By Sherri Sellers, DNP, APRN, WHNP-BC

CERVICAL CANCER SCREENING:

NEW
GUIDELINES/NEW
TECHNIQUE



I do not have any relevant financial relationships with any of the products mentioned in this presentation and therefore have nothing to disclose.

I will be discussing cervical cancer in this presentation. I may at times refer to the population foci as being female, but this is meant as a gender-neutral term and refers more broadly to people with a cervix.

YOUR MISSION IF YOU CHOOSE TO ACCEPT IT

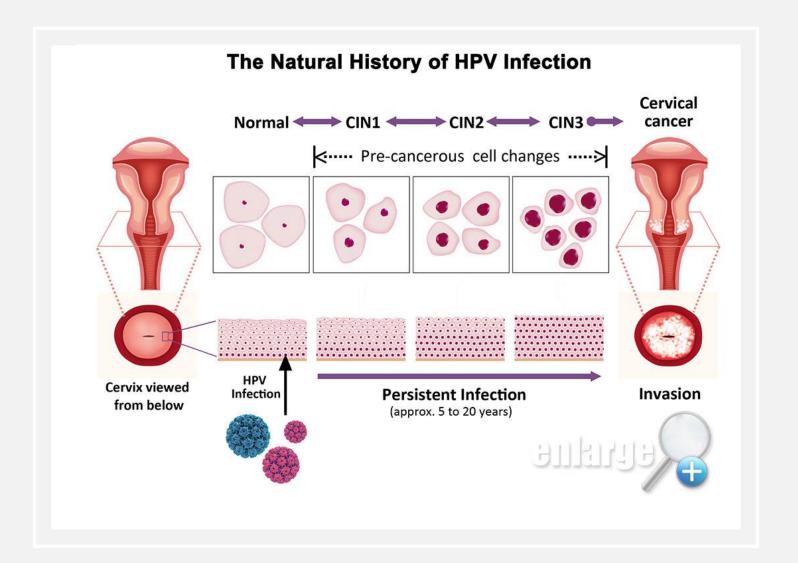
"Cervical cancer can be eliminated as a public health problem with high population-level coverage of vaccination against human papillomavirus (HPV), timely screening and early detection, and treatment of precancerous lesions."

OBJECTIVES

- Discuss the pathophysiology and epidemiology of cervical cancer
- Discuss primary and secondary prevention strategies
- Discuss new guidelines and technologies related to screening and management of abnormal screenings

PATHOPHYSIOLOGY OF CERVICAL CANCER

- High-risk HPV is responsible for virtually all (99.7%)
 cervical cancers
- Most HPV infections will resolve on their own w/in 1-2 years
- Persistent HPV infection
 - 5-10 years for dysplasia
 - ~20 years for cancer
- If left undetected/untreated:
 - Dysplasia of epithelial cells mild, moderate, high
 - Cervix, anus, oropharynx, penis, vagina, and vulva
- HPV infiltrates epithelial cells through unprotected intercourse or skin-to-skin contact, interfering with normal replication and division



HTTPS://WWW.CUHK.ED U.HK/SPHPC/HPVSELFSA MPLING/EN/CC-N-HPV.HTML

The life cycle of HPV Squamous Mid zone https://www.std-gov.org/stds/human_papillomavirus_hpv.htm

HIGH RISK V. LOW RISK HPV

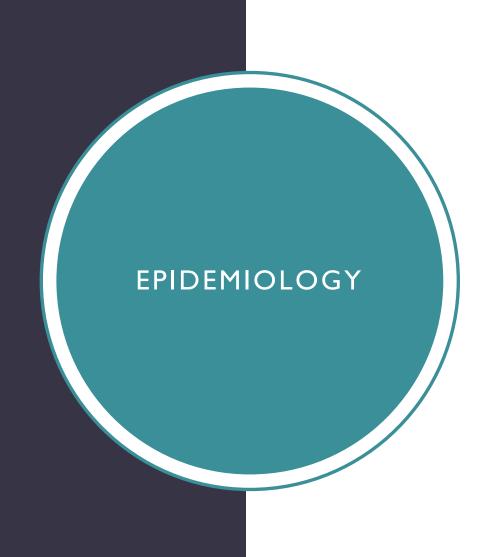
- 200 HPV viruses 40 transmitted sexually
- Low-risk types cause warts 2 main types
 - Genitals, anus, mouth, throat, nasal, and conjunctival
 - Most commonly, types 6 and 11
 - But also, 16, 18, 31, 33, and 35
- High-risk cause dysplasia/cancer 12 types
 - 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59

