Gender Affirming Cervical Cancer Screening for Trans Masculine Patients

Reisner SL, Deutsch MB, Peitzmeier SM, White Hughto JM, Cavanaugh T, Pardee DJ, McLean S, Marrow EJ, Mimiaga MJ, Panther L, Gelman M, Green J, Potter J.

THE FENWAY INSTITUTE

Trans Masculine Sexual Health Collaborative

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The Fenway Institute | Fenway Community Health

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HARVARD MEDICAL SCHOOL

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Boston Children's Hospital
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About the Study

Human papillomavirus (HPV) is the most common sexually transmitted infection (STI) in the United States, and cervical infection with one of several high-risk strains (hrHPV) is the cause of virtually all cervical cancers. Cervical cancer can be prevented with appropriate screening.

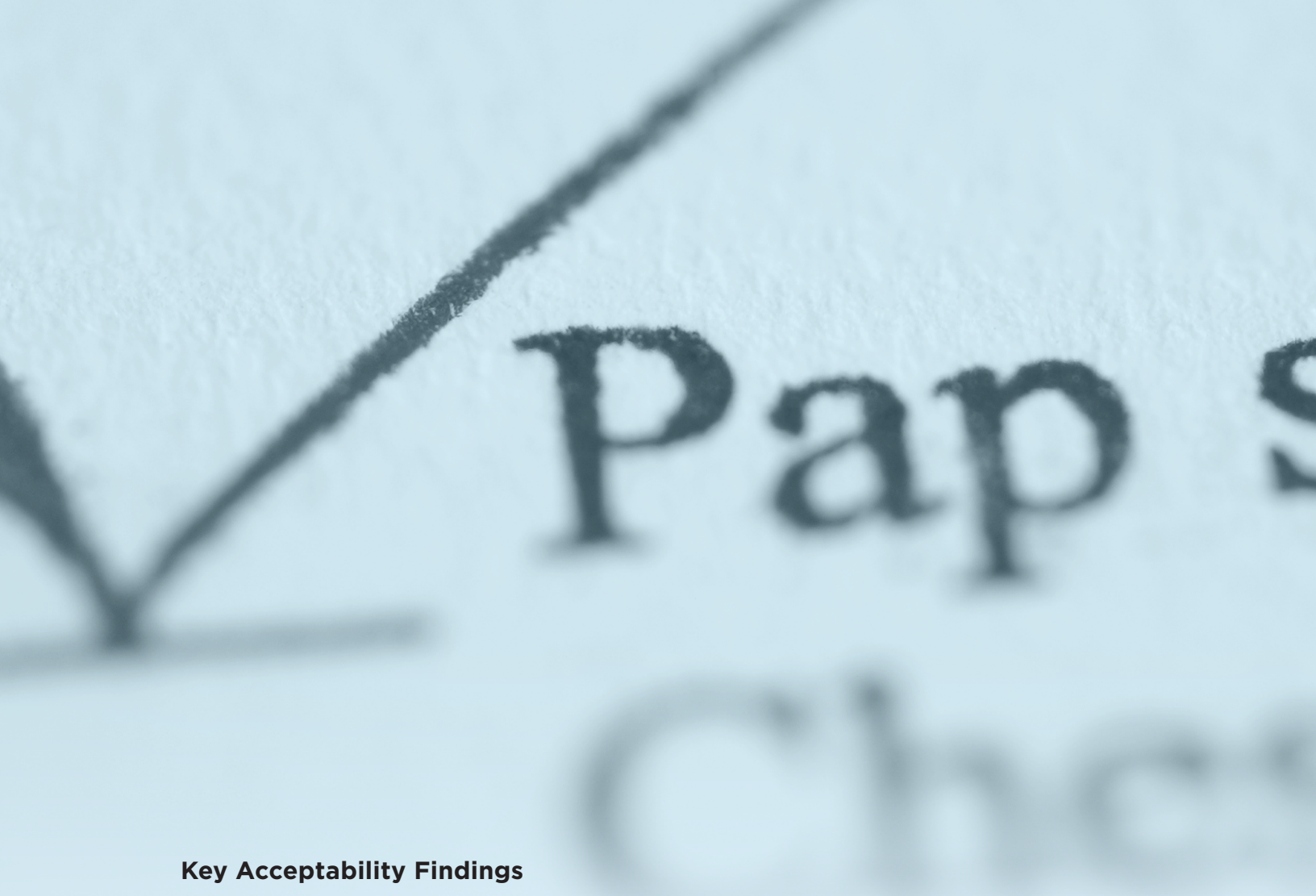
Current U.S. cervical cancer screening guidelines include cytologic Papanicolaou (Pap) testing every three years for individuals ages 21-65 years who have a cervix regardless of HPV vaccination status, with the recommendation of extending the screening interval to 5 years from ages 30-64 when a DNA test for cervical hrHPV infection is performed at the same time. In 2015, provider-administered cervical hrHPV DNA testing alone, without a Pap test, was proposed as an alternative primary screening methodology, although it has not yet been incorporated into US Preventive Services Task Force (USPSTF) guidelines.

Papanicolaou (Pap) testing is recommended to screen for changes to cervical cells that could lead to cancer for potential pre-cancerous changes to cervical cells in anyone with a cervix ages 21-64 years. However, Pap tests and pelvic exams can be particularly difficult for trans masculine (TM) individuals -- people who were assigned a female sex at birth and identify as male or on the masculine spectrum. We talked with members of the TM community about barriers to getting a Pap test. TM individuals expressed interest in alternative cervical cancer screening methods that do not require a speculum exam. There was a high level of interest in self-swabbing that would allow self-testing for hrHPV, given it causes over 99% of all cervical cancers.

Drawing from the voices of TM community members, The Trans Masculine Sexual Health Collaborative at The Fenway Institute at Fenway Health in Boston, MA conducted a study to examine the acceptability, feasibility, and effectiveness of a self-collected swab for hrHPV testing compared to provider-collected swabs for hrHPV testing. Between April 2015 and September 2016, 150 TM individuals enrolled in a one-time study visit and completed both testing methods (a provider-conducted and a self-collected frontal swab). The concordance of the test results, the extent to which they agreed in detecting the presence of HPV DNA, was assessed. This was done in order to make sure the test performed adequately and was scientifically sound for screening.

Key Clinical Findings

The gold standard refers to the current preferred method of diagnosing a particular disease. The “gold standard test” for HPV is a DNA test that can detect the presence of 13 high-risk HPV strains. This test is conducted on a cervical sample (sampled from the cervix) collected by a medical provider using a speculum. Using this test, 21 participants tested positive for high-risk HPV (15.9%). Study participants self-collected a frontal swab (sampled from the front hole). Compared to the gold-standard, the self-collected frontal swab for HPV DNA testing accurately detected approximately 7 out of 10 cases of hrHPV (71.4%)



Key Acceptability Findings

Acceptability is the extent to which people receiving a healthcare service consider that service to be appropriate. We conducted an exit interview with every participant to hear about their experiences with self-collection. The self-collected frontal swab for HPV was found to be highly acceptable. The majority of participants in the study preferred the self-swab for hrHPV detection over a provider-conducted test in most contexts. Some participants stated that their preference would depend on contextual factors, such as how trans-friendly/knowledgeable the medical provider seemed who would be collecting a cervical sample. Key benefits to self-collecting a sample that participants described were privacy, control, reduced invasiveness, and empowerment. Concerns of self-swabbing included: uncertainty about whether the procedure was performed correctly and accuracy of the test.

Conclusions and Key Recommendations

Clinical findings of the current study indicate that self-collected frontal swabs are less sensitive, or detect fewer cases of hrHPV, than provider-collected cervical swabs for high-risk HPV DNA detection. Nevertheless, self-swabbing may provide an acceptable screening method for TM patients who may avoid standard Pap tests. Data from this study and others show that TM individuals may avoid health care for a variety of reasons including fear of discrimination, dysphoria, or trauma history. For those who refuse Pap testing, offering self-swabs as a screening option to test for hrHPV may engage individuals in care who might otherwise not receive screening.

2. TERMINOLOGY

Cervix
The cervix is a cylinder-shaped neck of tissue that connects the vagina, or front-hole, and uterus

Cisgender
A person whose self-identified gender conforms to their sex assigned at birth; not transgender.

