Advances in Cervical Cancer Screening: Introducing the Self-Swab

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About Us

Mission:

To help our members, and the communities we serve, be healthy.

Vision:

To be the most highly regarded managed care plan in California.

PARTNERSHIP HEALTHPLAN of CALIFORNIA
A Public Agency

"We have the tools to eradicate cervical cancer through prevention and screening and we can implement them in our communities at highest risk of this disease"

– Janine Clayton, MD, FARVO, associate director for Research on Women's Health and director, Office of Research on Women's Health at the National Institutes of Health

Cervical Cancer and HPV Screening

- Percentage of women screened for cervical cancer in the US in 2018 (81 percent) remained below the Healthy People 2020 target (93 percent)
- Persistent human papillomavirus (HPV) infections with high risk HPV is the cause of cervical cancer
- Cervical pre-cancer, when detected via screening, can be successfully treated, which prevents cancer in most cases
- Invasive cancer is rare in the US with more than 90 percent of potential cases prevented by screening.
- 19 percent of women in the US are not up to date with established screening guidelines, and disparities persist among medically underserved populations.

HRSA 2022 March Guideline Adoption in Safety-net Care: Understanding the Prevention, Screening, and Management of Cervical Cancer in Safety-Net and Health Resources and Services Administration-Supported Settings of Care
Multilevel Approaches to Achieving Equity in Cervical Cancer Prevention, Screening, and Treatment in Federally-Supported Safety-Net Settings of Care

Rates of Overdue Cervical Cancer Screening 2019

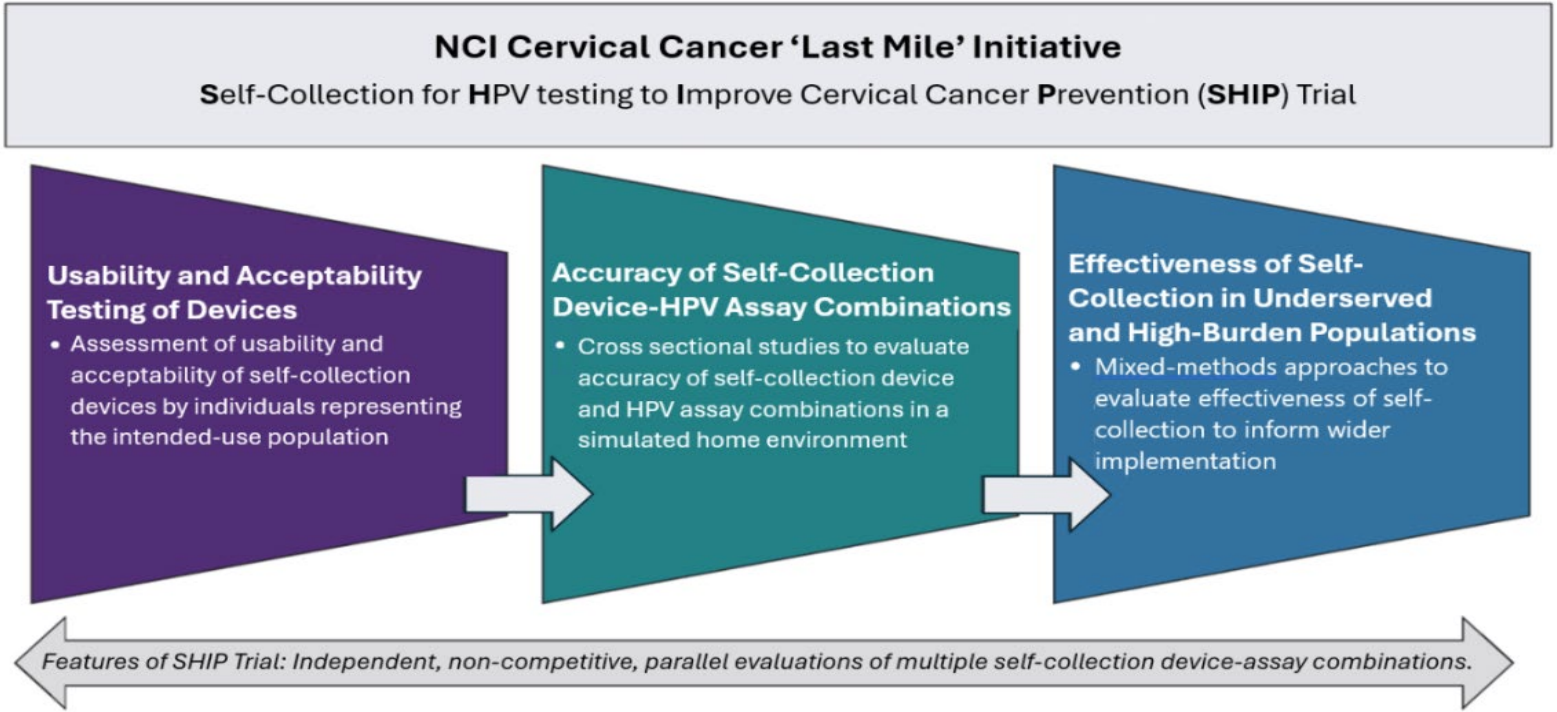
Racial and Ethnic Groups	
Non-Hispanic Black	22%
Non-Hispanic White	20%
Other (Including Alaska Native and American Indian)	27%
Geographic Groups	
Rural Women	26%
Urban Women	23%
Health Insurance Status	
Uninsured	42%
Public Insurance	28%
Private Insurance	18%

