

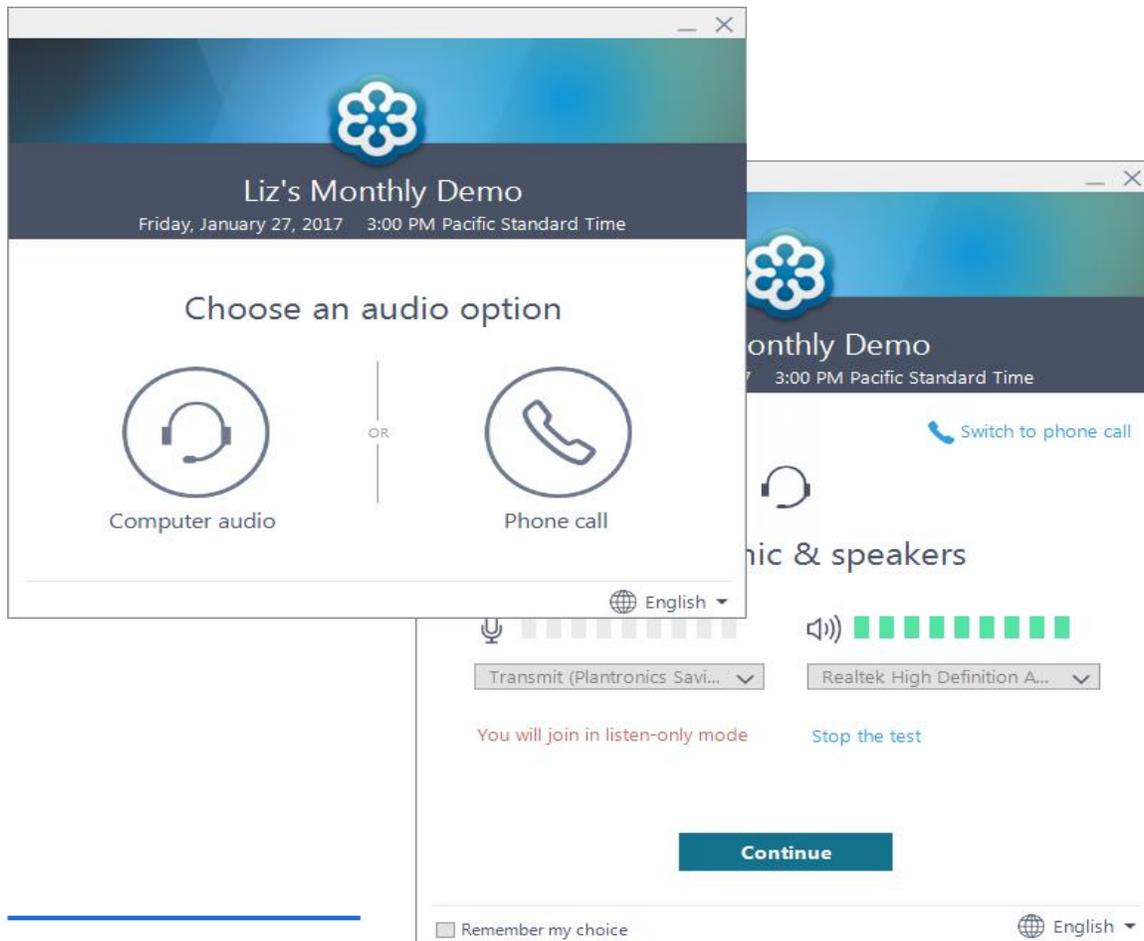


Implementing the 2019 ASCCP Risk-Based Management Guidelines for Abnormal Cervical Cancer Screening Tests in Your Practice