Concordance
The rate of agreement between two tests or variables (i.e., self-swab and provider swab).

Frontal
Throughout this report, we use the word "frontal" instead of the word "vaginal." When we say "frontal swab", we are referring to a swab that is inserted into the vagina. A frontal swab is inserted approximately two inches into the vagina; it does not reach the cervix.

FTM
Female-to-Male.

Latinx
A gender-neutral term for a person or people who come from, or whose family comes from, Latin America.

Gold standard test
A "gold-standard test" refers to a diagnostic test or benchmark that is the most accurate or is the best test to detect a disease or condition.

Human Papilloma Virus (HPV)
HPV is the most common sexually transmitted infection (STI) in the United States. There are over 150 different strains of HPV; certain high-risk strains (hrHPV) are known to be the primary cause of cervical cancer in people with a cervix.

Papanicolaou (Pap) test

A cervical cancer screening method that relies on the use of a microscope to look at a person's cervical cells, and detect abnormal cells that may develop into cancer if left untreated. The Pap test can also find noncancerous conditions, such as infections and inflammation. It can also find cancer cells. In populations that receive timely screenings, however, the Pap test identifies most abnormal cells before they become cancer. When a provider collects cells for a Pap test, they can also collect cells to test for HPV DNA. For this report, we will be mainly discussing the results of the DNA testing of cervical cells, not on the results of the Pap.

	Provider cervical sample collection, via Pap	Provider-collected frontal swab	Self-swab
Who does it?	Provider	Provider	Patient
Where are cells collected from?	Cervix	Frontal canal	Frontal canal
Is a speculum needed?	Yes	Yes*	No
Are the cells looked at under a microscope?	Yes	No	No
Is a hrHPV DNA test conducted on the cells?	Sometimes	Yes	Yes

**In clinical practice, a speculum is not needed for a provider-collected frontal swab. However, in this study, a speculum was used.*

Prevalence

The percentage of a population that is affected with a particular disease or condition at a given time.

Sensitivity

The ability of a test to correctly classify an individual having the disease or condition. It is measured on a scale of 0-100%, where 100% is highly sensitive. If a test is highly sensitive, it is very likely that any negative result is a "true negative" and the patient does not have the disease or condition.

Specificity

The ability of a test to correctly classify an individual as not having the disease or condition. It is measured on a scale of 0-100%, where 100% is highly specific. If a test is highly specific, it is very likely that any positive result is a "true positive" and the patient does have the disease or condition.

Swab

A small piece of soft, absorbent material (such as cotton or polyester) attached to the end of a stick used for taking specimens.

Trans Masculine (TM)

People who were assigned a female sex at birth and identify as male or on the masculine spectrum (including those who identify as trans man, transgender man, male/man, transsexual man, trans male, man of trans experience, masculine of center, boi, genderqueer, non-binary, and other diverse gender identity labels).

3. INTRODUCTION & STUDY BACKGROUND

Background

Pap tests and Trans Masculine Individuals

Human papillomavirus (HPV) is the most common sexually transmitted infection (STI) in the United States and cervical infection with one of several high-risk strains (hrHPV) is the cause of virtually all cervical cancers,[1] with 12,000 cervical cancer diagnoses occurring per year in the United States.[2] Papanicolaou (Pap) testing is recommended to screen for cervical abnormalities in anyone with a cervix ages 21-64 years at regular intervals determined by age, any history of abnormal tests, the kind of tests done, and any coexisting health conditions. However, the pelvic exam needed to obtain the cervical specimen can be particularly difficult for trans masculine (TM) individuals – people who were assigned a female sex at birth and identify as male or on the masculine spectrum.

Personal and interpersonal factors such as the gendered nature of testing (e.g., female waiting rooms, anatomical terminology, misgendering or use of incorrect pronouns), genital dysphoria, concerns about provider discrimination and insensitivity, and a history of trauma[3-9] can contribute to the emotional discomfort of testing, and can act as barriers to sexual health screening. Long-term testosterone use can also cause genital atrophy,[7,9] making pelvic exams more physically painful. Finally, structural barriers can prevent access to services (e.g., lack of health insurance, non-coverage of natal sex preventive services). These reasons, among others, can lead to the avoidance of and barriers to cervical cancer screenings for TM individuals.

Self-Swabs for HPV screening

A 2012 chart review of 350 TM patients at Fenway Health, a federally-qualified community health center in Boston, MA specializing in LGBT health,[10] found that 36% of TM patients were not up-to-date with cervical cancer screening.[11] In a series of follow-up interviews conducted by researchers at Fenway Health, TM patients expressed high levels of interest in a less invasive cervical cancer screening technique that would help them to feel more in control of their bodies.[12] When asked about self-collected HPV swabs as a primary screening method for cervical cancer, the vast majority (94%) were enthusiastic about having a more comfortable and "less invasive" option.[13]

Self-Swab effectiveness

Several preliminary studies examining the use of self-collected vaginal swabs for HPV testing among cisgender (non-transgender) women have shown high agreement with provider-collected cervical swabs for HPV testing,[14] and have suggested that self-collected vaginal swabs may perform adequately to be used as an initial screen for cervical cancer, though more studies are needed to verify this.[15-17] In a large clinical trial with thousands of cisgender women, provider-collected HPV DNA testing of cervical cells as a primary screening strategy for cervical cancer had superior sensitivity compared to a Pap test alone or Pap test with simultaneous provider-collected HPV DNA testing of cervical cells. However it is not clear if these findings would translate over to self-collected swabs.[18] Studies have also found self-collected vaginal swabs to be more acceptable to cisgender women than Pap tests.[19,20]

While Pap tests are part of the current standard for cervical cancer screening for anyone with a cervix, a retrospective analysis of patient charts at Fenway Health found that 1 in 10 (10.8%) of Pap test results were unsatisfactory for evaluation (not enough cellular material collected, or the material was otherwise unable to be examined properly under the microscope) for TM patients, compared to only 1.3% of cisgender women.[12] The length of time on testosterone was associated with an increased chance of

receiving an unsatisfactory Pap test. The potential difficulty and discomfort of obtaining a cervical specimen with TM patients, combined with the fact that infection with high-risk HPV types causes most cases of cervical cancers,[1] makes testing for the presence of high-risk HPV in frontal tissue via self-swabs first a potential alternative to Pap tests for TM individuals.

Study Aims

The purpose of this study was to compare different methods of sexual health screening developed specifically to meet the needs of TM patients. The study methods were developed to help address barriers to cervical cancer screening and STI screening among TM individuals.

In this study, TM participants self-collected frontal (i.e., vaginal) samples to screen for HPV, in addition to undergoing a provider cervical exam with a speculum to collect a cervical specimen in the usual way (Pap test) for cancer and HPV screening via a DNA test. Participants were also tested for other STIs – chlamydia and gonorrhea (frontal, rectal, throat), trichomoniasis, bacterial vaginosis, syphilis, and HIV.

The primary aim of this study was to test the acceptability, practicality, ease of use, and effectiveness of using a self-collected swab of the frontal (i.e., vaginal) canal to detect HPV DNA compared to a provider-collected cervical Pap test and HPV test, which is the current standard of care.

The secondary aim was to determine the rates of infection with HPV and other STIs among sexually active TM adults. The report presents HPV data only.

Overview of the Study Visit

Participants completed a one-time, in-person clinical visit lasting 3-4 hours at Fenway Health. All participants were compensated $100 for their participation; the first 50 participants were also given the option to complete an extended exit interview for an additional $10. During this visit, participants completed written informed consent, a comprehensive survey self-administered on an iPad, clinical testing for HPV, other STIs, and HIV, a cervical Pap test, and an exit interview. All participants completed self-collection of frontal and rectal samples in private, as well as provider-collected throat, frontal, and cervical samples for HPV, STIs, and a cervical Pap test. Participants were randomly assigned to complete either the self-collection or provider collection first. All study procedures were approved by the Fenway Health Institutional Review Board (IRB).

What is a provider-collected Pap test?

A provider conducted Pap test involves undressing from the waist down, and sitting or lying down on an exam table with open legs. A medical provider uses a tool called a speculum, which is a metal or plastic device, to open the frontal canal slightly so that the provider can see the cervix. The provider then inserts a small brush, swab, or spatula into the frontal canal reaching the cervix, rotates it to obtain cervical cells, and then places the cervical sample into a canister to be sent to a laboratory for assessment.