National Health Interview Survey 2019 https://www.cdc.gov/nchs/nhis/about/index.html
National Cancer Institute Feb 2022 Edward Winstead. Why are Many Women Overdue for Cervical Cancer Screening https://www.cancer.gov/news-events/cancer-currents-blog/2022/overdue-cervical-cancer-screening-increasing

Under-screening is Multifactorial

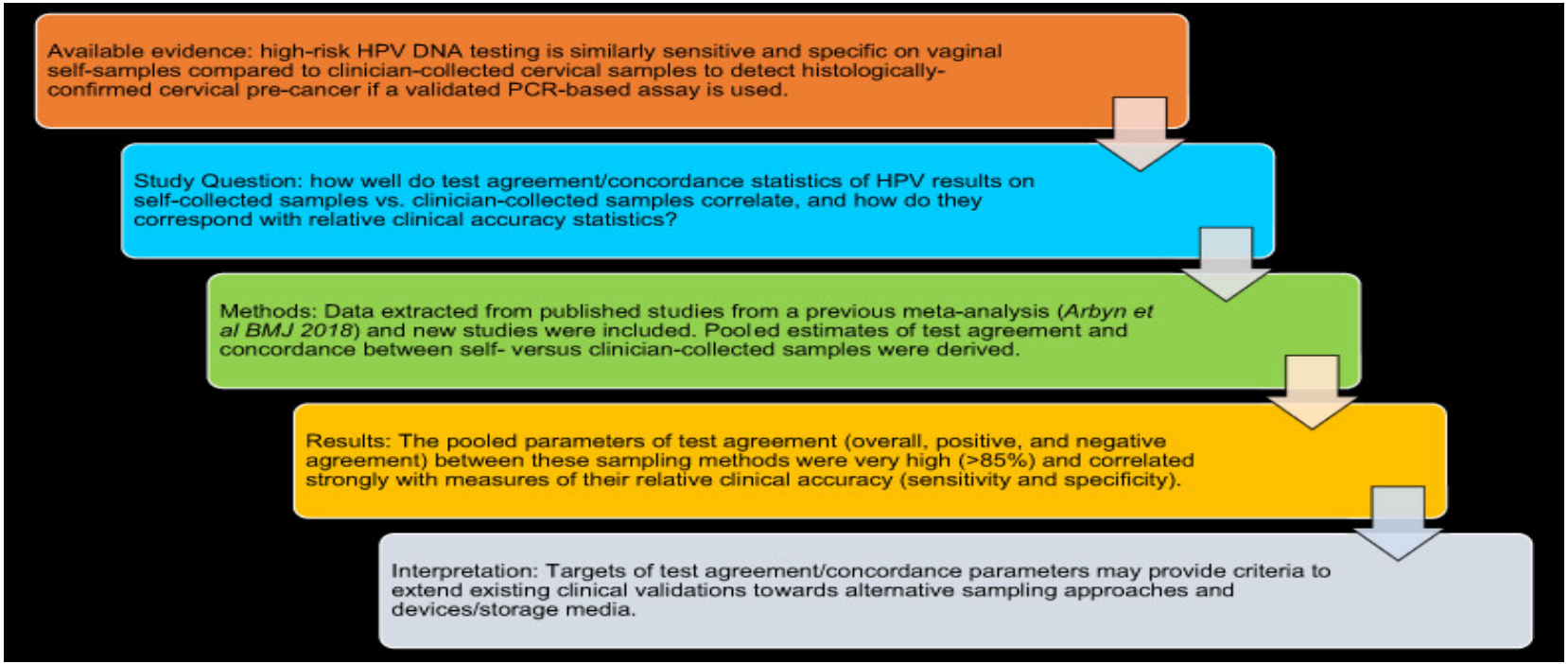
- Belief that screening is not needed
  - 60% of women aged 21 to 29 years and 55% of women aged 30 to 65 years said “not knowing they needed screening” was the reason for being overdue for screening.
- Lack of insurance/access to screening
  - This factor decreased 2005 → 2019 from 22% to 10% respondents
- Socio-economic
  - “Not knowing” was a factor for ALL socio-economic groups
- Cultural barriers
  - Race/ethnicity and gender identity especially

