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OFFICIAL TITLE: HPV DNA Testing through Mobile Mammography Unit

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Objectives: The purpose of this study was to explore the acceptability and feasibility of pairing self-collection of samples for HPV testing with mammography screening on UVA's mobile mammography unit.

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. Several barriers exist to women engaging in cervical cancer screening as recommended, including time, cost, distance, and clinic barriers. Self-collection of samples for HPV DNA testing has been found to be acceptable and feasible to implement in several geographic locations. Studying delivery methods for this technology is important to promote implementation.

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 pairing the HPV self-collection kits with mobile mammography could increase access to cervical cancer screening in women seeking mobile mammography.

Several barriers to accessing clinic-based care exist in this targe geographic area. This region is host to an annual episodic clinic organized by local partners and the organization Remote Area Medical (RAM). The UVA Mobile Mammography unit is a service offered at these episodic clinics.

Patient Selection:

Eligibility Criteria:

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 worked with the UVA mobile mammography unit to screen women seeking mobile mammography for eligibility. The research team documented eligibility screening, obtained informed consent, and performed teaching related to collecting a self-sample for HPV testing. Participants used a private exam room on the mobile mammography unit to collect their own sample. 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.

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 7/12/2016.

This study was closed by the PI on 4/12/2022. Results supported the hypothesis. Records to be retained for 6 years.