

CERVICAL CANCER SCREENING 2026: It's not your mother's Pap smear!

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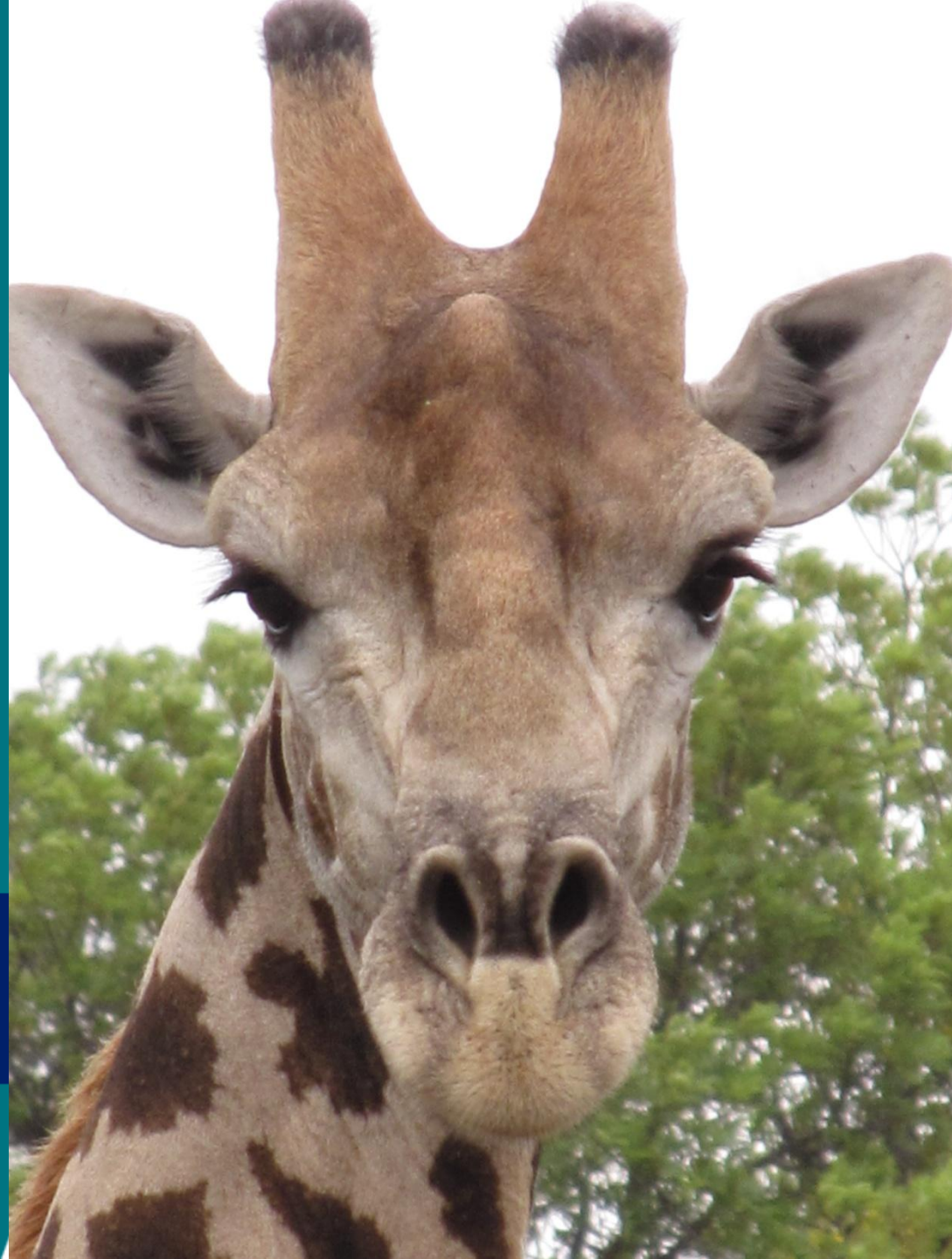
January 2026

Disclosures

- I have no financial conflicts of interest .
- The basic framework of this talk was prepared by the American Cancer Society's National Roundtable on Cervical Cancer. I have modified some slides and added others.

Objectives

- Review the 2026 updated recommendations for cervical cancer screening
- List the three commercial tests FDA approved for primary HPV screening and three follow-up modalities for a positive test
- Review the technique, efficacy and potential benefits of HPV self-collection



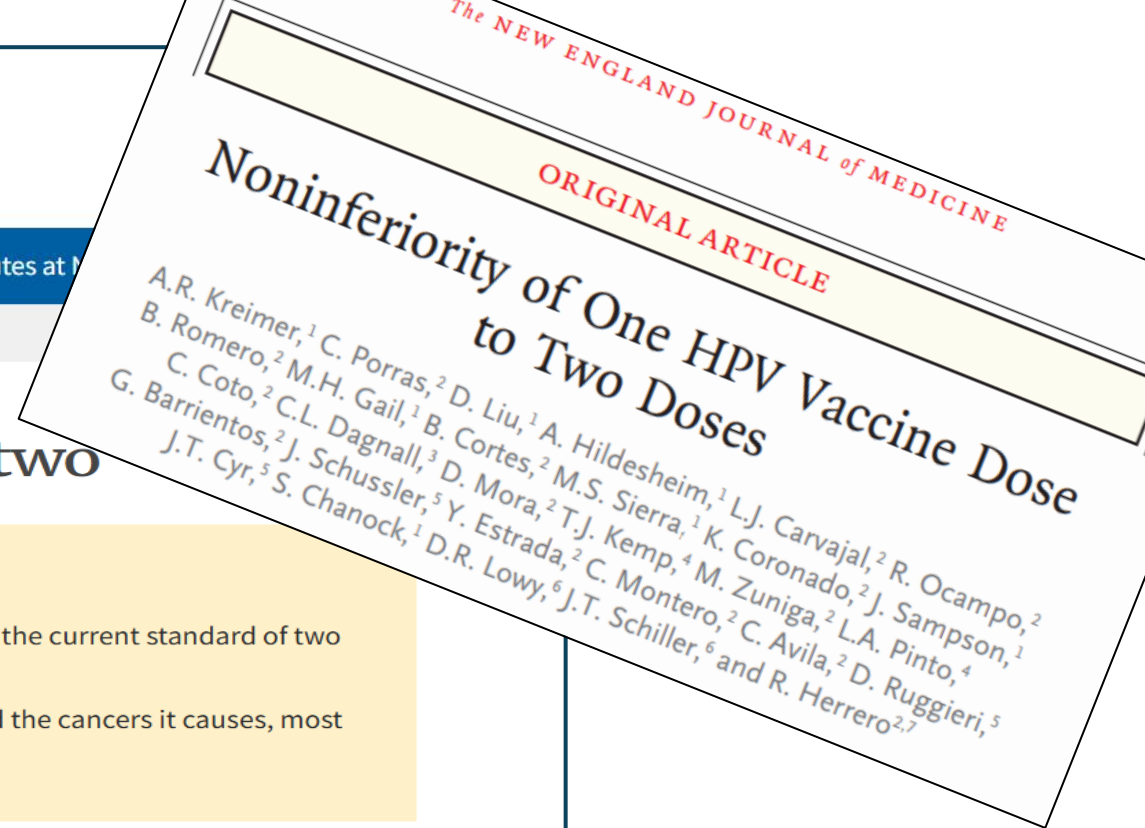
But first, some
breaking news...

-

One dose of HPV vaccine as effective as two

At a Glance

- A single dose of human papillomavirus (HPV) vaccine provided protection comparable to the current standard of two doses.
- The findings suggest that single-dose vaccine regimens could effectively prevent HPV and the cancers it causes, most notably cervical cancer.



Jan 15, 2026

Improving lives through the prevention and treatment of anogenital & HPV-related diseases

Practice Advisory: Updated Childhood Immunization Schedule Now Recommends a Single Dose of the Human Papillomavirus (HPV) Vaccine

The Centers for Disease Control and Prevention (CDC) has accepted changes to the pediatric vaccination schedule as recommended by the Department of Health and Human Services (HHS) for administration of the HPV vaccine to change from 2 doses to a single dose administered at 11 – 12 years old

Non-inferiority of one HPV Vaccine dose to two doses.

Kraimer, AR et al . NEJM. Dec. 18/25, 2025. 393:2421-33

Non-inferiority Analysis: One vs Two Doses, Nonavalent HPV Vaccine				
	No. of Participants	No. of Events	Cum. Events : Rate per 100 participants (95% CI) Events 12 to 60 mo	Rate Difference (95% CI)
New, infection with HPV 16 or 18 that persisted at least 6 months				
One dose	4851	23	0.48 (0.28, 0.75)	
Two doses	4849	13	0.27 (0.12, 0.51)	0.21 (-.09, 0.51)
P value				<.001
New, infection with HPV types 16, 18, 31, 33, 45, 52 or 58 that persisted at least 6 months				
One dose	4851	79	1.64 (1.25, 2.10)	
Two doses	4849	52	1.08 (0.75, 1.50)	0.56 (0.01, 1.11)
P value				<0.001

Rate difference is the rate for one dose minus the rate for two doses.

