated modelling show colposcopy numbers will remain steady. We will be sharing the updated modelling with colposcopy units in the near future.
29. If patient opts for LBC. do we ask the lab to routinely test for HPV and cytology?	If the participant chooses to have an LBC sample for primary screening, an HPV test will be performed first. Whether cytology testing is also performed will depend on the HPV result, as cytology will only be reported if the person is HPV-positive. The sample taker can request *HPV primary screening and cytology if required*, but if cytology is not mentioned on the request form and the HPV test is positive, the laboratory will add on cytology for LBC samples anyway.
30. How are glandular cells/results going to be captured with HPV screening?	HPV testing identifies whether HPV is present. Cytology will be reported for those testing positive for HPV. For those who do have cytology testing, the report will identify whether an endocervical component is present, as currently occurs. Abnormal glandular cells will also be reported in the usual way. There are a very small number of cervical cancers that are not related to HPV including a very small number of adenocarcinomas. These will not be detected by the HPV screening programme, so the clinical assessment of symptoms remains very important. Although there will be a very small number of cases that might be picked up by cytology that will be HPV negative, for glandular lesions as a whole, cytology is less sensitive than an HPV test for detecting glandular lesions – so more glandular disease will be detected using HPV testing than we currently do using cytology screening.
31. How will the 1% false negative be managed for HPV screening? Because they won't have a repeat swab for 5 years.	No test is perfect and even with perfect immunisation and HPV screening, a very small number of cervical cancers will still occur. Investigating symptoms of cervical cancer remains very important in any screening programme.

32. If the report is coming back as satisfactory, do they have enough of the squamous cells?	If a cytology sample is reported as satisfactory for reporting, then there will be an adequate number of squamous cells present. The only exception to this is that if any abnormal cells are identified, the sample is also reported as satisfactory regardless of the number of squamous cells, because further follow up of the abnormal cells identified is important. Reporting whether a cytology sample is satisfactory for reporting or not, will not change in the HPV primary screening programme, when cytology is done.
33. What is your recommendation if the screening date comes up when pregnant?	HPV and cytology testing are both safe in pregnancy.
34. What is incidence of vertical transfer of HPV mother to foetus?	This is very rare.
35. Will there be a service set up, similar to Outreach for overdue immunisations, if participants are not able to be reached after they return a positive self-test result?	Alongside the initial HPV implementation change in July , the programme has commissioned • three implementation research projects specifically focused on equitable participation • co-design of service delivery models with BSA. This research and co design work alongside the Parliamentary Review findings will inform changes to the future delivery of services after the foundation changes are in place.
36. Are there likely to be any changes to recommendations or funding for Gardasil vaccination post notification of HPV-positive results?	HPV vaccination is funded up to and including 26 years. As long as you have your first dose while still 26, HPV immunisation is funded. Pharmac are responsible for any changes to the eligibility of funded Gardasil vaccines. More information can be found here: https://www.health.govt.nz/our-work/immunisation-handbook-2020/10-human-papillomavirus
37. Can we push vaccination for boys?	Yes, HPV vaccination is free for everyone aged 9-26 years. The National Immunisation Programme is exploring ways to support increasing HPV vaccination uptake for everyone.
38. Can women over the age of 26 years have Gardasil vaccine if they want to pay for it?	Yes. The HPV vaccine is approved for use for females aged 9 - 45 years and for males aged 9 – 26 years. After age 26, participants are required to pay for the vaccine.
39. Can the HPV vaccine be given to a 25-year-old who has tested positive for HPV in swabs?	Yes, however the level of protection decreases after HPV infection has occurred. Protection will still occur for the HPV types that the individual hasn't been exposed to. HPV vaccination is not a therapeutic vaccine and cannot treat an HPV infection.

40. Should we continue cervical cytology screening on women who are engaged on HPV research, have a negative HPV test and now show they are due for cytology as per the Register?	The research staff will advise the management for participants in each of the research projects.
41. Any limitations of HPV swab testing?	The HPV test detects the DNA of the virus, and this can be done using a swab sample. A vaginal swab cannot be used for cytology.
42. What would you say to a participant whose HPV test shows positive when they have previously tested negative in cytology?	The new test checks for the presence of HPV, a virus. The current speculum (cytology) test checks for cell abnormalities. HPV may have been present previously, when their cytology was negative, but was never tested for. An HPV infection does not mean that a cervical abnormality is present. About 10% of the population will test positive for HPV whereas the proportion who have abnormal cytology is around 7%. Even patients who have not been sexually active for many years can suddenly develop a recurrence of HPV. An immune system compromised by illness or stress may see a very low-lying latent virus become active. Having HPV does not mean that a person or their partner is having sex outside their current relationship. The important issue after having an HPV-positive result after previous negative cytology is making sure that adequate follow-up occurs as cytology can miss disease that HPV testing may detect.
43. If a person has had cytology in 2022 with a normal result, next due in three years, how does that roll over with the new pathway ... do we screen them with an HPV swab in three years?	Yes, from July 23 participants will be offered an HPV test when they are next due for screening – If the participant has a negative HPV test, they move onto the new pathway.
44. Will HPV testing change the recommended screening interval for women on annual screening for reasons other than abnormal screens such as women who are immune suppressed?	The screening interval for those who are immune deficient is three-yearly HPV screening compared with five-yearly screening for immune competent people. This reflects the higher level of risk of cervical lesions for those who are immune deficient.

45. How does the new screening address the concerns regarding endometrial cells seen, needing a follow up?	Cervical screening is not a screening test for endometrial lesions. Currently, abnormal endometrial cells are reported if seen in a cytology sample, and this will continue. By far the majority of women with endometrial cancer present with abnormal bleeding and are not picked up when asymptomatic by cervical cytology.
46. Some women want to have a screen more often than the three years currently recommended. What do we say to these women? Should the swab be rejected if it comes in earlier than the five-year timescale?	A negative HPV test gives greater reassurance than a negative cytology test. There is robust evidence from large clinical trials in Europe and the UK, that the risk of developing cancer five years after a negative HPV test is very low, and is no greater than the risk three years after a negative cytology test. The screening interval is carefully chosen for clinical safety in the programme. Those who screen more frequently than is recommended, are using resources for very little benefit, that would be much better used elsewhere. To date, the NCSP has processed and reported any cytology samples taken in New Zealand, even if taken too frequently. This approach will continue in the new programme but as it is now much easier to take a sample for HPV testing, over-screening may be more of an issue, The NCSP will be monitoring this closely, and may need to limit inappropriate testing, if a significant number of early screens occurs.
47. Is this HPV test funded?	The programme is not fully funded, with most people paying a co-payment for cervical screening. Screening Support Services will continue to provide outreach services for people who experience barriers to accessing cervical screening. Te Whatu Ora is exploring approaches to support reducing cost barriers.
48. How long does it take for the result to be processed with results available from the lab?	The expected reporting time for an HPV screening result only, is within 3 days. If the HPV test is positive on an LBC sample, the laboratory has 10 working days to report the HPV result and the cytology result, which are always issued in one report if taken from the same sample.