



Cancer Prevention and Early Detection for Community Health Centers

**Session 1:
Promising Practices to Increase
Cervical Cancer Prevention and Early Detection**

January 29, 2025

This session is being recorded

Welcome

Anne Gaglioti, MD, MS, FAAFP

Vice President, Implementation Science



Agenda

1

Welcome

Anne Gaglioti, MD, MS, FAAFP

2

HPV Vaccination Rates and Trends

Age 9 Vaccination Initiation

Speaker: Rebecca Perkins, MD, MSc

3

Current State of Cervical Cancer

Promising Practice of Self Collection

Speaker: Kathy MacLaughlin,³ MD

4

Q & A

Anne Gaglioti, MD, MS, FAAFP

Learning Objectives

- 1 Understand HPV vaccination Rates and Trends**
- 2 Describe benefits of age 9 initiation as a best practice**
- 3 Understand the burden of cervical cancer in the US**
- 4 Understand the impact of social drivers of health on uptake of cervical cancer screening**
- 5 Review the evidence and effective implementation strategies for HPV self-collection**

Welcome To



Rebecca B. Perkins MD, MSc

Professor of Obstetrics and Gynecology
Tufts University School of Medicine
Tufts Medical Center

5



Kathy MacLaughlin MD

Associate Professor of Family Medicine
Mayo Clinic

HPV Self-collection Testing for Cervical Cancer Screening

Kathy MacLaughlin, MD

Associate Professor of Family Medicine
Mayo Clinic



Presentation Topics

1

Background: Cervical cancer screening and impact of social drivers of health

2

HPV Self-collection Testing: Who, what, where, when, why, and how

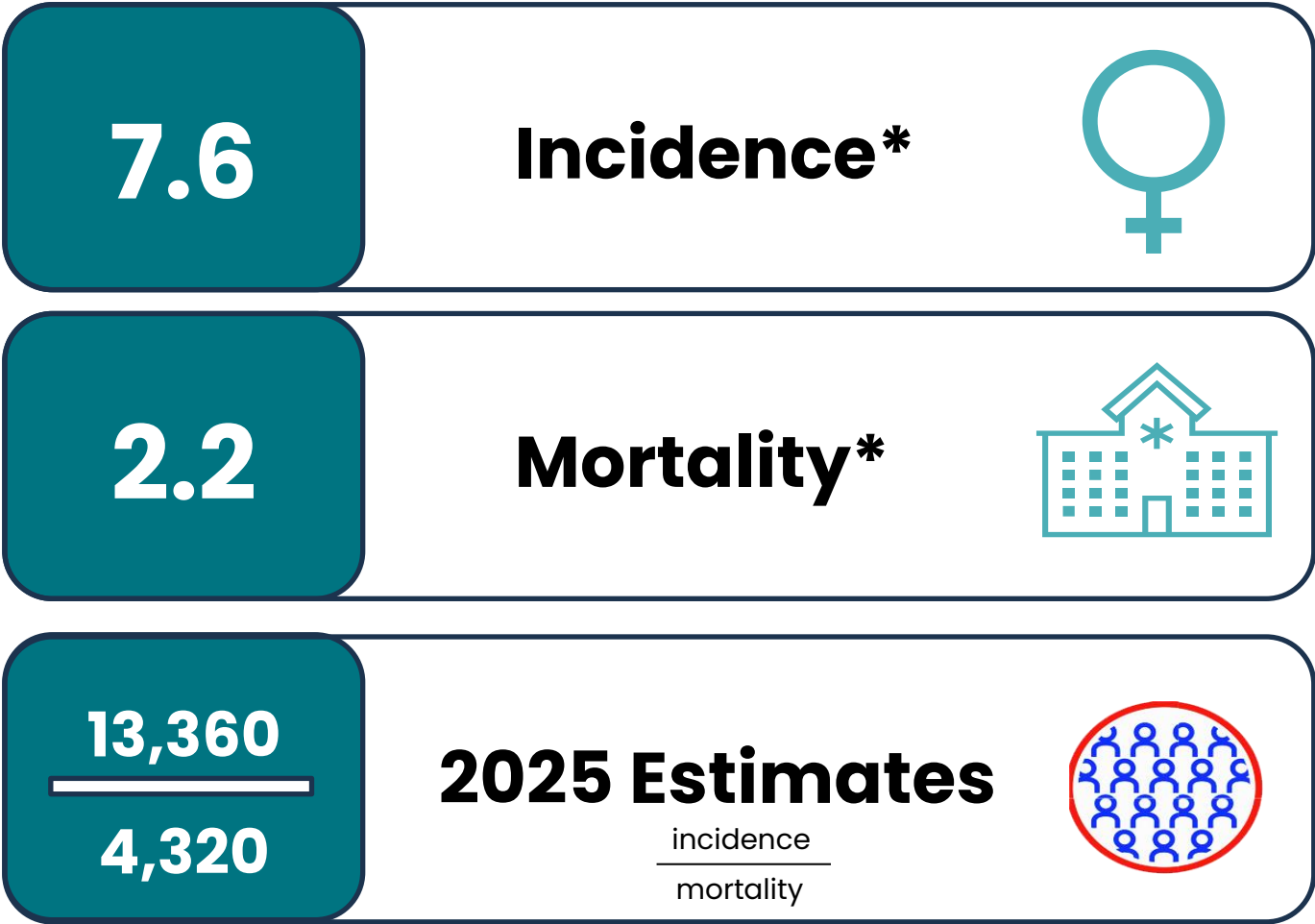
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Putting HPV Self-collection Testing into Practice