What is a provider-collected frontal swab?

A medical provider uses a tool called a speculum, which is a metal or plastic device, to open the frontal canal slightly. The provider then inserts a swab into the frontal canal, rotates it to obtain frontal cells, and then places the sample into a canister to be sent to a laboratory for assessment.

What is a self-collected frontal swab?

Self-collected frontal swabs can be completed in private (without the assistance of a medical provider). In this study, participants were invited to collect their samples in an exam room or a single-stall bathroom. They were provided instructions and given a brief explanation of the swabbing procedure, and then collected the sample in private. Participants were instructed to insert a swab approximately 2 inches into the frontal canal, and rotate the swab along the walls of the canal for 10-30 seconds. After collecting the sample, the participant deposited the swab into a canister of liquid and stirred the swab in the liquid for about 10 seconds, then discarded the swab and gave the canister to the research assistant. Participants were provided with a hand mirror and gloves, and were free to use whatever position they felt comfortable in when conducting specimen collection.

Community Engagement

The research team's philosophy and approach was to emphasize the role of diverse individuals with varying backgrounds and perspectives, and actively engage patients, practicing clinicians, and community members. Frequent patient and stakeholder engagement ensured that the project team produced and promoted high integrity, evidence-based information from research guided by patients, providers, and the broader health care community.

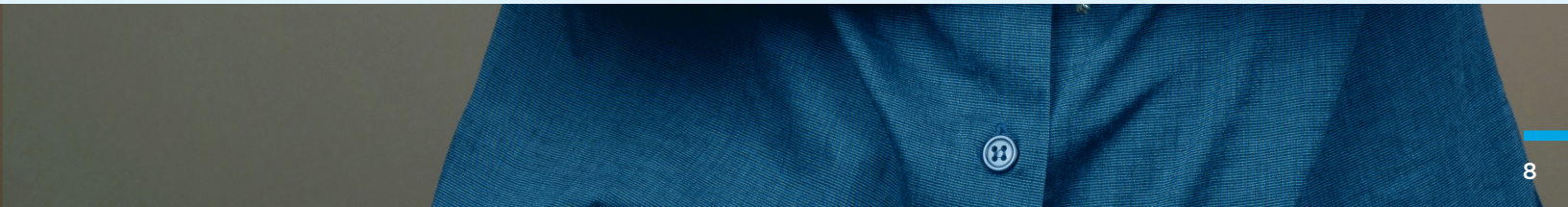
Community members, health care providers, and other stakeholders were continuously engaged in the research process by participating in a Task Force that guided study development, implementation, and dissemination. The Trans Masculine Sexual Health Collaborative Task Force included medical and mental health providers who serve transgender patients, diverse TM individuals, and representatives from allied health organizations across the Boston area.

The 10-member Task Force met bimonthly throughout the project, providing guidance on all aspects of the study, including study recruitment, flow of the clinical visits, focus group development, design of logo and recruitment flyers, and developing deliverables such as an instructional video for the self-swabbing procedure. The Task Force helped ensure that every step of this study was as inclusive, culturally competent, and gender-affirming as possible. Additionally, the research team hosted community events to publicize the study and further engage our local community in dialogue throughout the research process. At every step, community feedback was actively sought, and then thoughtfully integrated into the research process to maximize the applicability and usefulness of the study findings for diverse TM individuals and those who serve them.

"[Screening] still wasn't easy, but, I mean, I feel comfortable with taking care of my own medical issues. And so the empowerment of being able to -- in a most intimate way, and not have to be objectified or subjected to or be reduced to a subject or, less than that, by -- there's no judgment when you have to do it yourself. You don't have to worry about everybody else's interference in the middle of your own moment where you need privacy."

Organizations Represented by Task Force Members

- Massachusetts Transgender Political Coalition
- The Network/La Red
- The Meeting Point
- Massachusetts Commission on Lesbian, Gay, Bisexual, Transgender, Queer and Questioning Youth
- Boston Medical Center
- Beth Israel Deaconess Medical Center



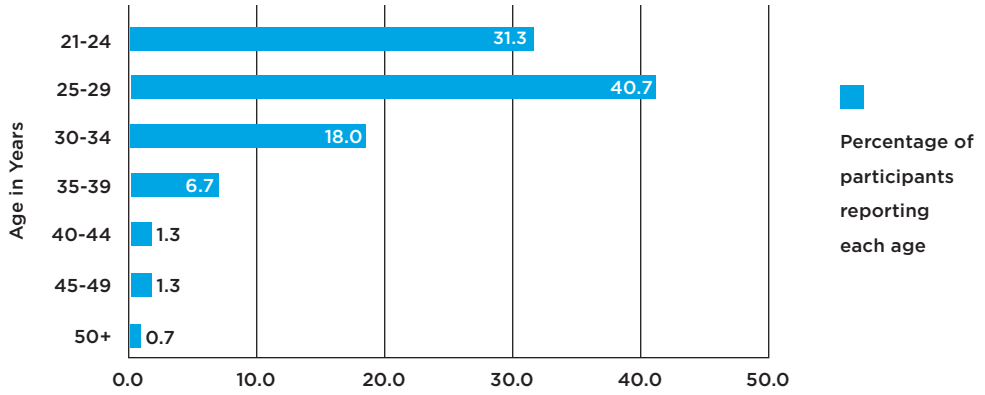
4. SURVEY FINDINGS

Demographics

Between April 2015 and September 2016, 150 trans masculine individuals participated in this study.

Participants reported a mean age of 27.5 years (range ages 21 to 50 years).

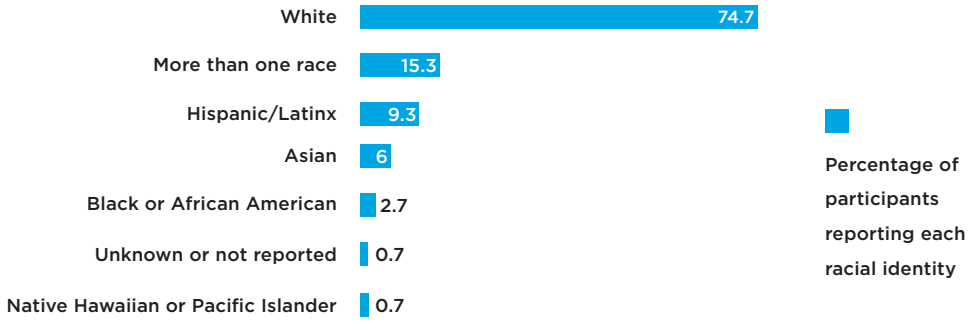
Figure 1:
Age group of participants (N=150)



Most participants (90.7%) reported completing at least some college or more, with 30.7% of the sample completing a Bachelor's degree and 30.7% completing some graduate school or more.

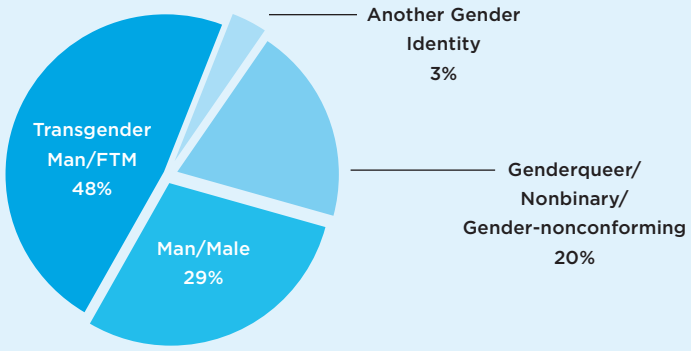
74.7% of participants identified as white, followed by 15.3% identifying as more than one race, and 6.0% as Asian. 14 participants (9.3%) identified as Hispanic/Latinx.