TABLE 1. Contribution of Carcinogenic Human Papillomavirus (HPV) Genotypes and CIN3+ Progression Risk for Progression to Cervical Intraepithelial Neoplasia (CIN) Grade 3 or Worse

Carcinogenic HPV type	% of Cervical Cancers	9-year risk of progression to CIN3+ of incident HPV infection	Risk Group
16	60.3	6.3	16
18	10.5	3.0	18/45
45	6.1	2.2	18/45
33	3.7	4.5	16-related
31	3.6	2.2	16-related
52	2.7	2.2	16-related
58	2.2	1.9	16-related
35	2.0	2.8	16-related
39	1.6	1.1	Other
51	1.2	1.1	Other
59	1.1	0.9	Other
56	0.9	0.8	Other
68	0.6	1.0	Other

DYSPLASIA/CANCER RISK FACTORS

- Sexual activity before age 18
- Multiple sexual partners, especially if highrisk
- Immunosuppression
 - HIV infection
 - Medications to suppress immunity organ transplant, autoimmune disease, cancer treatment
- Smoking and secondhand smoke exposure
 risk rises with increased use/exposure
- Reproductive factors
 - Oral contraceptives
 - Increased parity
- Obesity
- DES exposure rare



- Most common STI in the world
- Every year, HPV causes 37,800 cases of cancer in the US and 690,000 worldwide, resulting in 350,00 deaths from cervical cancer annually, making it the leading cause of death in women
- Estimated new cervical cancer cases in the US in 2025 – 13,360
 - Estimated cervical cancer deaths in 2025
 4,320
- Rates of cancer are higher in Black and Hispanic populations
 - With lower rates of screening and/or follow-up

"Cervical cancer is highly preventable and highly curable if caught early. Nearly all cervical cancers could be prevented by HPV vaccination, routine cervical cancer screening, and appropriate follow-up treatment when needed." – National Cancer Institute

PRIMARY PREVENTION

Education

- Only 51.1% are up-to-date w/ Health People goal of 80%
- Uptake is slower than other high-income countries and other vaccines

Vaccination

- HPV vaccine Gardasil 9 (6, 11, 16, 18, 31, 33, 45, 52, 58)
- Important to finish the series prior to sexual activity
- Girls and boys start at 9 or between 11-12
- Recommended up to 26 but can be given up to age 45
- Dosing
 - <15 2 doses
 - >15 and those with suppressed immunity 3 doses
- Vaccine is more effective in the younger ages stronger immune response and better completion rates

SECONDARY PREVENTION

Screening

- However, 25% of US women are not up-todate with screening
 - Higher income
 - Health insurance coverage
- Some screen too often
- Barriers to follow-up
 - Difficulty with healthcare system lack of knowledge, provider recommendation, health literacy
 - Financial costs, lack of insurance
 - Logistics childcare, scheduling, no regular care, competing demands, clinic hours

SECONDARY PREVENTION

Screening

- Groups under-screened and/or lost to follow-up/treatment
 - Ethnic minorities
 - Rural residents
 - Sexual and gender minorities
 - Certain religious sects
 - Limited English proficiency
 - Physical disabilities and comorbidities
 - Mental health diagnoses
 - History of sexual trauma

Barriers to screening are compounded when they exist in multiple categories or characteristics



- Contact with those in need at non-gyne visits
 - PCP
 - Specialty visits
 - Urgent care
- Mobile screening units and community-level outreach
- Travel vouchers for healthcare visits
- Staff training
- Patient navigators and professional interpreters
- Education
- One-on-one reminders letters and phone calls
- Show Me Healthy Women, FQHC's, Medicaid expansion
- HPV self-sampling

DEVELOPING SCREENING GUIDELINES

Updated 7-10 years through a consensus process

Guidelines developed independently by US Preventive Services Task Force (USPSTF) and the American Cancer Society (ACS)

Management recommendations are through the American Society of Colposcopy and Cervical Pathology (ASCCP)