SHIP Trial: Self Collection for HPV to Improve Cervical Cancer Prevention



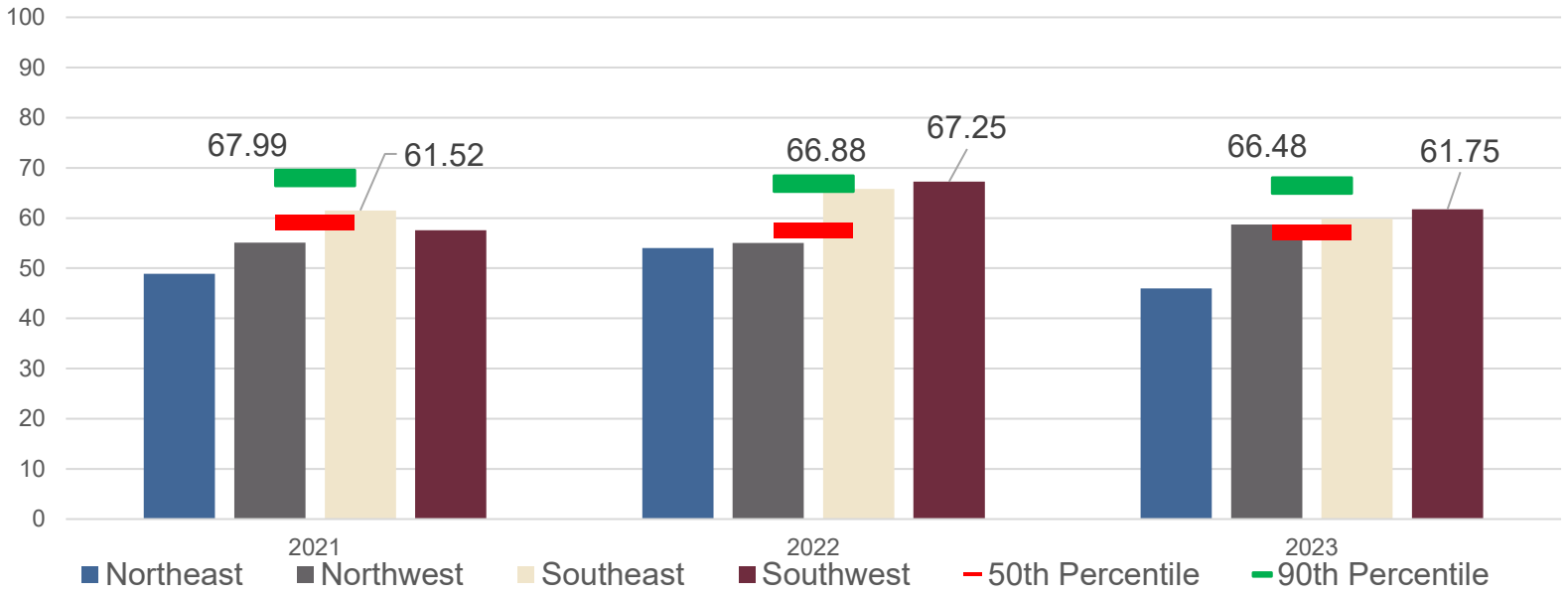
https://prevention.cancer.gov/lastmile

Self Swab Screening Increases Access and IS High Quality Care

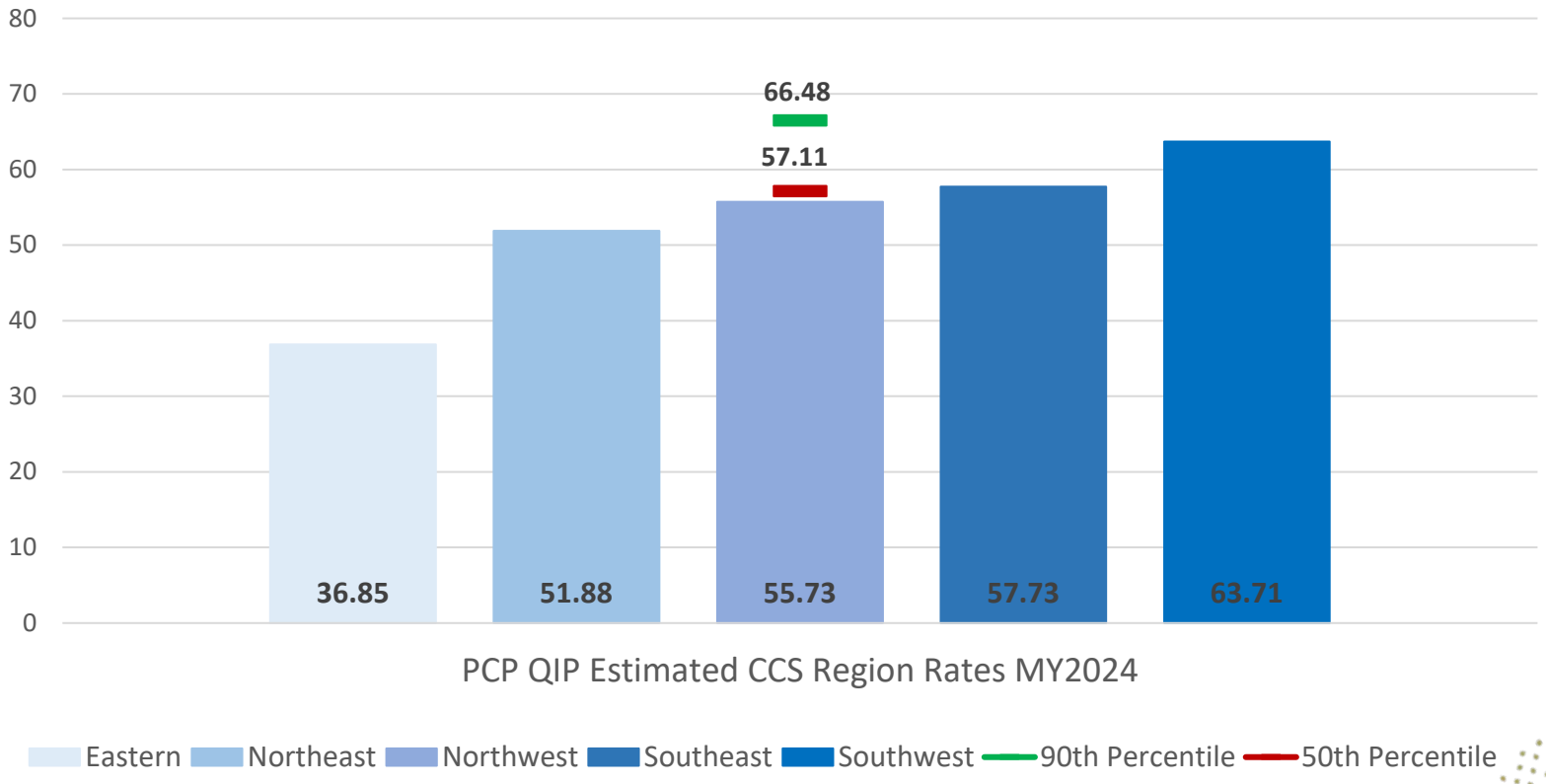


Meta-analysis of agreement/concordance statistics in studies comparing self vs clinician-collected samples for HPV testing in cervical cancer screening First published: 18 February 2022 https://doi.org/10.1002/ijc.33967

Partnership HEDIS Data: Cervical Cancer Screening



Partnership QIP data Cervical Cancer Screening



Cervical Cancer Screening Guidelines USPSTF

Population*	Recommendation	USPSTF Recommendation Grade†
Aged less than 21 years	No screening	D
Aged 21–29 years	Cytology alone every 3 years‡	A
Aged 30–65 years	Any one of the following: • Cytology alone every 3 years • FDA-approved primary hrHPV testing alone every 5 years • Cotesting (hrHPV testing and cytology) every 5 years	A
Aged greater than 65 years	No screening after adequate negative prior screening results§	D
Hysterectomy with removal of the cervix	No screening in individuals who do not have a history of high-grade cervical precancerous lesions or cervical cancer	D

Abbreviations: FDA, U.S. Food and Drug Administration; hrHPV, high-risk human papillomavirus testing.

News Flash: Self-Swab hrHPV tests approved by FDA in May 2024

- Allows for the patient to self-collect a vaginal swab in a health care setting for people aged 30 – 60 yo
- Specific kits/supplies approved: Beckon, Dickinson (BD) and Co. Onclarity HPV Assay and the Roche Molecular Systems, Inc. cobas HPV test
- HPV self-collection provides an opportunity to expand access to screening to those who are currently unscreened or under-screened. (Enduring Guidelines from ASCCP.org)

Managing Results: American Society of Colposcopy and Cervical Pathology (ASCCP)

March 2024 Proposed Guidelines

- Self-collected vaginal HPV is acceptable for cervical cancer screening for over 30 years old
- Self-collected vaginal samples results NEGATIVE, repeat testing in three years (clinician collected is five years)
- Self-collected Test (+) for 16/18, colposcopy is recommended

Partnership Cervical Cancer Screening Self Swab Pilot 2024

CONTEXT

International research suggests that self-swab sample collection method is an acceptable method for cervical cancer screening.

At home HPV tests were already available for patients to order independently.

Anticipated FDA approval

Research also shows that self-collected samples will increase uptake of cervical cancer screening.

Pilot Objectives

Acquire intelligence on successful implementation of a self-swab option in the primary care office

