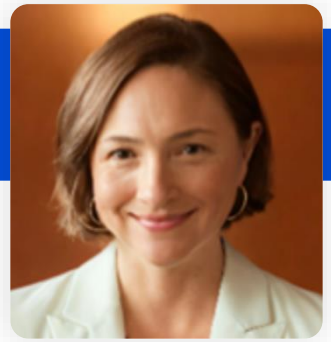
The impact of updated guidelines and self-collection on cervical cancer screening

Danielle Clement
M.Ed, MSN, WHNP-BC, AGNP-C

Danielle Pipher Clement is a Women's Health Clinical Manager for BD and a double board-certified women's health and adult gerontology nurse practitioner.



Danielle brings over a decade of professional experience in reproductive health, infectious diseases, STIs, cervical cancer, and COVID-19 clinical research and patient care from rural community health clinics to academic medical institutions.

She holds a Bachelor's and Master's degree in nursing from Duke University, a certificate in Reproductive Endocrinology and Infertility from the American Society for Reproductive Medicine (ASRM), a colposcopy certification from the American Society of Colposcopy and Cervical Pathology (ASCCP), and is credentialed as an HIV Specialist with the American Academy of HIV Medicine (AAHIVM).

Disclosure: Danielle is an employee of BD.

Learning objectives

After attending this webinar, the participants should understand:

Learning Objective 1:

The changing prevalence of HPV high-risk genotypes due to vaccination

Learning Objective 2:

Recent changes in ASCCP Guidelines

Learning Objective 3:

The importance of extended genotyping for patient risk stratification and management

Learning Objective 4:

The impact of FDA-approved HPV tests with self-collection in a healthcare setting

Why should I care?

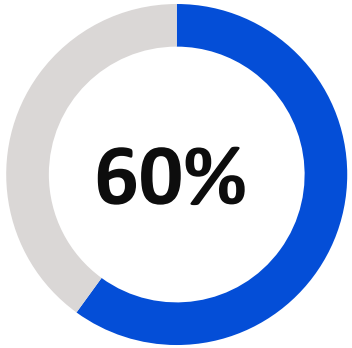
CxCa is a leading cause of cancer mortality, but one of the most preventable cancers with vaccination, screening & treatment

4th most common cancer among women globally

~14K new cases are diagnosed in US each year

>4K deaths occur in US each year

95% of cervical cancer is due to HPV



of cervical cancer cases diagnosed in US occur in under or never screened women

Key barriers to screening:

- Insufficient awareness
- Subjective patient experience
- Socioeconomic factors
- Logistical challenges

World Health Organization: A call to action[1]

In 2018, the WHO announced a global call for action to eliminate cervical cancer by 2030, focusing on three key areas.

To make this a reality the WHO has called for all stakeholders to unite behind these common goals.

Vaccination	90%	of girls fully vaccinated with the HPV vaccine by age 15
Screening	70%	of women are screened with a high-performance test by 35 and 45 years of age
Treatment	90%	of women identified with cervical disease receive treatment

Elimination has been defined as less than 4 cervical cancer cases per 100,000.

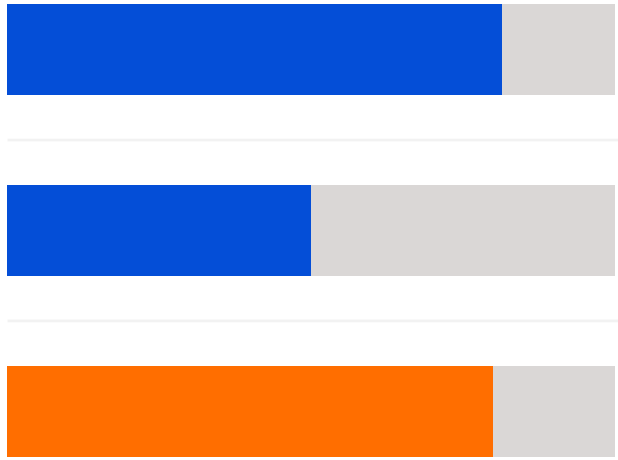
World Health Organization (Web Page) Cervical Cancer Elimination Initiative Updated 2023. Available online at: https://www.who.int/initiatives/cervicalcancer-elimination-initiative #cms Accessed August 21, 2024

The U.S. scorecard: Where do we currently stand?

New cases per 100,000 women per year (2016-2020)

Current	7.7[1]
WHO elimination benchmark	4[2]

Screening rate



Overall rate women aged 21-65	72.4%[3]
Rate in FQHCs	51%[4]
WHO elimination benchmark	70%[2]

The elimination goals are within reach, but we need to make sure vulnerable populations are not left behind. This is a core principle of the WHO call to action.[2]

It’s time to think outside the box. We need to invest in realistic solutions for improving health inequities and advocate for what is right to improve access to a healthy life for all women and people with a cervix!

. National Cancer Institute (Web Page) Cancer Stat Facts: Cervical Cancer. Updated Available online at: https://seer.cancer.gov/statfacts/html/cervix.html. Accessed: August 21, 2024 2. World Health Organization (Web Page) Cervical Cancer Elimination Initiative Updated 2023. Available online at: https://www.who.int/initiatives/cervicalcancer-elimination-initiative#cms. Accessed August 21, 2024 3. National Cancer Institute (Web Page) Cervical Cancer Screening. Updated August, 2023. Available online at: https://progressreport.cancer.gov/detection/cervical_cancer#field_description. Accessed: December 15, 2023 4. Amboree TL, Montealegre JR, Parker SL, et al. National Breast, Cervical, and Colorectal Cancer Screening Use in Federally Qualified Health Centers. JAMA Internal Medicine. Published online April 29, 2024.

