NHS
North East London
Cancer Alliance

YouScreen FAQs for participating GP Practices

1, Who is eligible for YouScreen?

Are all cervical screening non-attenders eligible?

Women are eligible for the study if they are:

- Aged between 25 and 64 years old
- **At least 6 months overdue cervical screening**
- Able to provide informed consent
- Registered at a participating GP practice in Barnet, Camden, Islington, Newham or Tower Hamlets
- Not on an early recall due to a previous abnormal or inadequate screening result
- Not under the care of colposcopy within the last 36 months and/or due for a Test of Cure
- Not known to be pregnant
- Not presenting with possible symptoms of cervical cancer (cervical screening tests are not diagnostic for cancer and women in whom cancer is suspected should be referred as appropriate)

Are women who have been ceased but missed their last screening eligible for YouScreen?

A woman who does not attend for her last routine screening appointment before she is automatically ceased due to age from the programme can be offered self-sampling in this trial.

Are HIV positive women eligible?

Yes, as long as they are at least 6 months overdue for their cervical screening. HPV prevalence is high in HIV positive women; however, the negative predictive value of HPV testing is very high.

Are women who have had their cervical screening abroad or privately eligible for YouScreen?

Yes, as long as they are at least 6 months overdue their screening. The NHS Cervical Screening Programme does not recognise tests taken outside of the programme.

Do vaccinated women need to be screened?

Yes, the vaccine does not eradicate HPV risk. Therefore,
HPV vaccinated women may still be at risk of developing cervical cancer and should be screened.

Why can't pregnant women take part?

There are no safety concerns with pregnant women self-collecting a vaginal swab, however the study advises against it because:

1. The CE-mark for the self-sampling device (Copan 552C.80 FLOQswab) does not currently cover pregnant women.
2. The NHSCSP recommend that pregnant women defer cervical screening until 12 weeks post-partum.
3. Ensuring adequate follow up for pregnant women who screen positive can be difficult within the lifetime of a study (colposcopy is less accurate due to hormone changes and excisional treatment to the cervix for high grade cervical disease is sometimes deferred until post-partum).

The national cervical screening database (NHAIS) does not hold accurate information on pregnancy therefore, some pregnant women may be sent YouScreen kits in the post (mailout kits). However, the study information (written materials and digital) clearly advise pregnant women not to use their YouScreen self-sampling kit.

What happens if a pregnant woman collects a self-sample?

Potentially, a woman who is pregnant will collect a self-sample in the YouScreen study (e.g. she may not have known she was pregnant).

Pregnant women who test HPV negative on a self-sample will have their next test due date reset as per usual and will be invited at the next screening round.

Pregnant women who test HPV positive on a self-sample will be advised in their results letter to have a follow up test as per study protocol – i.e. a clinician-taken sample for cervical screening. If GPs or practice nurses feel unable to do this, they should refer the woman to a cytology clinic within the local colposcopy service. Experienced clinical staff within colposcopy are more used to assessing a pregnant cervix.

What happens if a woman has had a termination and wants to collect a self-sample?

Women who have had a termination can complete a self-sample if they are 12 weeks post termination.

Are women who are virgins eligible for the study?

Women or people with a cervix who consider themselves to be virgins can complete a self-sample if they wish. The NHS cervical screening guidance recommends cervical screening regardless of sexual orientation, sexual history, or whether the person has had the HPV vaccination. Taking a self-sample will not alter a person's status of being "a virgin".

What should I tell women who suffer from endometriosis?

Women who suffer from endometriosis should be able to take a self-sample comfortably. As self-sampling does not stretch the posterior vaginal fornix, women with endometriosis are likely to find it more comfortable than speculum-based sampling.

2. About Self-Sampling

How accurate are self-samples?

