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Feasibility and acceptance of oral HPV detection in the dental office: results from the National Dental PBRN

D. Brad Rindal, DDS¹, Gregg Gilbert, DDS, MBA⁵, Claudia Carcelen⁵, Ellen Funkhouser, DrPH⁵, Emily Durand, BSDH¹, David A. Uppgaard, DDS⁹, Jeff Fellows, PhD³, Jana Ikeda, DDS, MPH¹⁰, Alexander Ross Kerr, DDS, MSD⁶, Branden Brar, BKin⁶, Valeria V. Gordan, DDS, MS, MS-Cl⁴, Sudhir Agarwal, DDS¹¹, Peter Barnett, DMD, MBA², Robert K. Pickard, MS, MPH, EdM⁷, Maura Gillison, MD, PhD⁸

¹HealthPartners Institute, Minneapolis, MN

²Private Practice, Plano, TX

³Kaiser Permanente Center for Health Research, Portland, OR

⁴College of Dentistry, University of Florida

⁵University of Alabama at Birmingham

⁶New York University College of Dentistry

⁷Ohio State University

⁸The University of Texas, MD Anderson Cancer Center

⁹Private Practice, Minneapolis, MN

¹⁰Private Practice, Boulder, CO

¹¹Private Practice, Jacksonville, FL

Abstract

Background.—Oral human papillomavirus (HPV) infection is the principal underlying cause of a dramatic rise in oropharyngeal cancer. Dentistry can play an important role in developing clinical algorithms for secondary prevention.

Methods.—This cross-sectional pilot study was conducted with practices of the National Dental Practice-Based Research Network. It evaluated the feasibility and acceptability of screening and testing procedures as judged by practitioners and patients. Tablets were used for patient screening, obtaining consent and administering a confidential oral HPV risk factor survey.

Corresponding Author: D. Brad Rindal, DDS. HealthPartners Institute, 8170 33rd Ave. Mail Stop 23301A, Bloomington, MN 55425
Telephone: 952-967-5026 **Fax:** 952-883-5004, Donald.b.rindal@healthpartners.com.

Contributions:

Conception and design of the study: Gillison, Gilbert, Fellows, Rindal

Acquisition of data: Carcelen, Durand, Uppgaard, Ikeda, Kerr, Agarwal, Barnett, Pickard

Analysis and interpretation of data: Gillison, Funkhouser, Rindal, Pickard, Barr, Agarwal, Kerr, Gilbert, Gordon, Fellows, Barnett

Drafting the article or revising it critically for important intellectual content: Rindal, Gillison, Funkhouser, Pickard, Kerr, Gilbert, Gordon, Fellows, Barnett, Durand

Final approval of the version to be submitted: All authors

Results.—Most patients (85%) were comfortable being asked about cigarette use, their sexual behavior (69%), and were interested in participating again (79%). Over 90% of practitioners were comfortable with study procedures except the extra time required for patient participation (75% comfortable). There were no problems with oral rinse collection as reported by patients or practitioners.

Conclusions.—It is feasible in community dental offices to collect oral rinses for HPV detection and to ask patients explicit questions about sexual history when using a tablet device for confidentiality

Practical Implications.—Discussing high-risk types of HPV and appropriately assessing that risk is a challenge for dental professionals. These results are positive from a research perspective but do not address the advisability of routine HPV screening in dentistry.

Keywords

HPV; oropharyngeal; cancer; risk; screening

INTRODUCTION

Oral human papillomavirus (HPV) infection is the principal underlying cause of a dramatic rise in oropharyngeal cancer incidence over the last several decades in the United States.^{1–3} If recent incidence trends continue, the annual number of HPV-positive oropharyngeal cancers is expected to surpass the annual number of cervical cancers by the year 2020.^{4–6} Approximately 70% of cancers of the oropharynx in the US are currently linked to HPV.⁷

Oral HPV16 infection confers an approximate 20-fold increase in risk for oropharyngeal cancer.⁸ However, the clinical utility of oral HPV detection for screening for oropharyngeal cancer is unknown. Population-based studies of oral HPV infection in the US have identified age, male gender, current smoking and high number of lifetime sexual partners as factors associated with oral HPV infection.^{9,10} HPV infection was greatest among black participants, those who smoked more than 20 cigarettes daily, current marijuana users, and those who reported 16 or more lifetime vaginal or oral sex partners.¹¹ The point prevalence in the US of an oral HPV infection by a cancer-causing HPV type is approximately 7.3% in men and 1.4% in women, corresponding to about 8.6 million people.^{10,11}

The recognition that oral HPV infection plays a role in the pathogenesis of oropharyngeal cancer has resulted in a paradigm shift in concepts of risk for cancer of the oral cavity.¹² Young individuals without a history of tobacco or alcohol use may nevertheless be at risk for oral cancer. The dental community is well positioned to play an important role in the development of clinical algorithms for secondary prevention of HPV-positive oral cancers. Oral disease detection is generally the responsibility of dentists and dental hygienists. Assessing for oral cancer risk factors is recommended as part of a clinical protocol.¹³ In the case of another HPV-caused cancer, cervical cancer, screening through detection of cytological alterations induced by HPV infection (the Papanicolaou smear) and, more recently, direct HPV DNA detection, has reduced the incidence of cervical cancer in the US by 80% over the last several decades.¹⁴ Whether analogous screening interventions, namely,

screening for a risk factor (HPV) rather than the disease of primary concern (cancer) are possible to stem the rising tide of HPV-positive oral cancer is currently unknown.

The primary objective of this pilot study was to evaluate the feasibility and acceptability of oral HPV detection in the dental practice setting as evaluated by participating patients (comfort with completing a survey containing smoking and sexual questions, the additional time to take the survey, and the collection of an oral rinse). The secondary objective were to: 1) evaluate the feasibility and acceptability as evaluated by staff (time for survey, effect on clinic flow, obtaining an oral rinse sample, addressing questions regarding HPV, and referring to specialist); 2) assess associations of patient characteristics with acceptability [comfort] of screening smoking and sexual behavior questions and likelihood of participating in future similar studies. This publication reports on data generated from the baseline screening in the dental office.

METHODS

This study was conducted in dental offices affiliated with the National Dental Practice-Based Research Network (Network), a consortium of dental practices and organizations established to answer questions raised by dental practitioners in everyday clinical practice. These include studies to evaluate the effectiveness of strategies to prevent, manage and treat oral diseases and conditions.^{15,16} The Network is comprised of general dentists, dental specialists, and hygienists. To become a member of the Network, practitioners complete an Enrollment Questionnaire (EQ, available at www.nationaldentalpbrn.org/enrollment.php) on characteristics of their professional experience and practice setting. The National Dental PBRN is administered by six regional administrative sites. See www.nationaldentalpbrn.org/maps-and-regions for the distribution of U.S. states and territories by region.

This cross-sectional pilot study (Figure 1) was designed to evaluate the feasibility and acceptability by participating dental practitioners and patients of screening and testing procedures that would ultimately be necessary for a larger prospective study of the natural history of high-risk oral HPV infections. The target recruitment was 30 practice locations, representing a variety of practice types and all six National Dental PBRN regions.¹⁵

To participate in this study, practitioners were required to attend a network orientation session or watch an orientation video and complete training in human subjects' protection. After completing these requirements, a Regional Coordinator provided a training session with the practitioner and staff that included an overview of the study, steps to complete the necessary forms, and answering questions. The network's applicable Institutional Review Boards approved the study.

Study patients were recruited during routine clinical visits with participating network dental practitioners. Patient eligibility criteria included: being age 30–69 years, and willing to provide an alternate contact outside one's household. Providing an alternate contact is a Network strategy to increase retention rates in longitudinal studies. Individuals under the age of 30 years and over the age of 69 are excluded from participation because data from the U.S. population indicate this age group is at extremely low risk for high-risk oral HPV

infection and oral cancer. Other exclusion criteria included prior receipt of an HPV vaccine, diagnosis of head or neck cancer, or intent to discontinue follow-up at the enrolling dental practice within the next 6 months. Practitioners were provided a tablet device that patients used to self-enroll through a secure web application. The web application screened for patient eligibility, explained the study, tested patients' understanding of study aims, obtained electronic consent, administered an oral HPV risk factor survey confidentially, and determined patient selection for oral rinse collection for oral HPV detection. The web application also evaluated subject acceptance of all study procedures using a short survey. Patients who qualified were provided with an informational handout entitled "Human Papillomavirus (HPV) and Oropharyngeal Cancer FAQ: Frequently asked questions and answers about high-risk oral HPV infection." It included a phone number for patients who had questions.