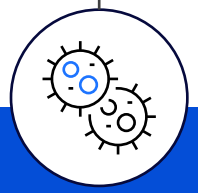
HPV testing over the years and trends in cervical cancer screening rates

The history of HPV testing

1960 -1980's

Pap smear able to detect cervical precancer & cancer, but **the cause is unknown**

1980 -1990's



Making the connection to HPV

Introduction of LBC

HPV testing for ASCUS+

2000 -2010's

FDA approval for the HPV vaccine

2010's

Introduction to automated HPV testing
Co-testing endorsed by ACS & ACOG
HPV vaccine becomes nonavalent
Partial genotyping introduced
Extended genotyping FDA approved

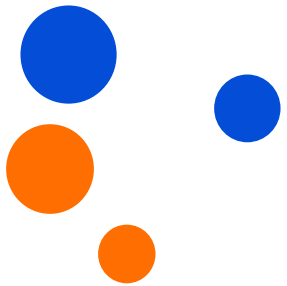
2020's

HPV primary testing endorsed by ACS

https://blogs.cdc.gov/cancer/2020/01/30/teal-and-white-yesterday-and-today-the-evolution-of-cervical-cancer-screening/
Lees BF, Erickson BK, Huh WK. Cervical cancer screening: evidence behind the guidelines. Am J Obstet Gynecol. 2016;214(4):438-443. doi:10.1016/j.ajog.2015.10.147

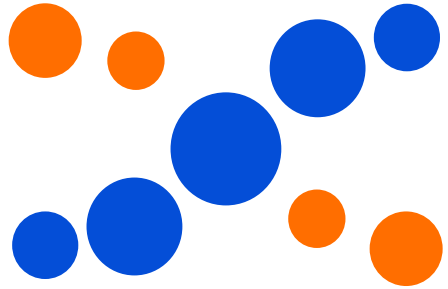
Why isn’t the vaccine enough to eradicate all cervical cancer?

The 4-valent HPV vaccine



- Approved by the FDA in 2006 for use in women 9-26 years old
- For the prevention of cervical cancer, precancerous genital lesions and genital warts due to HPV types 6, 11, 16 and 18[3]
- No longer distributed in the US

The 9-valent HPV vaccine

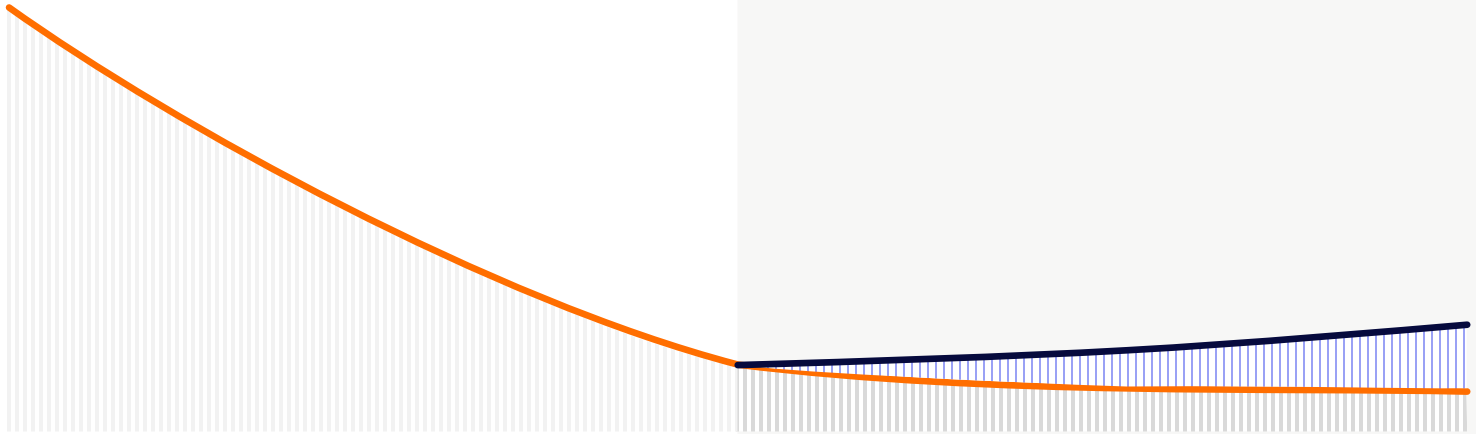


- Approved in 2014 for use in women 9-26 and men 9-15 years old[1]
- Targets 9 HPV genotypes (6, 11, 16, 18, 31, 33, 45, 52 & 58)
- Extended to individuals up to 45 years old in 2018[2]

1. FDA approves Gardasil 9 for prevention of certain cancers caused by five additional types of HPV. FDA. 2014. Accessed 3 Nov 2021. 2. FDA approves expanded use of Gardasil 9 to include individuals 27 through 45 years old. FDA. 2018. Accessed 3 Nov 2021. 3. FDA Licenses New Vaccine for Prevention of Cervical Cancer and Other Diseases in Females Caused by Human Papillomavirus. FDA. 2006. Accessed 3 Nov 2021.

We've come a long way, but it's time to shake the screening status quo

1975 2007 2021



Incidence rates declined by more than 50%, due to increased screening with the Pap test[2]

Incidence rates plateaued[3] with vaccination and USPSTF recommended screening methods and available testing options

Incidence rates increasing in critical populations

4.4%

annual increase in distant stage cancer in low-income women since 2007[4]

1.7%

annual increase from 2012 – 2019 in women aged 30 to 44[5]

Incidence in the US will decline more rapidly by increasing screening rates than by increasing vaccination rates[6]

Siegel RL, et al. Cancer statistics, 2020. CA: a cancer journal for clinicians. 2020;70(1):7-30. 2.American Cancer Society. Cancer Facts & Figures 2020. Atlanta: American Cancer Society; 2020. 3.National Cancer Institute. Cancer of the Cervix Uteri - Cancer Stat Facts. SEER. Published 2018. https://seer.cancer.gov/statfacts/html/cervix.html 4.Amboree TL, et al. Recent trends in cervical cancer incidence, stage at diagnosis, and mortality according to county-level income in the United States, 2000–2019. International Journal of Cancer. Published online January 25, 2024. 5.Cervical Cancer Statistics | Key Facts About Cervical Cancer. www.cancer.org. https://www.cancer.org/cancer/types/cervical-cancer/about/key-statistics.html#:~:text=for%20cervical%20cancer .- 6.Burger EA, et al. Projected time to elimination of cervical cancer in the USA: a comparative modelling study. The Lancet Public Health. 2020;5(4):e213-e222.

HPV assays available in the United States

Competitive overview of FDA-approved HPV assays

	Abbott Alinity m HR HPV assay	BD Onclarity™ HPV Assay	Hologic® Aptima® HPV 16, 18/45 Genotype Assay	Roche cobas® HPV test
HPV extended genotyping	✓ Individual results: 16, 18, 45 Pooled results: 2	✓ *Individual results: 16, 18, 31, 45, 51, 52* *Pooled results: 3*	X Individual results: 16 Pooled results: 2	X Individual results: 16, 18 Pooled results: 1
FDA-Approved for self-collection*	X	✓	X	✓
FDA-Approved for HPV primary screening	✓	✓	X	✓
Cellularity control	✓	✓	X	✓
DNA-based assay	✓	✓	X mRNA-based assay	✓
E6/E7 target region	X Target region: L1	✓	✓	X Target region: L1

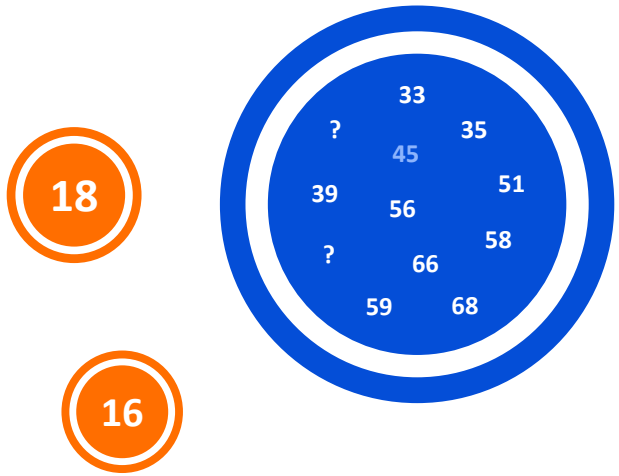
*In a healthcare setting

HPV genotyping: partial & extended

Individual identification of high-risk genotypes is essential to reveal the true risk of CIN3+ disease[1]

Partial genotyping:

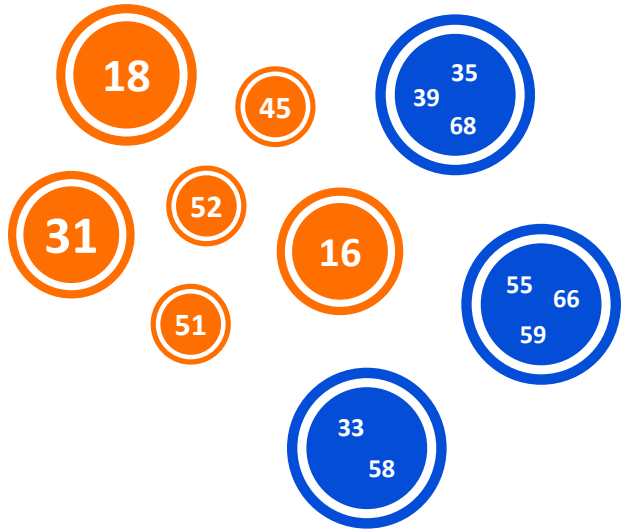
Only 2 high-risk HPV types individually identified



Individual results Pooled results

Extended genotyping with BD Onclarity™ HPV Assay:

6 high-risk HPV types individually identified



Individual results Pooled results

CIN, cervical intraepithelial neoplasia.

1. Bonde JH et al. *J Low Genit Tract Dis*. 2020;24(1):1–13

Why does HPV extended genotyping matter?

HPV extended genotyping can dramatically improve the patient experience

Enhances clinical management:
Connecting patients with the right treatment for them

Delivers more detail than other HPV tests:
Helping determine a patient's precancer and cancer risk

Supports personalized medicine:
Helping manage individual patient risk

Provides next-generation screening:
Supporting patients as high-risk HPV prevalence is changing

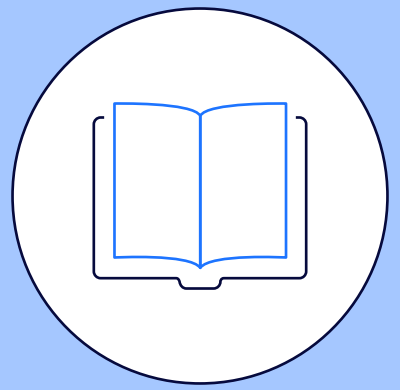
ASCCP - Enduring Consensus Cervical Cancer Screening and Management Guidelines

Enduring Guidelines aim to integrate new technologies and approaches that were not included in the 2019 guidelines process to:

- Improve cancer prevention for high-risk individuals
- Decrease unnecessary procedures in lower-risk individuals

Extended genotyping

Obesity



Dual stain

Self-collection

Vaccination

Recommendation #1

All extended genotyping assays

HPV extended genotyping is acceptable to guide clinical management in the setting of a positive HPV test result.

Recommendation #2

All extended genotyping assays

When multiple types are reported, management according to the type with highest cancer risk is recommended following the hierarchy **16, 18, 45, 33, 31, 52, 58, 35, 39, 51, 59, 56, 68, 66**.

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

Decreasing risk

www.asccp.org/Assets/80742b9b-2b64-4140-a81c-981eaab5ee26/638467215678330000/enduring-guidelines-extended-genotyping-summary-032224-pdf

Recommendation #3

BD Onclarity™ HPV Assay

In a screening setting using **primary HPV testing**, for patients who test positive for HPV types **56/59/66** and no other carcinogenic types:

One-year repeat testing recommended. (AII)

Colposcopy recommended if **HPV-positive for any HPV type** at the one-year follow-up.