P value is for non-inferiority of one dose to two doses

Non-inferiority of one HPV Vaccine dose to two doses.

Kraimer, AR et al . NEJM. Dec. 18/25, 2025. 393:2421-33

Vaccine Effectiveness: One vs Two Doses, Nonavalent HPV Vaccine				
	No. of Participants	No. of Events	Vaccine Effectiveness (95% CI)	P value
New, infection with HPV 16 or 18 at months 54 and 60				
One dose	4109	7	97.0% (94.3, 99.1)	
Two doses	4083	3	98.5% (96.7,99.7))	<.001
Survey (Control)	2990	159 / 160		
New, infection with HPV types 16, 18, 31, 33, 45, 52 or 58 that persisted at least 6 months				
One dose	4109	29	94.5% (92.3, 96.6)	
Two doses	4083	22	95.8% (93.8, 97.6)	<.001
Survey (Control) Infections months 0 and 6	2990	389 / 393		

Events for survey participants measured at months 0 and 6; recorded for one dose / two dose comparison



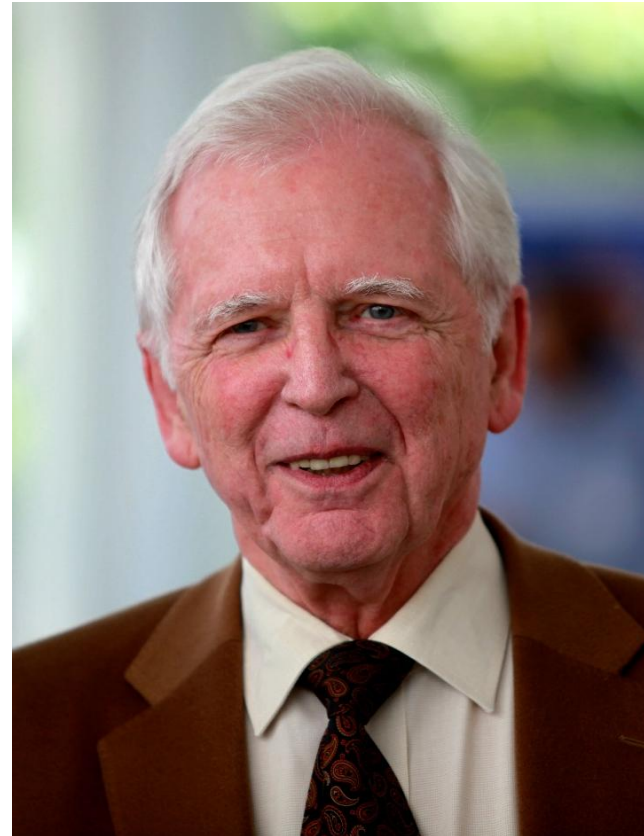
Background

Primary HPV Screening

Is it time to move away from the Pap test?



George Papanicolaou



Harald zur Hausen

Cervical Cancer in the United States



7.7

Incidence*



2.2

Mortality*



13,820

2024 Estimates



4,360

incidence
mortality

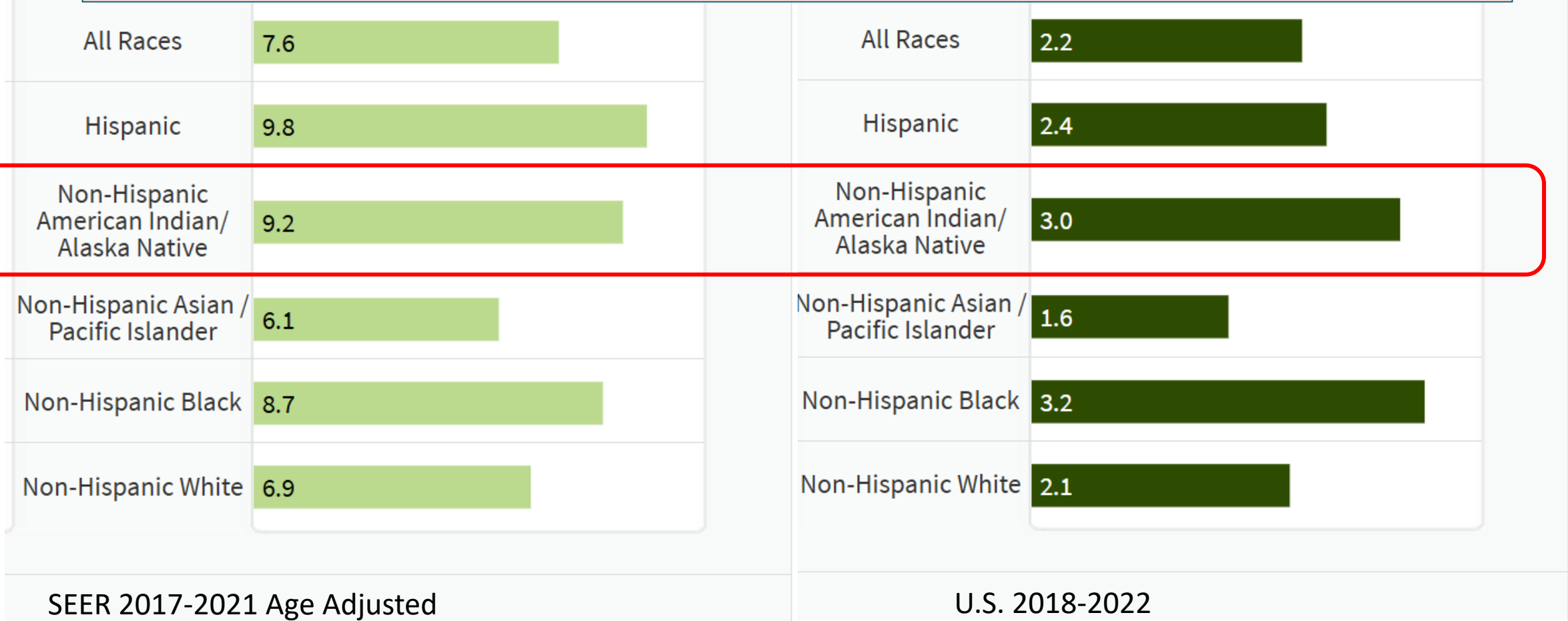
Almost all cases of cervical cancer are caused by high-risk types of human papillomavirus (HPV)

Cancer Facts and Figures 2024 →



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

The incidence and mortality in AI/AN persons is higher than the US all races.