The web application included a risk model for oral high-risk HPV infections, derived from a US population-based study of risk factors for oral HPV infection, including age, race, gender, current smoking, marital status, and lifetime number of sexual partners. The software selected for oral rinse collection all individuals who fell within the top three deciles of risk and a 10% randomly selected sample of those in the lower seven deciles of risk. The distributions of the demographic and behavioral variables in the study population are based on the weighted distribution of the same factors in the U.S. population as determined in a study conducted by the National Health and Nutrition Examination Survey.¹⁰ An oral rinse sample was obtained using a 30-second rinse and gargle with Scope™ or saline mouthwash, expectorated into a sterile specimen collection cup, sealed and stored at 4°C. Specimens were shipped by practice staff at least weekly to a central laboratory for HPV detection. While the web app functionally supported screening and enrollment function without study staff intervention, both dentists and dental hygienists recruited patients and assist with any questions they might have. A lead office staff were trained and responsible for storage and shipping samples in accordance with the study protocol.

Oral rinse samples were evaluated for the presence of high-risk HPV types (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68, and 73) as previously described.⁹ Samples with detectable high-risk HPVs were considered positive and reported to dental practitioners through the secure web application. Dentists who enrolled the patient, informed patients of test results utilizing standardized scripts and referred them to a Network Regional Coordinator if they had questions that the dentist could not address. Dr. Maura Gillison, the Study Principal Investigator, was available to address questions the dentist or Regional Coordinator could not address including concerns for individuals with a positive HPV test. Specific recommendations for follow-up care were not made because current evidence, including results from this study, does not support a certain protocol of follow-up and testing. The dentist did have the option of offering follow-up in their office or the office of a specialist but this study did not have a specific protocol other than to invite them into the second phase of this study, a six month follow-up for an examination and retesting for HPV infection. Those results are beyond the scope of this paper but will be reported in a future publication.

At study completion, practitioners completed a brief survey on their comfort with study procedures. All study instruments are available at <http://www.nationaldentalpbrn.org/study-results/risk-for-oral-cancer-study-rocs.htm>

Statistical analysis

Characteristics of the participating practitioners and patients are described. Practitioners' comfort with procedures are described; significance of differences according to whether or not the practitioner had a patient who tested positive for a high-risk HPV infection and number of oral rinse samples collected (using median split) were assessed with Fisher's exact test. Interest in participating in future similar studies was also obtained according to practitioner characteristics. Logistic regression was used to assess independence of associations with interest in participating in future similar studies.

Characteristics of participating patients are described, as well as their likelihood of participating again in a similar study, and comfort with tobacco and sexual questions as measures of feasibility. Because of the cluster-design of study, significance of differences of patient characteristics according to these characteristics were obtained using generalized estimating equations (GEE), implemented using PROC GENMOD in SAS with CORR=EXCH option. All characteristics with $p < 0.10$ after adjusting only for clustering of patients within the practice were included in the full model. This was followed with backwards elimination to identify independent associations with either likelihood of participating in future similar studies, and whether or not the patient was comfortable answering smoking and sexual questions, being retained if $p < 0.05$, in a final reduced model. Odds ratios (OR) and 95% confidence intervals (CI) were calculated from the models. All analyses were performed using SAS software (SAS v9.4, SAS Institute Inc., Cary NC).

RESULTS

Characteristics of the participating practitioners

The median age of the 37 participating practitioners was 53 years (Inter-quartile range [IQR]: 41 – 61), 20 (54%) were male, 26 (72%) non-Hispanic white, 7 (19%) Asian, and 3 (8%) were Hispanic/Latino. Self-described types of practice included owner of solo practice (n=15), owner with associates (n=5), associate (n=5), academic (n=5); large group practice (n=4) and public or community (n=2) practices, across the 6 network regions (Supplemental Table 1). Practitioners self-described as general dentists (n=30, 83%), dental specialists (3 periodontists, 1 orthodontist, and 1 oral surgeon) or hygienists (n=1).