Recommendation #4

BD Onclarity™ HPV Assay

In a screening setting using **co-testing**, for patients who test positive for HPV types **56/59/66** and no other carcinogenic types:

One-year repeat testing recommended for **NILM, ASC-US, and LSIL.**

Colposcopy recommended for **ASC-H, AGC, HSIL, or carcinoma**.

https://www.asccp.org/Assets/80742b9b-2b64-4140-a81c-981eaab5ee26/638467215678330000/enduring-guidelines-extended-genotyping-summary-032224-pdf

Recommendation #5 – BD Onclarity™ HPV Assay

Triage with DS or cytology recommended:

In a screening setting using **primary HPV or co-testing**, for patients who test positive for **HPV 45,33/58, 31, 52/35/39/68, 51** or combinations thereof, but **negative for HPV16 and HPV18.**

One-year repeat testing recommended:

If **DS-negative or NILM cytology.**

Colposcopy recommended:

If **DS-positive or cytology ASC-US, LSIL, ASC-H, AGC, HSIL, or carcinoma.** (AII)

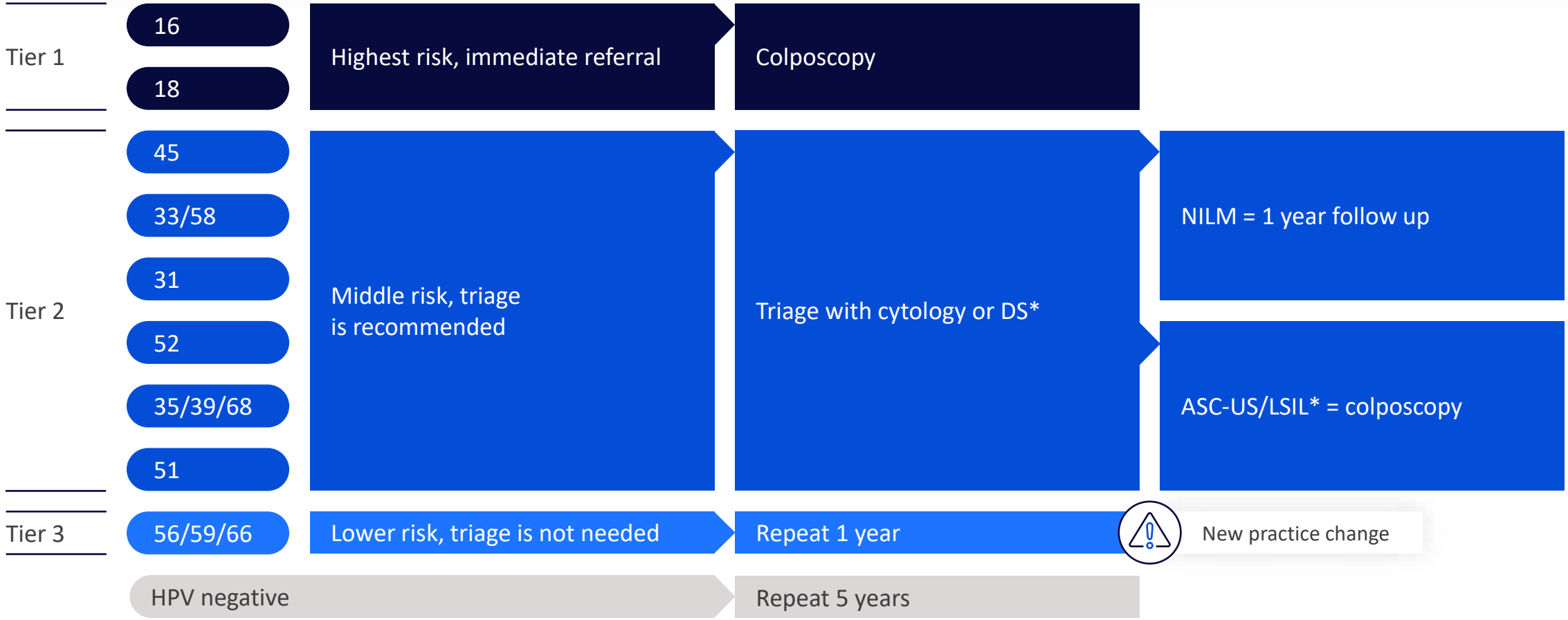
Colposcopy recommended:

For patients with initial results of **Dual Stain negative or NILM cytology** who undergo repeat HPV testing or co-testing at one year, if the repeat test is **HPV-positive for any type.**

https://www.asccp.org/Assets/80742b9b-2b64-4140-a81c-981eaab5ee26/638467215678330000/enduring-guidelines-extended-genotyping-summary-032224-pdf

ASCCP has separated the BD Onclarity™ HPV Assay channels into three different risk-based tiers, which inform new clinical recommendations

Patient management with BD Onclarity™ HPV Assay (Co-Testing / Primary HPV)



*Note: Dual Stain is not FDA approved for use as a triage with BD Onclarity™ HPV Assay

https://www.asccp.org/Assets/80742b9b-2b64-4140-a81c-981eaab5ee26/638467215678330000/enduring-guidelines-extended-genotyping-summary-032224-pdf

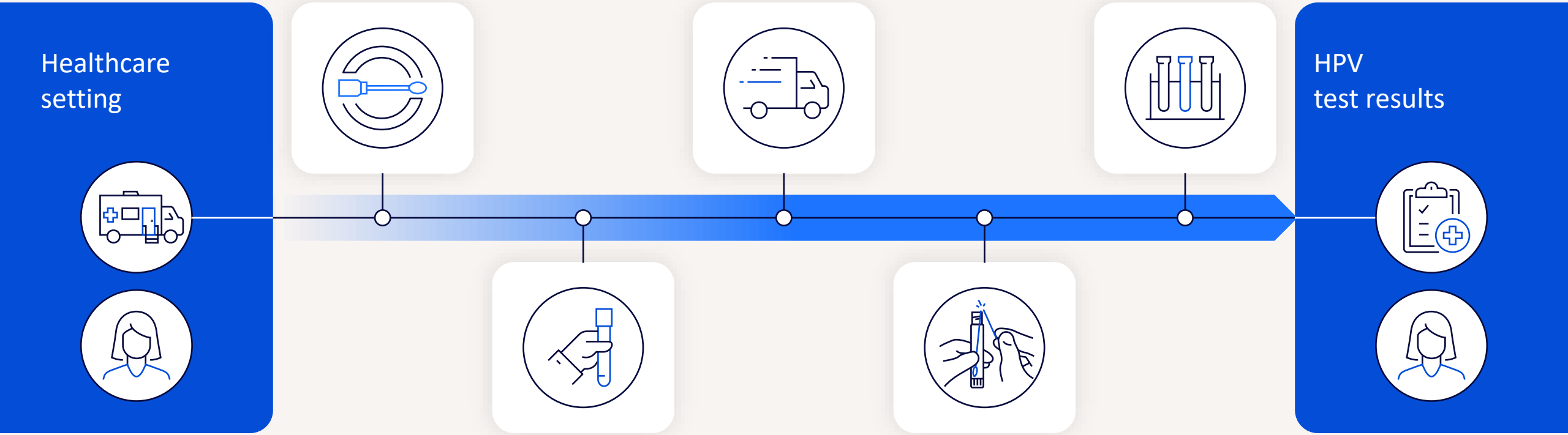
The impact of extended genotyping on clinical practice

- Extended genotyping is acceptable to guide clinical management of a positive HPV test result.
- Extended genotyping results provide additional risk stratification beyond a pooled HR result.
- HPV same type persistence is associated with a much higher risk of cervical precancer compared to a single time point detection.
- Lower risk associated with HPV 56, 59, 66 with recommend different patient management.
- Regional public health surveillance of patient populations and their HPV prevalence & disease outcomes.

HPV extended genotyping with BD Onclarity™ HPV Assay is appropriate for HPV primary screening and is also **approved for HPV self-collection in a healthcare setting!**

https://www.asccp.org/Assets/80742b9b-2b64-4140-a81c-981eaab5ee26/638467215678330000/enduring-guidelines-extended-genotyping-summary-032224-pdf

HPV self-collection in a healthcare setting



What is HPV self-collection?

Clinician ordered test in a healthcare setting

HPV primary screening

Vaginal specimen self-collected by the patient

Additional tool in the toolkit to reach under and never screened

HPV testing barriers and inequities

Barriers and inequities in access today include:

- Cultural concerns
- Insufficient awareness
- Uncomfortable with pelvic exam
- Sexual trauma
- Fear and embarrassment
- Socioeconomic factors

1. National Cancer Institute (Web Page) Cancer Stat Facts: Cervical Cancer. Updated Available online at: https://seer.cancer.gov/statfacts/html/cervix.html. Accessed: September 19, 2023. 2. Becton Dickinson and Company (Web Page) New Harris Poll Reveals Significant Gaps in Women's Knowledge About Cervical Cancer. Updated January 5, 2023. Available online at: https://news.bd.com/2023-01-05-New-Harris-Poll-Reveals-Significant-Gaps-in-Womens-Knowledge-About-Cervical-Cancer. Accessed: October 16, 2023. 3. Smith JS, Des Marais AC, Deal AM, Richman AR, Perez-Heydrich C et al. (2018) Mailed Human Papillomavirus Self-Collection With Papanicolaou Test Referral for Infrequently Screened Women in the United States. Sex Transm Dis 45 (1): 42-48.

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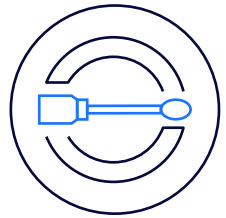


Self-collection offers a less invasive testing option that expands screening access.

1. National Cancer Institute (Web Page) Cancer Stat Facts: Cervical Cancer. Updated Available online at: https://seer.cancer.gov/statfacts/html/cervix.html. Accessed: September 19, 2023. 2. Becton Dickinson and Company (Web Page) New Harris Poll Reveals Significant Gaps in Women's Knowledge About Cervical Cancer. Updated January 5, 2023. Available online at: https://news.bd.com/2023-01-05-New-Harris-Poll-Reveals-Significant-Gaps-in-Womens-Knowledge-About-Cervical-Cancer. Accessed: October 16, 2023. 3. Smith JS, Des Marais AC, Deal AM, Richman AR, Perez-Heydrich C et al. (2018) Mailed Human Papillomavirus Self-Collection With Papanicolaou Test Referral for Infrequently Screened Women in the United States. Sex Transm Dis 45 (1): 42-48.

Self collection can improve screening participation

Self collection is demonstrated to increase screening participation and disease detection in eligible populations

Self collection is accepted by many clinicians, with one study finding over 80% of respondents were supportive of HPV self-collection in under or never screened individuals

79% of women would be comfortable self-collecting their own vaginal sample for cervical cancer screening[2]