Figure 2:
Racial identity of participants (N=150)



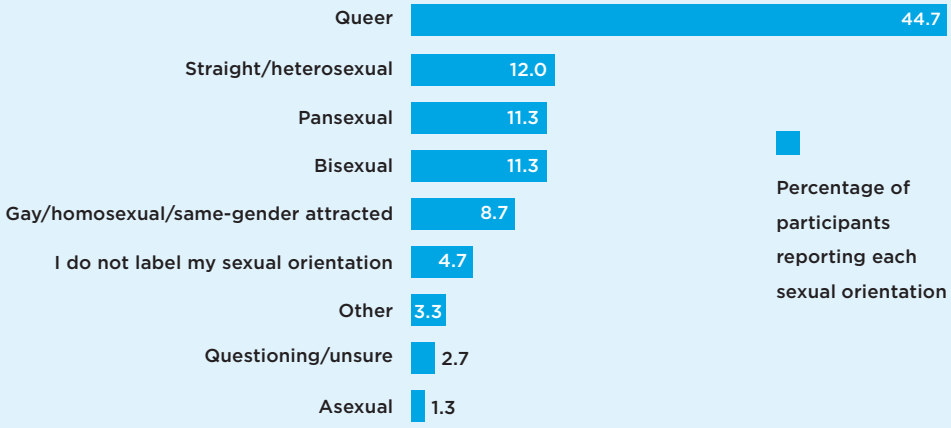
The most commonly reported gender identities were transgender man/FTM/man of transgender experience, with nearly half of participants (72 people, 48.0%) reporting one of these gender identities. The second most commonly reported identity was male/man (43 people, 28.7%), followed by genderqueer/gender non-conforming/non-binary (30 people, 20.0%).

Figure 3:
Self-reported gender identity (N=150)



The most commonly reported sexual identity was queer (67 people, 44.7%) followed by straight (18 people, 12.0%), pansexual (17 people, 11.3%), bisexual (17 people, 11.3%), and gay/homosexual/same-gender attraction (13 people, 8.7%).

Figure 4:
Self-reported sexual orientation of study participants (N=150)



When asked to report the gender identity of their sex partners within the 12 months, participants reported partners of diverse gender identities. Specifically, 91 participants (60.7%) reported having a cisgender woman as a sex partner; 61 (40.7%) reported having a cisgender man as a sex partner; 30 (20.0%) reported having a female-assigned gender non-conforming/non-binary person as a sex partner; 23 (15.3%) reported having a transgender man (FTM) as a sex partner; 18 (12.0%) reported having a transgender woman (MTF) as a sex partner; and 8 people (5.3%) reported having a male-assigned gender non-conforming/non-binary sex partner.

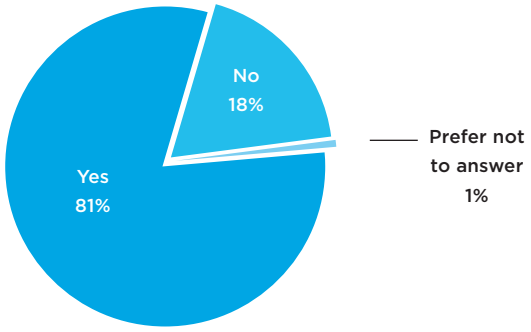
Insurance Status

Among 150 participants, 144 people (96.0%) reported currently having some form of health insurance. The most common forms of insurance reported were private, school or work insurance (45.3%), public insurance such as Mass Health, Medicaid, Medicare (30.0%), and parent's insurance (20.7%)

Pap Test Utilization

Most participants (122 people, 81.3%) had received a Pap test at least once in their lifetime; 27 people (18.0%) had never received a Pap test. Among the 122 individuals who had a Pap test, 36.9% reported that their most recent Pap test was one year ago or less; 17.2% reported that their most recent test was 1-2 years ago, 23.0% reported being tested 2-3 years ago, 13.9% reported being tested 3-5 years ago, and 9.0% reported that their most recent Pap test was more than 5 years ago.

Figure 5: Previous history of pap testing (N=150)



Testosterone Use

Participants were asked if they had ever used masculinizing hormones (e.g., testosterone) at any point in their life. Out of 150 participants, 121 people (80.7%) reported ever using hormones; among these participants, the average age of starting hormones for the first time was 23.3 years. Among the 121 participants who reported ever taking hormones in their lifetime, 113 people reported that they were currently taking hormones.

Figure 6: Self-reported current hormone use (N=121)

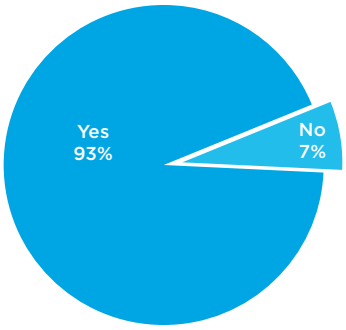
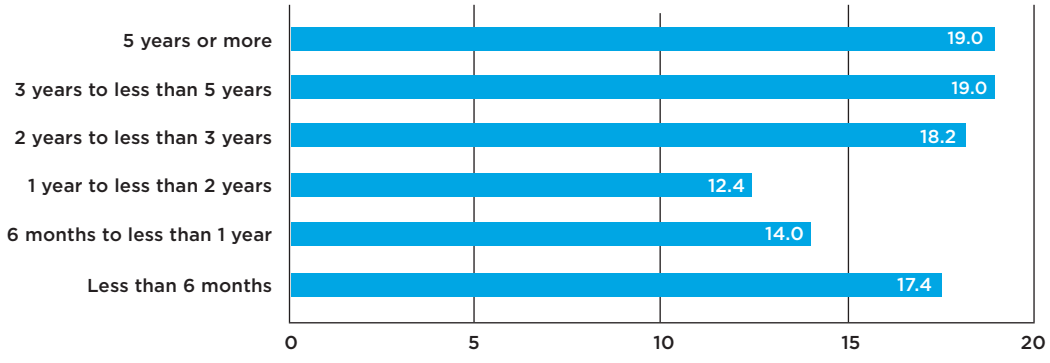


Figure 7: Self-reported length of time on hormones (N=121)

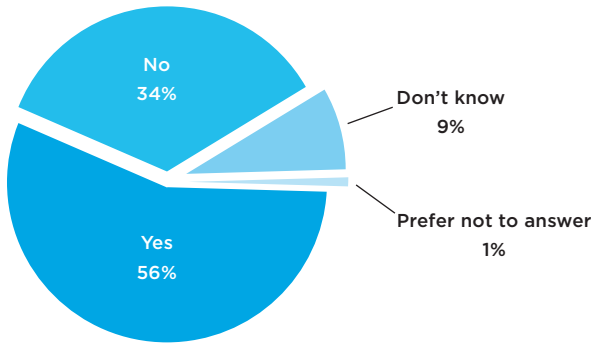


HPV Vaccination

Among 150 participants, 84 people (56.0%) reported that they had received a vaccination for HPV. A total of 52 people (34.7%) reported that they had never been vaccinated; 13 people (8.7%) were unsure, and 1 person did not respond.

The 84 participants who reported receiving the HPV vaccine were asked how many out of the 3 recommended doses they received. A total of 72 out of 84 participants (85.7%) reported having received all 3 doses, while 4 people (4.8%) reported receiving only 2 doses, 3 people (3.6%) reported receiving only one dose, and 5 people (6.0%) were unsure how many doses they received. Participants were asked to report the age that they received their first dose of the HPV vaccine. Out of 74 respondents, the average age at which they received their first dose of the HPV vaccine was 19.0 years.

Figure 8: Ever received HPV Vaccine (lifetime) (N=150)



5. CLINICAL FINDINGS

HPV Prevalence

The gold standard is the current preferred method of diagnosing a particular disease. The "gold standard" cervical HPV DNA test is a DNA test that can detect the presence of 13 high-risk HPV strains conducted on a cervical sample collected by a medical provider. Results for this test were received for 132 out of 150 participants; 18 participants were missing results for technical reasons (e.g., not having collected enough cells to run the test), the participant declined the test, or other reasons. Among the 132 participants with test results, 21 participants tested positive for HPV (15.9% prevalence).

Concordance of the self-collected frontal and provider-collected cervical swab for HPV

Concordance results are reported for the 131 participants with complete testing data (i.e., no missing results).

