Patient Information Sheet for Trans men and Non-binary People with a Cervix v2.0

HPV Methylation Self-testing Pilot in Transgender Individuals

We invite you to take part in a research study

- Before you make your decision, it is important for you to understand why we are asking you to take part and what it will involve.
- Please take time to read the following information carefully. Discuss it with your friends, relatives, or another clinician if you wish.
- You are free to decide whether to take part. If you choose not to, this will not affect any other aspects of your care and a clinician will take a standard cervical smear sample as normal. You can withdraw your consent to take part at any time. Ask us if there is anything that is not clear or if you would like more information.

Why is this study being done?

- The human papillomavirus (HPV) is a sexually transmitted virus. Most HPV infections are mild and clear within two years. However, on rare occasions, some types of HPV can cause a type of cancer that affects the cervix, vagina, labia, anus or throat.
- Therefore, cervical screening (sometimes called smear testing) is offered to those born with a cervix (those assigned female at birth) to look for these higher risk types of HPV and check for possibly harmful changes to the cervix.
- Much lower numbers of transgender and non-binary people access screening due to gender dysphoria, pain, or other reasons.
- We are hoping to see if self-sampling would be possible for transgender and non-binary people, and if it might make cervical screening easier for them.
- We will also investigate a new way of testing for HPV in the laboratory by looking for changes in DNA of the virus (methylation).

What are the possible benefits of taking part?

- The information we get from this study could help improve the cervical screening program for transgender and non-binary people in the future.
- You will receive the results of your standard cervical screening as normal.
- You will receive a £20 gift card by email once you complete the survey component of the study.

What are the disadvantages of taking part?

- We cannot promise the study will help you directly and you will not receive any extra treatment by taking part.
- It might mean your appointment takes a little longer while we discuss the study and explain self-swabbing.
- You will need to take extra samples yourself, as well as the standard sample taken by the clinician.

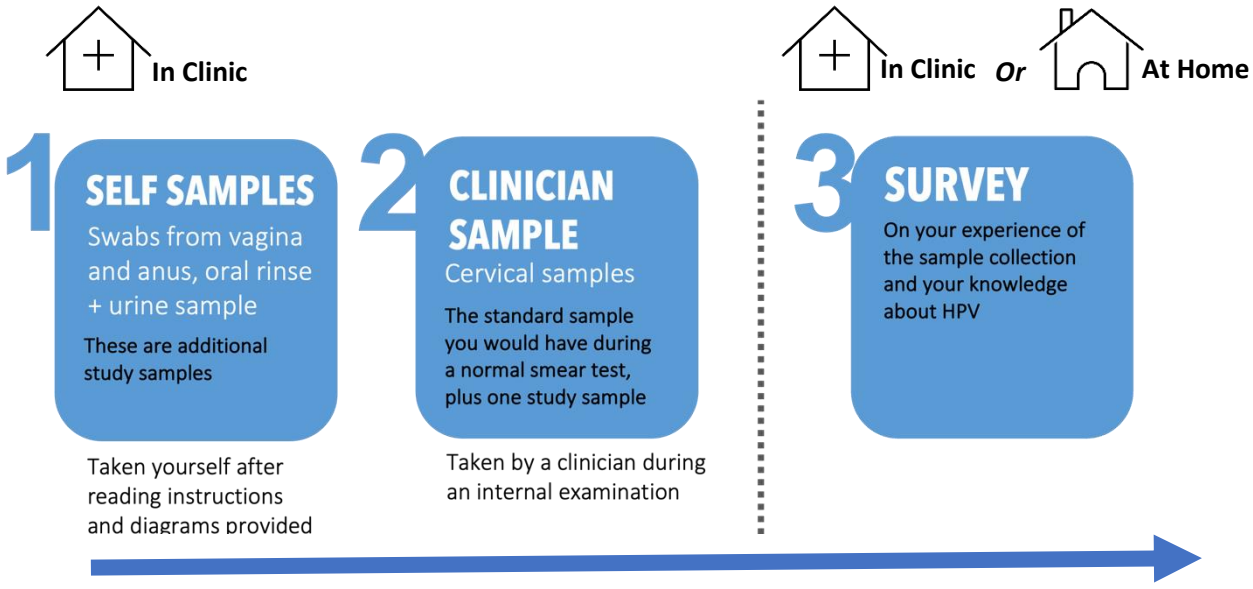
- There is a chance you could experience physical discomfort from swabbing and a small chance of light bleeding afterwards. This should stop on its own, but you should tell the clinic or your own doctor if it doesn't.
- Very rarely, you could develop an infection after self-swabbing and you should tell the clinic or your own doctor if this happens.
- It is possible you could experience dysphoria or emotional distress from swabbing or from completing our medical questionnaire or survey. This may be more likely if you have had a previous traumatic experience. If this happens, we will signpost you to further sources of support.