Self-samples have similar accuracy to conventional (clinician-taken) cervical screening tests. **Meta-analysis shows that self samples are similarly sensitive and slightly less specific than tests performed on clinician samples for HPV testing (Arbyn et al, BMJ 2018). The estimated sensitivity compared to the current gold-standard (HPV testing on clinician samples) is 0.99 (95% confidence interval 0.97 to 1.02). Since meta-analysis has concluded that compared with cytology, HPV testing is substantially more sensitive for prevalent CIN2+, one can infer that HPV testing of self-samples is more sensitive than is cytology on clinician-collected samples*

Should conventional (clinician-taken) cervical screening tests take priority over self-sampling?

If women wish to have the usual conventional cervical screening test they should do so as the current gold standard test on the NHS Cervical Screening Programme. However, it is important to remember that YouScreen will only offer self-sampling to women who haven't come for screening (i.e. non-attenders) and are unlikely to attend for conventional screening.

Can women take a self-sample if they have their period?

It is best for women to wait until their period is finished to take the self-sample. Small amounts of blood or discharge on the sample are unlikely to affect laboratory analysis.

Can women take a self-sample if they are using vaginal creams?

It is best to take the self-sample before applying or using vaginal creams such as thrush treatments or oestrogen treatments. This is to ensure that laboratory analysis of the sample is not affected by the creams/gels.

How long after giving birth can a woman take a self-sample?

YouScreen advises women to wait until 12 weeks post-partum to take a self-sample, as per the Cervical Screening Programme's recommendation. This is also the case for miscarriage.

How should I describe self-sampling to women?

Explain to women that they will take the sample themselves using a vaginal swab (like a long cotton bud). They can do this in a private area within the clinic or at home.

It's important to reassure women: Self-sampling is an accurate test. It is easy to do. Most women find it painless.

How should I explain to women how to take their self-sample?

Twist to remove the swab from the tube casing. There is a red mark on the stem of the swab where they should hold the swab. Gently insert it into the vagina until the red mark is reached (there's no need to reach their cervix), then slowly rotate it for 20 seconds (count slowly to 20). Withdraw the swab slowly and return it to the tube. Press the lid on to close.

Will HPV self-sampling be available after the study?

Currently self-sampling is only available in England as part of research studies or as privately taken tests.

Privately-taken tests are not recommended because they are not quality assured by the NHSCSP.

The National Cervical Screening Programme are currently assessing self-sampling and are likely to eventually introduce it into the Programme, however, the timeline for this is unknown.

Further information on this may be available before the YouScreen study has ended.

3. Opportunistic Kit Offer

How should I bring up self-sampling during the consultation?

We recommend allowing a few minutes at the end of the consultation to discuss self-sampling. The YouScreen EMIS template provides guidance on how to offer self-sampling and how to confirm eligibility. It also provides helpful phrases and key messages to enable you to make the offer easily and with confidence.

Can YouScreen kits be offered via virtual or telephone consultations?

Yes. The YouScreen EMIS template must still be completed **during** the consultation. This will ensure accurate recording of the kit ID assigned to the woman which will be required to assess key study endpoints.

Women offered kits in virtual or telephone consultations will be given the choice of collecting their kit from the practice or to receive it in the post. We have also provided your practice with pre-stamped envelopes.

Can admin or reception staff offer kits?

No. The YouScreen study protocol stipulates that the kit offer must be made during a clinical consultation by a **GP, Nurse, Healthcare Assistant/Practitioner, Pharmacist, Physician Associate, Nursing Associate**. As this is a research study any changes to the study protocol processes must first be approved by an Ethics Committee.

The YouScreen study team may consider submitting an amendment to the Ethics Committee to change the protocol if there is sufficient reason to justify this change in process. You will be notified by the YouScreen team if this happens.

Can YouScreen be offered by clinicians/nurses who are working remotely (e.g not from the practice?

No. YouScreen kits must remain in the practice and offering kits during remote consultations will not be possible at this time to ensure kit accountability is maintained (this is important given that this this is a clinical trial).

Can we contact or target women to offer self-sampling (e.g. via accuRx)?