Enduring Consensus Guidelines
for Cervical Cancer Screening and
Management (Enduring
Guidelines) – a standing
committee (19 members)
evaluating new technologies and
approaches

2019 ASCCP Risk-Based Management Consensus Guidelines 3 new technologies – Selfcollected vaginal swabs, Extended genotyping, and P16/Ki67 Dual Stain

ENDURING GUIDELINES MISSION

- Continuously evaluate new technologies and approaches to cervical cancer screening, management, and surveillance
- To selectively incorporate new technologies and approaches with adequate supportive data to more effectively improve cancer prevention for high-risk individuals and decrease unnecessary procedures in low-risk individuals.
- To consider health equity and health disparities during the consensus guidelines
 process by assuring inclusion of diverse populations in the evidence review and
 risk assessment, and by developing recommendations that provide a choice of
 well-validated strategies that can be adapted to different settings

Screening

HPV alone, HPV-cytology cotesting, cytology



Management

Triage, colposcopy, surveillance



Treatment

USPSTF

Cervical Cancer Screening Recommendations

American Cancer Society

Cervical Cancer Screening Guidelines

ASCCP

Risk-Based Management Consensus Guidelines (co-developed with 20 societies)

ASCCP

Colposcopy Standards Recommendations

Areas covered by Enduring Guidelines

FIGURE 1. Overview of cervical screening and management guidelines in the United States. The figure summarizes the continuum from cervical screening to management and treatment of cervical precancers for prevention of cervical cancer and related US guidelines. The Enduring Guidelines process primarily addresses management of abnormal screening results but may extend to specific questions related to screening and treatment. HPV, human papillomavirus; USPSTF US Preventive Services Task Force.

CURRENT CERVICAL CANCER SCREENING GUIDELINES

	ACOG 2021	USPSTF 2018	ACS 2020	
Age to start	21		25	
Age to end	65 years old			
	If 3 consecutive negative cytology tests or 2 negative cytology plus HPV tests or 2			
	negative HPV tests with the most recent within the prior 5 years			
	and no abnormal tests within the prior 10 years (ACS) and no CIN2+ within the prior			
	25 years			
Screening	Ages 21-65: Cytology every 3 yrs		HPV testing alone every 5 yrs	
test options	or		or	
and intervals	Ages 21-29: Cytology every 3 yrs		Cytology + HPV testing every 5 yrs	
	And then		or	
	Ages 30-65: HPV testing alone every 5 yrs or		Cytology every 3 years	
	cytology plus HPV testing every	5 yrs		

[#] In adequately screened women (3 negative cytology results or 2 negative co-tests in prior 10 years, most recent co-test within 5 years)

^{*}If primary HPV testing is not available, individuals aged 25-65 y should be screened with cotesting every 5 years or cytology alone every 3 years (acceptable) (strong recommendation)

CHARACTERISTICS OF CERVICAL CANCER SCREENING TESTS

Method	Every	If started at 30, lifetime reduction in the number of cervical cancer deaths from 8.34 to
Cytology	3 yrs	0.76 deaths per 1000 women
hrHPV-only	5 yrs	0.29 deaths per 1000 women
Co-test	5 yrs	0.30 deaths per 1000 women

ACOG 2021: "All three screening strategies are effective, and each provides a reasonable balance of benefits (disease detection) and potential harms (more frequent follow-up testing, invasive diagnostic procedures, and unnecessary treatment in patients with false-positive results)."

(Policar, 2025)

ACOG RECOMMENDATIONS

Apply guidelines to the <u>average-risk</u> individuals

Those with a cervix

No signs or symptoms of cervical cancer

Without a diagnosis or h/o high-grade cervical lesion (>CIN2)

No DES exposure in utero

No compromised immune system



Be consistent in your practice among clinicians and collaborators

HYSTERECTOMY – IMMUNOCOMPROMISED - DES

	Panel on Opportunistic Infections – Immunocompromised (CDC, 2021)
Age to start screening	21
Age to end screening	None (lifelong screening)
Screening test options and intervals	Ages 21-29: Cytology <i>every year x3 years</i> → after 3 annual normal cytology results, cytology every <u>3 years until 30</u>
	Ages 30-65: After 3 negative annual cotests or cytologies,
	 Cytology alone <u>every 3 years</u>, or
	 Co-testing <u>every 3 years</u>
	 HPV-alone testing is not endorsed