What happens if I don't take part?

Taking part in this study is entirely optional. If you decide not to take part, it will not change the care you receive. A clinician will take your standard cervical smear sample as normal.

What will happen during the study?

- A clinician will first check that you are eligible to take part in the study and provide you with all the information needed to get your informed consent.
- If you join the study, you will be asked to fill out some forms about your demographics and medical history.
- Following this, you will be given instructions on how to carry out the self-swabs, oral rinse and urine sample required for this study.
- A clinician will then carry out a standard cervical smear as normal, taking one extra swab at the same time for the study.
- We will then be able to compare the standard cervical sample with the self-taken samples.
- You will be asked to complete a survey about your experience, as well as questions on your health knowledge and sexual practices. This will take about 20 minutes.
  You can do this on a tablet in the clinic or receive it by email if you feel more comfortable to complete it at home.



What happens after the study?

- You will receive a letter as normal with your standard cervical screening results, as well as details on when your next cervical screen is due, or any follow up testing needed.

- We will not send you the results of your study samples
- The results from the study samples will not affect when your next cervical screen is due.
- Please visit your GP if you experience any concerning symptoms such as bleeding or discomfort in the areas sampled. If your GP has concerns, they can have a call with a clinician to discuss further.
- We hope that the overall results of the study will be available in the next two years.

What will happen to my samples?

Your samples will be sent to the United States where they will be stored until all participants samples have been collected. They will then all be tested for HPV by using an established test and the experimental methylation test. We will also look at some of the samples under the microscope. We will keep your samples for testing within this study for up to 5 years.

We will ask your permission to keep additional samples for use in future research into HPV by the same study team. This includes looking at DNA from the virus but also your own cells in the sample. Nobody outside the study team will be able to use your samples.

If you give permission for us to do this, after 5 years, we will remove DNA from the cells for storage and dispose of remaining sample. If you do not give permission, all remaining samples belonging to you will be destroyed at the end of 5 years.

How will we use information about you?

We will need to use information from you for this research project.

This information will include your name, date of birth, telephone number and email address. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

Some of your information will be sent to the United States of America They must follow our rules about keeping your information safe.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team, or
- by sending an email to _____

The research sponsor's Data Protection Officer can be contacted via email to: data-protection@qmul.ac.uk

What if I change my mind?

If you change your mind, you should inform your recruiting site as soon as possible either by speaking to the research team at the appointment or afterwards using the email_____ .

You can tell us which of your samples or data you allow to continue to be included in the study. Please note if the study have been analysed, it will no longer be possible for your data to be removed. Any of your remaining samples can be destroyed. This will not affect your care in any way.

Will my GP know I have taken part?

Your GP will not know you have participated in this study. Your care team can tell you more about whether other tests at your visit will be available to your GP. If you have received an NHS cervical screening test before, your results may be sent to your GP automatically.

What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak to the researchers at your recruiting clinic who will do their best to answer your questions. Please email: _____

If you remain unhappy and wish to complain formally, you can do this by contacting the NHS PALS service[_____]

How have patients and the public been involved in this study?

This study was codesigned and coproduced with members of the transgender and non-binary community on the research team. We have formed a Community Advisory Board who have reviewed the overall study and its documents, including this information sheet. This Board will also guide us on the best ways to tell the community about the results of the study and review any publications of the study results.

Who is carrying out the study?

The sponsor for the study is Queen Mary, University of London. This a collaborative project between:

- Queen Mary University of London – UK
- National Institutes of Health (NIH) – USA

The study is funded by the NIH.
This study has been approved by the local Research Ethics Committee.
IRAS number: 319364

How to contact us

If you want to learn more, or have any questions about this study, you can contact the study team: