Participant Information Sheet 1

Survey on women with Lynch Syndrome as part of the research on Preventing Endometrial Cancers (PRESCORES study)

We would be very grateful if you could consider taking part in this survey. Before you do, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Do discuss it with your family, friends, healthcare professionals or others if you wish. Please ask if there is anything you do not understand or if you would like more information.

Aim of this survey

The aim of this survey is to understand the quality-of-life of women with Lynch Syndrome. We want to help prevent cancer of the lining of the womb (also called endometrial cancer). Women with Lynch Syndrome are at high risk of developing womb cancer. Some people with Lynch Syndrome choose to have an operation to remove their womb to prevent this cancer before it develops. This is called a hysterectomy.

We want to understand if this operation has any impact on a person's quality-of-life. We want to compare the results of people who have had this operation to those who have not. We would like as many responses as possible from people with Lynch Syndrome, both from people who have had this operation and those who have not.

If you wish to take part after reading the information, please follow this link:
https://redcap.link/prescores1

You will first be asked to complete the **consent form**. After this you will be able to complete the **survey**. This takes around 10 – 15 minutes.

Background Information

Womb (endometrial) cancer is the most common cancer that is specific to women. Some people, such as those with Lynch syndrome, have a high risk of developing this cancer. This is because they have an alteration or fault in their DNA or genetic code.

Some people with Lynch Syndrome choose to have an operation to remove the womb to prevent this cancer. This is called a hysterectomy. They have this after completing their family. We want to understand if this operation has an effect on someone's quality-of-life. Very little research has taken place into this prevention surgery, although there is much more research into the treatment of cancer.

All operations have potential benefits and risks. The major benefit of this operation is that it prevents cancer. There are also drawbacks. This includes the inability to have children after the operation. This operation is normally a keyhole operation (laparoscopy), although sometimes a larger cut is required, which leaves a larger scar.

There are several possible risks from the surgery such as bleeding, infection, and a very small chance of major complications. The operation will take around a month to recover from, but can sometimes take longer. There may be longer-term effects such as on bladder function and on sexual function.

Usually the fallopian tubes and ovaries are removed at the same time as the womb, as women with Lynch Syndrome are also at an increased risk of ovarian cancer. Removing the ovaries causes a person to go through the menopause, if they have not gone through this already. This may result in symptoms such as hot flushes, night sweats, vaginal dryness and mood changes. Hormone replacement therapy can treat these, but it is not always fully effective. An early menopause can also have long term health effects.

We hope to compare the quality-of-life of those who have had this operation to prevent womb cancer, to those who have not. This will help us understand the effects of this operation. In order to make a fair comparison, we need to know a little about your background. This is why the survey asks some questions about your medical history, and details about an operation, if you have had this.

This survey is very important for us. Once we know the impact of this operation, we can see if more people should be offered this operation to prevent womb cancer.

Many people are at increased risk of womb cancer. They may have Lynch Syndrome, or they may not. This includes women with very common conditions such as diabetes and obesity or some cancer genes. Many of these people do not know that they are at increased risk. Many people are not offered any treatments to prevent this cancer. Some of these people may benefit from this operation to prevent womb cancer, or other hormone preventions. We want to conduct this research to find out who would benefit from different womb cancer prevention options.

We hope to prevent many more womb cancers in the future, instead of only treating them once they develop. This survey is very important for us to do that.

QUESTIONS & ANSWERS

Why have you been invited to take part in this survey?
You have been invited because your healthcare team, research team or support group believe that you have Lynch Syndrome.

Do you have to take part?
You do not have to participate in this study if you do not wish to. Your participation in this survey is entirely voluntary. If you do take part, you are free to withdraw at any time without giving a reason. This will not affect your current or future healthcare. You can choose not to answer any individual question in the survey and move on.

What are the possible benefits of taking part?
By taking part, you will help us understand the effects of surgery to prevent womb cancer. This will help us determine whether other people would benefit from this prevention surgery. Your participation in this survey will thus hopefully benefit the health of women at high risk of womb cancer in the future.

You will not personally benefit from taking part in this survey.

What do you have to do to take part in the survey?
You will need to follow this link to fill in the survey consent form, and then the questionnaire. This takes around 10 – 15 minutes. Please only complete the survey once.

What will happen if you don't want to carry on with the survey?
You are free to withdraw from the survey at any time, through personal choice and without giving any reason for doing so. If you change your mind after completing the consent form, you can still opt out by not completing the survey. You can also choose not to answer any individual question in the survey and move on.

If you wish to withdraw, we would not use your data for any further analysis. However, any analysis already completed on your data would still be kept in the study.

Should you become mentally incapacitated or in the event of your death, during the course of this project, we would continue to include your information in this research study. Should you lose capacity to consent during the course of the study and the study team become aware of this, then further analysis will not be undertaken but any analysis already completed on your data would still be kept in the study.

How will we use information about you?
We will use the information you provide for this research project. This information will include your name. 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. Your data will have a code number instead.

We will keep all information about you safe and secure.

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.

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/
- our leaflet available from http://www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to wpp-prescores@qmul.ac.uk

Do you need to provide your contact details?
No, this is not essential.

What is the second consent form for?
If you would be happy to be contacted by the research team in the future, then you may optionally provide your contact details using Consent Form B. If you do choose to provide this information, the research team may contact you in the future to ask if you are interested in taking part in future research. Any future research you are informed about will be ethically approved by an independent Research Ethics Committee. You do **not** have to participate in any future research by signing this form.

Do not provide this information if you do not wish to be contacted by the research team in the future.

Who are the researchers involved in this project?
The project will be run by health professionals under the leadership of Professor Ranjit Manchanda and coordinated by Queen Mary University of London, who are the sponsor. The people involved are:

Professor Ranjit Manchanda	Consultant Gynaecological Oncologist, Royal London Hospital & Professor, Queen Mary University of London
Professor Rosa Legood	Assistant Professor, London School of Hygiene and Tropical Medicine
Dr Kevin Monahan	Consultant Gastroenterologist at the Family Cancer Clinic, St Marks Hospital
Dr Samuel Oxley	Clinical Research Fellow Gynaecological Oncology, Queen Mary University of London
Dr Adam Brentnall	Senior Lecturer in Statistics, Queen Mary University of London
Dr Munaza Ahmed	Consultant Clinical Geneticist, North East Thames Cancer Genetics Service
Dr Adam Rosenthal	Consultant Gynaecologist, University College London Hospitals
Professor Gareth Evans	Professor of Medical Genetics, University of Manchester
Dr Adam Shaw	Consultant Clinical Geneticist, Guy's & St Thomas's NHS Foundation Trust

If you need to contact someone about the research, whom should you contact?
If you have any questions or concerns regarding the survey, please contact the study team using the contact details below.

Email: wpp-prescores@qmul.ac.uk

Write to:
PRESCORES Research Team
Wolfson Institute for Population Health
Centre for Prevention, Detection and Diagnosis
Queen Mary University of London
Charterhouse Square
London EC1M 6BQ

Who has reviewed the survey?
The survey has been reviewed by a number of experts and some patients and their representatives. All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee. The survey has been reviewed and given a favourable opinion by Surrey Research Ethics Committee, reference 22/PR/1167. Research Ethics Committees are made up of healthcare professionals and members of the public who are not connected to the study.

What will happen to the results of the survey?
The results of this survey will be presented at conferences and published in a scientific journal. They will also be made available through supporting charity websites. Your personal details will not be mentioned in any publication.

The results of this survey will contribute towards further work to determine whether more people should be offered surgery to prevent endometrial cancer, on the NHS.

What if you have any concerns or worries?
If you have any concerns or questions you should initially contact the PRESCORES team who will do their best to answer your questions. The contact details are provided above If there is something that you are unhappy with, please contact Patient Advisory Liaison Service (PALS) as an initial point of contact if you have a complaint. Please telephone 0203 594 2040 or email rlhpals@bartshealth.nhs.uk, you can also visit PALS by asking at any hospital reception.

Please quote reference 280449 in all correspondence. All communication will be treated in strict confidence.

For further independent information or support please contact:

Lynch Syndrome UK
Website: https://www.lynch-syndrome-uk.org/

Eve Appeal
Email: office@eveappeal.org.uk
Website: www.eveappeal.org.uk

GO Girls
Email: hello@gogirlssupport.org
Web site: https://www.gogirlssupport.org/