	ASCCP 2024 DES Exposed
Age to start	Not stated, but 21 presumed
Age to end screening	"Discontinue screening beyond the age of 65 provided they otherwise meet criteria for cessation of screening"
Screening test options and intervals	 Annual cytology with "separate cervical and vaginal cytology of all 4 walls" Visual inspection of the upper vagina and vaginal sidewalls Bimanual exam with palpation of the upper vagina and vaginal sidewalls

COMMON PATIENT QUESTIONS

- If someone has been fully vaccinated, do they need to be screened?
- Is it necessary to screen if someone has never been sexually active?
- Do I still need to be screened at normal intervals if:
 - I am only with female partners?
 - I have multiple partners?
 - I have a new sexual partner?
 - I am pregnant?
 - I don't have a cervix?

DRAFT USPSTF SCREENING GUIDELINES

Ages 21-29

Recommend screening every 3 years with cervical cytology alone in women ages 21 to 29 years

Ages 30-65

Every 5 years with clinician- or patient-collected HPV primary screening for ages 30 to 65 years

Alternative Method

As an alternative to HPV primary screening for women ages 30 to 65 years, recommend continued screening every 3 years with cervical cytology alone or screening every 5 years with co-testing (high-risk HPV testing in combination with cytology)



- Highlighting the differences between the 2018 USPSTF:
 - Primary HPV testing is the preferred method AND
 - Only starting at age 30 for screening with primary HPV (not 25) AND
 - Every 5 years
 - Includes self-collected specimen

The rationale is that cervical cytology is subjective and has a relatively low sensitivity compared to HPV testing, which is an objective test with higher sensitivity

KIM ET AL DRAFT MODELING REPORT 2025

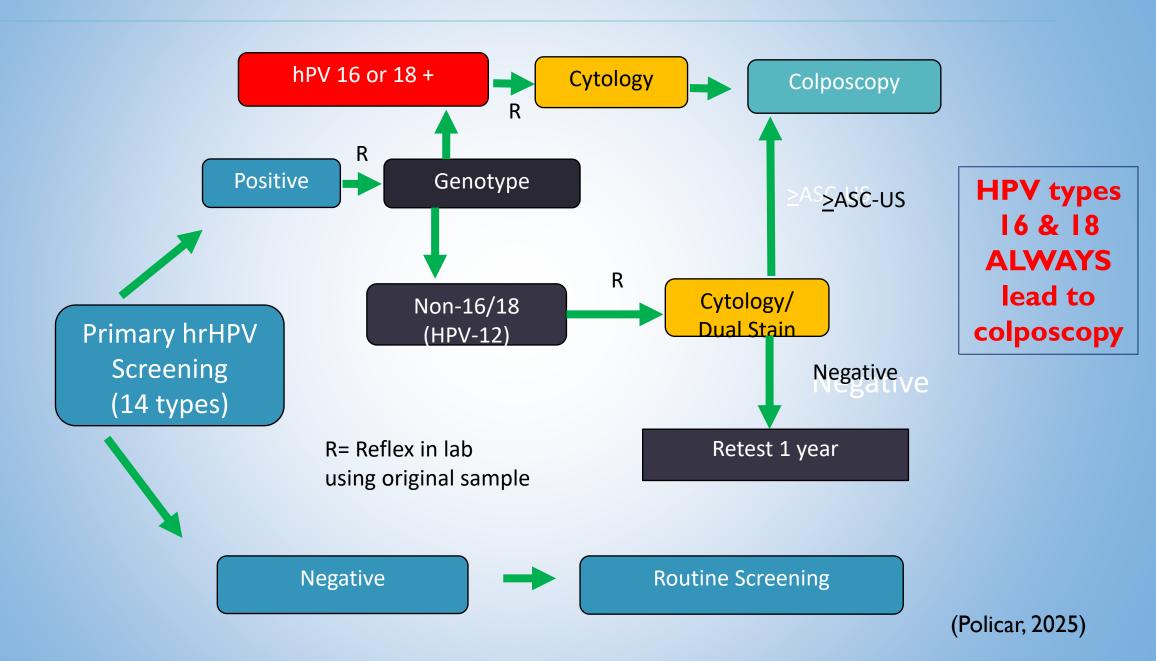
Strategy	Tests	Colposcopies	Cancers	Cancer deaths
No screening	0	0	15.21	7.32
Cytology q3, 21-65y	16,445	719	3.39	1.46
Cytology + HPV q5, 30-65y	22,865	1,179	2.12	0.92
HPV q5, 30-65y	13,217	1,029	2.33	0.99