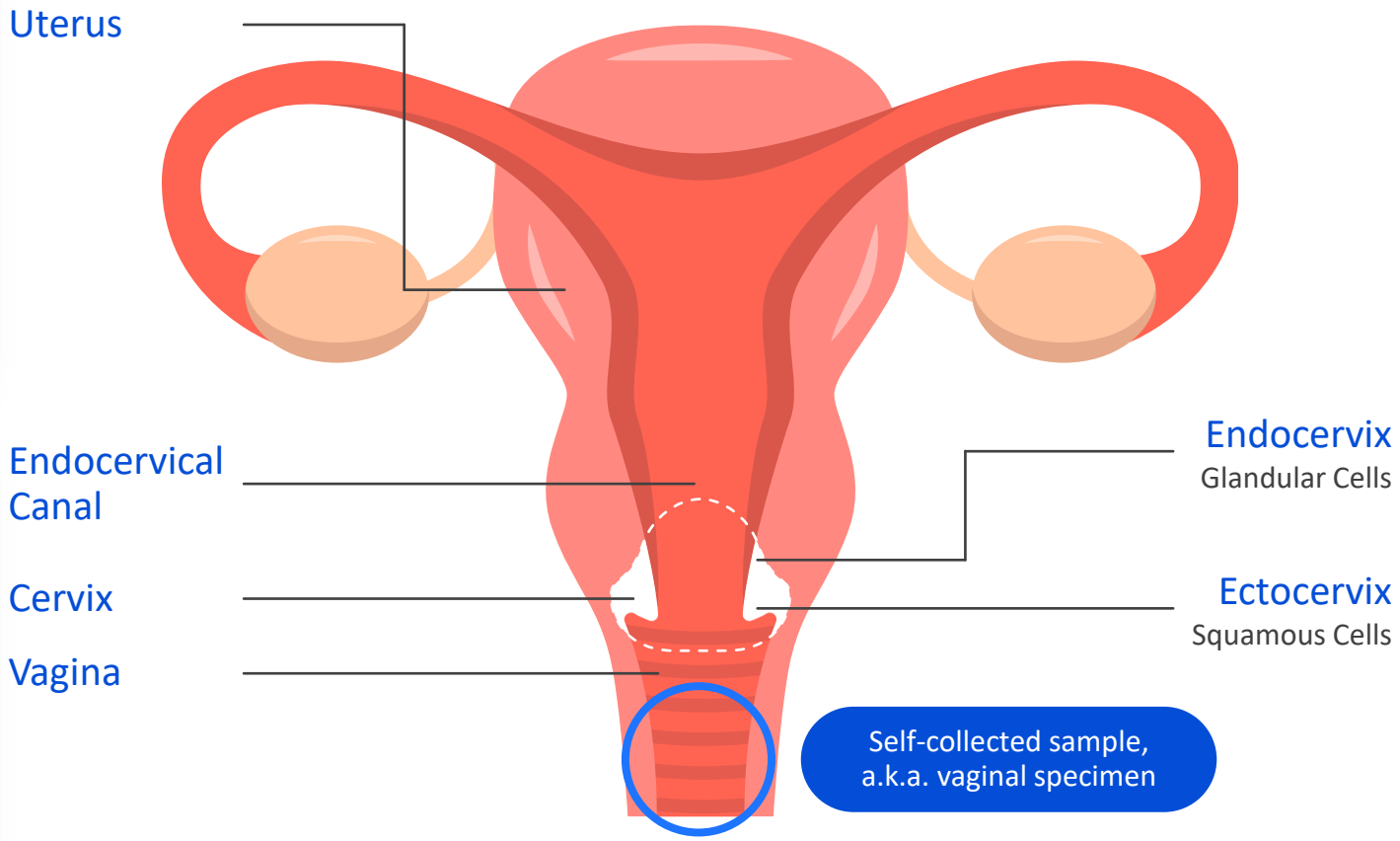
1. National Cancer Institute (Web Page) Cancer Stat Facts: Cervical Cancer. Updated Available online at: https://seer.cancer.gov/statfacts/html/cervix.html. Accessed: September 19, 2023. 2. Becton Dickinson and Company (Web Page) New Harris Poll Reveals Significant Gaps in Women's Knowledge About Cervical Cancer. Updated January 5, 2023. Available online at: https://news.bd.com/2023-01-05-New-Harris-Poll-Reveals-Significant-Gaps-in-Womens-Knowledge-About-Cervical-Cancer. Accessed: October 16, 2023. 3. Smith JS, Des Marais AC, Deal AM, Richman AR, Perez-Heydrich C et al. (2018) Mailed Human Papillomavirus Self-Collection With Papanicolaou Test Referral for Infrequently Screened Women in the United States. Sex Transm Dis 45 (1): 42-48.

Self-collection method

This specimen type tests for HPV only because the specimen is from the vagina, not the cervix.

It can only be used with **HPV primary screening.**

Self-collected vaginal specimens are collected with a swab or brush depending on the assay manufacturer. It does not require a pelvic exam.

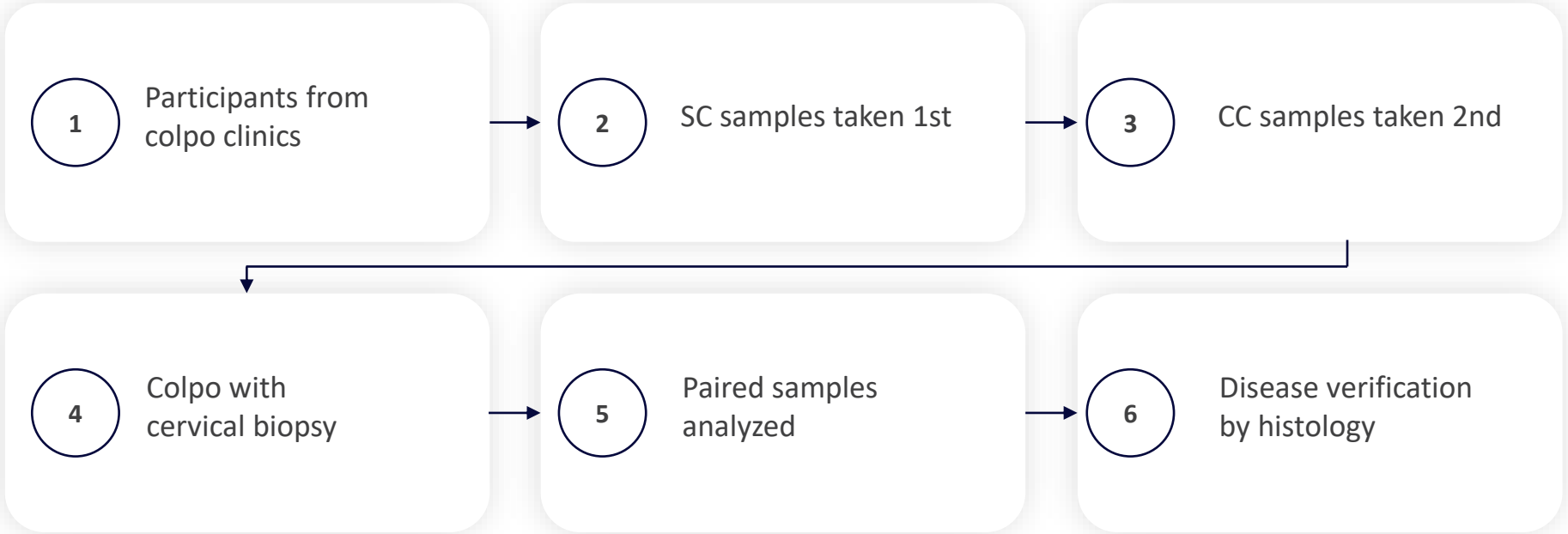


The VALHUDES protocol

VALidation of HUman papillomavirus assays and collection DEvices for HPV testing on Self-samples[1]

