UNC GILLINGS SCHOOL OF GLOBAL PUBLIC HEALTH

Gillings Innovation Labs
Gateway to a World of Public Health

Making Cervical Cancer Screening More Cost Effective

Assay using a new HPV E6 test to screen cancer has broad clinical implications

Comparing results between home kits and laboratory analysis

A new study funded by the Gillings Gift is investigating the clinical performance of the human papillomavirus E6 assay (HPV E6) as a triage test for early detection of high-grade cervical precancers (CIN2+). Using this test could reduce the number of women who are referred to a secondary colposcopy screening and lower the overall cost of screening. Through a collaborative effort between epidemiologists, clinicians, and pathologists at University of North Carolina at Chapel Hill and the University of Nairobi, this research is to conduct a clinical validation to ensure that cost-effective screening will net the same accurate results as costlier medical techniques.

- ***Controlled assessment. Shared evaluation.***
  Globally, invasive cervical cancer is the second most common cancer, with notably higher incidence rates in resource-limited areas. This Gillings School test group includes a total of 200 sex workers screened for HPV infection, the main cause of cervical cancer. Women with HPV-positive results will be referred to E6 triage screening. E6 results will be compared to those of pathology-confirmed high-grade cervical precancerous lesions as evaluated by professionals in cytology and pathology labs in Nairobi, Kenya, and rechecked at UNC.

- ***Milestones and deliverables***
  This is an ancillary study to UNC research planned in Mombasa, Kenya in which a group of sex workers who tested HPV positive will be evaluated. The hypothesis of this novel assay is that detection of precancerous cervical disease can occur at home at a reduced cost, netting the same results as more expensive testing at a hospital. The study will compare the sensitivity, specificity and predictive values of the OncoE6™ Cervical Test (Arbor Vita) in detecting high-grade intra-epithelial neoplasia or even more severe disease (CIN2+) through the testing of E6 proteins among women found to be HPV positive. The novel direct detection of the cancer-causing viral E6 oncoprotein should result in high clinical specificity and positive predictive value, by detecting specifically those women in need of treatment from among the many more with clinically less relevant HPV infections.

Leadership

Jennifer Smith, PhD., is associate professor in the UNC Gillings School of Global Public Health's Department of Epidemiology. Dr. Smith's new research focuses on epidemiological studies of human papillomavirus (HPV) and cervical cancer worldwide (primarily in North Carolina, China, South Africa and Kenya).

IMPACT!

How many women with HPV go undiagnosed due to the high cost of lab testing or the lack of access? If the hypothesis of this new study is borne out, women at risk will be able to self-test at home and obtain accurate results for CIN2+ detection. Separating women who need treatment from those who don't can result in substantial savings and improved public health.

GOAL
To assess whether the E6 assay's greater specificity for the detection of high-grade cervical neoplasia can improve the triage to treatment of women identified as HPV positive. Another aim is to create effective working partnerships between the pathology departments of UNC and University of Nairobi for quality control on the histological readings.

PARTNERS
University of Nairobi, Kenya