CDC CERVICAL CANCER STUDY

Study barcode ID

Patient Consent Form

Full study title: Follow-up Study of HPV Testing Among Women Undergoing Routine Cervical Cancer Screening

Conducted by: Centers for Disease Control and Prevention (CDC) and Battelle Memorial Institute

CDC Principal Investigator: Vicki Benard, Ph.D.

Battelle Task Leader: Diane Manninen, Ph.D.

Funded by: CDC Division of Cancer Prevention and Control, Atlanta, Georgia, U.S.A.

Why is this study being done?

The CDC Breast and Cervical Cancer Early Detection Program pays for breast and cervical cancer screening for low income women who do not have health insurance. Cervical cancer is cancer of the bottom third of your womb. It can be prevented by regular screening with Pap tests. Now there is a newer test that can be used along with the Pap test to screen women for cervical cancer. This newer test looks for human papillomavirus, or what we call HPV. HPV is a virus that can cause a common infection in men and women. This infection is very common and often goes away by itself. But sometimes it causes abnormal Pap tests and leads to cervical cancer. CDC is conducting a study of the HPV test in 14 clinics in Illinois. The results of this research study will help CDC decide whether or not to provide HPV testing along with Pap testing to women in other states.

How many people will take part in the study?

You are one of 8,000 women being asked to take part in the study. You were selected because you are here today for your regular Pap test, you are between 30 and 60 years old, you have not had a hysterectomy or cervical cancer, you are not pregnant, and your last Pap test was normal.

What does it mean to participate?

If you are eligible and willing to participate, the following will occur:

- You will be asked a few questions to determine that you are eligible for the study.
- During your pelvic exam the clinician will collect a specimen for a Pap test, as usual. The clinician will also collect a specimen for an HPV test. The HPV test will take only one or two minutes to do. The HPV specimen will be sent to the CDC lab for testing.
- If your Pap test or your HPV test results are abnormal, clinic staff will contact you and tell you if you need additional tests or procedures.
- Clinic staff will give us some information from your medical and billing records. This will include the results of your Pap test and any necessary follow-up tests. Clinic staff will also give us information about your clinic visits (date, purpose, tests performed) over the next three years.
- You will be asked to fill out a survey today. The survey will take approximately 20 minutes to complete. We will give you $5 to thank you for taking the time to fill out the survey today.
- We will send you another survey by mail in about 18 months and again in about 3 years. These surveys will take approximately 10 minutes to complete. To thank you for taking the time to fill out these surveys, we will send you $5 along with each survey.

What will be done with my specimens?

Your HPV specimen will be sent to a CDC lab for testing. Your specimen will only have a study identification number on it. It will not be labeled with your name or any other information that could be used to identify you. The specimen will be tested with one or more HPV tests. We will store your specimen for up to ten years after the end of the study for possible future testing. Then we will destroy it. If you would like to have your specimen destroyed sooner, you can contact the Battelle Task Leader, Dr. Diane Manninen. You can call her at (206) 528-3140 and ask us to destroy your specimen.

By marking one of the boxes below, I indicate my preference for storing my specimen. If I do not mark a box, I understand that I have granted CDC the right to store my specimen for up to 10 years after the end of the study.

- ☐ I consent to let CDC store my specimen for up to 10 years after the end of the study for possible future testing.
- ☐ I prefer that CDC destroy my specimen at the end of the study.

Will I benefit from this study?

A benefit of joining the study is that you will be tested for HPV and find out the results of your test. You will receive the results of today's clinical HPV test and any follow-up clinical HPV tests free of charge. The costs for any additional follow-up tests or treatments will be handled in the same way that they would have been handled if you had not been part of this study.

What are the risks of participating in this study?

The HPV test will be performed as part of your regular pelvic exam. A risk of joining the study involves the possibility of learning that you have HPV and the disappointment that you could feel from that information. Some survey questions are personal and intimate and could make you feel uncomfortable. You are free to decide whether to answer these or any other questions. We will do everything that we can to keep your test results and your survey responses confidential. However, there is a slight risk that somebody other than study staff will see your results or the answers to the questions.

Will the information I give be kept confidential?

Your name will not be included on your HPV specimen or other study documents. A study number will be used to identify you and your documents. This number will be known only by you and study staff. The link between your number and name will be stored and locked in a safe place. Information you give us and all test results will be treated as confidential medical records according to U.S. law.

The study staff is required to keep your identity confidential and your name will never be in study reports. Your survey answers, your HPV and Pap test results, and other information about your medical care will be combined with those from other women in the study before they are shared with others. The research findings will never personally identify you.

What else do I need to know about the study?

You do not have to join this study. If you choose to join the study, you can decide not to answer specific questions and you can leave the study at any time. The study investigators will use the information collected from you during the study up until the time you leave the study. Joining or not joining the study will not affect your relationship with clinic staff or the medical care you receive.

What if I have questions, comments, or concerns?

This consent form explains the research study. If you have any questions or concerns about the study or the informed consent process, please feel free to ask the study staff. If you have other questions you may call the Battelle Study Manager, Chris Jones, toll free at 1-866-649-7122. If you have questions or concerns about your rights as a human subject, you may call the Battelle Human Subject Representative at 1-877-810-9530, ext. 500.

Approvals

The study protocol and this informed consent form have been reviewed by the institutional review boards of CDC and Battelle.

Yes, I agree to participate in this study:

By signing this consent form, I am saying that I have read the consent form and have had the chance to ask questions and am satisfied with the answers and explanations. I agree to join the Cx3 Study. I also agree to allow the clinic to release information from my medical and billing records related to this study. My signature below shows that I voluntarily join in this research project. I will keep a copy of this signed and dated consent form.

_____

Subject's Signature

_____

Participant's Printed Name Date

_____

Signature of Clinic Staff

_____

Staff Member's Printed Name Date

NOTE: ONE COPY OF THE INFORMED CONSENT WILL BE KEPT IN THE PARTICIPANT'S CLINIC MEDICAL RECORD. ANOTHER COPY MUST BE SENT TO BATTELLE. A THIRD COPY MUST BE GIVEN TO THE PARTICIPANT.