SEER 2017-2021 Age Adjusted Rates per 100,000 persons

U.S. 2018-2022

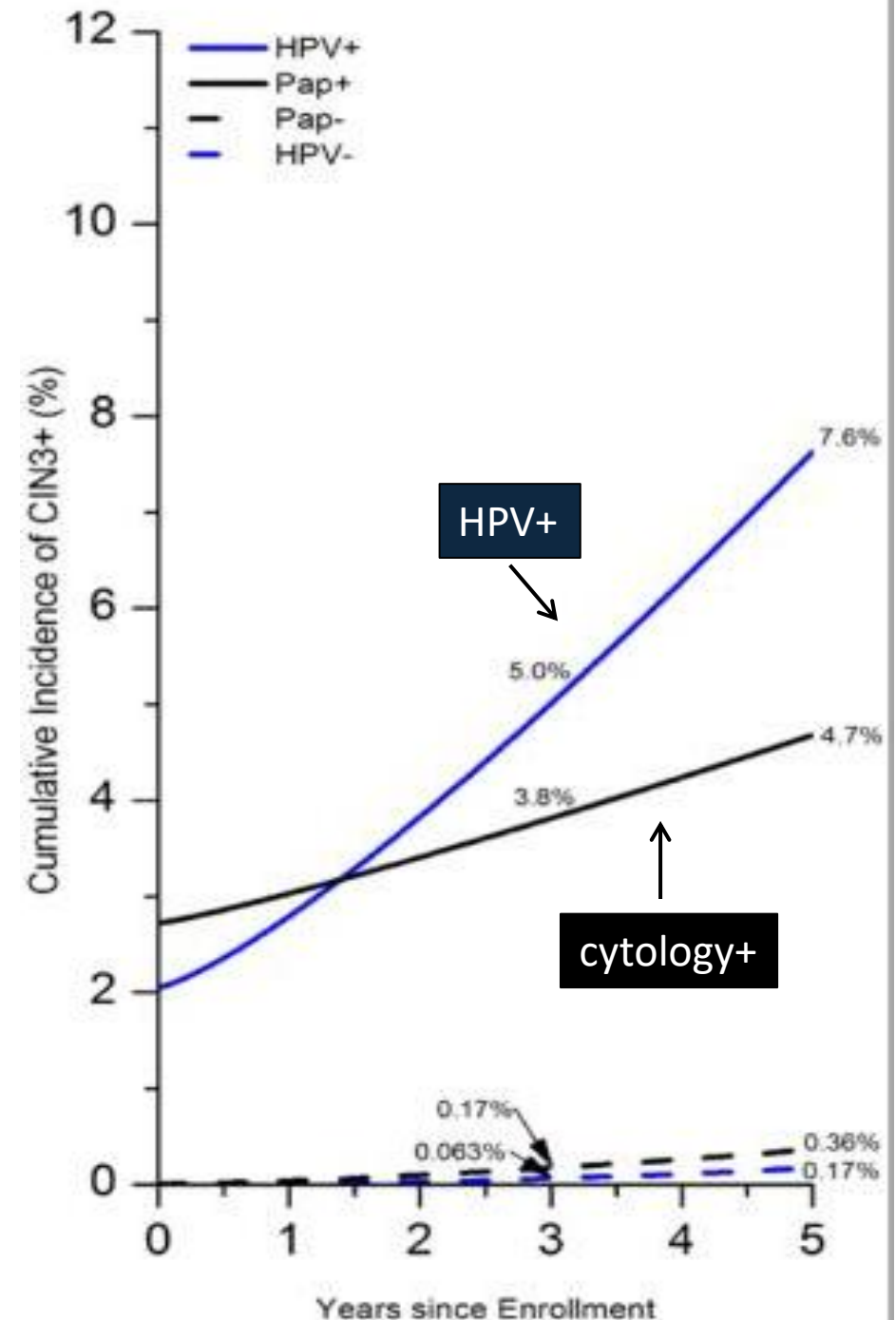
Who gets cervical cancer in the United States?

- Estimated annual contributions to squamous cervical cancer screening failures in the U.S.

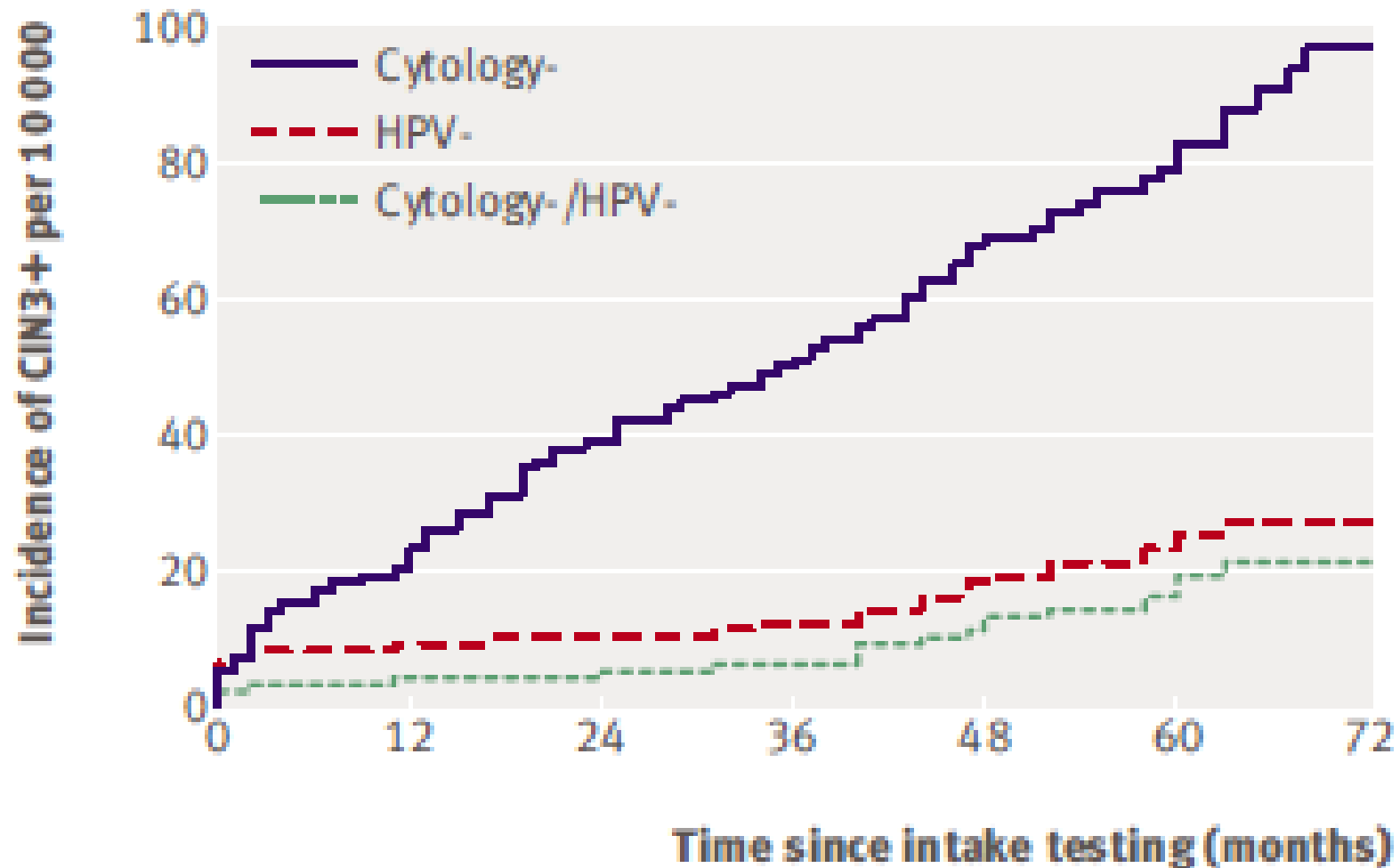
	<u>%</u>	<u>No. of women</u>
Never screened	50	6,000
>5 yrs since screened	10	1,200
Errors in follow up	10	1,200
Errors in sampling or interpretation	30	3,600
Total	100	12,000

HPV Testing Predicts Future Risk Better than Cytology

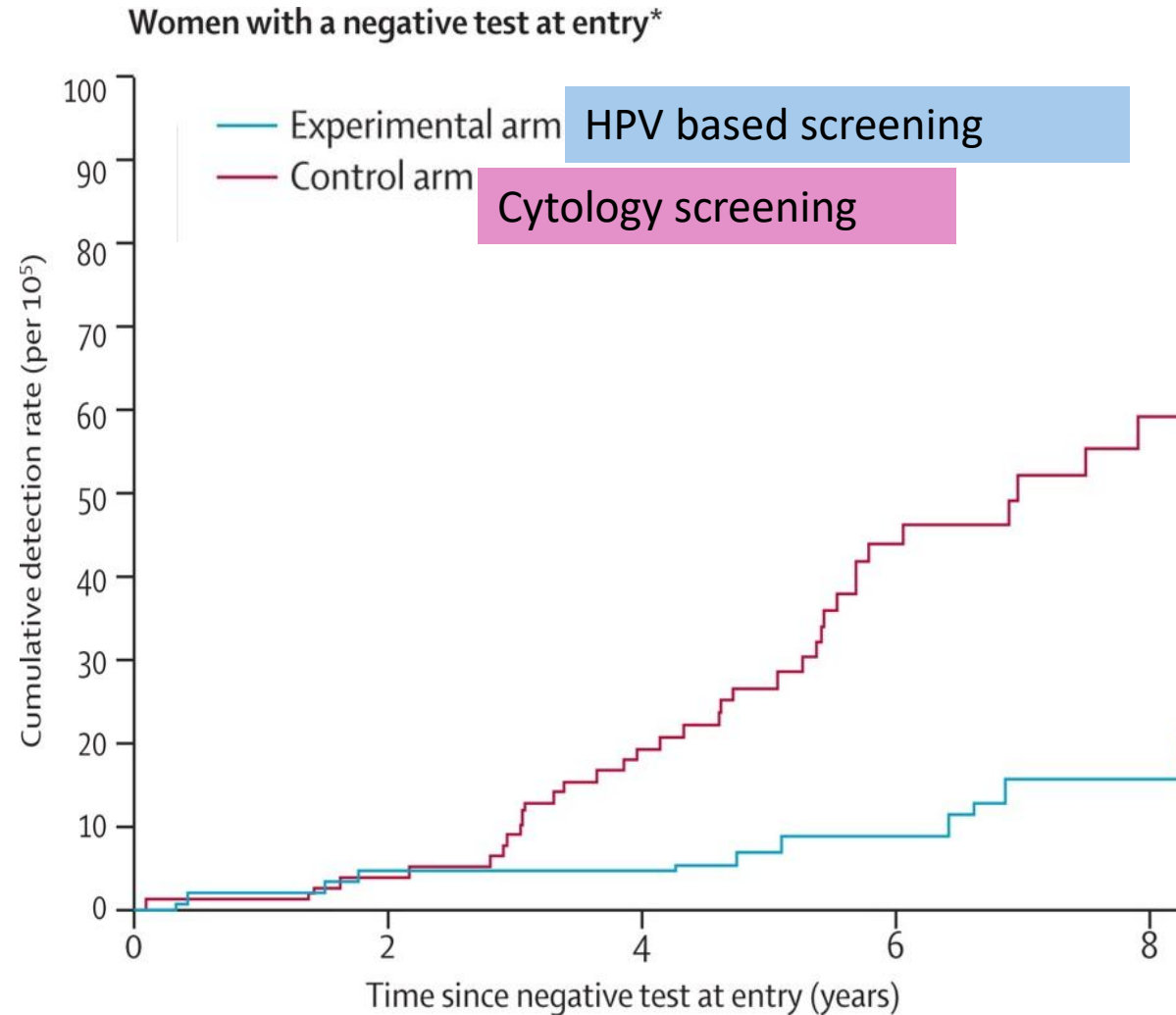
- **Persistent type-specific HPV infection** is the etiological agent for the majority of cervical cancers due to the ability of hrHPV to persist and drive cell proliferation in the cervical transformation zone.
- Majority of HPV infections **spontaneously regress** and of those that progress, there is a long period of latency.
- Both HPV and cytology predicted risk on the date of screening.
- However, HPV was more predictive of the 5-year risk of CIN3 and cancer.¹