Median number of patients enrolled per practitioner was 25 (IQR: 17–19; range 3 – 50), and median number of oral rinse samples collected per practitioner was 8 (median=8, IQR: 5–12, range 0 – 22). Patients were enrolled between 8/15/2016 and 2/15/2017; the number of days a practitioner enrolled ranged from 10 to 177 days (median = 110).

Characteristics of participating patients

A total of 1,298 patients were offered the opportunity to participate in the study, of whom 1,252 (96.5%) agreed to be screened for eligibility (Figure 2). Six patients had premature study withdrawals between indicating interest and meeting eligibility requirements. One patient was confused about use of the tablet. Two patients decided not to continue and no explanation was provided. One patient had received the HPV vaccine already and another was unwilling to provide another person's contact information (study eligibility requirement). One withdrawal was due to poor internet access. One patient withdrew during the risk factor survey process because he or she was "offended" by the sexual behavior questions. Three participants withdrew without explanation after consenting but before answering survey questions. One patient withdrew because he or she did not have time to wait. Of those screened 1041 (83.1%) met study eligibility criteria. Reasons for exclusion from participation included: unwillingness to provide contact information for persons other than self (n=110); prior receipt of an HPV vaccine (n=42); and intent to leave the dental practice within 6 months (n=32). Of the 1,041 eligible patients, 1,030 (98.9%) consented to the study, of whom 1,025 completed visit 1 (only 5 did not complete). Seven patients withdrew after completing the survey and prior to oral rinse sample being collected; they gave no reason for withdrawal.

The demographic characteristics of the study population are shown in Table 1. The median age was 49 years (IQR: 39– 58; range 30 – 69), 65% were female, majority were non-Hispanic white (67%), with 13% African-American, 12% Hispanic/Latino and 4% each Asian and other/multi-racial. The majority were married/living together (67%). Education ranged from high school or less (16%) to advanced (post-bachelor) degrees (22%). Regional representation varied from 11% in South Central to 24% in Northeast region.

Risk behaviors: The majority of patients had never smoked (62%); 13% (n=135) currently smoked. Among the 135 current smokers, 90 smoked 21 or more days in the past 30 days and only 4 smoked 21 or more cigarettes a day on days they smoked (heavy smokers). Among males, the mean number of opposite-sex lifetime sexual partners (vaginal, oral, or anal sex) was 21 (sd=76) [median=8, IQR: 3–20; range 0 – 1,000]. Twenty seven (7%) reported a same-sex partner. Among females, the mean number of opposite-sex lifetime sexual partners (vaginal, oral, or anal sex) was 9 (sd=16) [median=5, IQR: 2–10; range 0 – 300]. Fifty-five (8%) reported a same-sex partner.

Patient-reported comfort with study procedures

After completing all procedures included in the enrollment visit, patients reported their comfort level with all procedures on a five-point Likert Scale (Supplemental figure 1). A majority (85%) reported (agreeing or strongly agreeing with) being comfortable with being asked about their cigarette use, and a majority (69%) reported being comfortable with being asked about their sexual behavior. In univariable analysis (adjusted only for clustering of patients within practice), patients who reported current smoking were less likely to be comfortable answering questions regarding either smoking or sexual behavior (Smoking questions: OR=0.3, 95% CI: 0.2–0.5, p=0.004; Sexual questions: OR=0.6, 95% CI: 0.4–0.9, p=0.04). (See Supplemental Table 2 for regression analysis.)

Regarding likelihood of participating in future similar studies, a majority (79%) reported they were likely/highly likely to participate. We evaluated factors associated with likelihood of participating in future studies. We observed strong associations between being comfortable with questions regarding smoking and sexual behavior among those likely to participate in future similar studies ($p < 0.001$ for all comparisons; presented in Supplemental Table 3).