We know that GP practices routinely search and print out a list of women who are due for cervical screening, then call them to offer an appointment. Please do not use these lists to target women to offer YouScreen. This is not part of the study. The study is designed to assess the opportunistic offer and targeting women to offer kits would affect the study's ability to evaluate this accurately. Before self-sampling can be introduced it is important to demonstrate that offering self-sampling in a sustainable and scalable way will increase uptake.

What if a woman overdue screening contacts the practice to ask for YouScreen?

Please tell them that because YouScreen is a research study with strict eligibility criteria kits cannot be requested and women cannot opt into the study. Kits are being offered under certain conditions as the study is testing these approaches to find out how effective and scalable they will be for a wider roll out.

Is there a chance that women in the study will be offered a kit more than once?

Yes. Women who receive a mailout kit may also be offered a self-sampling kit opportunistically or women may be offered a kit opportunistically more than once. We don't anticipate that this will cause any issues. Women can simply reject the opportunistic or mail out offer(s).

What if a woman has refused routine screening and is overdue, can a kit be offered?

In this in instance, if the woman has refused routine screening, is overdue by at least six months and is attending for any other reason, then she may be offered a self-sampling kit.

4. EMIS

How do I print the YouScreen lab request/consent form from EMIS?

Open the woman's record in EMIS. Click on the YouScreen EMIS alert. This will launch the YouScreen EMIS template. Choose "yes" and enter the **kit ID**. Press F8 to save. The lab request/consent form should automatically launch. Ensure that the women's details and the Kit ID have been merged correctly. Note that lab request/consent forms launched via the template are read only (cannot be edited), you can only amend the merged document by hand once printed.

Please note that if the template is opened and completed again it will be recorded as a new event/offer and therefore, could lead to errors in data analysis for the study.

How do I reprint the YouScreen lab request/consent form from EMIS?

In EMIS web, navigate to Add document>choose New Letter>search for the YS lab consent form.

Lab request/consent forms produced in this way are editable. Ensure you check the correct kit ID has merged onto the form, please amend it on the document within EMIS if it is incorrect.

What if the Kit ID has not merged onto the lab request consent form in EMIS?

We are aware that the Kit ID does not auto merge/populate onto the lab request consent form from time to time. We understand this to be a bug in EMIS. Though we have raised this issue with EMIS we have not received a resolution. We advise that every lab request consent form is checked carefully before printing to ensure the kit ID (and other information) has merged correctly. If the Kit ID is missing or incorrect, please enter it by hand after printing. Note: you will be unable to edit the form prior to printing as it is read-only.

Will the YouScreen EMIS alert still appear if a woman has previously been offered a kit?

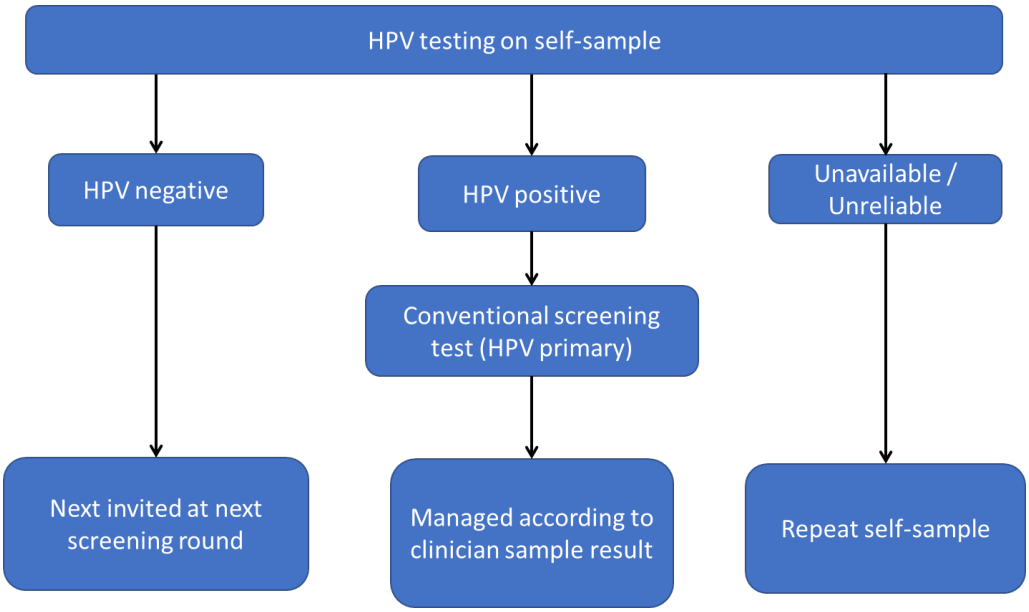
Yes. The YouScreen EMIS flag will only disappear once the woman has been screened For example, If a woman declines a YouScreen offer the YouScreen EMIS template should be completed (also providing the reason she declined); the next time the woman consults, the YouScreen EMIS alert will still appear. We designed it like this due to experience from previous self-sampling studies where, we found that some women changed their minds at a later date.

