

NHS London SelfScreen Opportunistic HPV Self-Sampling Pathway: Frequently Asked Questions



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Inclusion and Exclusion Criteria

- 1. Regarding the temporary exclusions (such as recent gynecological operation, unusual bleeding or pelvic pains), at what point after these exclusions can HPV SS be offered?**

This will vary depending on the gynecological symptoms or type of procedure and, where applicable, the individual's post-operative recovery. The decision regarding the appropriateness of performing a vaginal sample collection should be made by a qualified healthcare professional who can assess the patient's clinical condition and determine when it is safe to proceed.

- 2. Being on an early recall pathway is stated as an exclusion criterion. Does this include people with HIV who need annual screening and are overdue?**

Yes, this does include people living with HIV.

- 3. Can a patient request self-sampling if their GP does not offer it?**

No, a patient cannot request self-sampling in a general practice if the practice does not offer it.

- 4. If you have a patient that has never been sexually active and has always refused to have a speculum, can they self-sample?**

Yes, an individual who has never been sexually active is eligible for HPV self-sampling if they are at least 6 months overdue and meet other inclusion criteria. Individuals can have HPV without being sexually active.

Making the Offer

1. Who can take the samples? Does it have to be people who have done the HPV SS training, completed the assessment, and have a sample taker code?

To be eligible to make an offer of HPV self-sampling, a healthcare professional must:

- work clinically in a participating site AND
- have completed a live training session for the HPV self-sampling pathway OR completed the Learning Hub training AND
- have completed the HPV self-sampling self-assessment on the Learning Hub and passed.

Nurses and doctors do not need to be registered sample takers to make the offer, as long as they meet the criteria above.

The following healthcare professionals are also eligible to offer HPV self-sampling, in line with the national cervical screening programme (as per the [NHS Cervical Screening Education Pathway](#)), provided that they are trained cervical sample takers with a valid PIN recorded in the London Cervical Sample Taker Database:

- NMC registered nursing associates*
- NMC registered midwives
- physician associates who are registered on the Physician Associate Managed Voluntary Register (PAMVR) or with the GMC
- registered healthcare professionals working in integrated sexual health (ISH) clinics
- registered paramedics working in primary care

* Delegation arrangements for registered nursing associates who are cervical sample takers apply to the HPV self-sampling programme. This means that a doctor or registered nurse must be present at the enrolled site when the registered nursing associate is making an offer of self-sampling to a patient and when this self-sampling is undertaken, to indirectly supervise their practice.

2. How can we make the offer to house-bound patients?

The offer can be made to house-bound patients who meet the inclusion criteria.

The HPV self-sampling Professional Guidance must be observed including:

- Good practice in sample handling must be observed: [Guidance for acceptance of cervical screening samples in laboratories and pathways, roles and responsibilities - GOV.UK](#)
- The offer must be made by a healthcare professional who has completed the HPVSS training
- Self-collection must be supervised (not necessarily directly observed) by a healthcare professional and assistance provided if required. The clinician making the offer is responsible for the patient across the entire screening pathway, including failsafe and follow up.
- Patients must be given key information to make an informed decision and offered clinician-collected speculum screening if preferred.

3. When you say the clinician needs to offer the woman or person with a cervix a self-sample OR a clinician-taken sample, would the clinician-taken sample involve using the HPV self-sample swab or is this the normal cervical screening sample?

Women and people with a cervix should always be offered the choice, if eligible, to have a clinician-taken sample with a speculum (which is gold standard) or a self-sample. If they decide to take the self-sample but have difficulty taking their own self-sample, the healthcare professional can assist the patient in taking the sample.

4. Are the instructions available in other languages?

Yes, the Patient Information Leaflet, the Patient Instruction Leaflet, and the Patient Instruction Videos are available in multiple languages. Participating sites were also sent paper copies of the instruction leaflet in multiple languages. Patients can access the instruction leaflet in a language other than English by scanning the QR code on the leaflet included in the sample bag.

5. Is the tQuest form the same as for healthcare professional cervical screening samples?

Accessing the tQuest form is the same, but on the first page you should ensure you select HPV Self-Sampling so that the correct form appears.

