Clinicaltrails.gov Identifier: NCT03139669

OFFICIAL TITLE: Cultural Acceptability and Feasibility of HPV Cervical Self-Collection Aided by Lay Navigators

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Objectives: The purpose of this study was to explore the acceptability and feasibility of at-home self-collection of samples for HPV testing through a lay navigator delivery network.

Background: Cervical cancer is preventable, and caused almost exclusively by high risk genotypes of the Human Papillomavirus (hrHPV). Strong tools exist for prevention of developing this slow-growing cancer, including vaccination against hrHPV, screening through Pap testing/cytology and/or HPV testing, and treatment options for pre-cancerous and cancerous lesions. In far Southwest Virginia, particularly in Appalachian counties, there are higher incidence and mortality rates of cervical cancer than in non-Appalachian counties.

Based on a long-term research network through the University of Virginia's Cancer Center Without Walls Initiative, the research team worked closely with a Community Advisory Board (CAB) made up of representative stakeholders from this target geographic area in order to inform study procedures, recruitment, and the delivery model of the screening strategy. The goal was to see if at-home self-collection when kits were distributed by a lay navigator from the target communities could be a feasible and acceptable way to increase cervical cancer screening.

Patient Selection:

Eligibility Criteria:

Lay Navigators:

18+ years of age

Received UVA delivered lay navigator training

Living in Virginia Planning Districts/Health Department Districts 1 and 2

Participants:

Women

30-64 years of age

Living in Virginia Planning Districts/Health Department Districts 1 and 2

Exclusion Criteria:

Pregnant

History of hysterectomy

History of cervical cancer

Screened by Pap test/cytology within the last 3 years/HPV test within the last 5 years

Inclusion of Women: Only women were targeted for recruitment.

Inclusion of Children: HPV testing is not recommended for women younger than 30 years of age in the US.

Study Procedures:

Recruitment and screening: The research team trained 64 lay navigators with the University of Virginia lay navigator training, including cancer prevention resources beyond cervical cancer prevention only. Lay navigators received study-specific training and materials, including participant screening checklists, informed consent documents, and a kit for participants (once documented as eligible and once informed consent was received) to collect their own sample for HPV testing. Participants also completed a paper-based survey, including sub-scales on attitudes/beliefs about cervical screening prevention, including self-collection of samples, health literacy, and relevant demographics. Each kit also contained a survey for lay navigators to complete, documenting the number of participants they attempted to recruit and their feedback on study procedures. Consents and completed kits were mailed back to the University of Virginia for sample processing.

Procedures: All participants were called by phone to deliver results. If a participant who tested negative could not be reached after 5 attempts on the primary and secondary phone number provided, a mailed letter was sent to the address they had provided. All participants who tested positive for hrHPV were contacted by phone and navigated to a local clinic for follow up testing.

Statistical Considerations:

Sample size: This study was a feasibility pilot in order to help generate relevant data for future study designs. Endpoints included number of kits distributed and number of kits completed.

Analysis plan: Descriptive statistics included age (years/median), parity, hrHPV positivity rate, caregiver status (children/parent/other), smoker (yes/no), recipient of social assistance (yes/no), health literacy (adequate/marginal/limited), having seen a healthcare provider in the last year (yes/no), having a healthcare provider recommend a Pap in the last year (yes/no), cost perception, and awareness of Virginia's Every Women's Life program.

This study was approved by the University of Virginia IRB on 10/27/2015.

This study was closed by the PI on 8/27/2019. Results supported the hypothesis. Records to be retained for 6 years.