Compared to the gold-standard cervical DNA test (testing cervical cells for HPV DNA), the self-collected frontal swab for the HPV DNA test (testing frontal cells for HPV DNA) had a sensitivity of 71.4%. This means that on average, the self-collected frontal swab accurately detected approximately 7 out of 10 cases of HPV. The self-collected frontal swab for HPV had a specificity of 98.2%, meaning that out of 110 negative results from the gold-standard cervical DNA test, the self-swab incorrectly detected 2 positive results (i.e., self-collected frontal swab indicated positive for HPV, but the gold-standard cervical test was negative). For the purpose of this analysis, these are considered to be "false positives".

Concordance of self- and provider-collected frontal swabs

A total of 53 participants had a provider-collected frontal HPV DNA test (collected from the frontal canal, but NOT in the cervix); these data were compared to the self-collected frontal HPV DNA test. Compared to the provider-collected frontal swab, the self-collected frontal swab had a sensitivity of 85.7% and a specificity of 97.9%.

Concordance of provider-collected frontal swab and provider-collected cervical swab

The provider-collected frontal HPV swab was also compared to the provider-collected cervical HPV test. Compared to provider-collected cervical test, the provider-collected frontal swab had a sensitivity of 85.7%.

How many cases of HPV did each test detect?

Provider cervical sample collection, via Pap	Provider swab	Self-swab
10 out of 10	8 out of 10	7 out of 10

6. ACCEPTABILITY FINDINGS

Patient acceptability of the self-swab

In qualitative exit interviews, the majority of participants stated that they preferred the experience of conducting a frontal self-swab for HPV detection over the experience of a provider test in most contexts. While some participants expressed absolute preference for the self-swab, others stated that their preference depended on contextual factors, such as the level of trans-competence of the medical provider, the clarity of the self-swab instructions, and the reliability of the self-swab to detect HPV DNA. Only a few participants indicated an exclusive preference for a provider-administered test.

Participants cited a variety of positive aspects about the experience of self-swabbing, including ease, privacy, minimized invasiveness, and a sense of empowerment.

"The best part of collecting [my] own samples was... getting to have the privacy while I was doing it."

"[Self-swabbing is] kind of a weird concept, but it was much easier than I expected it to be and it was nice to be able to do it in private... it was super simple and straightforward after hearing the directions."

"When I do it or the routine that self-swabbing is much quicker and is not, doesn't seem as invasive, you know, it's not up in the cervix."

"When you do it yourself, as opposed to somebody else doing it, since you can feel all your muscles, you feel what you're feeling, you know, you can make yourself a lot more comfortable. Like, you can feel it out, take your time, you know what I mean? Way better than somebody who can't feel what you're feeling, you know, controlling you. So, that was a big plus too... So if something doesn't feel comfortable, maybe you can just ... not move it around as much, or something, or you know, instead of having to have somebody else deal with it."

"Self [swab] influences the way I feel about my health... because then I have more, I guess, I have more part in it... I didn't take any regular Pap smears... I think if I had the option to self-collect, it would have been more [likely to screen], because I was always kind of afraid of the gynecologist."

"[Screening] still wasn't easy, but, I mean, I feel comfortable with taking care of my own medical issues. And so the empowerment of being able to -- in a most intimate way, and not have to be objectified or subjected to or be reduced to a subject or, less than that, by -- there's no judgment when you have to do it yourself. You don't have to worry about everybody else's interference in the middle of your own moment where you need privacy."

Concerns about the self-swabbing experience were also noted by participants. Concerns included uncertainty about whether they had performed the procedure correctly, distrust of accuracy of the test, experiencing anxiety and dysphoria during self-collection, and physical pain.

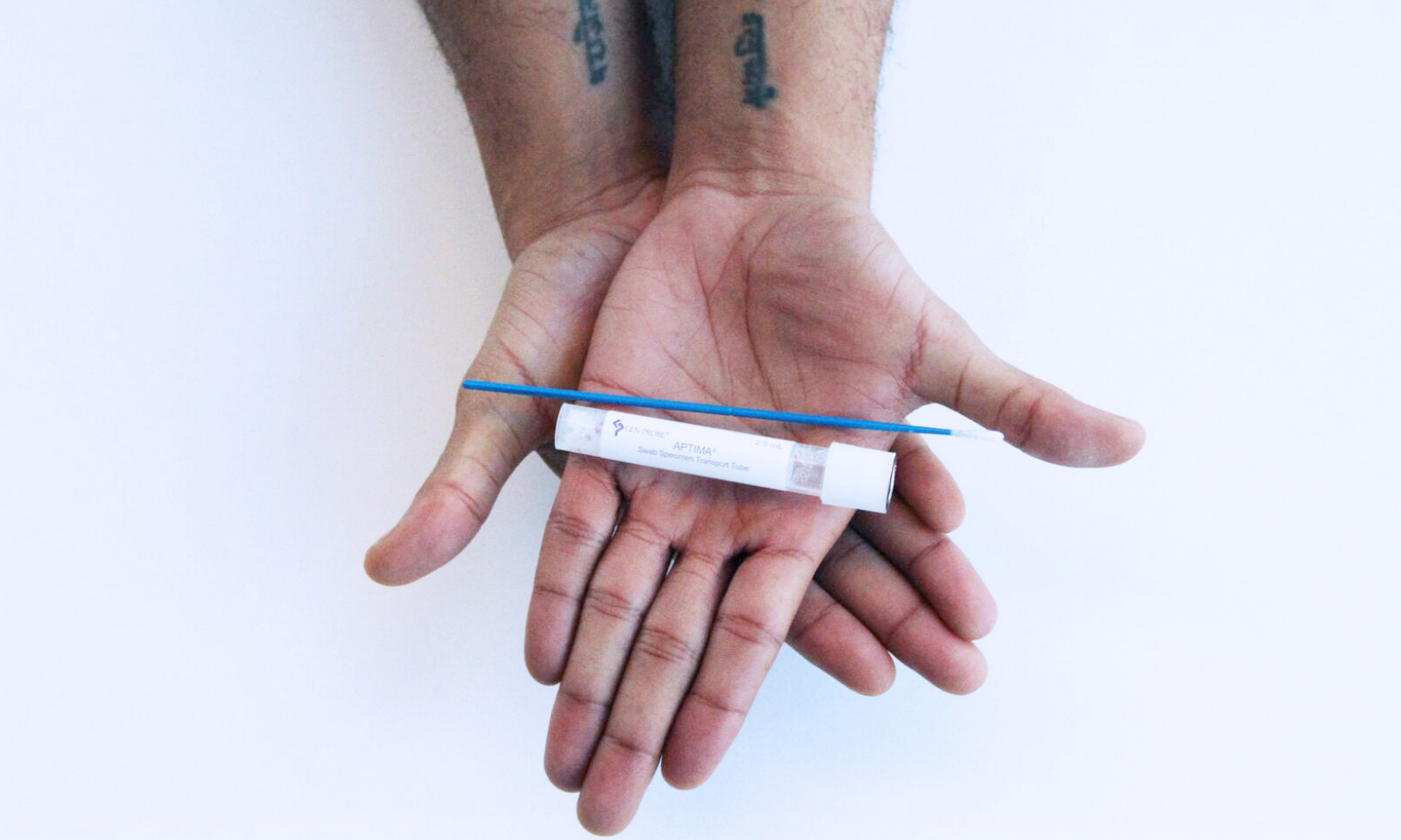
"I was nervous. I was nervous about doing it right. I was also just generally kind of anxious, because I don't really -- dealing with that part of my body makes me a little anxious."

"It was a little awkward. But it wasn't -- like I don't really have that much body dysphoria. I think I was just a little nervous that I was going to like mess it up in some way."

"I understand how it would be preferred for folks, but I would be concerned about the accuracy of it."

"Because you're doing it yourself, you're like looking, which is kind of more uncomfortable in a way too, whereas like if a provider does it, like you don't have to look."

"I went in as much as I could without -- I mean, it wasn't as painful after a certain point, of getting in there. But I feel like it -- probably pain could have, you know, because obviously it's really dry down there anyways, you know, with the atrophy."



In general, privacy was the most frequently mentioned appeal of the self-swabbing procedure, and technical uncertainty was the most frequently mentioned concern. Participants expressed hope that their comfort with and trust of the procedure would increase with practice and with clear, comprehensive instructions.

Even when citing concerns about their own experience of self-swabbing within the study, many participants indicated that they felt it is important that TM individuals have options regarding HPV screening methods. Many participants stated that having choices about screening would benefit the TM community by empowering individuals in their own health care and increase screening uptake overall.