Fewer tests, fewer colpos, but slightly more cancers with primary HPV

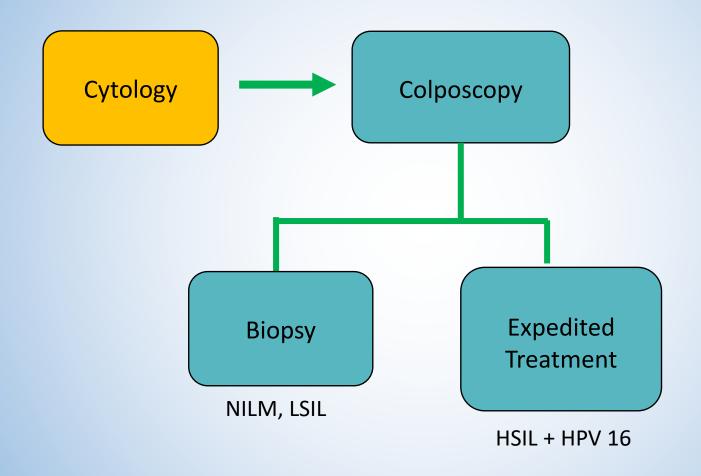
HPV TESTING

- Only 3 FDA-approved tests for <u>primary HPV</u>
 - Cobas
 - BD Onclarity
 - Alinity
- However, 6 are approved for HPV testing done with cytology (cotesting)
 - Cobas
 - BD Onclarity
 - Alinity
 - Hybrid Capture 2
 - Cervista
 - Aptima (E6/E7)
- These tests will all test for 13-14 different types of high-risk HPV

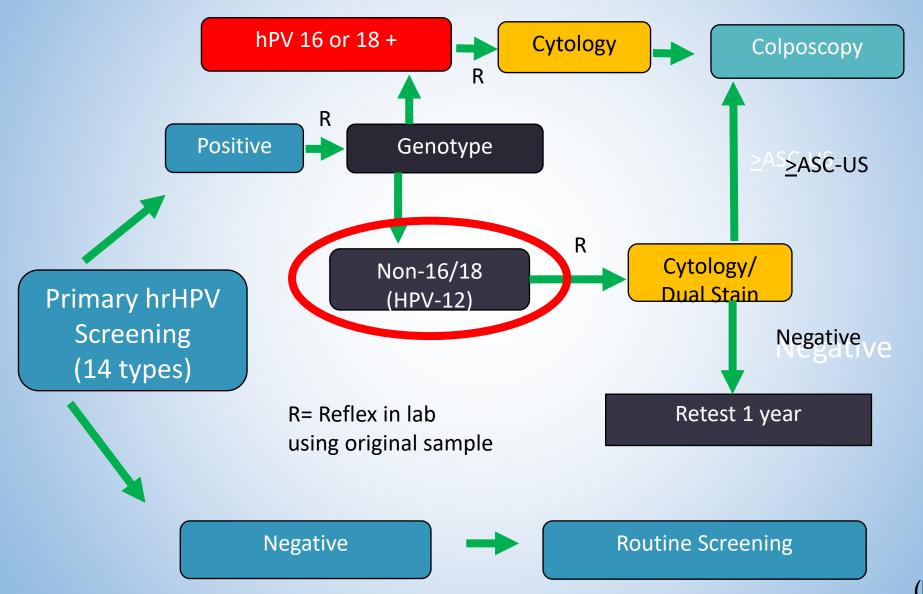
Primary HPV Screening Algorithm

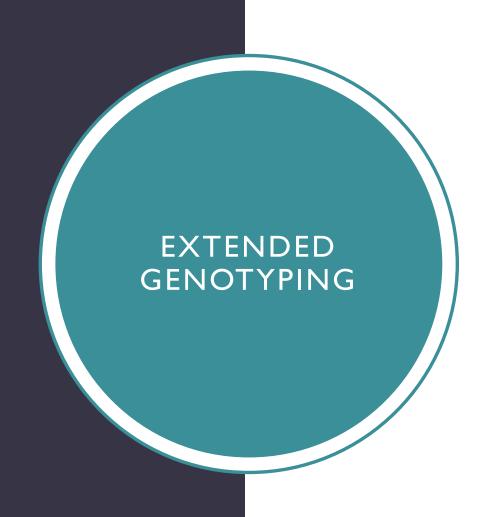


Primary HPV Screening Algorithm



Primary HPV Screening Algorithm – Extended Genotyping



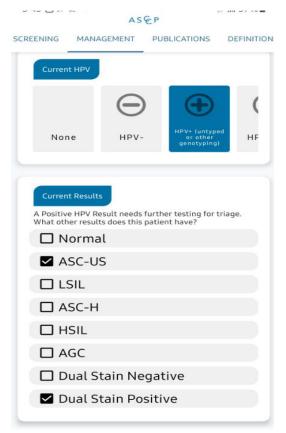


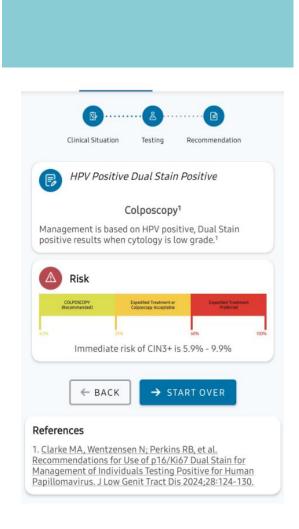
- A 2nd guideline recently developed by the Enduring Guidelines Committee
- Genotypes a positive high-risk HPV result
- Specific type is resulted and interpreted in the context of current and prior cytology
- Some extended HPV genotyping test results will lead to colposcopy in some persons with minimally abnormal cytology who would otherwise have had repeat testing in 1 year



- A 3rd guideline added by the Enduring Guidelines Committee
- PI6 a marker that detects HPV-related oncogene activity
- Ki67 a marker for cell proliferation
- When both P16 and Ki67 are detected in the same cell, there is a strong association with precancerous cellular changes (CIN3+)

Knowing if a Dual Stain is positive or negative helps to target those at higher risk and in need of diagnostic testing and treatment, while reducing unnecessary procedures for those at low risk





THANK GOODNESS FOR THE ASCCP APP

TABLE 7. Summary of Management With Extended HPV Genotyping and p16****/Ki-67 Dual Stain (DS) for Patients Undergoing Screening and Follow-Up of Low-Grade Abnormalities.

	Current HPV	Current DS result	Past history	Management
HPV 16/18	16 and/or 18	N/A¹	N/A	Colposcopy with collection of cytology if available
HPV 45,33/58, 31, 52/35/39/68,	45,33/58, 31, 52/35/39/68, 51 or untyped/other	DS Positive ²	N/A	Colposcopy
51 Untyped or	45,33/58, 31, 52/35/39/68, 51 or untyped/other	DS Negative ³	Normal ⁴ or colposcopy <cin2<sup>5 within past 1 year</cin2<sup>	Repeat HPV test in 1 year
"other" types when 16 and 18 are not present	45,33/58, 31, 52/35/39/68, 51 or untyped/other	N/A	HPV+ without colposcopy (i.e. current test is 2 nd consecutive HPV+)	Colposcopy
59/56/66	59/56/66	N/A	Normal or colposcopy <cin2 1<br="" past="" within="">year</cin2>	Repeat HPV test in 1 year ²
	59/56/66	N/A	HPV+ without colposcopy (i.e. current test is 2 nd consecutive HPV+)	Colposcopy

For patients with a history of high-grade histology or cytology or following treatment, 2019 guidelines should be followed, but for those individuals, colposcopy is recommended for any HPV+ result and for all cytology LSIL or higher (even if HPV negative).

[&]quot;N/A: not applicable; test result, if obtained, would not affect management.

⁶If cytology is performed in a cotesting setting, colposcopy is recommended for all results including NILM.