Development of Precancer Over 6 Years in Women Screened with Cytology, HPV, and Cotesting



Screening with HPV decreases the risk of invasive cancer better than screening with cytology: *Pooled Analysis of 4 European RCTs*



Ronco G, Dillner J, Elfstrom KM et al. Lancet Nov 3, 2013

How should we screen? As of December, 2025: Two Sets of Guidelines

- US Preventive Services Task Force recommendations 2018
- The American Cancer Society issued new guidelines in July, 2020.



Comparison of cervical cancer screening guidelines

Age	< 21	21-25	25-29	30-65	>65
USPSTF 2018	No screening	Cytology every 3 yrs	Cytology every 3 yrs	hrHPV test only: every 5 yrs OR Co-test: every 5 years or Cytology: every 3 yrs	Discontinue if adequate prior screening
ACS 2020	No screening	No screening	Primary HPV test every 5 yrs* OR Co-test: every 5 years OR Cytology: every 3 yrs	Primary HPV test every 5 yrs* OR Co-test: every 5 years or OR Cytology: every 3 yrs	Discontinue if adequate prior screening

*FDA approved test for primary screening, preferred regimen | **Co-test:** cervical cytology plus high risk HPV test (hrHPV) | **Cytology:** cervical cytology (Pap smear) alone

USPSTF Cervical Cancer: Screening 2018. <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/cervical-cancer-screening>.

Fontham ETH, et al. Cervical cancer screening for individuals at average risk: 2020 guideline update from the American Cancer Society. *CA Cancer J Clin.* 2020; 70: 321-346.

But change is in the air...



DRAFT USPSTF recommendation Dec.10, 2024

Period of public comment ended Jan 13, 2025

Recommendation Summary

Population	Recommendation	Grade
Women ages 21 to 65 years	<p>The USPSTF recommends screening for cervical cancer every 3 years with cervical cytology alone in women ages 21 to 29 years and then every 5 years with clinician- or patient-collected high-risk human papillomavirus (HPV) primary screening in women ages 30 to 65 years.</p> <p>As an alternative to HPV primary screening for women ages 30 to 65 years, the USPSTF recommends continued screening every 3 years with cervical cytology alone or screening every 5 years with high-risk HPV testing in combination with cytology (cotesting).</p>	A
Women younger than age 21 years	The USPSTF recommends against screening for cervical cancer in women younger than age 21 years.	D
Women older than age 65 years	<p>The USPSTF recommends against screening for cervical cancer in women older than age 65 years who have had adequate prior screening and are not otherwise at high risk for cervical cancer.</p> <p>See the "Practice Considerations" section for discussion of adequate prior screening and risk factors that support screening after age 65 years.</p>	D
Women with a prior hysterectomy and no cervix	The USPSTF recommends against screening for cervical cancer in women who have had a hysterectomy with removal of the cervix and do not have a history of a high-grade precancerous lesion (i.e., cervical intraepithelial neoplasia [CIN] grade 2 or 3) or cervical cancer.	

IN PROGRESS

But that was a year ago.

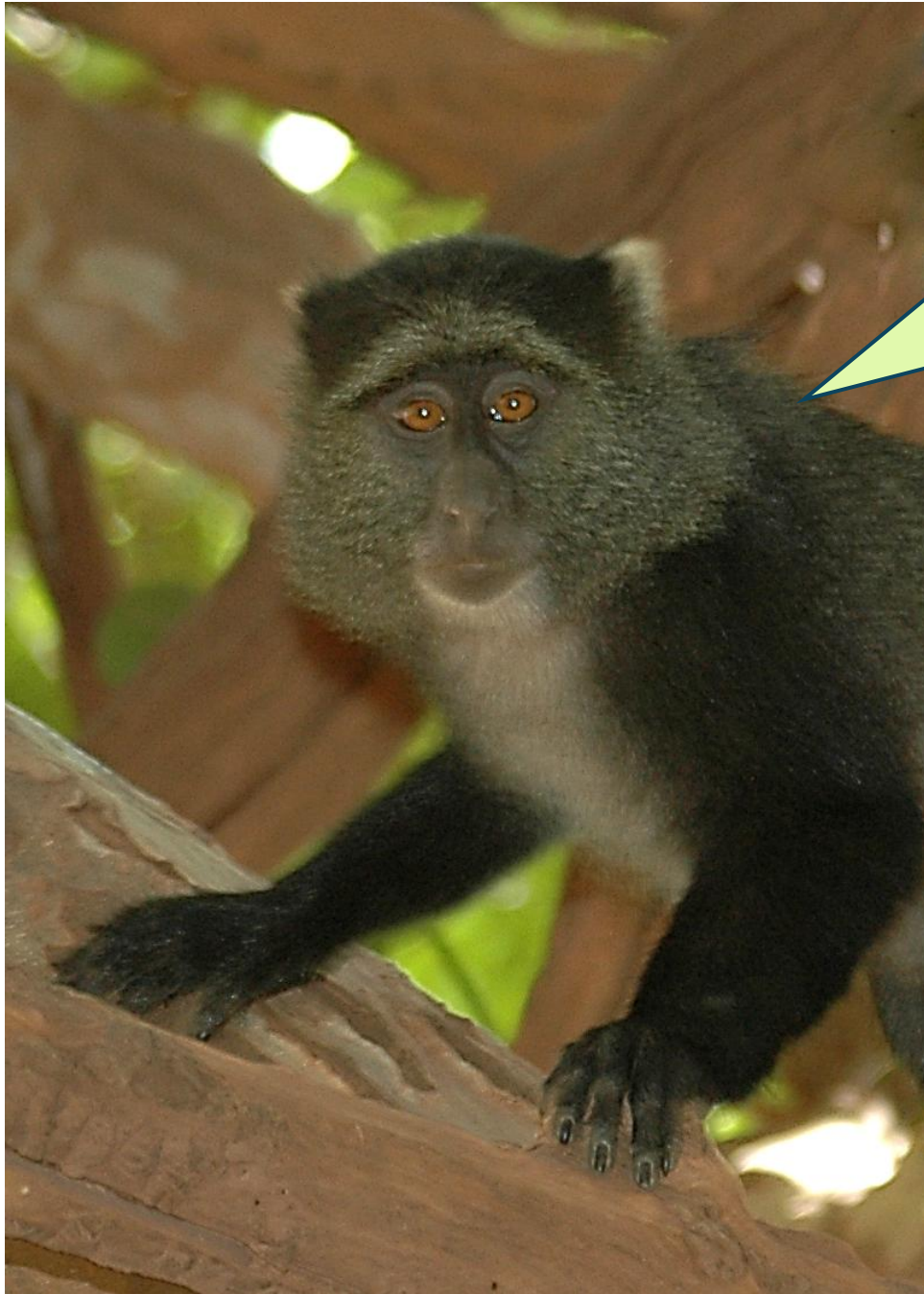


agw

The USPSTF has been missing in action since.



agw



Fortunately, in the early days of 2026, other organizations have stepped into the breach...