"But yeah, this is definitely something that would benefit trans men if you can do it, and even if it is better than nothing, it is still better than nothing, which is what a lot of guys are getting. Harm reduction is totally a thing. And in terms of that, it was not deep enough to make me feel dysphoric. I am -- it was- it felt more like the mouth swab than it felt like -- I didn't have to go very deep, I didn't have to poke particularly hard at any place that is sensitive or painful. And so in terms of things that I have to do for health care, that was actually pretty minor. I would call the self-swabbing a pretty painless procedure for anyone who can at least masturbate comfortably."

"[Self-swabbing is] kind of a weird concept, but it was much easier than I expected it to be and it was nice to be able to do it in private... it was super simple and straightforward after hearing the directions."

7. CONCLUSION

Clinical findings of the current study indicate that self-collected frontal swabs are able to detect about 71% of people who had a positive provider-collected cervical HPV test (i.e., gold standard).

The sensitivity of the self-collected frontal swab for HPV DNA detection in this sample is consistent with sensitivity findings from studies of cisgender women, which found an overall sensitivity of 74% and a specificity of 88% for self-collected vaginal swabs in cisgender women in comparison to provider-collected specimens.[21] Clinicians and researchers have consistently made the case that self-swabs are accurate enough that they should be offered to cisgender women who otherwise cannot or would not access Pap testing, but that self-swabs should not be offered to all cisgender women due to their reduced accuracy compared to provider-collected tests. Based on similar findings in this study, we believe a similar set of guidelines can be followed with TM patients.

While the sensitivity of the self-collected frontal swab indicates that provider-conducted cervical testing is still the "gold standard" for detecting HPV DNA accurately, self-collected frontal swabs demonstrated reasonable accuracy. HPV DNA testing using a self-collected frontal swab is a potential alternative screening option to the Pap test for TM patients who may otherwise decline or not have access to cervical cancer screening. Self-swabbing of the frontal canal may be a reasonable alternative in a comprehensive harm-reduction model of care, particularly for TM patients who avoid health care.

Data from this study and others[22,23] show that TM individuals may avoid health care for a variety of reasons including fear of discrimination, dysphoria, or trauma history. For TM who refuse Pap testing, offering self-collected frontal swabs as a screening option may engage individuals in sexual health care who would otherwise not get screening of any kind. Many participants noted that they appreciate the idea of having a choice about how to screen for HPV, and some stated that they felt empowered by the option to self-swab. Some participants asserted that the option to self-swab would increase their engagement in sexual health care, which they would otherwise avoid.

In considering participant feedback, it is important to also note that data from this study are affected by a self-selection bias. The 150 TM individuals who volunteered to participate in this study are, by virtue of their choice to volunteer, those who are likely to be less averse to health care than some other TM individuals or communities. Individuals with higher levels of health care avoidance, and who may benefit most from the option to self-swab, are probably underrepresented in this study. Also, since many of the participants had undergone screening within the past 3 years, this may have biased our findings to find lower rates of HPV than in a more general population of TM individuals.

"Self [swab] influences the way I feel about my health... because then I have more, I guess, I have more part in it... I didn't take any regular Pap smears... I think if I had the option to self-collect, it would have been more [likely to screen], because I was always kind of afraid of the gynecologist."

An important finding in this study is that, among the 150 TM individuals screened, prevalence of hr-HPV was comparable to percentages shown in other populations (i.e., cisgender women). TM individuals are indeed at-risk for contracting HPV at similar levels to cisgender women.[24]

8. RECOMMENDATIONS FOR PATIENTS

Self-collected frontal swabs detect fewer cases of hrHPV compared to traditional cervical HPV DNA testing conducted by a medical provider; self-testing may miss about 3 out of 10 cases of HPV. A cervical Pap test (potentially with hrHPV co-testing depending on patient age and screening history) still represents the gold standard for cervical cancer screening. However, for patients who are unwilling or unable to undergo a Pap test, a frontal self-swab for hrHPV DNA testing may present a reasonable alternative.

For more information about what may be the best option for you, please visit **http://fenwayhealth.org** or **http://www.transmaschealth.org**.

APPENDIX 1: METHODS

Written Informed Consent:

Participants met with a Research Assistant to review the informed consent form which described visit components and ask any questions before agreeing to participate in the study.

Survey:

Participants then completed a survey on an iPad in a private room, lasting approximately 45-75 minutes.

Blood Draw:

A Phlebotomist conducted a blood draw to test for HIV and syphilis.

Randomization:

The participants were randomly assigned to either complete self-collection first, followed by provider-collection; OR provider-collection first, followed by self-collection. All participants completed both testing methods.

Self-Collection:

Participants were brought to a private room at Fenway Health (choice of exam room or bathroom). The research assistant provided instructions on how to collect and package the samples, and answered any questions before leaving the participant in private. Using a swab (similar to a long Q-tip®, the participants then collected:

- A frontal swab for HPV testing.
- A frontal swab for Gonorrhea and Chlamydia testing.
- A rectal swab for Gonorrhea and Chlamydia testing.

Provider-Collection:

Participants met with a Fenway Health Physician (MD) or Nurse Practitioner (NP). The provider asked several questions to understand the recent sexual health history of the participant. The provider then explained the testing procedures and answered any of the participant's questions. The provider then collected:

- A throat swab for Gonorrhea/Chlamydia testing.
- A frontal swab for HPV DNA testing.*
- A frontal swab for Gonorrhea and Chlamydia testing.
- A frontal swab for trichomonas testing.
- A frontal swab for bacterial vaginosis testing.
- A cervical sample (Pap test) using a small brush and spatula to test for HPV DNA and check for abnormal cervical cells.
- Provider conducted frontal HPV swab was added at participant number 95.

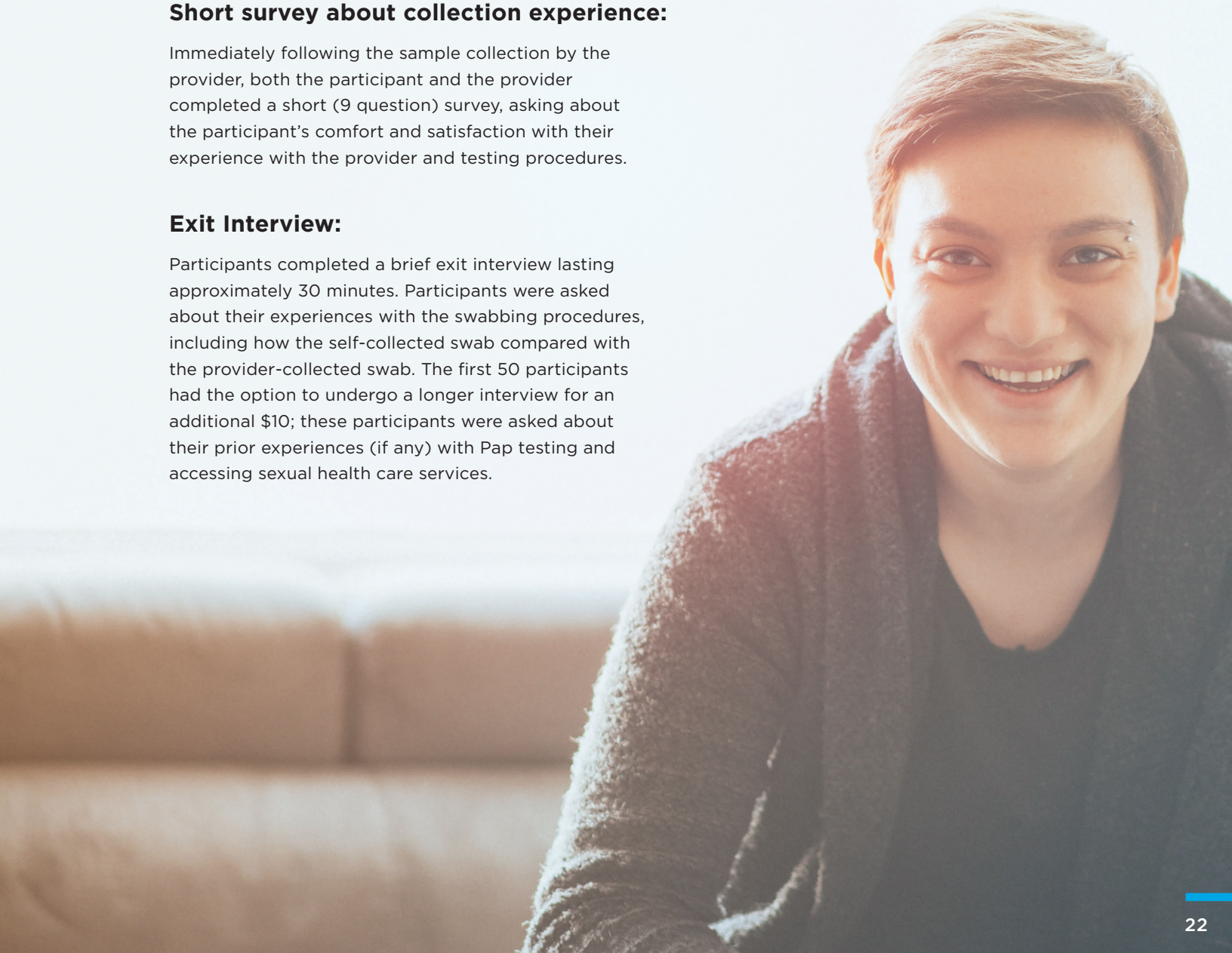
**Provider conducted frontal HPV swab was added at participant number 95.*