After adjustment for clustering of patients within practice, only female gender ($p = 0.001$) and age less than 40 years ($p = 0.03$) were significantly associated with increased likelihood of participating in future similar studies. They retained their significant associations in the final model (female gender: OR=1.6, 95% CI: 1.2–2.1, $p = 0.03$; being less than 40 years of age: OR=1.6, 95% CI: 1.1–2.4, $p = 0.03$). (Supplemental Table 2)

Practitioner survey

Practitioners (36 of 37) completed a survey reporting their comfort with all study-related procedures on a five-point Likert scale (Supplemental Table 4). Over 90% reported high comfort with all study procedures except the extra time required for patient participation, for which 75% were comfortable.

Twelve (32%) practitioners had at least one patient who tested positive for a high-risk HPV. Comfort with the study procedures did not differ by whether or not the practitioner had a patient with a high-risk HPV test result (all $p \geq 0.2$), by number of patients enrolled or by number of oral rinse samples collected (all $p \geq 0.4$), nor were there any patterns suggested, namely, practitioners who had a patient with a high-risk HPV test result or who collected more samples were not consistently more (or less) comfortable with study procedures (Table 2).

Interest in future similar studies

Of the 37 participating practitioners, 69% ($N = 25$) reported that they were interested in participating in future similar studies, 28% ($N = 10$) said maybe, and 1 reported no interest; 58% ($n = 25$) reported that their patients had asked about their HPV test results. Interest in future participation did not differ significantly by whether or not a practitioner had a patient with a high-risk HPV test result (75% vs. 58%, $p = 0.4$). There was a difference by number of oral rinse samples collected. Practitioners who had collected more samples were more likely to be interested in participating in future studies (Wilcoxon rank sum $p = 0.048$). When assessed by median of number of samples collected, a higher proportion of practitioners who collected above the median were interested in future participation (89% vs. 50%, $p = 0.03$).

DISCUSSION

Practitioners were overall very comfortable with implementing the study procedures within the flow of daily clinical practice. The more challenging aspects of implementing the study in clinic work flow were related to enrolling the patient and the time required for the patients to complete the risk survey. Only 1 provider was not interested in participating in a future study on HPV screening. A key conclusion from this study is that it is feasible to ask patients in community dental offices sensitive questions about sexual history for a research

study of this nature. This questioning was facilitated by a tablet device that allowed patients to answer questions in a confidential manner and these answers were not made available to the dentist nor were they part of a clinical record.

Targeted practitioner recruitment for this study was designed to represent the practitioner enrollment within the Network. This comprised a purposive approach to include proportional representation of practice type and region of the country. Dental practitioners enrolled in the Network at large have much in common with the United States population of dental providers¹⁶. Patients recruited into this study were intended to be representative of dental patients based on gender, race-ethnicity, marital status, education, age and region of the country. With high levels of practitioner comfort with study procedures, many over 95%, we did not have the power to detect differences. By virtue of the small sample of practitioners needed for this pilot study, not all groups (e.g., Black/African-American practitioners and some dental specialists) were well-represented.

The comfort with the sexual questions ranged from 58% to 74% comfort, and comfort with the smoking questions ranged from 75% to 91%. This suggests that patients are more comfortable answering questions about smoking status as compared to asking about sexual behavior. Overall there is still substantial comfort with being asked about sexual behavior in the dental office. We identified only one other study examining oral HPV in dental settings, which was conducted in Scotland¹⁷ and which reported few missing responses in the questionnaire and high levels of disclosure of risk behaviors.

Results from our study found that patients who are female and less than 40 years of age were independently and significantly associated with increased likelihood of participation in future similar studies. This finding may be explained in part by women being aware of the HPV link related to cervical cancer and thus more accepting of HPV screening.¹⁸ A recent study examined HPV awareness in association with head and neck cancer at a screening event. The study reported that women were 2.5 times more likely than men and younger individuals were also more likely to be aware of the HPV link.¹⁹ Younger age groups are more likely to be aware of HPV risk as they are targeted for HPV vaccination.^{20,21}

The study has a number of limitations. The first to consider is that it is a feasibility study. Although this is not a limitation per se, it needs to be considered when evaluating all results presented. The study was not designed or powered to identify patient characteristics associated with specific aspects of the study, namely, comfort with smoking and sexual questions and likelihood of participating in future similar studies. We report them as preliminary data as a way to evaluate the study population representativeness. Differences by gender may play an important role in the future as more women (and men, to a lesser extent) will be receiving an HPV vaccine. Testing associations between practitioner characteristics and likelihood of participating in future studies was a secondary objective; associations presented in this study should only be considered suggestive. Even if statistically significant, results were obtained from only 37 practitioners, who were purposively not randomly selected. The study was also not powered to assess items after referral, such as follow-up rate. Only 19 patients tested positive for high-risk HPV. If they had any patients to refer for high-risk follow-up, most practitioners only had only one such patient.