What happens if we think a woman is eligible but the EMIS alert is not present?

The EMIS alert is coded to only flag women who are eligible for YouScreen so please do not offer YouScreen kits unless the EMIS alert is present. If, after checking the YouScreen eligibility criteria, you are still unsure as to why the EMIS alert is not present, please email youscreen@kcl.ac.uk for further support. Ensure you **do not send** patient identifiable information to this email address.

5. Self-Sample Clinical Management

What is the clinical management for self-sampling?



HPV Negative

The vast majority (~85%) of women will test HPV negative on a self-sample.

Women who test HPV negative will be invited at the next screening round in 3 or 5 years depending on their age. If they are aged 60 and above, they will be ceased from cervical screening according to the usual ceasing criteria.

HPV Positive

Approximately 15% of women will test HPV positive on a self-sample.

Women who test HPV positive will be advised in their results letter to book for a follow up test at their GP practice which will be a conventional screening test (HPV primary screening test). They can have this straight away, there's no need to wait for cells on the cervix to regenerate.

Women who have a clinician-taken follow up test will then be managed according to that result under the usual HPV primary screening pathway (i.e. the clinician taken sample result will override the self-sample result).

Compliance to follow up for an HPV positive result on self-samples is usually high (over 80%). Because of Covid and the difficulty some women are having in getting smear appointments, we are asking GP practices to contact women to make a follow up appointment. Remember, numbers will be small.

HPV Unreliable or Invalid

A small number of women will have an "unreliable" self-sample test result (due to insufficient DNA on the sample) or will have their sample rejected by the lab (an "invalid" result). These women will be sent a repeat self-sample kit in the post by a mailing company.

If a woman has two consecutive unreliable and/or invalid self-sample results, they will be advised to book a for a conventional test at their GP Practice.

Why do women who test HPV positive on a self-sample need a follow up test?

An HPV positive test result by itself doesn't tell you if there are abnormal cells on the cervix that need further investigation. A cytology test is needed for this and cytology can't be performed on a self-sample (because cells haven't been collected directly from the cervix).

If the woman tests HPV positive on this follow up clinician-taken sample, a reflex cytology test will be performed at the laboratory and this result will inform the next step in management.

Why would a woman test HPV positive on a self-sample, then HPV negative on a clinician-taken (conventional) sample?

There are several reasons why this might happen.

Self-samples collect a mixture of vaginal and cervical cells and therefore, may also detect vaginal HPV infections. The HPV infection may have been cleared by the woman's immune system. It could also be due to the self-sample and the clinician-taken sample being analysed on different HPV testing platforms which can pick up different HPV types and/or have different performance characteristics for sensitivity/specificity to HPV.

From a clinical perspective, because the clinician-taken sample has been sampled directly from the cervix and has tested HPV negative, this indicates that women's risk of having a cervical abnormality is still low, even though the self-sample tested HPV positive.