Develop educational materials for members

Planning

Recruited five providers in four regions

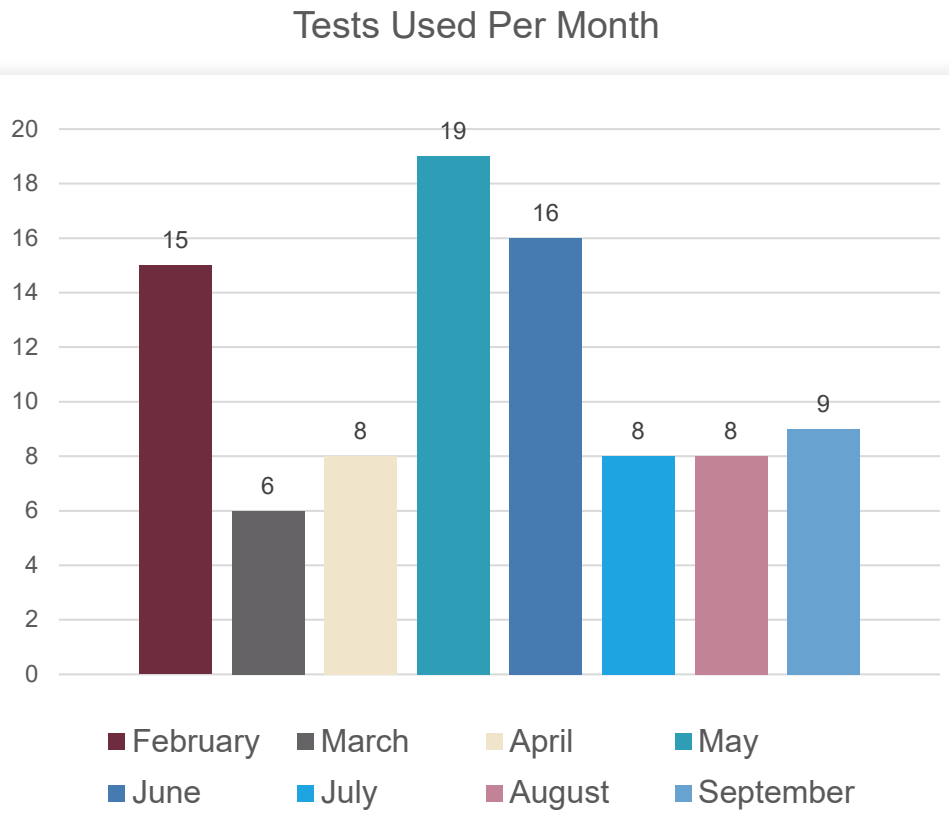
Criteria for patient inclusion in pilot:

- Current Partnership member
- At least 30 years old
- Have declined a cervical cancer screening through traditional method

200 Test Kits to complete by May 31, 2024

Implementation

- First tests used February 5, 2024.
- Three large practices used 89 test kits.
- Pilot was called to a close September 2024.