American Cancer Society Update: Self-collected vaginal specimens for HPV

Perkins RB et al. Ca Cancer J Clin 2026;e70041

- Primary HPV testing is the preferred screening modality for average risk women. (Reaffirms 2020 recommendation)
- Clinician-collected cervical specimens are preferred
 - 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 year repeat is intentionally conservative during roll-out in the US.
 - *Recommendations only apply to HPV assays and kits with an FDA indication for primary HPV screening using self-collection of vaginal specimens and should be used in the settings (clinic or home) for which they have FDA approval.*

HRSA supported Women's Preventive Services Guidelines

Guidelines:

- Age 21-29: Screen with cytology alone q3 yrs.
- Age 30 – 65: Primary HPV testing (Preferred) or cotesting q5 yrs.
 - Cytology q 3yrs if HPV testing not available
- Self-collected HPV testing is appropriate and should be offered to women at average risk

- Published in Federal Register Jan. 5, 2026
- Requires coverage by insurance plans without copay, coinsurance, deductible or other cost-sharing starting with plan year 2027.

American Cancer Society Update: Exiting screening

Perkins RB et al. Ca Cancer J Clin 2026;e70041

- Criteria to exit screening for an *average* risk woman or person with a cervix:
 - Two consecutive negative HPV screening tests (preferred) or co-testing (acceptable) at ages 60 and 65
 - If primary HPV tests or cotesting is not available, 3 consecutive negative cytology tests at recommended intervals with the last negative test at age 65 are acceptable.
 - If self-collected HPV testing is used, the 3 year testing interval should be used*.

**If ages of testing deviate from 60 and 65, tests should follow the appropriate intervals with the final test at age 65 or older.*

Criteria updated to make guidance clearer and more easily implemented than previous versions.

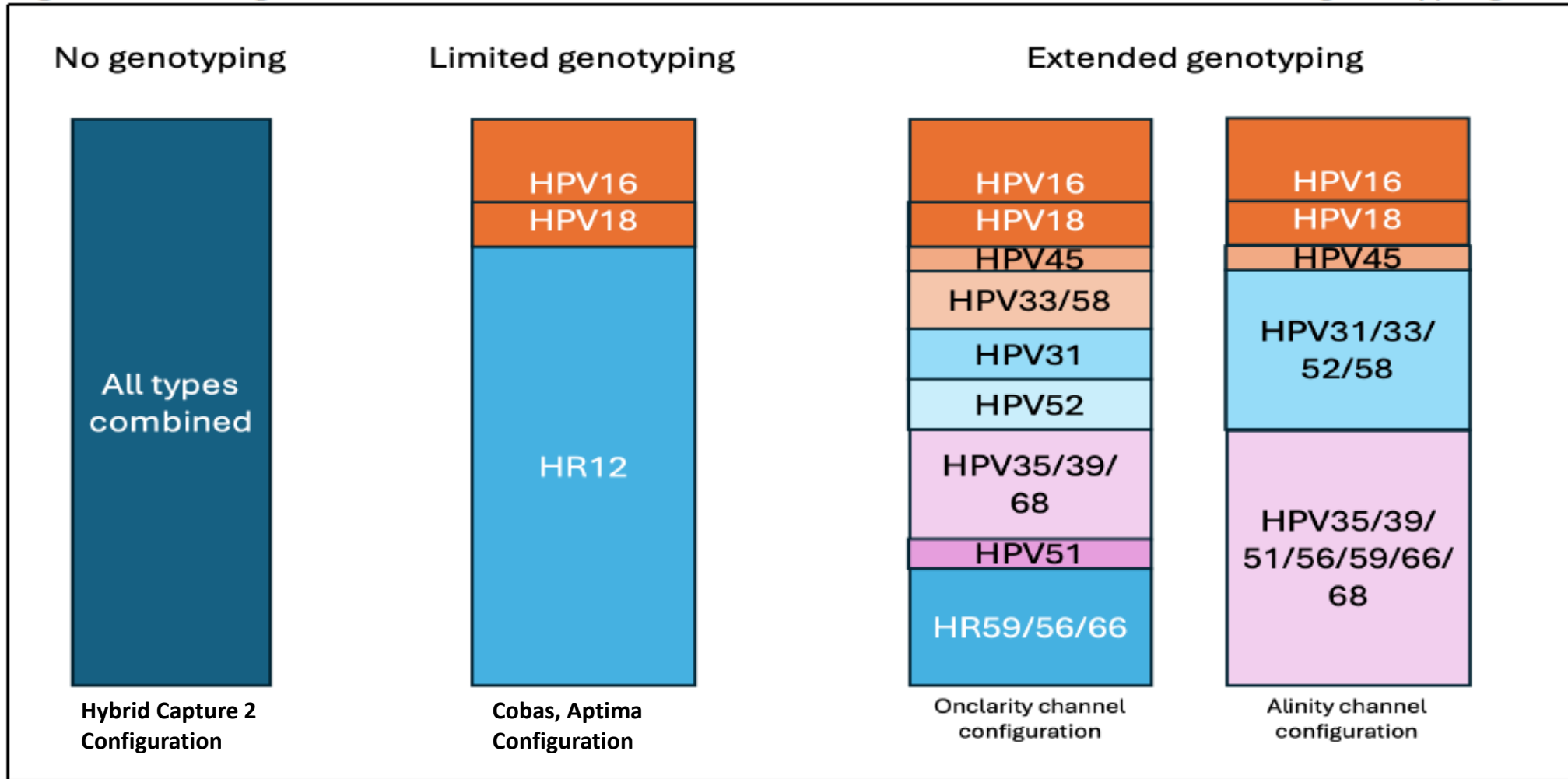
American Cancer Society Update: Exiting screening (cont.)

Perkins RB et al. Ca Cancer J Clin 2026;e70041

- Cervical cancer screening may be discontinued by individuals of any age with limited life expectancy.
- Screening is not recommended for individuals who have undergone hysterectomy with removal of the cervix for benign indications.
- Individuals should continue screening after age 65 years if they have the following risk factors:
 - a. HIV-positive or immunosuppression
 - b. History of a positive HPV test or abnormal cytology (Pap test) result of low-grade squamous intraepithelial lesion or higher in the past 10 years
 - c. History of cervical precancer in the past 25 years (cervical intraepithelial neoplasia grade 2 or grade 3 or adenocarcinoma in situ)
 - d. History of cervical cancer at any time.

Genotypes reported in different HPV DNA tests

Figure 1: Configuration of HPV tests without, with limited, and with extended genotyping



HPV tests are not all the same.

FDA-approved HPV Tests Marketed in U.S.

Assay	HC2 (Digene)	Aptima (Hologic)	Cobas (Roche)	Onclarity (BD)	Alinity m (Abbott)
Detection of...	HPV DNA	HPV E6/E7 mRNA	HPV DNA	HPV DNA	HPV DNA
# of HPV types	13	14	14	14	14
Approved for primary screening and self collection	No	No	Yes	Yes	Yes
Assay type	RNA-DNA hybrids	E6, E7 mRNA	PCR	E6, E7 PCR	PCR
Internal control for specimen adequacy	No	No	Yes	Yes	Yes
HPV 16/18 genotyping available	No	Yes 16, 18/45 11 other	Yes 16, 18, 12 other	Yes 16, 18, 45, 31, 51, 52, [33,58], [56,69,66], [35,39,68]	Yes 16, 18, 45. [31,33,52,58] [35,39,51,56,59,66,68]
Comments					FDA approved November 2, 2023

HPV tests are not all the same.

Three are FDA approved for primary HPV screening and self-collection

Assay	HC2 (Digene)	Aptima (Hologic)	Cobas (Roche)	Onclarity (BD)	Alinity m (Abbott)
Detection of...	HPV DNA	HPV E6/E7 mRNA	HPV DNA	HPV DNA	HPV DNA
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Comments					FDA approved November 2, 2023



Self-Collection HPV Testing

May 15, 2024

The Washington Post
Democracy Dies in Darkness

FDA approves self-collection screening for virus that causes cervical cancer

Women's health advocates view the move as crucial to stamping out the preventable disease.

By [David Ovalle](#) and [Rachel Roubein](#)

Updated May 15, 2024 at 4:45 p.m. EDT | Published May 15, 2024 at 7:00 a.m. EDT

What is self-collection HPV testing?

Self-collection HPV testing is primary HPV testing.

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

Self-collection is when a patient uses a collection kit 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 self-collection HPV testing?