Can women still have a conventional screening test after returning a self-sample?

No. By returning a self-sample, women are consenting for this to be their screening test, in place of conventional screening. Once the self-sample is analysed any tests taken after will be rejected by the lab (unless their self-sample is HPV positive or unavailable/insufficient as these women are invited to take a subsequent sample / screening test).

6. Sample Handling

Do self-samples have any special handling requirements?

No. Self-samples can be stored at room temperature.

How are self-samples returned to the lab?

For self-samples collected in the practice, please place the samples in the purple bags for your usual cervical screening courier collection by CSL.

Note that the samples should be in the sealed plastic specimen bags with the completed laboratory request consent form that are supplied in the YouScreen kit.

Self-samples collected at home can be returned for free via any Royal mail post boxes using the packaging provided in the YouScreen self-sampling kit.

Encourage women to post their self-samples to the lab as soon as possible (within 5 days of self-collection).

Can a pre-printed label be used to label the self-sample tube e.g. TQuest or other?

No, please do not label over the existing sample tube label as the lab will reject the sample if anything is obscured. The kit number, date sample taken and expiry date are all pre-printed onto the sample label with space for patient details to be handwritten.

What if a woman drops her swab?

You can issue a replacement kit (using the EMIS template). Ensure that the old kit is discarded and not mixed with the contents of the replacement kit as kit contents are unique to the kit ID number.

7. Self-Sample Results

How will GP practices & women receive self-sample results?

GP practices will receive results electronically from the Cervical Screening Laboratory via as per usual. Women will receive their results via the post.

What shall I tell women who test HPV positive on a self-sample?

HPV infection is very common and does not mean cancer will ever develop. Most people will have an HPV infection at some point in their life without knowing. Usually it goes away on its own. However sometimes it may be long- lasting, and this may cause cell changes in the cervix.

Women who are HPV positive on a self-sample require a follow up test which will check the cells on the cervix. We strongly recommended you attend for any follow up tests and appointments. During these, if there is a problem it can usually be treated and prevent cervical cancer from developing.

What shall I tell women who test HPV negative on a self-sample?

They are at very low risk of having an abnormality on their cervix at this time. They will next be invited to screening again at the usual time. In the meantime, if they develop gynaecological symptoms (unusual vaginal bleeding or discharge or bleeding after sex), they should see their GP.

What shall I tell women if they ask if HPV infection means their partner has been unfaithful?

Not necessarily, they may have acquired HPV from earlier sexual partners and unknowingly become a carrier. HPV may stay in your body for a long time – sometimes decades – but be dormant or clinically insignificant, which means a test will not detect it. However, it can become active again and then be picked up by a test.

Women can be directed to the Jo's Cervical Cancer Trust YouScreen helpline 0808 801 0408 or website https://www.jostrust.org.uk/information/hpv

8. Other questions

What shall I tell women about their data usage for the study?

YouScreen will collect anonymous data on all women who are eligible for the study, regardless of whether or not they return a self-sample. This data will allow us to assess our study endpoints which will tell us about how effective self-sampling is and what groups of women self-sampling appeals to. The study will only collect information relevant to cervical screening. All information will be kept confidential and securely. No personal identifiers will be collected at any time.

Women can opt out of this if they choose to by informing the GP practice. The local study lead has details on the process for YouScreen data opt-out.

Will translated materials be provided for women?

The YouScreen patient information booklet, pre-notification letter and invitation letters have been translated into the top 5 most commonly requested languages in North Central & North East London **(Turkish, Bengali, Polish, Arabic, Somali)**. This is signposted to women on the Small c website at www.smallc.org.uk/youscreen

The Small c website also has the “Recite me” translation tool for over 100 languages and text to speech functionality for 30 languages.

An animation video with instructions on how to collect a self-sample can be found at www.smallc.org.uk/youscreen

Will self-samples count towards QOF?

Yes. HPV negative self-sample results will count towards QOF.