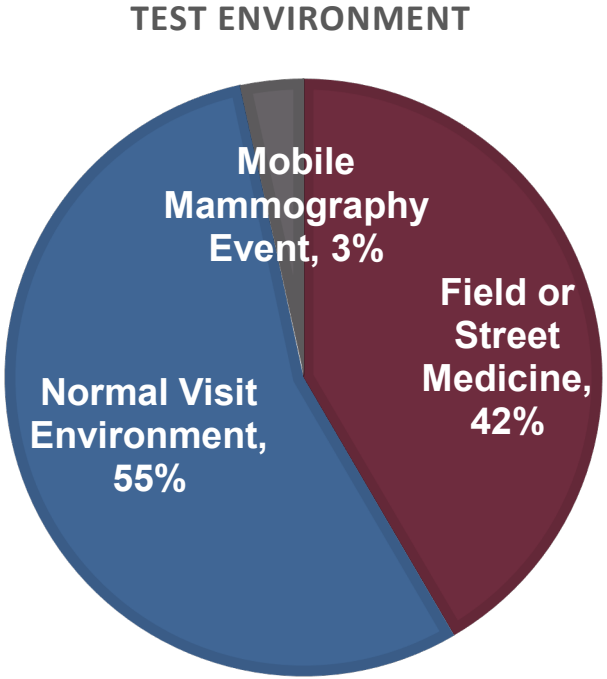


Implementation

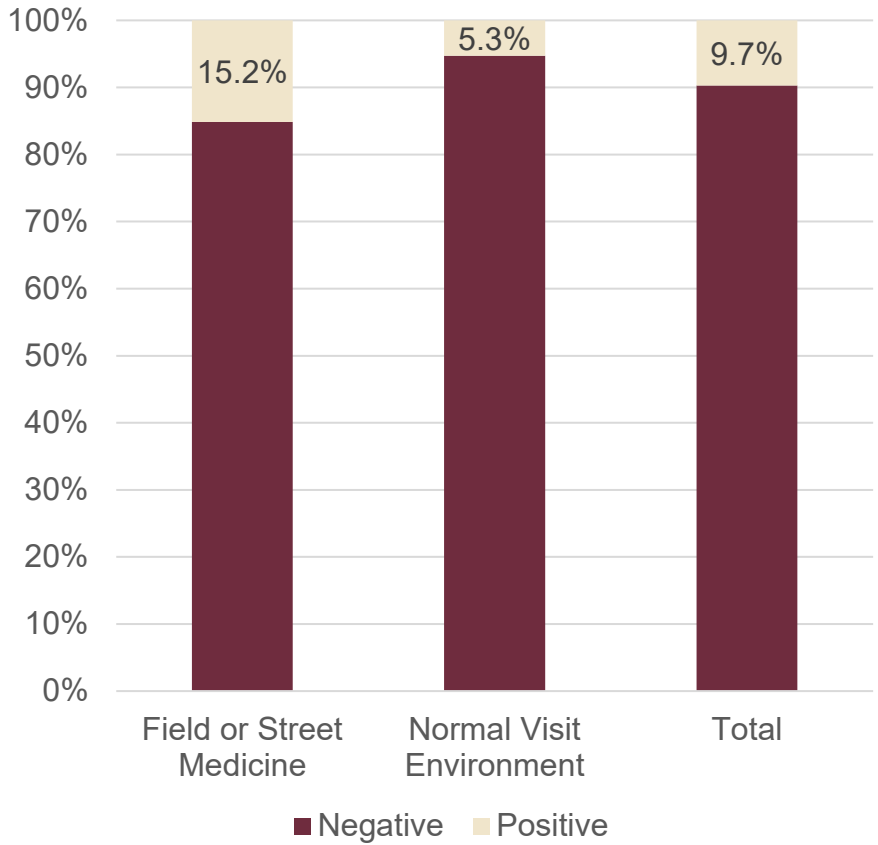
2 of 3 practices started in their field / mobile medicine environment.

1 of these expanded to brick-and-mortar practice after slow start.

1 did a mini-test of integrating self swab option at their mobile mammography events.



Test Results by Collection Site



Lessons Learned

- Patients are ready for this option.
- Small pilot show individuals who do not otherwise have access to screening can access screening and understand their risk for cervical cancer.
- Providers are ready for this option for their patients.
- Provider concern: If patients aren't willing to do a pelvic exam for screening, will they be willing to do a colposcopy if the test is positive?
- Not the end all be all: Some patients still aren't interested in the screening, even if the sample can be self collected. "What if it's positive, what then?" – *street medicine patient.*

Talking with Patients About the Self-Swab

- **NO** pelvic exam is needed
- The patient does **NOT** need to completely undress
- Patient can complete the collection themselves in the office, without special preparation or hygiene
- When results are **normal,** repeat testing is due in 3 years
- Abnormal test indicates a risk for cervical cancer, follow up tests will be needed
- Emphasize their autonomy, agency, and privacy in the process

Cervical Cancer Screening Self-Swab: Priority Populations

- Individuals who haven't been screened prior
- Individual who aren't sure of their last screen
- Average risk individual with more than three years (cytology) or five years (hrHPV) since last screen
- Individuals who are hesitant of or decline pelvic exam
- Transgender males
- Higher risk populations: unhoused, those who frequently move, change primary care providers, miss appointments, or have been treated for other STIs

Patients for Whom Self-Swab HPV Cervical Cancer Screening if NOT Appropriate

TABLE 4 - Clinical Scenarios for Which Self-Collection Cannot be Used as HPV Testing Alone Is Not Currently Recommended