Background

Cervical Cancer in the United States



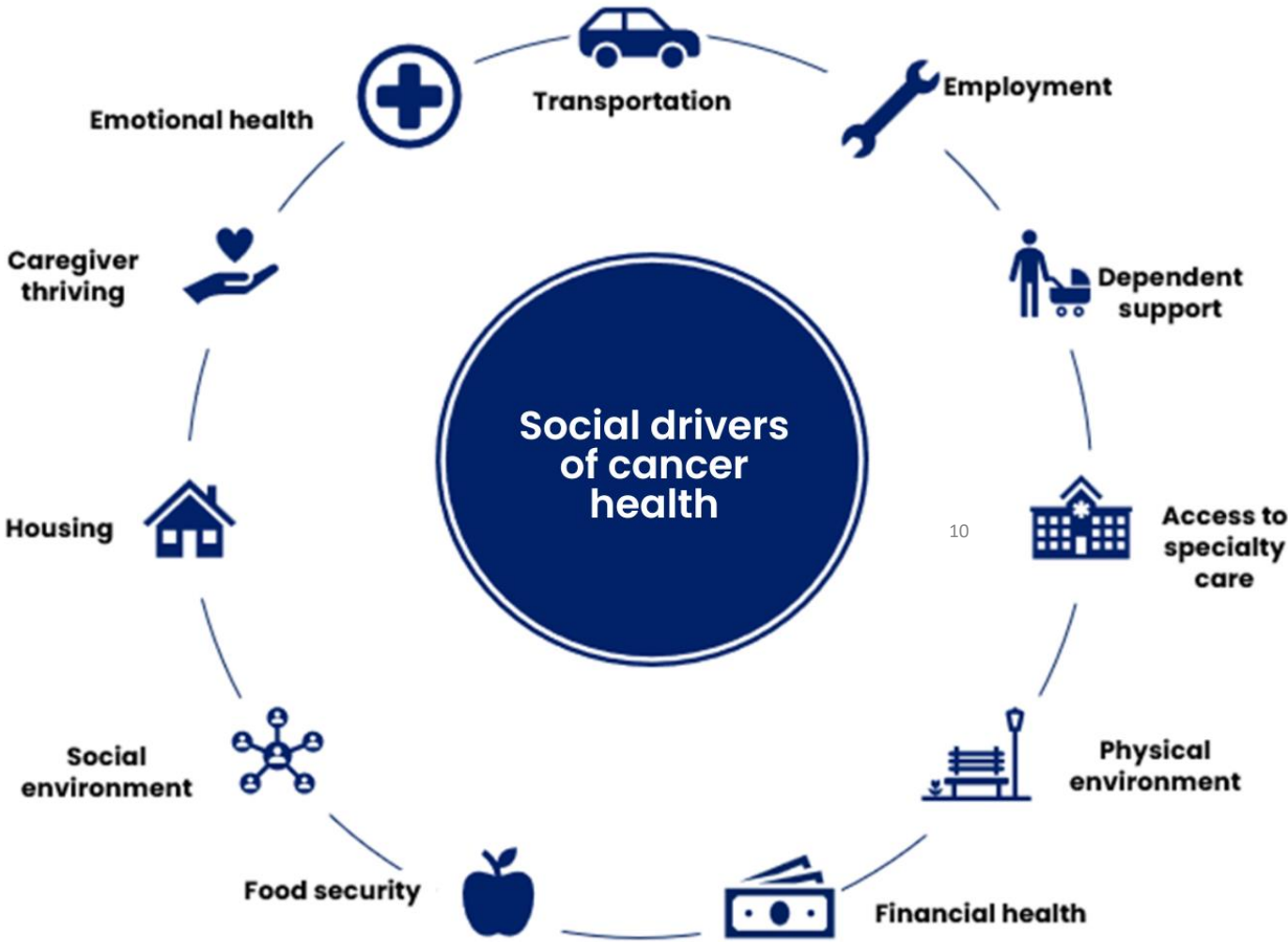
*Average annual rate per 100,000, age adjusted to the 2000 US standard population

Almost all cases of cervical cancer are caused by high-risk types of human papillomavirus (HPV)

Pulled from
Cancer Facts and
Figures 2025 →



Health-related Social Needs and Social Drivers of Health (SDoH) Contribute to Health Disparities