Designed as a diagnostic test accuracy study that aims to compare the clinical sensitivity and specificity of particular hrHPV assay(s) on vaginal self-samples collected with hrHPV testing on matched clinician-taken samples.[1]

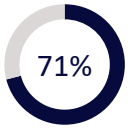
VALHUDES study design:



The VALHUDES framework is an internationally accepted protocol for validation of HPV assay/self sample device combinations for primary screening

1. Latsuzbaia A, Vanden Broeck D, Van Keer S, Weyers S, Donders G, et al. 2022. Validation of BD Onclarity HPV Assay on Vaginal Self-Samples versus Cervical Samples Using the VALHUDES Protocol. Cancer epidemiology, biomarkers & prevention : a publication of the American Association for Cancer Research, cosponsored by the American Society of Preventive Oncology 31:2177-84 2. Cadman L, Reuter C, Jitlal M, Kleeman M, Austin J, et al. 2021. A randomised comparison of different vaginal self-sampling devices and urine for human papillomavirus testing - Predictors 5.1. Cancer epidemiology, biomarkers & prevention : a publication of the American Association for Cancer Research, cosponsored by the American Society of Preventive Oncology Published OnlineFirst on January 29, 2021; DOI: 10.1158/1055-9965.EPI-20-1226

PMA study comparison: a bird's eye view

	BD	Roche	Roche
	FLOQSwabs®[1]	FLOQSwabs®[2,3]	Evalyn® Brush[2,3]
Paired self & clinician specimens compared	✓	✓	✓
VALHUDES protocol used	✓	X	X
Study group from Colposcopy clinic	✓	X	X
CIN2+ detection measured (sensitivity & specificity)	✓	X|Agreements measured	X|Agreements measured
Sample size	286	487	532
HR HPV positivity rate	 71% N=203	 26% N=127	 30% N=160
*Vaginal invalid rate	1.0%	4.3%	4.3%
Cervical invalid rate	0.3%	0.0%	0.4%

*First Vaginal Sample

1. BD Onclarity™ HPV Assay 8089894(08) 2024-06 2. cobas® HPV Qualitative nucleic acid test for use on the cobas® 5800/6800/8800 Systems 2024. 09199578001-incrementEN 3. SUMMARY of SAFETY and EFFECTIVENESS DATA (SSED). https://www.accessdata.fda.gov/cdrh_docs/pdf19/P190028B.pdf

Workflow comparison

	BD	Roche
Vaginal collection	✓	✓
FLOQSwabs® device	✓	✓ & Evalyn® Brush
Patient collection method Rotate collection device in lower vagina for 10-30 sec	✓	✓
Dry transport to lab Collection device recapped and sent to lab	✓	**X** Transported in ThinPrep® LBC Vial
Specimen resuspended at lab	✓	**X** At collection site by HCP
Specimen directly transferred Swab broken off into diluent tube	✓	**X** Swirl & Toss Collection Device
Resuspended in lytic buffer	✓	**X** Resuspended in ThinPrep®
3ml resuspension volume	✓	**X** 20ml of ThinPrep® Aliquot sample into cobas HPV Tube

1. BD Onclarity™ HPV Assay 8089894(08) 2024-06
2. cobas® HPV Qualitative nucleic acid test for use on the cobas® 5800/6800/8800 Systems 2024. 09199578001-incrementEN

Guidelines for HPV self-collection

Recommended by guidelines globally as an alternative approach to clinician-based collection in cervical cancer screening services for eligible women.[1-3]

Supported as a screening method by both the ACS[4] and under evaluation of USPSTF.[5]

ASCCP has provided their draft recommendation for management of abnormal screening results via HPV self-collection.[6]

Approved for use with extended genotyping to facilitate accurate risk-stratification, appropriate clinical management, and tracking of HPV genotype shifts.[7-10]

1. Cancer Council Australia (2022). National Cervical Screening Program: Guidelines for the management of screen-detected abnormalities, screening in specific populations and investigation of abnormal vaginal bleeding. Available online at: https://www.cancer.org.au/clinical-guidelines/cervical-cancer/cervical-cancer-screening. Accessed: October 22, 2023. 2. 75World Health Organization (2021). WHO guideline for screening and treatment of cervical pre-cancer lesions for cervical cancer prevention, second edition. Geneva: World Health Organization. Available online at: https://www.who.int/publications/i/item/9789240030824. 3. 76World Health Organization (2022). WHO recommendations on self-care interventions - Human papillomavirus (HPV) self-sampling as part of cervical cancer screening and treatment, 2022 update. Available online at: Accessed: September 13, 2023. 4. https://pressroom.cancer.org/releases?item=1325#:~:text=ACS%20guidelines%20recommend%20primary%20HPV,comparable%20to%20clinician%2Dcollected%20samples. 5. https://www.uspreventiveservicestaskforce.org/uspstf/document/final-research-plan/cervical-cancer-screening-adults-adolescents 6. https://www.asccp.org/Assets/80742b9b-2b64-4140-a81c-981eaab5ee26/638467215678330000/enduring-guidelines-extended-genotyping-summary-032224-pdf 7. Becton Dickinson and Company (Web Page) BD ONCLARITY™ HPV ASSAY IS THE ONLY FDA-APPROVED HPV TEST THAT INDIVIDUALLY IDENTIFIES HPV 31. Updated 2023. Available online at: https://womenshealthsolutions.bd.com/cervicalcancer/hpv31?utm_source=google&utm_medium=CPC&utm_campaign=7014W000001BHuB&utm_content=bd_fy23_whc_onclarity_mainplan_google_SEM&gad_source=1&gclid=EAIaIQobChMIlYP6_PalggMVWYfCCh290AI9EAAYASAAEgJLCfD_BwE. Accessed: November 2, 2023. 8. Becton Dickinson and Company (Web Page) HPV 31 Identification. Updated 2023. Available online at: https://womens-health-solutions.bd.com/cervical-cancer/extended-genotyping/hpv-31-identification#:~:text=A%20systematic%20review%20of%2016,threshold%20for%20referral%20to%20colposcopy. Accessed: December 14, 2023. 9. Mejilla A, Li E, Sadowski CA (2017) Human papilloma virus (HPV) vaccination: Questions and answers. Can Pharm J (Ott) 150 (5): 306-315. 10. Becton Dickinson and Company (Web Page) The clinical value of extended genotyping. Updated 2023. Available online at: https://hpv-genotype-evidence.bd.com/extended-genotyping/. Accessed: January 10, 2024.