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

Self-collection testing has:

- **Higher sensitivity** than cytology
- **Commensurate sensitivity and high agreement** with clinician-collected primary HPV testing samples

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

[Download Full Issue](#)

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

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  

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

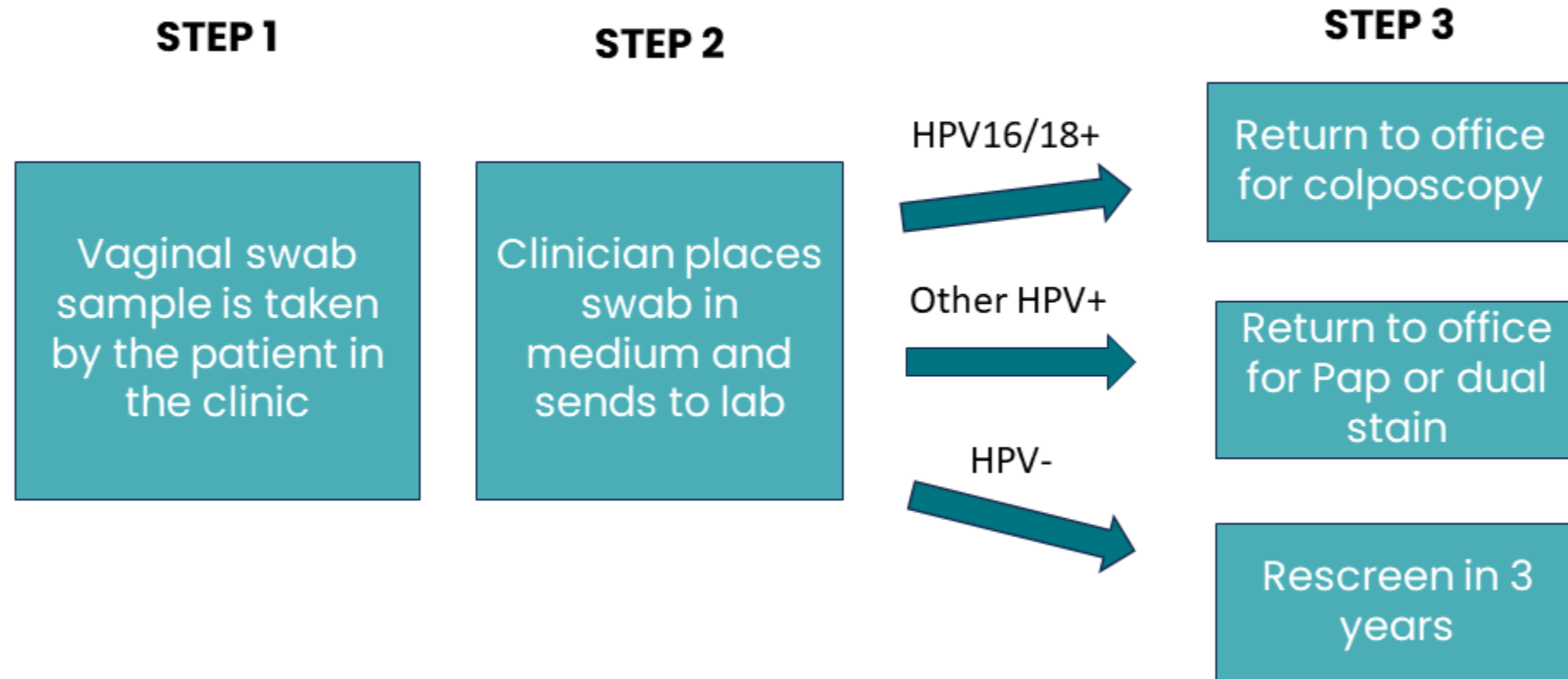
Arbyn M et al BMJ 2018;363 :k4823

- Self-collected samples are 99% as sensitive for CIN 2+ and CIN 3+ as clinician collected samples provided a PCR test is run. (CI 0.97-1.02)
 - Signal amplification tests were 85% as sensitive (CI 0.80-0.89)
- Specificity to exclude CIN 2+ was 2-4% lower for self collected samples than clinician collected samples on PCR.
- Response to direct offer of self-sampling kits is significantly higher in underserved communities than invitations for clinician screening.

How is self-collection done?



How is self-collection HPV testing done?



FDA requires all approved tests and collection devices be used in a clinical setting except Teal Wand device which can be used in a home setting by prescription.

Self-collection: Approved tests and collection devices

Roche Cobas HPV Test

Approved Collection Devices

FLOQSwab
Evalyn Brush
Teal Wand

BD Onclarity HPV Test

Approved Collection Device

FLOQSwab

Abbot Alinity m HR HPV Assay

Approved Collection Devices

Evalyn Brush
Qvintip swab (simpli-COLLECT system)

Evalyn Brush



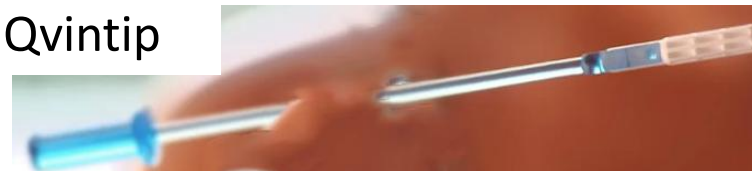
Teal Wand



FLOQSwab



Qvintip



What should patients know before choosing self-collection?



Patients should know that if they receive a positive result, they must return for a speculum exam for dual-stain or cytology testing.



About 1 in 10 patients will receive a positive result.

[Learn more about HPV testing →](#)



What Happens After a Positive HPV Test?

Partial Genotyping (16/18/Other)