Also, demonstrating that it is feasible to screen for HPV in dental practices does not equate with supporting such screening. It is a first step in the process to determine if routine screening is advisable. Potential harm from implementing HPV screening includes unnecessary patient anxiety and inefficient use of healthcare resources. Until more-precise screening strategies or tests become available, routine screening in dental offices is not indicated.

Conclusions

This was the first National Dental PBRN study to use an anonymous, patient-administered screening tool and the first to support electronic data collection through a tablet-device-delivered secure web application at the point of care. Both activities were successful and can likely be reproduced in practice settings in the future to facilitate pilot research on other sensitive or complex topics. We are, however, in an era where our understanding of a patient's complete risk profile for oral cancer has become more complex. Educating patients about risk factors for oral cancer must now include a discussion of HPV infection as well as alcohol and tobacco use. How to discuss HPV as a risk factor and meaningfully assess that risk, presents a new challenge both for dental professionals and healthcare broadly. These results, while positive from a *research* feasibility standpoint, do not yet support HPV screening as a routine part of dental care. .²²

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1:
Study Design

Figure 2.
Study Participant Recruitment within Dental Practices

*Six patients withdrew between indicating interest and ascertaining eligibility.

Table 1.

Patient characteristics, likelihood of participation in future similar studies and comfortable with smoking and sexual questions in risk factor survey.

	Overall (n=1,025)		Likely to participate again (n=806)		Comfortable with smoking questions (N=876)		Comfortable with sexual questions (n=699)	
Characteristics	N	Col % ¹	N	Row % ²	N	Row % ²	N	Row % ²
Demographics								
Gender								
Male	363	35%	267	74%	306	84%	256	71%
Female	662	65%	539	81%	570	86%	443	67%
Cluster adjusted p ³				0.01	0.4		0.11	
Race ⁴ -ethnicity								
White	682	67%	537	79%	598	88%	463	68%
Black/African-American	136	13%	109	80%	107	79%	95	70%
Asian	46	4%	40	87%	42	91%	36	78%
Other/multi-racial	40	4%	29	73%	30	75%	23	58%
Hispanic/Latino	121	12%	91	75%	99	82%	82	68%
Cluster adjusted p				0.16	0.2		0.4	
Marital status								
Married/living together	630	61%	496	79%	542	86%	431	68%
Separated/Widowed/Divorced	314	31%	246	78%	262	83%	217	69%
Single, never married	81	8%	64	79%	72	89%	51	63%
Cluster adjusted p				0.99	0.7		0.7	
Education								
High school or less	169	16%	124	73%	141	83%	122	72%
Some college/AD degree	278	27%	215	77%	221	79%	181	65%
College, 4-yr degree	352	34%	285	81%	311	88%	240	68%
Advanced degree	226	22%	182	81%	203	90%	156	69%
Cluster adjusted p				0.2	0.065		0.5	
Age (years)								
30–39	264	26%	222	84%	234	89%	193	73%
40–49	255	25%	199	78%	210	82%	171	67%
50–59	292	28%	223	76%	253	87%	196	67%
60–69	214	21%	162	76%	179	84%	139	65%
Cluster adjusted p				0.2	0.4		0.3	
Network Region								
Midwest	157	15%	126	80%	134	85%	108	69%
Northeast	250	24%	211	84%	217	87%	185	74%
South Atlantic	195	19%	142	73%	163	84%	128	66%
South Central	112	11%	86	77%	93	83%	73	65%
Southwest	172	17%	131	76%	143	83%	113	66%