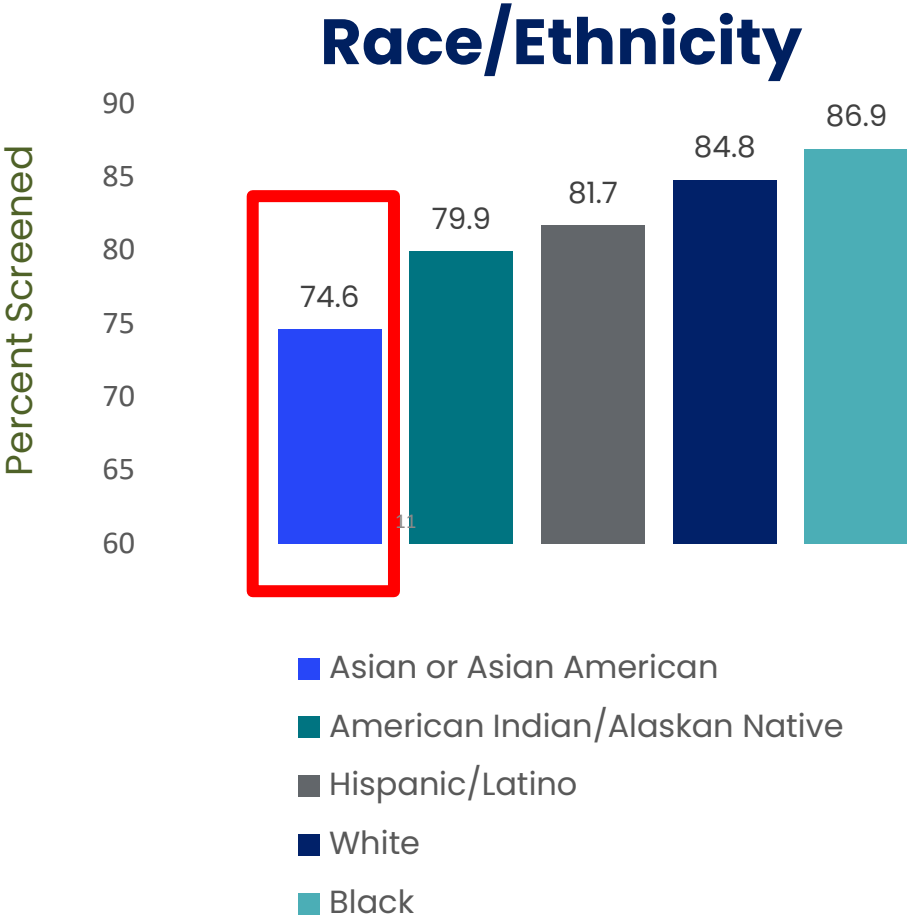
People who do not have access to the resources that **protect, improve, and maintain good quality of life** can cause them to experience unfair and **unjust cancer disparities**.

Learn more about health equity and cancer disparities→



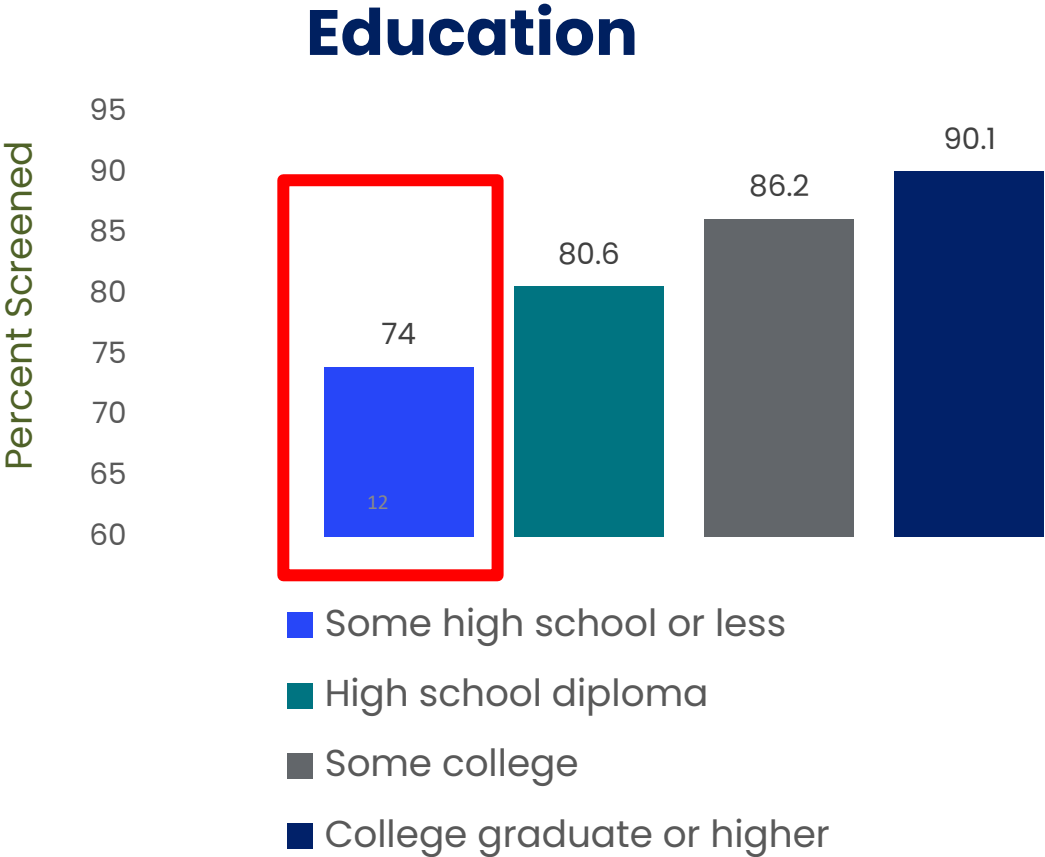
Impact of SDOH: Cervical Cancer Screening