Presenters: Patty Cason, MS, FNP-BC and Michael Policar, MD, MPH

July 23, 2020

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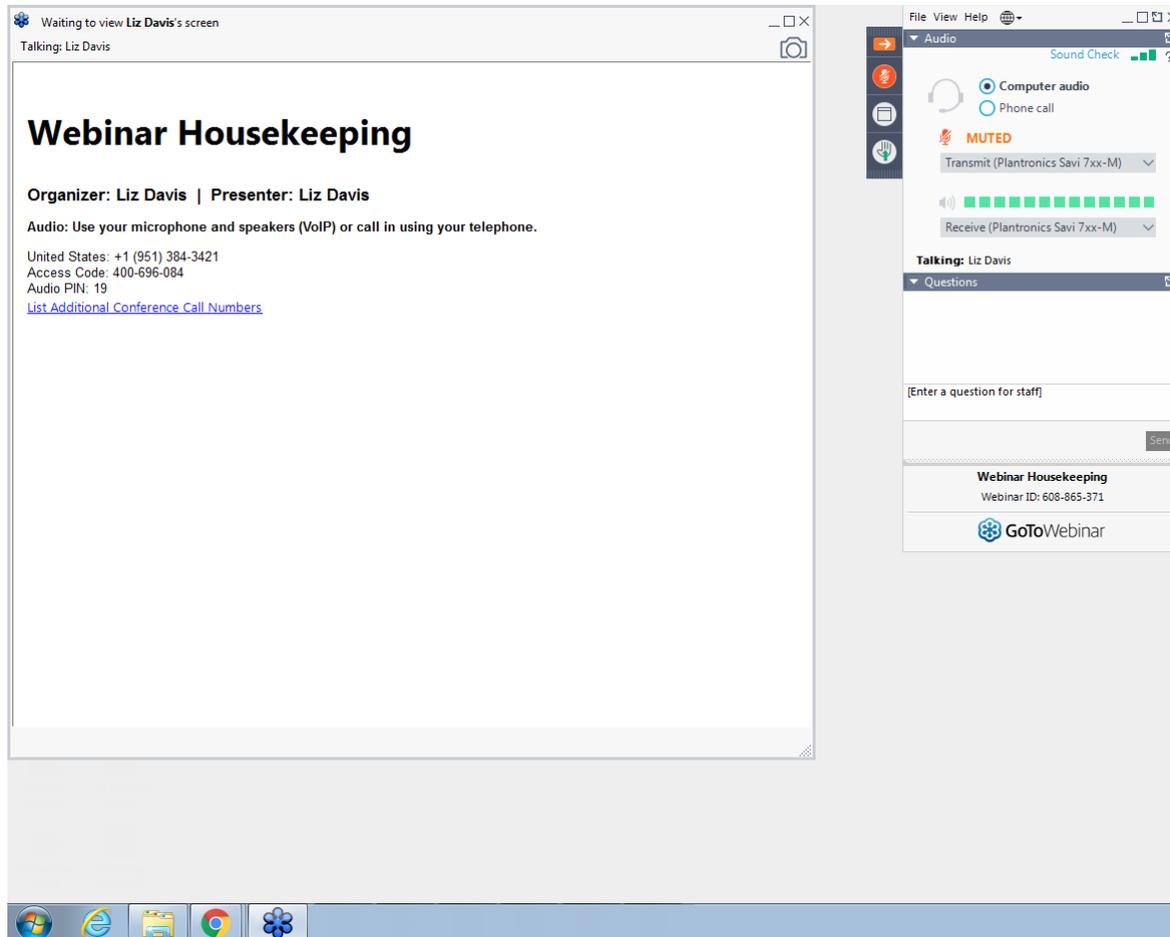