Taking the Swab

1. Can the patient take the swab to the toilet or other private area, or do they have to stay in the consultation room?

Patients can complete the self-sample in any suitable private space on the premises. The healthcare professional does not need to physically observe the patient taking the sample.

2. Can the patient take the sample in the same way as they would do any other self-swab (e.g., can do this standing up)?

Yes, patient self-collection instruction are available online [here](#). The patient can self-collect the sample in the position that they find most comfortable.

Analysis of Swabs

1. If a woman or person with a cervix takes a swab and this is blood stained, what is the acceptance criteria by the lab?

A swab with blood visibly present should not be sent for testing. The individual should be offered the opportunity to complete a self-sample at another time.

Results and Follow-up

1. How long does it take for the patient to receive the test results?

The patient will receive the results within 2 weeks, as is the case in the regular cervical screening programme.

2. If patients have a positive HPV result on the self-sample, do we have to wait 3 months before performing the healthcare professional taken test?

No, this should be performed as soon as possible.

3. If requiring a speculum test post self-sampling, is it the healthcare professional's responsibility to chase these patients if they fail to attend? If so, how many attempts?

The healthcare professional making the offer of HPV self-sampling is responsible for the entire pathway, including following up the results. It is their responsibility to ensure the woman or person with a cervix is invited to a healthcare professional taken speculum sample and to encourage them to do so. There is no mandated number of attempts, but effort must be made to explain the importance of having this sample taken.

4. For patients aged 25–49, normal recall results are set for every 5 years — could you please confirm if that's correct?

No. At the present time, if a woman or person with a cervix has a negative result from a HPV self-sample, they will be recalled as per the previous 25-49-year-old interval of three years. This is subject to review.

5. Can the patient have a self-sample on the next screen if they had a self-sample this time?

Following a negative HPV self-sample result, subsequent recall invitations will be for routine clinician sampling. As per the current opportunistic HPVSS



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guidelines in London, the individual may be offered HPVSS when they are 6 months overdue. The NHSCSP HPV self-sampling policy may change in the future.

The Device

1. What is the shelf life of the HPV self-sampling device?

Sample-takers / healthcare professionals should review the expiry dates on devices before use.

2. When are practices going to receive the self-sample swabs?

Participating sites need to order the self-sample swabs via FormStack:
https://pathologyforms.formstack.com/workflows/hpv_surgery_supplies

3. How often can I reorder self-sample kits?

Sites can re-order grab bags once their current stock is running low.

4. What is the maximum number of kits each GP practice can order?

A maximum of 50 grab bags can be ordered at any one time.

The Programme

1. You've said it's better for the patient to have the cervical sample taken in the usual way (i.e., speculum/health professional), but that there is no difference in outcome between this and the self-sample. Can you expand on this?

A clinician-taken sample is the best option and has been shown to routinely detect HPV and prevent cancer. For those already attending routine cervical

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screening, a shift to self-sampling might result in a programme that is not yet proven to be of equal efficacy. There are national plans for further studies to consider whether self-sampling could be used for primary screening.

Evidence comparing clinician sampling and self-sampling has demonstrated a relative Sensitivity range of 94.2-97% and relative Specificity range of 91.3-99.3%

2. We are using the swabs without liquid, which is an off-label use. Why are we doing this and are we indemnified if it is later found that dry swabs are in fact less accurate and miss more positives?

The combination of the Copan FLOQswab transported dry to the laboratory and processed on the Roche Cobas HPV assay has been validated for use in the NHS Cervical Screening Programme. Further details on the HPVValidate study are available here: [hpv-self-collection-test-accuracy-report-hpvalidate-lot1.pdf](#)

When comparing self-sampling vs. clinician sampling, the relative sensitivity for CIN2+ was 0.945 and relative specificity was 0.972.

The London Clinical Executive Group approved the off-label use of this combination in primary care.

EMIS, SystemOne, and tQuest

1. We are having issues with tQuest. Who can we contact for help?

helpdesk@tdlpathology.com or 020 7307 7365