Cervical Cancer Screening % Aged 21–65y, United States, 2021



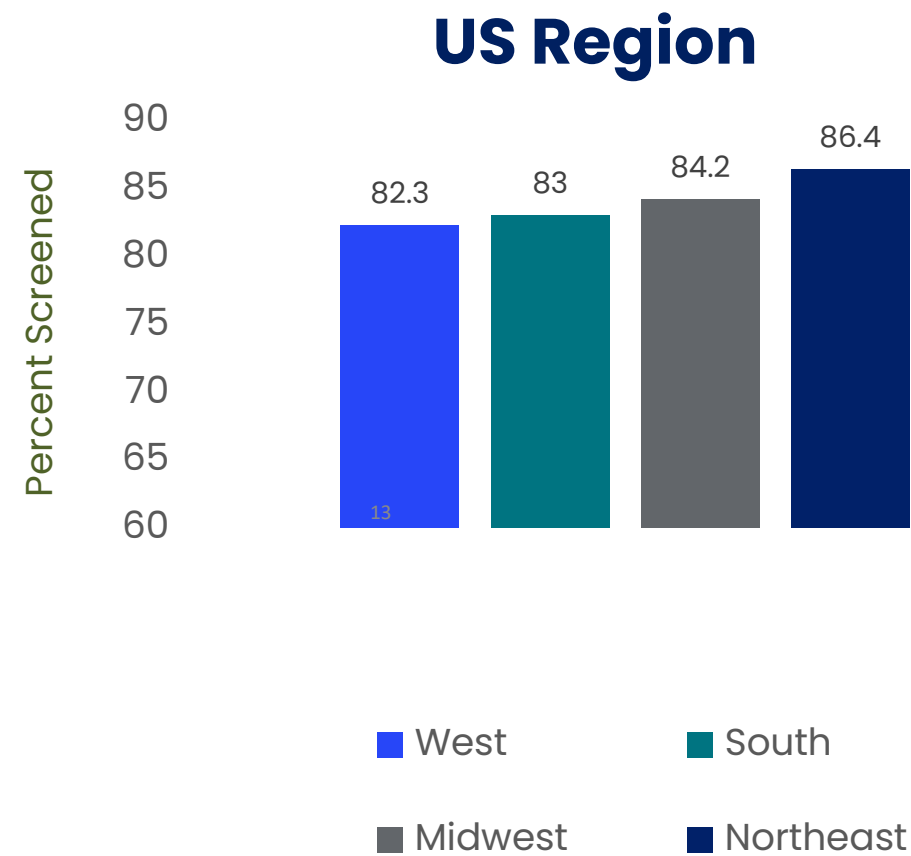
Impact of SDOH: Cervical Cancer Screening