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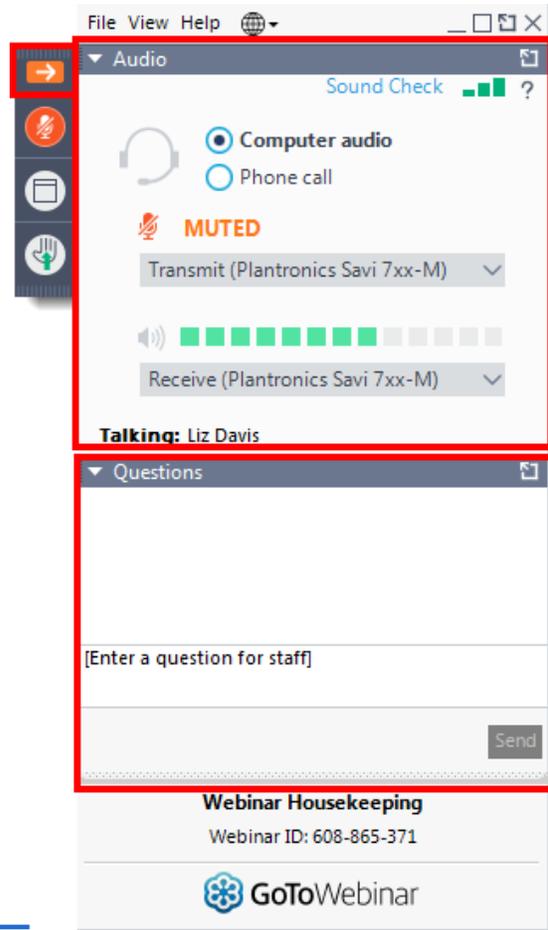
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Presenters



Michael S. Policar, MD, MPH
Professor Emeritus
California Prevention Training Center
OB/GYN & Reproductive Sciences
UC San Francisco School of Medicine



Patty Cason, MS, FNP-BC
Member of ASCCP Board of Directors
Member of the Communications Workgroup that created
the 2019 Risk-Based Management Consensus Guidelines
Envision Sexual and Reproductive Health

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Patty Cason, MS, FNP-BC

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Michael Policar, MD, MPH

CA Prevention Training Center

Disclosures

Cason

Member board of directors ASCCP

Policar

None

Objectives

- Describe the risk-based paradigm for managing abnormal cervical cancer screening test results.
- Explain how risk-thresholds guide the clinical actions of immediate treatment, colposcopy, and short-interval follow up
- Demonstrate use of the ASCCP app to apply the new guidelines to patient care

Outline

- Welcome and Introductions
- Background: why is this important to Family PACT providers?
- A Roadmap through the 2019 Guidelines
- Obtaining and Using the ASCCP APP
- Guideline content (emphasis on guiding principles and how the 2019 guidelines differ from the 2012 guidelines)
- Implementation of the 2019 Guidelines in your practice
- Questions and answers

Why Is This Important to Providers?

- When Family PACT started (1996), cervical cytology screening...
 - Was done annually
 - For sexually active women of all ages
 - Were “smears” on a glass slide, read by a cytotechnologist
 - All grades of CIN were treated by cryotherapy
- Since then, Family PACT has added...
 - Liquid based cytology, HPV-alone screening, co-testing
 - Computer-assisted evaluation of cytology
- Family PACT followed the 2006 & 2012 ASCCP guidelines

Clinical Practice Alert

February 2020

CERVICAL CANCER SCREENING

Family PACT covers cervical cancer screening when provided in conjunction with the provision of family planning services, but not as a stand-alone service. The Program has adopted the current guidelines of the U.S. Preventive Services Task Force¹ (USPSTF) with additional recommendations from the American College of Obstetricians and Gynecologists (ACOG)² and the multidisciplinary partnership of the American Cancer Society, the American Society for Colposcopy and Cervical Pathology (ASCCP), and the American Society for Clinical Pathology.³

KEY RECOMMENDATIONS



Cervical cytology screening should begin at 21 years of age and be performed every three years for females between 21-29 years of age.



For females 30 and older, options for cervical cancer screening include:

- Cervical cytology alone every 3 years.
- HPV alone testing every 5 years.
- Co-testing cervical cytology and hr-HPV testing every 5 years.