ASCCP 2024 Proposed Recommendations for self-collection

Draft Recommendation #1

Self-collected vaginal HPV testing is acceptable for cervical screening.

Draft Recommendation #2

When self collected (vaginal) HPV test results are negative in the screening setting, repeat testing in 3 years is recommended.

Draft Recommendation #3

When self collected (vaginal) HPV test results are negative in the surveillance setting, repeat testing is recommended per 2019 guidelines for negative primary HPV testing results (i.e., 1 or 3 years depending on risk).

Draft Recommendation #4

When self collected (vaginal) HPV test results are positive for HPV 16/18, referral for colposcopy is recommended.

Draft Recommendation #5

When self collected (vaginal) HPV test results are positive for HPV HR12/other (not 16/18) or untyped, management as for 2019 guidelines is recommended.

Draft Recommendation #6

When extended genotyping results for self collected (vaginal) HPV test results are available, management as for the extended genotyping guidelines is recommended.

https://www.asccp.org/enduring-guidelines-process

Health equity & cervical cancer

The impact of updated guidelines and self-collection on cervical cancer screening

Partnering with the NCI to advance health equity

We are working to make comprehensive HPV testing accessible to all women

BD is an active stakeholder in the National Cancer Institute's (NCI) *Last Mile Initiative.* Participants in this public-private partnership include the NCI, the National Institutes of Health (NIH), the Food and Drug Administration (FDA), and industry stakeholders, such as BD.[1,2] The initiative aims to[1]:

- Facilitate discussions to secure FDA approval of self-collection HPV tests, which can be done at home or in a healthcare setting and sent for analysis
- Raise awareness about self-collection to change and inform clinical practice
- Support a study of HPV self-collection tests called the *Self-sampling for HPV Testing to Improve Cervical Cancer Prevention Trial* or *SHIP Trial*

The SHIP Trial will also evaluate strategies to implement self-collection approaches that reach women in underserved and high-burden populations who are not screened or are inadequately screened for CxCa.[1]

1. https://prevention.cancer.gov/major-programs/nci-cervical-cancer-last-mile-initiative 2. https://www.fda.gov/news-events/press-announcements/fda-roundup-may-17-2024

Working towards health equity

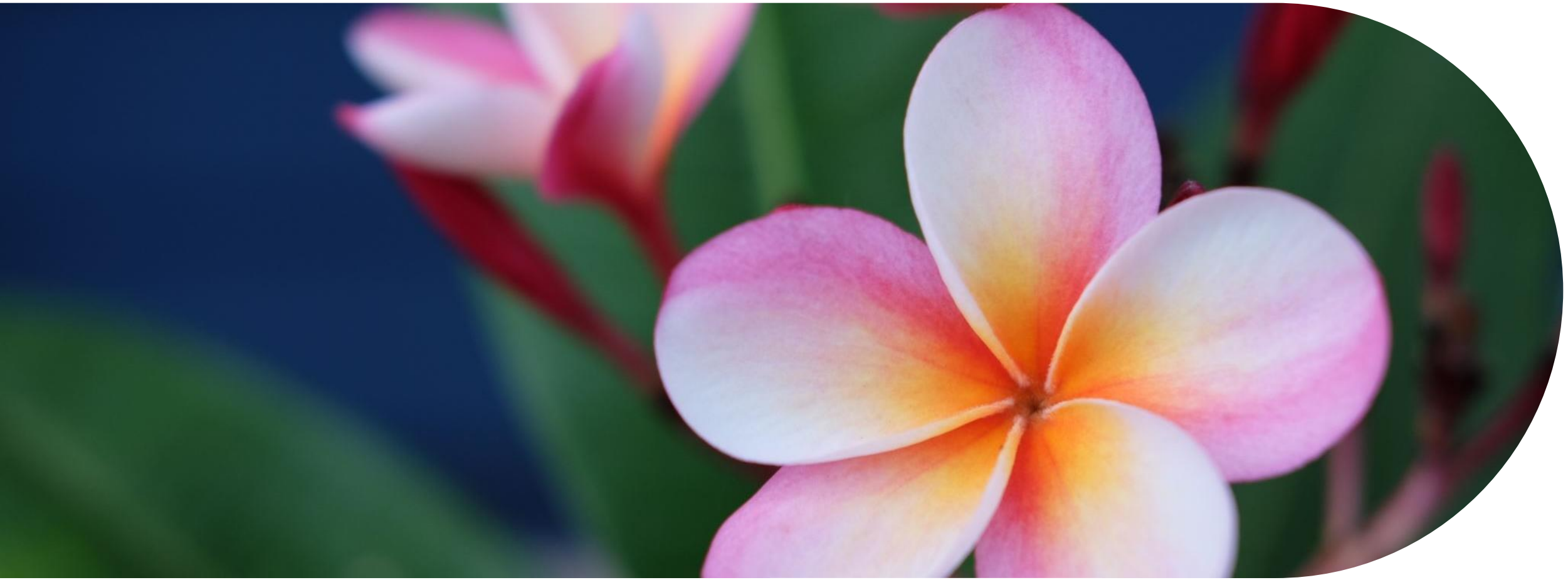
Few diseases reflect health inequities as much as cervical cancer

>95% of those affected are young, undereducated women who live in the world's poorest communities.

HPV is a human virus and a global public health concern.

Access to simple, primary preventative services is about gender equity.

https://cdn.who.int/media/docs/default-source/cervical-cancer/230519-ccei-brochure.pdf?sfvrsn=8f15a050_5&download=true



“This is a moment of significance because it represents a commitment to centering the needs of women and girls and valuing their bodies and their lives, and it is a necessary step toward a brighter future for all people.”

Prof Senait Fisseha, Co-Chair of the WHO Director-General’s Expert Group on Cervical Cancer Elimination