Cervical Cancer Screening % Aged 21–65y, United States, 2021



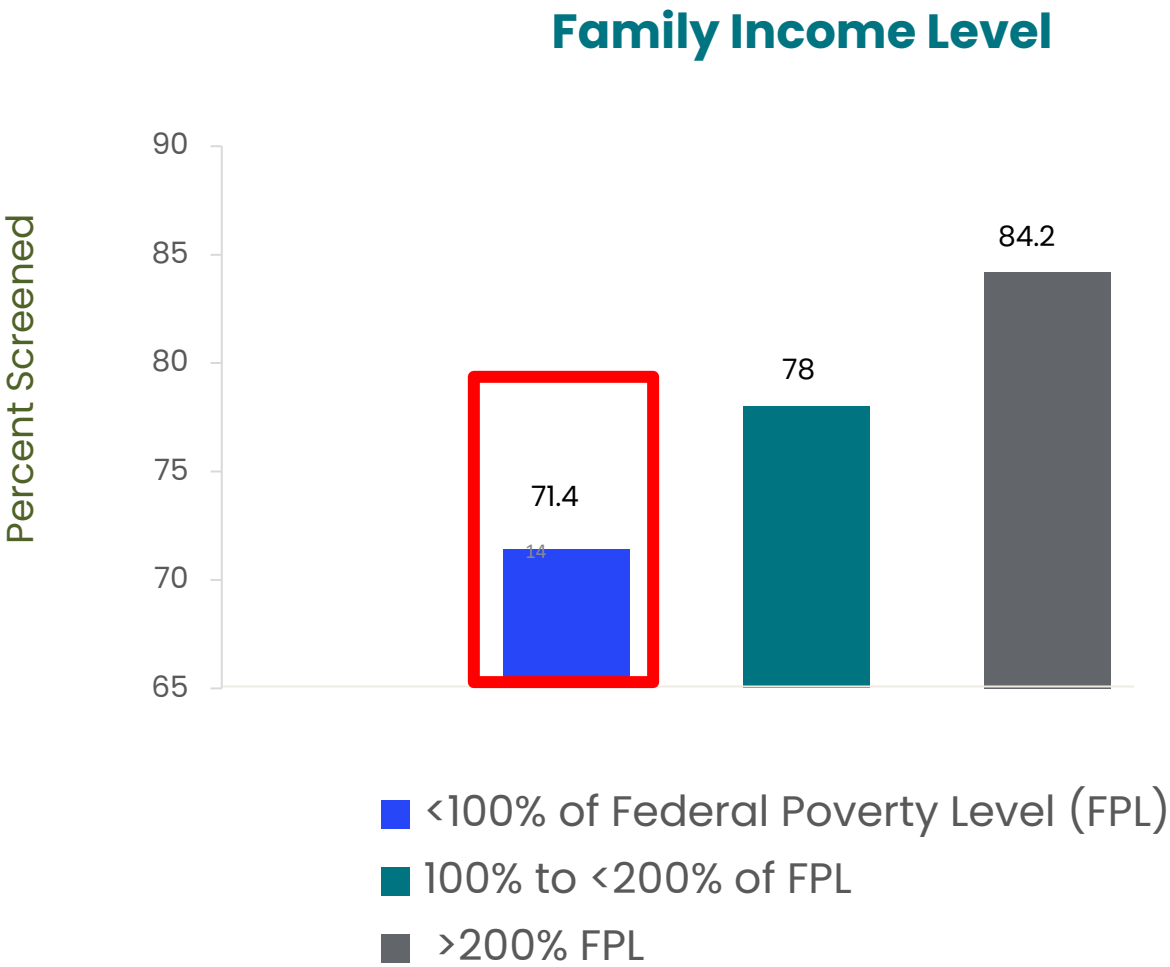
Impact of SDOH: Cervical Cancer Screening

Cervical Cancer Screening % Aged 21–65y, United States, 2021



Impact of SDOH: Cervical Cancer Screening (cont.)

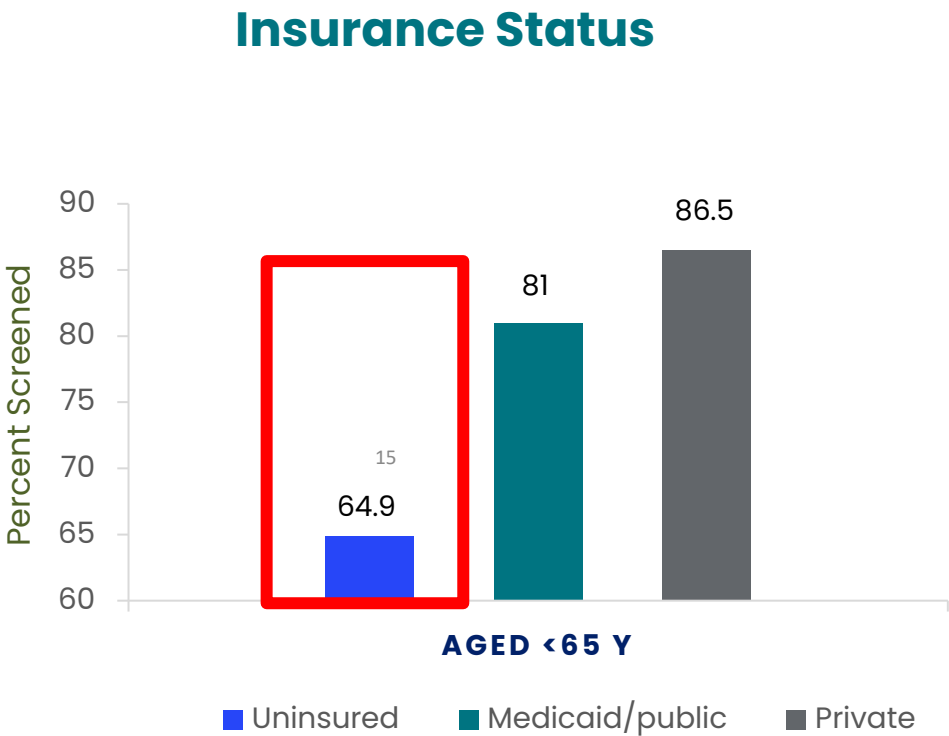
Cervical Cancer Screening %, United States, 2021



Source: <https://acsjournals.onlinelibrary.wiley.com/doi/epdf/10.3322/caac.21703>

Impact of SDOH: Cervical Cancer Screening (cont.)