^{&#}x27;If cytology is performed in a cotesting setting, repeat HPV testing in 1 year is recommended for NILM, ASCUS, or LSIL results. Colposcopy is recommended for ASC-H, AGC, or HSIL results.

^{*}Normal screening history per patient or documented in medical record.

[&]quot;Cervical intraepithelial neoplasia grade 2 or less severe.

CLINICIAN V. SELF-COLLECTION HPV TESTING

- Performed similarly in paired samples equally sensitive
 - Self-collected 90%
 - Clinician-collected 93%
- Both methods are substantially more sensitive than cytology alone
- Clinician-collected cervical specimens *preferred*, but self-collected vaginal specimens are *acceptable* for primary HPV screening of asymptomatic average-risk individuals
- BOTH collection types are to be done in-office
- Reflex cytology And DS testing can only be done on cliniciancollected samples

Self
Collected
3-year interval

Clinician
Collected
5-year interval

USPSTF DRAFT CERVICAL CANCER SCREENING RECOMMENDATIONS

- Clinician-collected cervical specimens are preferred, and self-collected vaginal specimens are acceptable
- When self-collected vaginal specimens are HPV-negative in the screening setting, repeat testing in 3 years is recommended
- 3. When self-collected vaginal specimens are positive for HPV 16 and/or 18, direct referral for colposcopy with concurrent cytology collection is recommended
- 4. When self-collected vaginal specimen HPV test results are: a) positive for HPV (untyped), b) negative for HPV 16/18 and positive for HPV HR12 (other); or c) negative for HPV 16/18 and positive for HPV 45, 33/58, 31, 52, 35/39/68, 51 or combination thereof, obtaining a clinician-collected specimen for cytology or dual stain is recommended. Subsequent management of cytology or dual stain results per management guidelines is recommended

USPSTF DRAFT CERVICAL CANCER SCREENING RECOMMENDATIONS

- 5. When self-collected vaginal specimen HPV test results are positive for HPV types 56/59/66 and no other carcinogenic types, I-year repeat testing is recommended. If HPV-positive for any HPV type at the I-year follow-up, colposcopy is recommended
- 6. In the surveillance setting, clinician-collected cervical specimens are preferred. If a clinician-collected cervical specimen cannot be obtained, a self-collected vaginal specimen is acceptable following shared decision-making. If a self-collected vaginal specimen is obtained, management per 2019 guidelines is recommended

CLINICIAN VIEWS ON SELF-SWAB

Positive Views

- Increase access to care
- Non-invasive/patient-centered
- Believe patients can do it and already do for other tests
- Consider ways to help implement testing for patients, in office

Negative Views

- Believe patients will not and cannot do it
- Concern of accuracy and lack of knowledge
- Concern about missing something else
- Fiscal concerns

Ambivalence

- Need education
- Need for guidelines and professional organization endorsement

WHO IS NOT A CANDIDATE FOR SELF-COLLECTION?

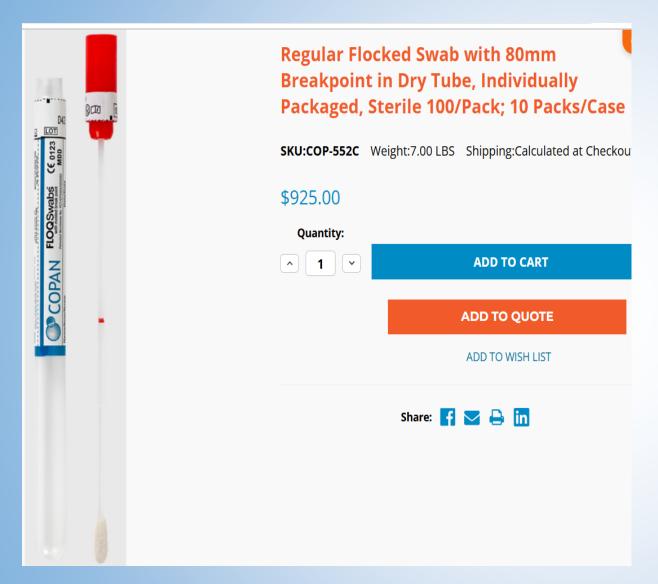
TABLE 4. Clinical Scenarios for Which Self-Collection Cannot be Used as HPV Testing Alone Is Not Curre	rently Recommended
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Clinical scenario	Current recommended screening test	Reference
People living with HIV	Cytology with or without HPV testing, depending 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.