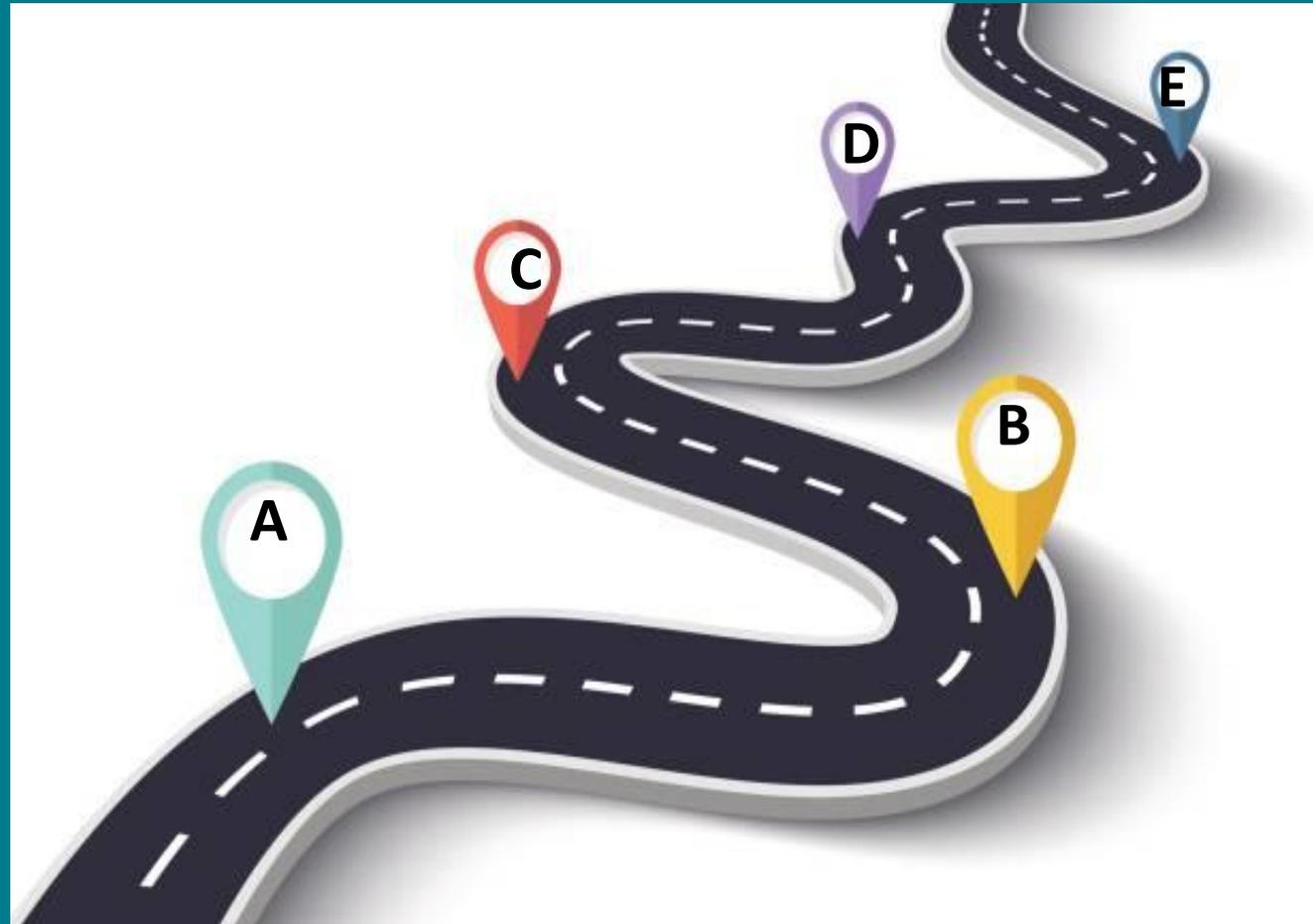
- Age ranges
- Screening intervals
- HIV positive and immunocompromised females
- Family PACT cervical cancer screening benefits

https://familypact.org/wp-content/uploads/2020/03/Cervical-cancer-CPA_stylized_20200219_EQ_rem.pdf