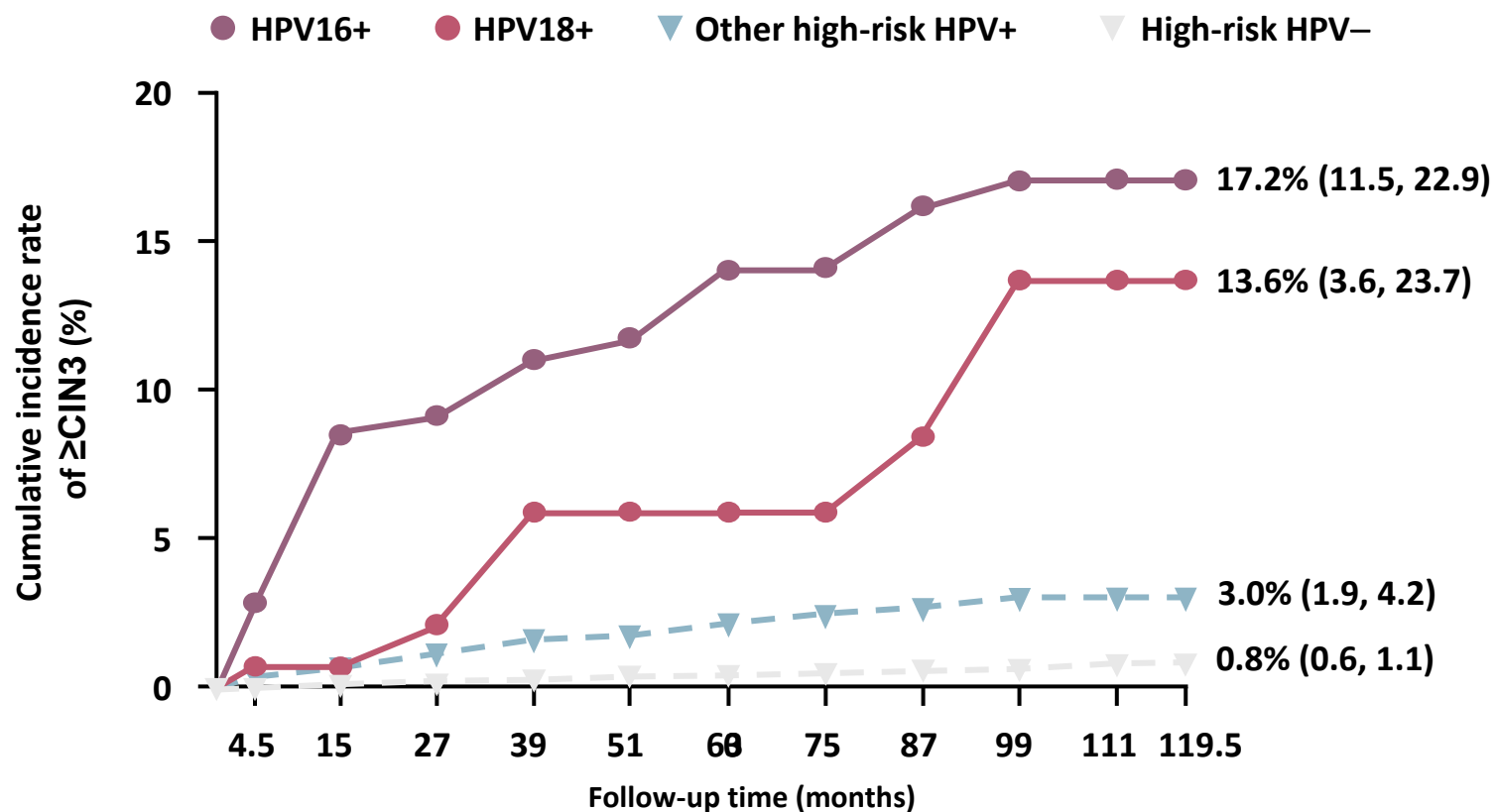
Extended Genotyping

Cytology

Dual-stain p16/Ki-67

Not All HPV Genotypes are the Same

Cumulative Risk of \geq CIN 3 Based on HPV Genotype at Baseline

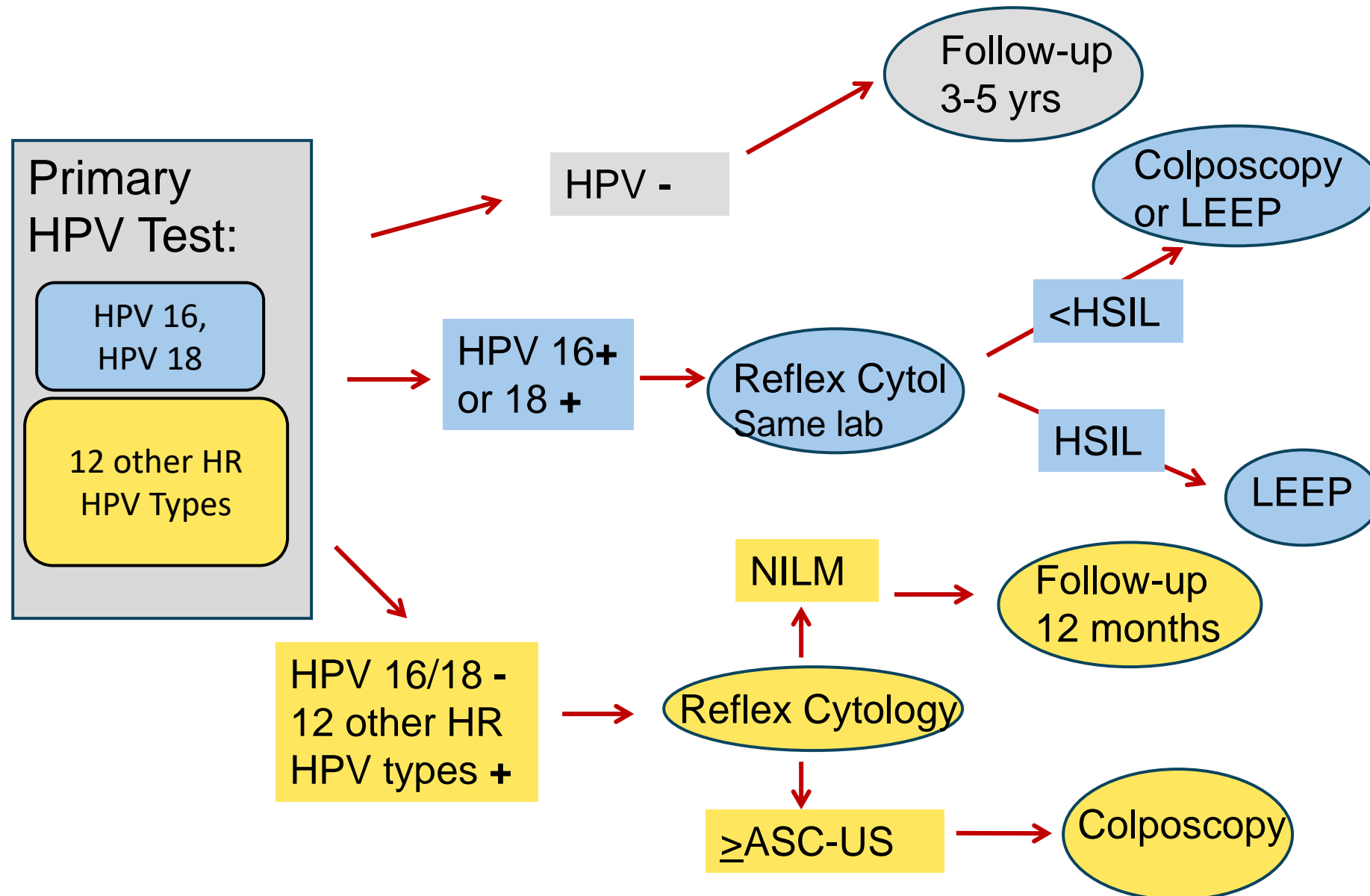


At time zero, Pap negative or minimal abnormality

Algorithm Using Cytology Follow-up after Primary HPV Screening

Huh et al Gynecol Oncol 2015

Perkins et al J Lower Genital Tract Dis 2020



OPEN

Applying Results of Extended Genotyping to Management of Positive Cervicovaginal Human Papillomavirus Test Results: Enduring Guidelines

L. Stewart Massad, MD,¹ Megan A. Clarke, PhD,² Rebecca B. Perkins, MD,³ Francisco Garcia, MD,⁴ David Chelmow, MD,⁵ Li C. Cheung, PhD,² Teresa M. Darragh, MD,⁶ Didem Egemen, PhD,² Thomas S. Lorey, MD,⁷ Ritu Nayar, MD,⁸ Morgan Newman, MSW,⁹ Carolann Risley, PhD, NP,^{2,10} Robert A. Smith, PhD,¹¹ Nicolas Wentzensen, MD, PhD,² and Enduring Consensus Cervical Cancer Screening and Management Guidelines Committee

Journal of Lower Genital Tract Disease • Volume 00, Number 00, Month 2025

Risk stratification based on HPV genotype

Figure 1: Carcinogenic HPV genotypes with cancer attribution and risk of precancer progression

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	Lower risk
51	1.2	1.1	Lower risk
59	1.1	0.9	Lower risk
56	0.9	0.8	Lower risk
68	0.6	1.0	Lower risk

Massad LS, et al. J Lower Genital Tract Dis. Jan 10 2025

IARC. Cervical Cancer Screening IARC Handbooks of Cancer Prevention Volume 18. Published online 2022.

High-risk HPV Type Groupings and Cancer risk

Highest Risk

	% of cervical cancers	9 year risk HPV+→ CIN3+
Type 16	60.3%	6.3 %
Type 18	10.5%	3.0%

Intermediate Risk

	% of cervical cancers	9 year risk HPV+→ CIN3+
Types 31,33/58,45,51, 52,35/39/68	0.6-6.1%	1.0-4.5%

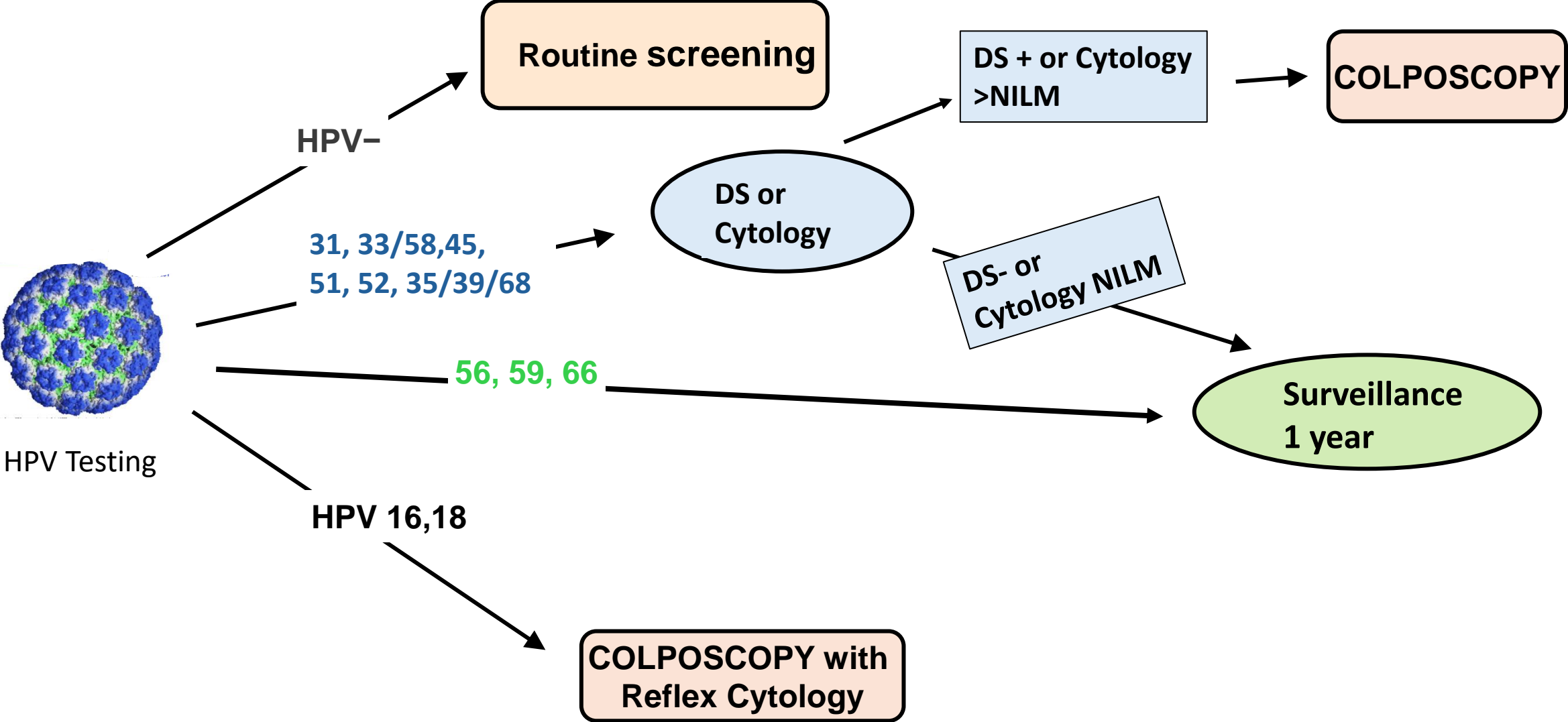
Lowest Risk

	% of cervical cancers	9 year risk HPV+→ CIN3+
Types 56,59,66	Negligible – 1.1%	<1%