- I. And those with abnormal bleeding or discharge manage according to relevant protocols
- 2. Anyone in a follow-up period

WHO IS A GOOD CANDIDATE FOR SELF-COLLECTION?

- Average-risk people with a cervix
- Lack of available clinicians
- Difficulty accessing gyne care
- Clinician does not perform pelvic exams
- Lack of time in the office visit
- Limited mobility
- Vaginismus
- History of sexual trauma
- Gender dysphoria
- Not comfortable with clinician
- Preference for self-collection



https://www.stellarscientific.com/

Instructions:

- Insert a few cm into the vagina
- Rotate the swab for 20-30 seconds
- Remove and place in accompanying container





Benefits of the Evalyn Brush:

- Flexible bristle technology for comfort and maximum yield.
- Sterilized and individually packed.
- Labeling with 2D barcode or data matrix.
- · Full color IFU with step by step graphics.
- Made in The Netherlands.
- · Validated with PCR based assays.
- Dry sample: no liquid in the mail.
- Built-in features to assure correct sample taking.
- All-in one: Sampler / IFU / Container in one attractive looking device.
- Available with a unique RFID chip for fast processing in the lab.
- Selected as the best self-sampling device by the Dutch and Danish cervical screening programs.
- Designed by women for women.





Instructions:

- Insert like a tampon-the wings control depth
- Push plunger until a click
- Rotate handle 5 times until another click
- Remove the brush and retract, then cap

https://www.roversmedicaldevices.com/cell-sampling-devices/evalyn-brush/

01

Order a kit & connect with a provider

Once you order a Teal at-home collection kit, you'll have a brief virtual visit with a Teal provider to review your screening history and the at-home screening process.

If you're eligible, the provider will prescribe the kit, and it will be shipped to your home.

02

Collect your sample & mail to lab

Receive the kit and collect your sample in the comfort of your home. Teal support is available to answer any questions along the way.

Once you're done, seal your sample and ship it to the lab.



03

Get results & connect with a provider

Get easy to understand results in your secure Teal portal. If follow-up care is needed, you can connect virtually with a Teal provider to discuss next steps and coordinate your referral care.



- FDA approved
- Only available in CA currently
- Over time it will expand to other states
- Barriers removed by home kits
 - Work schedules
 - Dependent care commitments
 - Transportation
 - Emotional deterrents
- SELF-CERV study 85.7% said that the home kit would most likely keep them upto-date with their screening

However, at-home testing is <u>still not</u> in our current or draft guidelines

(Policar, 2025; Wentzensen et al., 2025)

WHAT ABOUT THE WWE?

- Per ACOG (reaffirmed in 2024), WWE should include the following:
 - Counseling about maintaining a healthy lifestyle and minimizing health risks including reproductive health topics, such as contraception and STI services
 - Screening, evaluation, and counseling on immunizations
 - Comprehensive history
 - Usual subjective history
 - Family history helps assess risk
 - But include bone health, vulvovaginal symptoms, and sexual health
 - Physical exam may or may not be required shared decision making
 - Pelvic and breast exam indicated based on history and symptoms

SET UP & BILLING/CODING

Set up

- Decide on swab FDA approved only
 - BD Onclarity HPV Assay with the Copan 522C.80 swab
 - Roche cobas assay with Evalyn brush or Copan swab
- Pick a compatible lab
 - Must know which swab you are using

Billing/Coding

- CPT codes for specific tests are billed by the pathology lab
- Collection swabs for self-collection are not billable
- ZII.51 (Encounter for screening for HPV) among other codes

SUMMARY

- We reviewed the pathophysiology of cervical cancer low and high-risk HPV types
- Primary prevention is crucial to decreasing our numbers
- Same three screening methods from prior guidelines
- New guidelines for management offer more precision and detail but can be more complicated
 - Include 3 ways to manage a positive HPV test: cytology, cytology plus HPV genotyping, and dual stain
- New technology addresses barriers to care for a diverse population in need of screenings and is currently approved for in-office testing

More changes are on the way that will increase access to much-needed screenings and management of cervical pathology

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