Short survey about collection experience:

Immediately following the sample collection by the provider, both the participant and the provider completed a short (9 question) survey, asking about the participant's comfort and satisfaction with their experience with the provider and testing procedures.

Exit Interview:

Participants completed a brief exit interview lasting approximately 30 minutes. Participants were asked about their experiences with the swabbing procedures, including how the self-collected swab compared with the provider-collected swab. The first 50 participants had the option to undergo a longer interview for an additional $10; these participants were asked about their prior experiences (if any) with Pap testing and accessing sexual health care services.



Appendix 2: Tables

Table 1.

Demographic characteristics of TM sample (n=150).

SOCIO-DEMOGRAPHICS	MEAN	SD
AGE IN YEARS, CONTINUOUS		
Range: Ages 21-50 Years	27.5	5.7
RACE/ETHNICITY		
American Indian or Alaska Native	0	0.0
Asian	9	6.0
Native Hawaiian or Pacific Islander	1	0.7
Black or African American	4	2.7
White	112	74.7
More than one race	23	15.3
Unknown or not reported	1	0.7
HISPANIC/LATINO		
Hispanic or Latino	14	9.3
Not Hispanic or Latino	133	88.7
Unknown or not reported	3	2.0
GENDER IDENTITY		
Man/Male	43	28.7
Transgender man/FTM	72	48.0
Genderqueer/Non-binary	30	20.0
Another gender identity	5	3.3
EDUCATION - HIGHEST LEVEL		
High School or equivalent	14	9.3
Some college (1-3 years)	44	29.3
College graduate (4 year college degree)	46	30.7
Graduate school	46	30.7
EMPLOYMENT - CURRENT		
Employed full time	44	29.3
Employed part time	68	45.3
Unemployed	34	22.7
Prefer not to answer	4	2.7
STUDENT - CURRENT	**N**	**%**
Yes	52	34.7
No	97	64.7
Prefer not to answer	1	0.7
INCOME		
$19,999 or less	45	30.0
$20,000 - $39,999	32	21.3
$40,000 - $59,999	15	10.0
$60,000 - $79,999	16	10.7
$80,000 or more	26	17.3
Don't know	13	8.7
Prefer not to answer	3	2.0
INSURANCE		
No health insurance	4	2.7
Public insurance (Mass Health, Medicaid, Medicare)	45	30.0
Private, school or work insurance	68	45.3
Parent's insurance	31	20.7
Prefer not to answer	2	1.3

Table 2.

Self-reported access to health care (n=150)

HEALTH CARE ACCESS	MEAN	SD
SELF-RATED HEALTH		
Excellent	16	10.7
Very good	61	40.7
Good	58	38.7
Fair	13	8.7
Poor	2	1.3
PROBLEMS ACCESSING HEALTH CARE - PAST 12 MONTHS		
Yes	21	14.0
No	127	84.7
Never sought out health care	1	0.7
Prefer not to answer	1	0.7
TROUBLE ACCESSING SPECIFIC HEALTH CARE SERVICES - PAST 12 MONTHS	**N=21**	
Primary care (annual check-up, doctor visit when sick)	14	66.7
Sexual health care (Pap test, HIV testing, STI screening, contraceptives)	3	14.3
Specialty care (dermatologist, gastrointestinal care, cardiologist, radiologist)	10	47.6
Behavioral health care (mental health counseling, psychiatric medications)	15	71.4
Substance abuse treatment (substance abuse counseling, AA meetings)	1	4.8
Wellness services (acupuncture, massage, chiropractor)	7	33.3
Dental care (cleaning, cavity filling, root canal)	6	28.6
Other (pharmacy)	1	4.8
SATISFACTION WITH HEALTH CARE - PAST 12 MONTHS		
Very satisfied	41	27.3
Mostly satisfied	83	55.3
Neutral	18	12.0
Mostly dissatisfied	5	3.3
Very dissatisfied	3	2.0

Table 3.

Sexual orientation & sexual partnering (n=150)

SEXUAL ORIENTATION & SEXUAL PARTNERING	n=150	
SEXUAL ORIENTATION	**N**	**%**
Gay/homosexual/same-gender attracted	13	8.7
Straight/heterosexual	18	12.0
Bisexual	17	11.3
Queer	67	44.7
Pansexual	17	11.3
Questioning/unsure	4	2.7
Asexual	2	1.3
I do not label my sexual orientation	7	4.7
Other	5	3.3
NUMBER OF PARTNERS - PAST 36 MONTHS	**MEAN**	**SD**
Range (0 to 50)	6.2	7.5
GENDER OF SEXUAL PARTNERS - PAST 36 MONTHS	**N**	**%**
Cisgender man	84	56.0
Cisgender woman	119	79.3
Transgender man	34	22.7
Transgender woman	29	19.3
Male assigned sex at birth - Gender non-conforming	14	9.3
Female assigned sex at birth - Gender non-conforming	42	28.0
NUMBER OF PARTNERS PAST 12 MONTHS	**MEAN**	**SD**
Range (0 to 40)	3.2	4.2
GENDER OF SEXUAL PARTNERS - PAST 12 MONTHS	**N**	**%**
Cisgender man	61	40.7
Cisgender woman	91	60.7
Transgender man	23	15.3
Transgender woman	18	12.0
Male assigned sex at birth - Gender non-conforming	8	5.3
Female assigned sex at birth - Gender non-conforming	30	20.0

Table 4.

Gender affirmation (social, legal, and medical) (n=150)

GENDER AFFIRMATION	n=150	
SOCIAL GENDER AFFIRMATION	**N**	**%**
Yes	131	87.3
No	16	10.7
Prefer not to answer	3	2.0
LEGAL GENDER AFFIRMATION		
Yes	86	57.3
No	64	42.7
HORMONE USE - LIFETIME		
Yes	121	80.7
No	29	19.3
TIME CONSISTENTLY ON HORMONES - LIFETIME	**N=121**	
Less than 6 months	21	17.4
6 months to less than 12 months	17	14.0
12 months to less than 3 years	37	30.6
3 years to less than 5 years	23	19.0
5 years or more	23	19.0
AGE IN YEARS STARTED HORMONES	**MEAN**	**SD**
Range (ages 4 to 43 years)	23.3	4.6
HORMONE USE - CURRENT	**N**	**%**
Yes	113	93.4
No	8	6.6
TOTAL AMOUNT OF TIME ON HORMONES	**N=121**	
Less than 6 months	21	17.4
6 months to less than 1 year	17	14.0
1 year to less than 2 years	15	12.4
2 years to less than 3 years	22	18.2
3 years to less than 5 years	23	19.0
5 years or more	23	19.0
PLANS TO USE HORMONES IN FUTURE	**N=37**	
Yes	13	35.1
No	3	8.1
Don't Know	21	56.8
TRANSGENDER SURGERIES	**N=150**	
Chest surgery (FTM reconstruction/bilateral mastectomy)	58	38.7
Chest surgery (breast reduction without breast removal)	6	4.0
Facial or neck surgery	8	5.3
Oophorectomy (removal of both ovaries and fallopian tubes)	3	2.0
Partial or Supracervical Hysterectomy (removal of uterus, cervix intact)	2	1.3
Metoidioplasty genital surgery without urethral	1	0.7

Table 5.