Modified from Massad LS, et al. J Lower Genital Tract Dis. Jan 10 2025

**Applies to BD Onclarity only*

Primary HPV Screening with Extended Genotyping*



Primary HPV Testing for Screening: *Potential Benefits of Extended Genotyping*

- Improved risk stratification for high risk types other than types 16/18 (HR other)
 - Creates intermediate risk pool including types 31, 33, 45 that may require immediate colposcopy
 - Identifies genotypes at very low risk (56, 59, 66)
- By identifying individual genotypes, allows more precise identification of type-specific persistence, a higher risk condition than persistence of pooled HPV positivity. (Not yet recommended. More studies needed)

Recommendations for Use of p16/Ki67 Dual Stain for Management of Individuals Testing Positive for Human Papillomavirus

Megan A. Clarke, PhD, MHS,¹ Nicolas Wentzensen, MD, PhD,¹ Rebecca B. Perkins, MD,² Francisco Garcia, MD, MPH,³ Deborah Arrindell,⁴ David Chelmow, MD,⁵ Li C. Cheung, PhD,¹ Teresa M. Darragh, MD,⁶ Didem Egemen, PhD,¹ Richard Guido, MD,⁷ Warner Huh, MD,⁸ Alexander Locke, MD,⁹ Thomas S. Lorey, MD,¹⁰ Ritu Nayar, MD,¹¹ Carolann Risley, PhD,^{1,12} Debbie Saslow, PhD,¹³ Robert A. Smith, PhD,¹⁴ Elizabeth R. Unger, MD, PhD,¹⁵ L. Stewart Massad, MD,¹⁶ and for the Enduring Consensus Cervical Cancer Screening and Management Guidelines Committee

Journal of Lower Genital Tract Disease 2024 Apr1; 28(2) :124-30

p16/Ki-67 Dual Stain

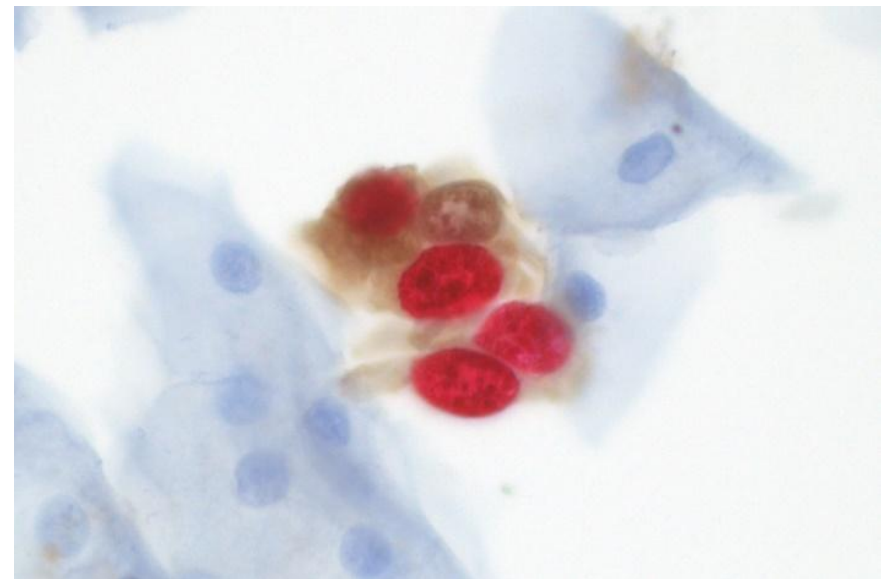
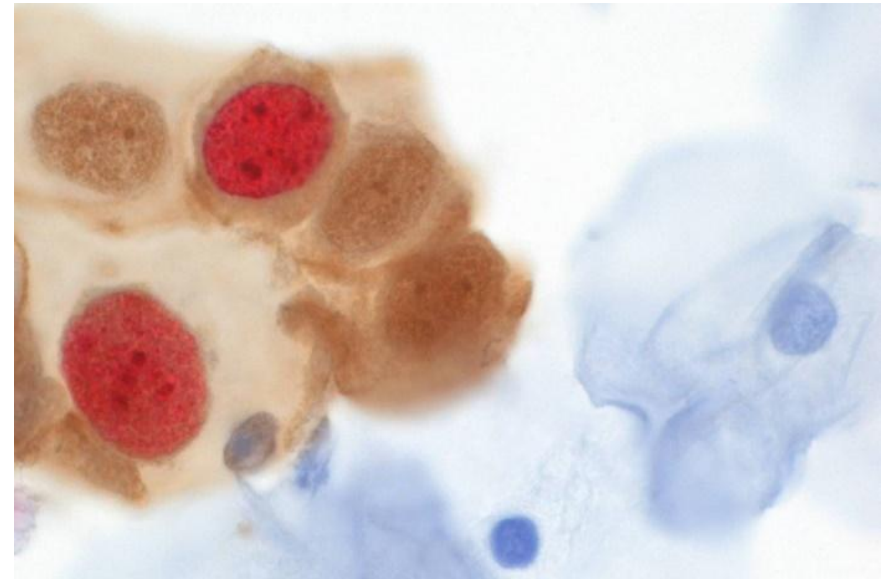
FDA approved CINtech PLUS 3/2020

The positivity of p16/ki-67 strongly indicates the presence of high-grade dysplasia.

- Ki-67 is a marker of cell proliferation
- Ki-67 stains the nucleus red
- Co-expression of p16 and Ki-67 indicates a loss of cell cycle regulation – a hallmark of neoplastic transformation
 - Under physiologic conditions, they should not show expression in the same cells.

Red nuclear stain: Ki-67

Brown cytoplasmic stain: p16



Slide modified from Teresa Darragh, MD

Recommendations for Triage with Partial Genotyping plus Dual Stain

- Patients testing HPV positive on primary HPV testing or cotesting and who are dual stain positive should proceed to colposcopy.
- If HPV test is positive for HPV 16 or 18, colposcopy is recommended regardless of Dual stain result.
- If Dual stain negative except if HPV 16 or 18+ (i.e. positive for 12 other HPV types) One year follow-up with HPV based testing is recommended.
- In cotesting situation, if HPV positive for 12 other HPV types only and cytology is NILM, ASC-US or LSIL:
 - If DS + → Colposcopy (Without DS, these patients would f/u in one year)
 - If DS - → Follow-up in one year
- In cotesting situation, if HPV positive for 12 other HPV types only and cytology is ASC-H, HSIL or AGC:
 - Use of Dual stain not recommended.

Clinical Advantage of Triage with Partial Genotyping plus Dual Stain

Fewer colposcopies

CIN3+ risk of 16/18 positive with negative dual stain falls below colposcopy threshold

These patients brought back for surveillance in one year

More patients returned to routine screening

Patients testing 16/18 negative plus dual stain negative

Fewer colposcopies per CIN3+ diagnosis

Greater efficiency

Conclusions

- Cervical cancer screening with HPV is more sensitive than cytology alone; almost all of the efficacy of cotesting comes from the HPV component.
- Primary HPV screening allows for self-collection, which can increase screening coverage among hard to reach persons.
- The FDA appears poised to recommend primary HPV testing as the preferred screening method.
- Persons with a negative HPV test should get a repeat screen in 3-5 years. Positive tests will be triaged based on cytology and/or dual stain.
- If a self-collected HPV is positive, a speculum exam will be required.
- Data is insufficient to recommend cytology vs dual stain vs extended genotyping as triage for a positive screening HPV test.

Thank you.



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