Cervical Cancer Screening %, United States, 2021



Average Risk Cervical Cancer Screening

	USPSTF 2018	ACS 2020	ACOG 2021
<21 years	No screening	No screening	No screening
21-24 years	Pap every 3 yrs	No screening	Pap every 3 yrs
25-29 years	Pap every 3 yrs	Primary HPV every 5 yrs Co-test every 5 yrs Pap every 3 yrs	Pap every 3 yrs
30-65 years	Pap every 3 yrs Co-test every 5 yrs Primary HPV every 5 yrs	Primary HPV every 5 yrs Co-test every 5 yrs Pap every 3 yrs ¹⁶	Pap every 3 yrs Co-test every 5 yrs Primary HPV every 5 yrs
>65 years	Discontinue if exit criteria met	Discontinue if exit criteria met	Discontinue if exit criteria met

Guidelines were developed before the approval of HPV self-collection testing.

Data from: US Preventive Services Task Force. Screening for Cervical Cancer: US Preventive Services Task Force Recommendation Statement. JAMA. 2018 Aug 21;320(7):674-686. Fonham ETH et al. Cervical cancer screening for individuals at average risk: 2020 guideline update from the American Cancer Society. CA Cancer J Clin. 2020 Sep;70(5):321-346. ACOG Updated Cervical Cancer Screening Guidelines. Practice Advisory April 2021. <https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2021/04/updated-cervical-cancer-screening-guidelines>

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USPSTF Guidelines are currently being drafted to include self-collection testing and will be finalized in the coming months.

ACS cervical cancer screening guidelines →





HPV Self-Collection Testing

What is HPV self-collection testing?

HPV Self-collection testing is primary HPV testing.

- PCR is done to evaluate the presence of HPV DNA.

Self-collection is when a patient uses a collection device to take a vaginal sample that will be tested for HPV.

- This can be used as an alternative to clinician-collected cervical specimens.

Self-collection is an additional option for cervical cancer screening.

- It may help increase screening in populations who have never been screened or are overdue for screening.

How effective is HPV self-collection testing?

Three meta-analyses have been done to evaluate HPV self-collection testing

Self-collection testing has:

- consistently shown to be **more sensitive** at detecting CIN2+ than cytology alone in the first round of screening*
- **Comparable sensitivity and high agreement** with clinician-collected primary HPV testing samples

**although less specific, so better suited to a screening test; a more sensitive test is better at ruling out a condition—a negative result is likely a true negative, while a more specific test is better at ruling in a condition— a positive result is more likely to be a true positive*

ARTICLES | VOLUME 15, ISSUE 2, P172-183, FEBRUARY 2014

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Accuracy of human papillomavirus testing on self-collected versus clinician-collected samples: a meta-analysis

Dr Marc Arbyn, DrTMH • Freija Verdoodt, PhD • Prof Peter J F Snijders, PhD • Viola M J Verhoef, MD • Eero Suonio, MD • Lena Dillner, PhD • et al. [Show all authors](#)

Detecting cervical precancer and reaching underscreened women by using HPV testing on self samples: updated meta-analyses

Marc Arbyn,¹ Sara B Smith,² Sarah Temin,³ Farhana Sultana,^{4,5} Philip Castle,^{2,6} on behalf of the Collaboration on Self-Sampling and HPV Testing