Characteristics	Overall (n=1,025)		Likely to participate again (n=806)		Comfortable with smoking questions (N=876)		Comfortable with sexual questions (n=699)	
	N	Col % ¹	N	Row % ²	N	Row % ²	N	Row % ²
Western	139	14%	110	79%	126	91%	92	66%
<i>Cluster adjusted p</i>				<i>0.3</i>		<i>0.6</i>		<i>0.5</i>
<u>Smoking status</u>								
Never	634	62%	503	79%	567	89%	448	71%
Former	256	25%	197	77%	214	84%	171	67%
Current	135	13%	106	79%	95	70%	80	59%
<i>Cluster adjusted p</i>				<i>0.8</i>		<i>0.005</i>		<i>0.09</i>
Sexual behaviors								
Among men (n=363)								
<u>Number women ever had sex with (quartiles)</u>								
0–3	100	28%	69	69%	87	87%	69	69%
4–8	82	23%	61	74%	69	84%	61	74%
9–20	108	30%	83	77%	88	81%	73	68%
21 or more	73	20%	54	74%	62	85%	53	73%
<i>Cluster adjusted p</i>				<i>0.6</i>		<i>0.6</i>		<i>0.7</i>
<u>Ever had sex with man</u>								
Yes	27	7%	21	78%	19	70%	16	59%
No	336	93%	246	73%	287	85%	240	71%
<i>Cluster adjusted p</i>				<i>0.5</i>		<i>0.11</i>		<i>0.16</i>
Among women (n=662)								
<u>Number men ever had sex with (quartiles)</u>								
0–2	181	27%	148	82%	152	84%	128	71%
3–4	135	20%	102	76%	121	90%	81	60%
5–9	172	26%	146	85%	144	84%	117	68%
10 or more	174	26%	143	82%	153	88%	117	67%
<i>Cluster adjusted p</i>				<i>0.2</i>		<i>0.3</i>		<i>0.2</i>
<u>Ever had sex with woman</u>								
Yes	55	8%	41	75%	44	80%	34	62%
No	607	92%	498	82%	526	87%	409	67%
<i>Cluster adjusted p</i>				<i>0.2</i>		<i>0.2</i>		<i>0.4</i>

¹Some column percentages do not sum to 100 due to rounding.

²Percentage within level of demographic/risk behavior characteristic.

³Significance of differences in proportions adjusted only for clustering using generalized estimating equations.

⁴Race groups are all non-Hispanic/Latino.

⁵NE: Not estimable

Table 2.

Practitioner comfort with study procedures overall and according to whether or not had a patient who received a high-risk HPV test result and to whether or not the practitioner processed 9 or more oral rinse samples.

	All	Had a patient in the study with a positive test for High-risk HPV		Processed	9 oral rinse samples
	(N=36)	Yes (N=12)	No (N=24)	Yes (N=18)	No (N=18)
Study procedure¹	%²	%²	%²	%²	%²
Education and training for the protocol	100%	100%	100%	100%	100%
Recruiting patients for the study	97%	100%	96%	100%	94%
Consenting patients to the study	97%	100%	96%	100%	94%
Answering questions about the study	97%	100%	96%	100%	94%
Collecting oral rinse specimens	97%	92%	100%	100%	94%
Patients completing 1st oral HPV risk factor survey	94%	100%	92%	100%	89%
Storing oral rinse specimens	94%	92%	96%	100%	89%
Shipping oral rinse specimens	92%	92%	92%	89%	94%
Providing test results to the patients (NA=2)	91%	82%	96%	88%	94%
Answering questions about test results (NA=3)	91%	80%	96%	88%	94%
Extra time required for patient to participate ³	75%	67%	79%	83%	67%
<u>Did patients ask about HPV test results</u>					
Yes	58%	75%	50%	67%	50%
No	39%	17%	50%	33%	44%
Don't know	3%	8%	0%	0%	6%
<u>Interested in participating in future similar studies</u>					
Yes	69%	58%	75%	89%	50%
Maybe	28%	42%	21%	11%	44%
No	3%	0%	4%	0%	6%

¹ Response options: Completely comfortable, comfortable, neutral, somewhat uncomfortable, completely uncomfortable, or not applicable (NA)

² Percentage completely comfortable or comfortable excluding NA

³ Completely acceptable or acceptable