ROADMAP: 2019 ASCCP Risk-Based Management Consensus Guidelines

SECTION

- A. Executive summary
- B. Introduction
- C. Guiding principles
- D. Methods



Section E. Paradigm Shift: Clinical Action Thresholds (CATs)



Recommendations for

E.1 Surveillance

E.2 Colposcopy

E.3 Treatment

E.4 Clinical situations leading to recommendation

Section F: Updates Related to Pathology Reporting and Lab Tests



- F.1 2-tier LAST terminology (histologic LSIL/HSIL)
- F.2 Primary HPV screening (replaces 2015 interim guidance)
- F.3 Statement on HPV tests

Section G: Management of Rare Cytology Results



G.1 (AGC) or adenocarcinoma in situ (AIS)

G.2 Unsatisfactory cytology

G.3 Absent transformation zone on cytology

G.4 Benign endometrial cells in premenopausal patients or benign glandular cells post-hysterectomy

Section H: Colposcopy Practice Standards and Exceptions to Colposcopy Clinical Action Threshold



H.1 ASCCP Colposcopy Standards

H.2 Exceptions to colposcopy threshold

Section I: Management Based on Histology (Biopsy) Results



- I.1 HSIL, not further specified
- I.2 HSIL (CIN 2 or CIN 3)
- I.3 CIN 2, and concerned about the potential effect of treatment on future pregnancy outcomes
- I.4 LSIL (CIN 1) or less, preceded by ASC-H or HSIL cytology
- I.5 LSIL (CIN 1) diagnosed repeatedly for at least 2 years
- I.6 AIS (Adenocarcinoma in-situ)

Section J. Surveillance After Abnormalities



- J.1 Tests and testing intervals when managing abnormal results (HPV-alone preferred)
- J.2 Short-term follow-up after treatment for HSIL
- J.3 Long-term follow-up after treatment for high-grade histology or cytology
- J.4 Long-term follow-up after LSIL without evidence of histologic or cytologic high-grade abnormalities

Section K: Management of Special Populations



- K.1 Younger than 25 years
- K.2 During pregnancy
- K.3 Immunosuppression
- K.4 Older than 65 years with a history of prior abnormalities

ASCCP Risk-Based Management Consensus Guidelines



The ASCCP Management Guidelines App is Now Available

Streamline navigation of the ASCCP Risk Based Management Consensus Guidelines with the **NEW** ASCCP Management Guidelines App

- Evidence-based management guidelines
- Simple navigation
- Uncomplicated guidance

Cost:
\$9.99



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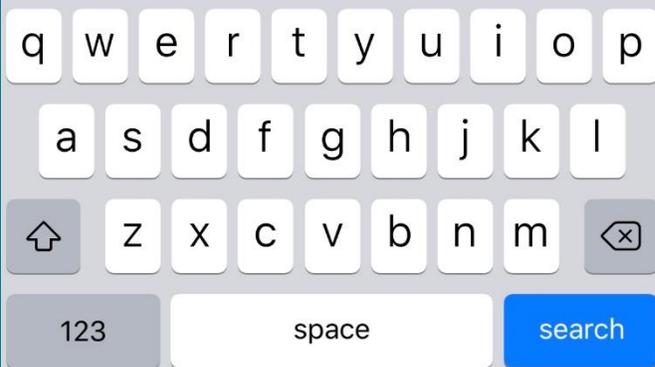


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ASCCP Managem...