Pap & HPV testing history; HPV vaccination history (n=150)

PAP & HPV TESTING HISTORY	n=150	
PAP TEST HISTORY - LIFETIME	**N**	**%**
Yes	122	81.3
No	27	18.0
Prefer not to answer	1	0.7
TIME SINCE LAST PAP TEST	**n=122**	
1 year ago or less	45	36.9
More than 1 year ago but not more than 2 years	21	17.2
More than 2 years ago but not more than 3 years	28	23.0
More than 3 years ago but not more than 5 years	17	13.9
More than 5 years ago	11	9.0
INADEQUATE PAP - LIFETIME	**n=150**	
Yes	22	18.0
No	91	74.6
Don't know	9	7.4
ABNORMAL PAP - LIFETIME	**n=122**	
Yes	20	16.4
No	86	70.5
Don't know	15	12.3
Prefer not to answer	1	0.8
COLPOSCOPY - LIFETIME	**n=20**	
Yes	9	45.0
No	9	45.0
Don't know	2	10.0
BIOPSY - LIFETIME	**n=20**	
Yes	3	15.0
No	14	70.0
Don't know	3	15.0
HEARD OF HPV	**n=150**	
Yes	82	54.7
No	31	20.7
Don't know	37	24.7
DIAGNOSED WITH HPV - LIFETIME	**n=150**	
Yes	11	7.3
No	135	90.0
Don't know	3	2.0
Prefer not to answer	1	0.7
RECEIVED HPV VACCINE	**n=150**	
Yes	84	56.0
No	52	34.7
Don't know	13	8.7
Prefer not to answer	1	0.7
NUMBER OF DOSES OF HPV VACCINE	**n=84**	
1	3	3.6
2	4	4.8
3	72	85.7
Don't know	5	6.0
	n=74	
AGE IN YEARS WHEN FIRST RECEIVED HPV VACCINE	**MEAN**	**SD**
Range (ages 11 to 34 years)	19.0	4.8

REFERENCES

1. National Cancer Institute (NCI). Fact sheet: HPV and Cancer. 2013; http://www.cancer.gov/cancertopics/factsheet/Risk/HPV. Accessed 8/1/2013.

2. Group USCSW. United States Cancer Statistics: 1999–2013 Incidence and Mortality Web-based Report. Atlanta (GA): Department of Health and Human Services, Centers for Disease Control and Prevention, and National Cancer Institute 2016; Available at: http://www.cdc.gov/uscs.

3. Kaufman R. Introduction to Transgender Identity and Health. In: Makadon H, Mayer KH, Potter J, Goldhammer H, eds. The Fenway Guide to Lesbian, Gay, Bisexual, and Transgender Health. Philadelphia: American College of Physicians; 2008:331-363.

4. Driak D, Samudovsky M. Could a man be affected with carcinoma of cervix?--The first case of cervical carcinoma in trans-sexual person (FtM)--case report. Acta Medica (Hradec Kralove). 2005;48(1):53-55.

5. Feldman JL. Preventive care of the transgendered patient: An evidence-based approach. In: Ettner R, Monstrey S, Eyler E, eds. Principles of Transgender Medicine and Surgery. Binghampton, New York: Haworth Press; 2007:33-72.

6. Kenagy GP. Transgender health: findings from two needs assessment studies in Philadelphia. Health Soc Work. Feb 2005;30(1):19-26.

7. O'Hanlan KA, Dibble SL, Young-Spint M. Total laparoscopic hysterectomy for female-to-male transsexuals. Obstet Gynecol. Nov 2007;110(5):1096-1101.

8. Rachlin K, Green J, Lombardi E. Utilization of health care among female-to-male transgender individuals in the United States. J Homosex. 2008;54(3):243-258.

9. van Trotsenburg MAA. Gynecological Aspects of Transgender Healthcare. International Journal of Transgenderism. 2009;11:238-246.

10. Reisner SL, Bradford J, Hopwood R, et al. Comprehensive transgender healthcare: the gender affirming clinical and public health model of Fenway Health. Journal of urban health : bulletin of the New York Academy of Medicine. Jun 2015;92(3):584-592.

11. Peitzmeier SM, Khullar K, Reisner SL, Potter J. Pap test use is lower among female-to-male patients than non-transgender women. American journal of preventive medicine. Dec 2014;47(6):808-812.

12. Peitzmeier SM, L. RS, P. H, Potter J. Female-to-male transgender patients have high prevalence of unsatisfactory Paps compared to non-transgender females: Implications for cervical cancer screening. J Gen Intern Med. 2014.

13. McDowell M, Pardee DJ, Peitzmeier SM, et al. Cervical cancer screening preferences among female-to-male transgender individuals: Patient-collected human papillomavirus vaginal swabs versus provider-administered Pap tests. LGBT Health. under review.

14. Petignat P, Faltin DL, Bruchim I, Tramer MR, Franco EL, Coutlee F. Are self-collected samples comparable to physician-collected cervical specimens for human papillomavirus DNA testing? A systematic review and meta-analysis. Gynecol Oncol. May 2007;105(2):530-535.

15. Harper DM, Noll WW, Belloni DR, Cole BF. Randomized clinical trial of PCR-determined human papillomavirus detection methods: self-sampling versus clinician-directed--biologic concordance and women's preferences. Am J Obstet Gynecol. Mar 2002;186(3):365-373.

16. Sellors JW, Lorincz AT, Mahony JB, et al. Comparison of self-collected vaginal, vulvar and urine samples with physician-collected cervical samples for human papillomavirus testing to detect high-grade squamous intraepithelial lesions. Cmaj. Sep 5 2000;163(5):513-518.

17. Wright TC, Jr., Denny L, Kuhn L, Pollack A, Lorincz A. HPV DNA testing of self-collected vaginal samples compared with cytologic screening to detect cervical cancer. Jama. Jan 5 2000;283(1):81-86.

18. Mayrand MH, Duarte-Franco E, Rodrigues I, et al. Human papillomavirus DNA versus Papanicolaou screening tests for cervical cancer. N Engl J Med. Oct 18 2007;357(16):1579-1588.

19. Dannecker C, Siebert U, Thaler CJ, Kiermeir D, Hepp H, Hillemanns P. Primary cervical cancer screening by self-sampling of human papillomavirus DNA in internal medicine outpatient clinics. Ann Oncol. Jun 2004;15(6):863-869.

20. Nobbenhuis MA, Helmerhorst TJ, van den Brule AJ, et al. Primary screening for high risk HPV by home obtained cervicovaginal lavage is an alternative screening tool for unscreened women. J Clin Pathol. Jun 2002;55(6):435-439.

21. Ogilvie GS, Patrick, D.M., Schulzer, M., Sellors, J.W., Petric, M., Chambers, K., White, R. and FitzGerald, J.M. Diagnostic accuracy of self collected vaginal specimens for human papillomavirus compared to clinician collected human papillomavirus specimens: a meta-analysis. Sexually transmitted infections. 2005;81(3):207-212.

22. Agénor M, Peitzmeier, S.M., Bernstein, I.M., McDowell, M., Alizaga, N.M., Reisner, S.L., Pardee, D.J., Potter, J. . Perceptions of cervical cancer risk and screening among transmasculine individuals: patient and provider perspectives. Culture, Health, & Sexuality. 2016;18(10):1192-1206.

23. Peitzmeier SM, Agénor, M., Bernstein, I., McDowell, M., Alizaga, N.M., Reisner, S.L., Pardee, D.J., Potter, J. "It can promote an existential crisis": factors influencing Pap test acceptability and utilization among transmasculine individuals. . Qualitative Health Research. under review.

24. Center for Disease Control and Prevention (CDC). Other Sexually Transmitted Diseases 2011 Sexually Transmitted Diseases Surveillance. 2011; http://www.cdc.gov/std/stats11/other.htm#hpv. Accessed 8/1/2013.

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