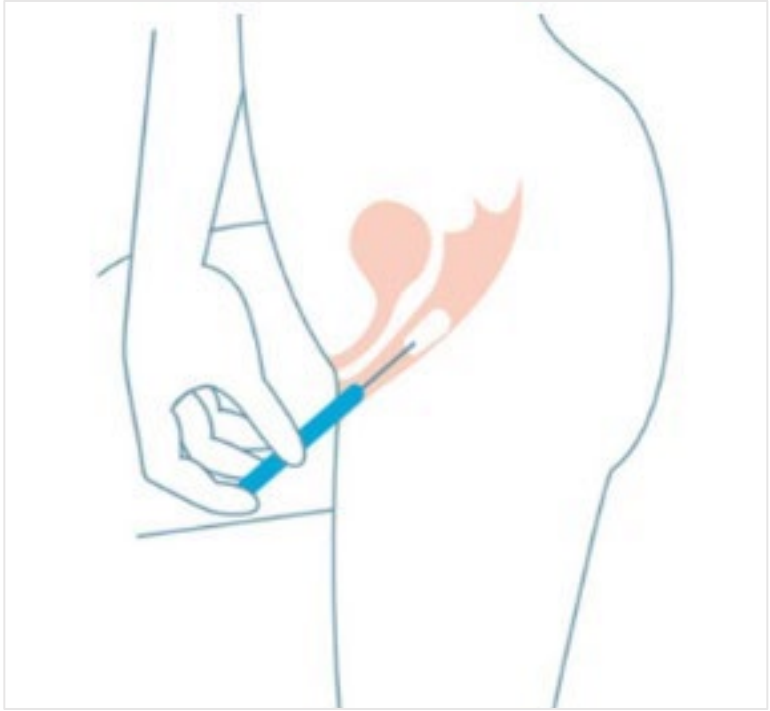
Clinical scenario	Current recommended screening test	Reference
People living with HIV	Cytology with or without HPV testing, depending on age	Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV. CDC. Published online August 18, 2021. https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-opportunistic-infections/
In utero diethylstilbestrol exposure	Cytology	ASCCP Clinical Consensus: Screening Recommendations for Clear Cell Adenocarcinomas in People Exposed to DES In Utero. Marcus J, Nelson E. Linder, M et al. Journal of Lower Genital Tract Disease 28(4):p 351–355, October 2024.
Surveillance after colposcopy for atypical glandular cells in which no CIN2+ found	Cytology with HPV testing (cotesting)	2019 ASCCP Risk-Based Management Consensus Guidelines for Abnormal Cervical Cancer Screening Tests and Cancer Precursors. Perkins RB, Guido RS, Castle PE, et al. 2019 ASCCP Risk-Based Management Consensus Guidelines Committee. J Low Genit Tract Dis. 2020 Apr;24(2):102–131.
Surveillance after diagnosis of adenocarcinoma in situ*	Cytology with HPV testing (cotesting)	2019 ASCCP Risk-Based Management Consensus Guidelines for Abnormal Cervical Cancer Screening Tests and Cancer Precursors. Perkins RB, Guido RS, Castle PE, et al. 2019 ASCCP Risk-Based Management Consensus Guidelines Committee. J Low Genit Tract Dis. 2020 Apr;24(2):102–131.

*After excision with negative margins and no cancer found in patients not undergoing hysterectomy.

How to complete the Self Swab

HPV Test Steps

- Wash your hands.
- Place the swab at least 2 inches into the vagina.
- Gently twist the swab for 10 to 30 seconds. Make sure the swab touches the sides of the vagina.
- Put the swab in the tube. Close the tube tightly.
- Give the tube to the clinical staff.
- Clinical staff will process collection swab in Thin Prep fluid, label and package for Lab (see lab instructions)



How to access supplies for your practice

Quest Labs

- HPV DNA (16,18, Other High Risk), PCR, self-collected
  - Vaginal specimen collected using a Roche FLOQSwabs® 552C.RM,
  - Swab immersed in vial with ThinPrep® fluid, swab swirled for 20 seconds, removes swab and re-cap vial with fluid/sample lining up the marks on the vial and cap.
  - CPT code 87626
  - Test Code 14263
  - Contact for supplies

LabCorp

- HPV DNA (16,18, Other High Risk), PCR, self-collected
  - Vaginal specimen collected using a Roche FLOQSwabs® 552C.RM,
  - Swab immersed in vial with ThinPrep® fluid, swab swirled for 20 seconds, removes swab and re-cap vial with fluid/sample lining up the marks on the vial and cap.
- Pilot program April 7, 2025 (practices can order) with Go Live May 2025
- Contact your rep for supplies

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Questions?