INNOVATIVE TOOLS AND METHODS

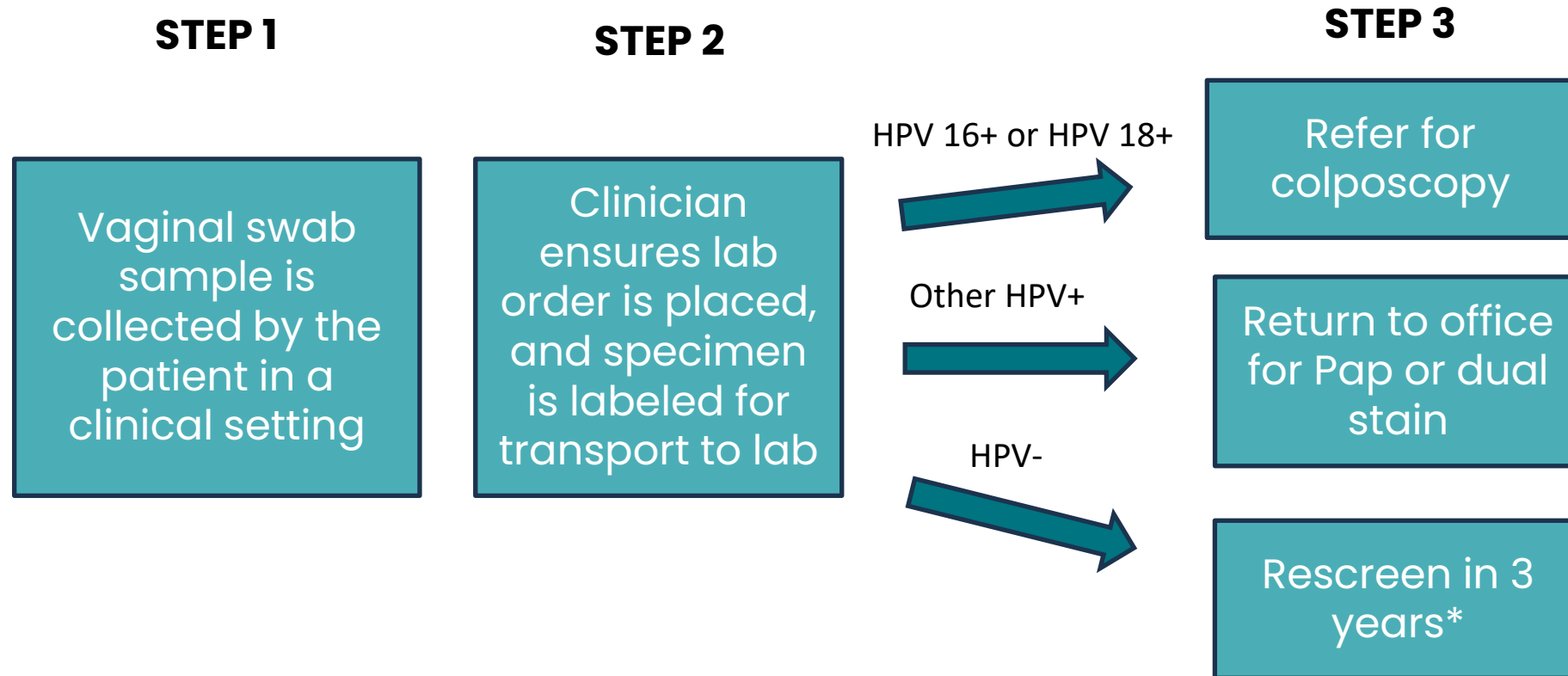
Short Report

IJC INTERNATIONAL JOURNAL OF CANCER

Meta-analysis of agreement/concordance statistics in studies comparing self- vs clinician-collected samples for HPV testing in cervical cancer screening

Marc Arbyn^{1,2} | Philip E. Castle^{3,4} | Mark Schiffman⁴ | Nicolas Wentzensen⁴ | Brandy Heckman-Stoddard³ | Vikrant V. Sahasrabudhe³

How is the HPV self-collection test done?



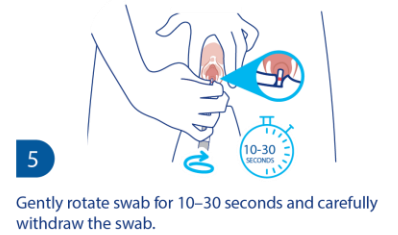
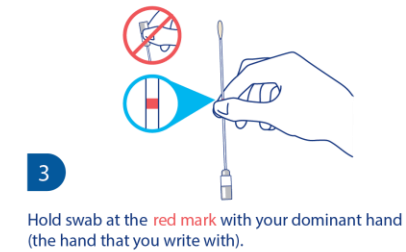
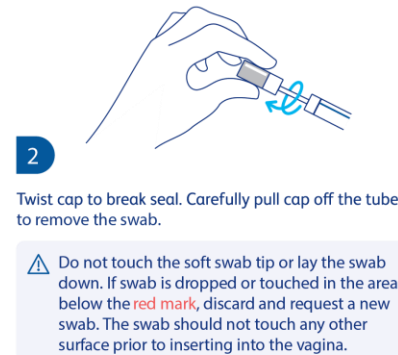
Not FDA-approved for at-home collection yet

**This may change with more evidence and/or with USPSTF updates*

How is HPV self-collection test done? (cont'd)

Patient Self-collection Steps for Copan Swab (device partnered with BD and Roche)

1. Wash hands
2. Open the swab carefully. Avoid touching the area below the **red** mark towards the tip.
3. Hold the swab at the red mark.
4. Use your other hand to spread the skin of the vaginal opening and carefully insert the swab into the vagina up to the red mark.
5. Gently rotate the swab for 10–30 seconds and then remove the swab.
6. Place the swab back in the tube and make sure the cap is secured.
7. Give your healthcare provider the recapped swab.



Pictures: adapted from Becton, Dickinson and Company (BD)

Who is eligible for HPV self-collection testing?

Eligible

- Barrier to speculum exam
- Must be eligible for primary HPV testing
- Asymptomatic (not to be used for diagnostic testing if Abnormal bleeding, pelvic pain, vaginal discharge)
- Patients should not be actively experiencing menstrual bleeding or have used a vaginal product within 2 days.

Not eligible

- History of cervical cancer
- HIV+ or other immunosuppression
- History of in utero DES exposure
- If 21 to 29 years old
- If the patient has Medicare insurance



What are potential benefits of HPV self-collection testing?



HPV self-collected screening is more sensitive and accurate than the Pap test alone and about as accurate as clinician-collected HPV testing.



