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AHNS Cancer Prevention and Community Service Award Committee,

Despite a highly effective and safe HPV vaccine, we do not anticipate significant reductions in oropharyngeal cancer (OPC) incidence in the U.S. until 2060, and most individuals born in the 20th century will not at this point have nor acquire effective protection from future vaccination. In the absence of screening programs, patients are often diagnosed at advanced stages, requiring aggressive treatments with lifelong health consequences and increased early mortality. Consequently, we have begun an NIH U01-supported OPC screening effort (TEJAS: https://www.bcm.edu/healthcare/clinical-trials/h-54917) designed for 1,100 men and women aged 45-69 years. This work will allow participants to have remote biospecimen sampling at home or near their home with biofluids tested for 2 highly sensitive and specific biomarkers, and those with positive results (approximately 1-1.5% of those tested) to undergo in-person head and neck exam, nasopharyngoscopy, and neck ultrasound. Our previous screening work (TRINITY: https://clinicaltrials.gov/study/NCT02897427?cond=TRINITY&rank=6) has already identified 2 cancers among biomarker positive individuals and has several remaining in serial follow-up. We believe strongly that this new project (TEJAS) addresses a critical gap in the prevention and early detection of HPV-related OPC, the most common HPV-associated cancer in the U. S. These patients typically present with metastatic cancer due to the lack of early detection programs, and consequently they usually require multimodality treatments with lifelong consequences. This project proposes an innovative approach to screening for HPV-related OPC through remote self-sampling methods, aiming to improve accessibility and outcomes for underserved populations.

We are applying for this AHNS Cancer Prevention and Community Service Award to enhance our outreach to low resource settings in our state, namely the Rio Grande Valley and rural East Texas, to offer these innovative cancer screening opportunities to a broader population outside of our urban/suburban Houston location. These funds would enhance outreach to the most underserved regions of the state specifically through a targeted social media campaign to these areas during April 2025, including the Oral Head & Neck Cancer Awareness Week (April 16-22).

TEJAS (Texas Early detection of Hpv Associated cancers Study)
Biomarkers such as serum antibodies to HPV16 early oncoproteins (HPV16 E Abs) and circulating tumor-modified HPV DNA (ctmHPVDNA) have demonstrated high sensitivity and specificity in detecting HPV-related cancers. However, their use has primarily relied on clinical blood sampling, limiting accessibility for many individuals, especially those in underserved or remote areas. Persistent oncogenic HPV is a well-established risk factor for anal and cervical cancers, but data on the natural history and persistence of oral oncogenic HPV as a risk factor for OPC remain limited. TEJAS aims to address these gaps by evaluating the feasibility, acceptability, and performance of non-invasive, self-collected samples, including oral rinse, saliva, and urine. These novel approaches have the potential to enable mailed sample collection, expanding access to screening for populations with limited healthcare resources. By facilitating earlier detection of OPC, this strategy could reduce the need for aggressive treatments, prevent late-stage diagnoses, and ultimately improve survival outcomes for those at risk of HPV-related OPC.

Target Population: 1,100 individuals aged 45–69 years from the general population

Methods: Study involves a prospective cohort of 1,100 individuals aged 45 to 69 years from the general population. Blood samples will be collected at a local facility or at the subject's home, and participants will self-collect saliva, oral rinse, and urine samples. The presence of circulating tumor-modified HPV DNA (ctmHPVDNA) in blood, oral rinse and urine samples will be assessed. Oral HPV will be detected in oral rinse by Roche Cobas HPV Test. HPV16 E antibodies will be tested in blood and saliva using a RAPID ELISA method developed by the Arizona State University Biodesign Institute. The prevalence and persistence of oral oncogenic HPV over 18 months will be reported. Descriptive statistics will document the successful completion rates of self-sampling and assay testing. Subjects with positive test results and persistence of oral oncogenic DNA will undergo a comprehensive head and neck cancer screening visit at the Baylor College of Medicine ENT Department, conducted by head and neck surgeons. Data from these head and neck examinations, including findings from nasopharyngoscopy and neck ultrasound, throat swabs for oncogenic HPV DNA will be incorporated into the analysis to provide a detailed assessment of screening outcomes

Expected Outcome:
To evaluate test characteristics, feasibility, and acceptance of non-invasive self-collected samples for HPV-related cancer screening. This study focuses on establishing the diagnostic accuracy and reliability of remote self-sampling methods (oral rinse, saliva, and urine) in detecting biomarkers such as HPV16 E antibodies and circulating tumor-modified HPV DNA (ctmHPVDNA). The study will provide critical insights into the feasibility of using these biomarkers for early detection and monitoring, contributing to the development of non-invasive screening strategies for HPV-related cancers.

Expected Impact:
The findings of this study have the potential to revolutionize HPV-related OPC screening by enabling broader accessibility through low-cost, at-home sampling methods. This approach could significantly enhance early detection, reduce the burden of late-stage cancer diagnoses, and improve patient outcomes through localized and less invasive treatments offered to early stage cancers. By addressing gaps in current prevention and screening strategies, the research will also contribute to reducing health disparities, particularly in underserved and remote populations, while laying the groundwork for large-scale population-based screening programs and informed public health policies.

Other Support:
This work is supported by an NIDCR U01 grant (PI: Sturgis) with annual budget of approximately $680,000, but limited funds are available for advertising and outreach, precisely what this award would be used for.

Thank you for considering support of this project. We are confident it represents a meaningful step forward in addressing the pressing need for accessible and effective screening methods for HPV-related OPC, with the potential to significantly improve public health outcomes.

Sincerely,

Erich M. Sturgis, MD, MPH
And the TEJAS Research Team