Attachment A.

National Health and Nutrition Examination Survey (NHANES)
HPV Prevalence Among U.S. Men Pilot Study (ages 14-59)

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HPV Prevalence Among U.S. Men Pilot Study (ages 14-59):

Eligibility: Sample persons aged 14-59 years or older are eligible for the Human Papillomavirus (HPV) Prevalence Among U.S. Men Pilot Assessment. The maximum number of respondents would be 200.

Informed Consent: Written informed consent will be obtained as part of the regular National Health and Nutrition Examination Survey (NHANES) consent process in the Mobile Examination Center (MEC) exam

Exclusion Criteria: Males who have cognitive disability will be excluded from the study.

Specimen Collection: The specimen of cells from the penis will be self-collected, non-invasively, by male survey participants, 14-59 years old. This will be done in private, in the MEC restroom, using a dry swab. After collection, participants will place the swab in a vial of transport media and snap the swab handle off to permit tight closure of vial. Written instructions for the above self-collection will be given to participants and explained by the MEC Physician.

Report of Findings: Participants will be able to call NHANES for results.

Summary of Pilot Study:
EVALUATION OF GENITAL SELF-SAMPLING METHODS FOR HPV DETECTION IN MEN
University of Hawaii
Primary Investigator Dr. Brenda Hernandez

450 males aged 14 -59 years were enrolled into a cross-sectional study evaluating different collection devices for HPV, and self-collection vs provider collection. Each man had a self-collected and provider collected specimen and were randomized to receive a different order of collection. The three different methods evaluated included a regular swab (dry), emery paper or foam swab (dry). All specimens were put into STM (specimen transport medium).

Baseline characteristics of the men are described below:

Characteristic		**Number**	**%**
Age	14-19	60	13.3
	25-29	125	27.8
	30-39	101	22.4
	40-49	96	21.3
	50-59*	68	15.1
Race/ethnicity	White	205	45.6
	Hawaiian/Other Pacific Islander	94	20.9
	Asian	52	11.6
	Black	23	5.1
	Native American	2	0.4
	Mixed race/ethnicity	74	16.4
Marital Status	Single/Never married	324	72
	Ever married/living as married	126	28
Education	Less than high school	49	10.9
	High School Graduate/GED	96	21.3
	Some post-high school	193	42.9
	Bachelor's degree	67	14.9
	Graduate or professional degree	45	10

Time for collection
The median time of self-collection was 4.3 minutes, but there were differences by collection method with a median time of self-collection of 6 minutes for the emery method, and a median time of 3.5 and 3.3 minutes for the swab and foam, respectively.

Collection and participant assessment
Most enrolled men followed directions and washed hands before (64.7%) and after collection (74.2%).

- Ease of understanding the instructions: 63.8% men thought they were very easy, and 33.5% men thought they were easy.
- Ease of collection: 60.4% men thought the collection method was very easy, and 38.7% thought it was easy.
- Comfort: Most men thought specimen collection was either very comfortable (36.9%) or comfortable (55.7%). None thought the specimen collection was very painful and 94.7% thought the specimen collection was not painful.

About ½ of men preferred the self-collection (54.9%) and the other half preferred provider collection.

Adequacy of method
A measure of adequacy of the specimen is detection of b globin. Most specimens had adequate beta globin detection regardless of self-collection or provider-collection: beta globin detection for self-collection was 94.4% and for provider collected was 95.6%. Order of collection did not seem to affect the b globin detection. There were no statistically significant difference in beta globin detection by method.

Conclusions:
Given the challenges of using emery paper for a large sampling like NHANES, the fact that it took longer to collect and was more challenging for the men in this pilot study, and that the yield in b globin was not significantly different, the preference by the study staff is to use a regular swab or foam as the method for self-collection of specimens in males, in NHANES. The regular swab would be more cost-effective than the foam, and thus is preferred by the study staff for NHANES. The instructions used in this pilot were easy to use and understand and could be used in NHANES as well.