It may be more appealing to patients with limited mobility, history of sexual trauma, gender diversity, medical mistrust, or discomfort with speculum exams.



Clinicians who offer in-clinic self-collection do not need to do a speculum exam, freeing up time to address other patient concerns.

What should patients know before choosing self-collection?



About 1 in 10 patients will receive a positive result.



If patient receives a positive result for HPV 16 or HPV 18, they must be referred for colposcopy (speculum exam included).



If the patient receives a positive result for other HPV (not 16 or 18) using Roche, or if they have HPV types grouped as 45, 33/58, 31, 52/35/39/68, or 51 using BD, the patient must return for a speculum exam for dual-stain or cytology testing.

**Learn
more
about
HPV
testing**



How does self-collection compare to clinician collection?

	Clinician-collected	Self-collection
Who takes the sample?	Clinician	Patient (in-clinic)
Where is the sample taken from?	Cervix	Vagina
Is a speculum used?	Yes	No
What lab test is run?	PCR to detect HPV DNA/HPV genotyping	PCR to detect HPV DNA/ HPV genotyping
What other tests can be run on the sample?	Pap/cytology, dual stain	None
Next steps if HPV+?	Patient will need to return only if colposcopy is required	Patient will need to return. If HPV16/18+, for colposcopy. If positive for other HPV+, for Pap or dual stain
How often should screening occur if HPV-?	Every 5 years	Every 3-5 years
Is it more accurate than Pap testing alone?	Yes	Yes

NCI Cervical Cancer 'Last Mile' Initiative

'Self-collection for HPV testing to Improve Cervical Cancer Prevention' (SHIP) Trial

Purpose

- Evaluating whether self-collection HPV testing in a **home-environment** is an acceptable alternative to clinician-collected samples in a health care environment

Scope

- Assessing accuracy, usability, and accessibility
- Enrolling in both rural and urban counties in 25 centers across the United States
- Focusing efforts to reach underserved and under-screened populations



Putting HPV Self-Collection Testing into Practice

Which self-collection tests are FDA-approved for primary HPV screening?

Roche
cobas[®]
with Copan 522C.80 swab or
Evalyn brush

BD
Onclarity[™]
with Copan 522C.80 swab

Test results:

- Both use a PCR assay to detect the same 14 HPV types.
- Results include HPV 16/18 genotyping.

Before implementing:

- First step is making sure your practice can offer primary HPV testing.
- Check with your lab to ensure they can work with one of these options.
- Contact the manufacturer to get both written and video-based instructions for proper use.

Learn more about transitioning to primary HPV testing on the National Roundtable on Cervical Cancer website →



Will insurance cover HPV self-collection tests?

Self-collection testing is primary HPV testing.

- Primary HPV testing is part of current USPSTF cervical cancer screening recommendations, which informs most coverage decisions for most major insurance plans.
- Since CPT codes already exist for primary HPV testing, how the sample is collected is not expected to change the billing code.
- The same ICD-10 code is used for all cervical cancer screening tests, including self-collection (cervical cancer screening visit code Z12.4).



USPSTF, United States Preventive Services Task Force
CPT, current procedural terminology

IT and EHR Considerations

EHR Order

Create a new vaginal self-collect order.

CPT Codes

Self-collected and clinician-collected samples use the same laboratory HPV test code.

ICD-10 Visit Codes

Use existing cervical cancer screening visit code Z12.4 for self-collect visits and for return visits, if needed.

Screening interval

Adjust EHR reminders and prompts for the appropriate intervals.

EHR, electronic health record
IT, information technology
CPT, current procedural terminology
ICD-10, International Classification of Diseases 10

Key Takeaways

- 1 SDOH impact cervical cancer screening uptake.**
Current screening rates are lower in people who are minoritized, low-income, LGBTQ+, and recent immigrants. Members of these groups are at the highest risk for cervical cancer.
- 2 HPV Self-collection testing is a new screening option.**
An advantage of self-collection is that it may be more acceptable to patients with limited mobility, history of sexual trauma, gender diversity, medical mistrust, or discomfort with speculum exams.
- 3 HPV Self-collection testing should be repeated after 3 years if result is negative.**
This is expected to increase to five years after more research is done.*
- 4 Patients must return for follow-up if the HPV self-collection testing result is positive.**
About 1 in 10 results is expected to be positive.
- 5 HPV Self-collection testing is primary HPV testing.**
It is expected to be covered by insurance and the CPT codes and ICD-10 codes are not expected to change.

**USPSTF draft recommends five years for women aged 30–65.*

Poll

- **Professional Role**
- **How would you describe your knowledge of HPV vaccination?**
- **Moving forward, I will routinely recommend the HPV vaccination to patients starting at the age of 9.**
- **How would you describe your knowledge of self-collection HPV test?**
- **As a result of today, you intend to take action to implement self-collection HPV testing.**

Reminders:

- Post webinar: You will receive an email communication with recording and resources
- Session 2: colorectal cancer screening
 - Last week of March

Partner Acknowledgement



Funder Acknowledgement

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THANK YOU!

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