Medical

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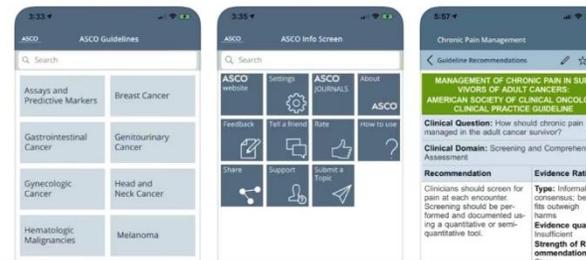


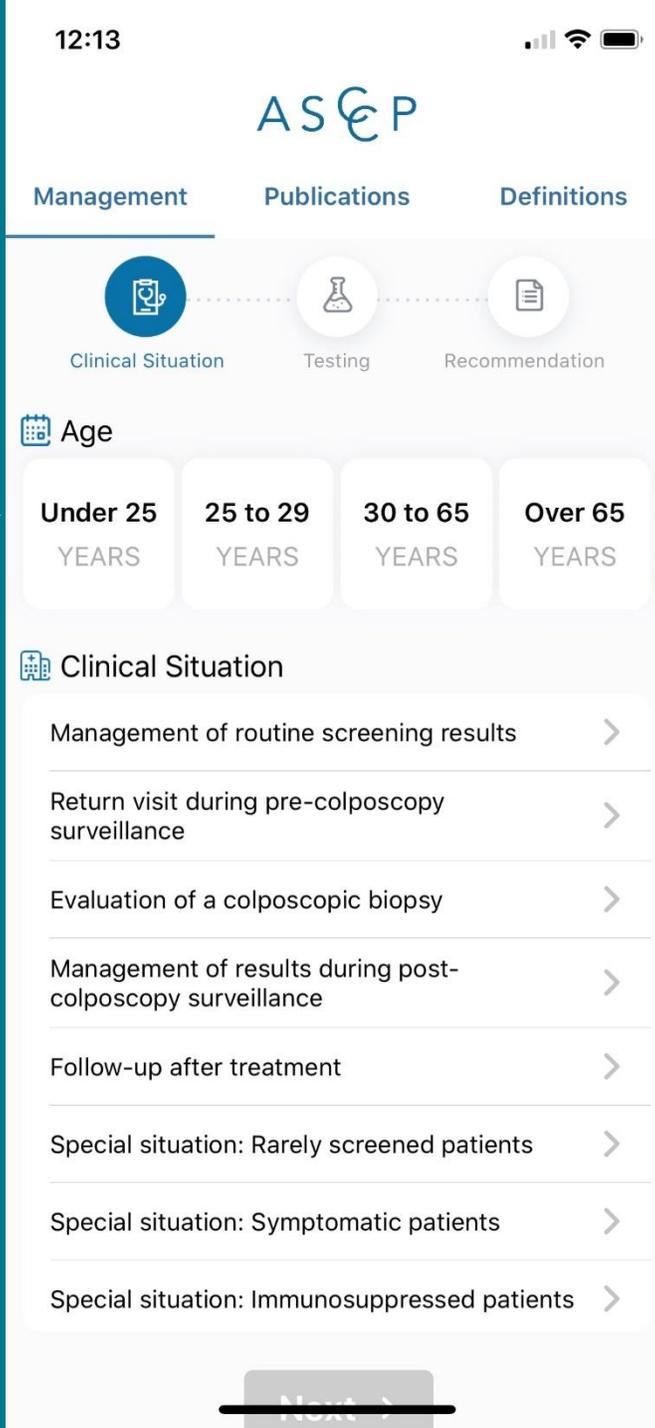
ASCO Guidelines

Medical

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Enter demographics

If no clinical situation is selected, it reverts to most recent



Management

Publications

Definitions



Clinical Situation



Testing



Recommendation

Calendar icon Age

Under 25
YEARS

25 to 29
YEARS

30 to 65
YEARS

Over 65
YEARS

Building icon Clinical Situation

Management of routine screening results >

Return visit during pre-colposcopy surveillance >

Evaluation of a colposcopic biopsy >

Management of results during post-colposcopy surveillance >

Follow-up after treatment >

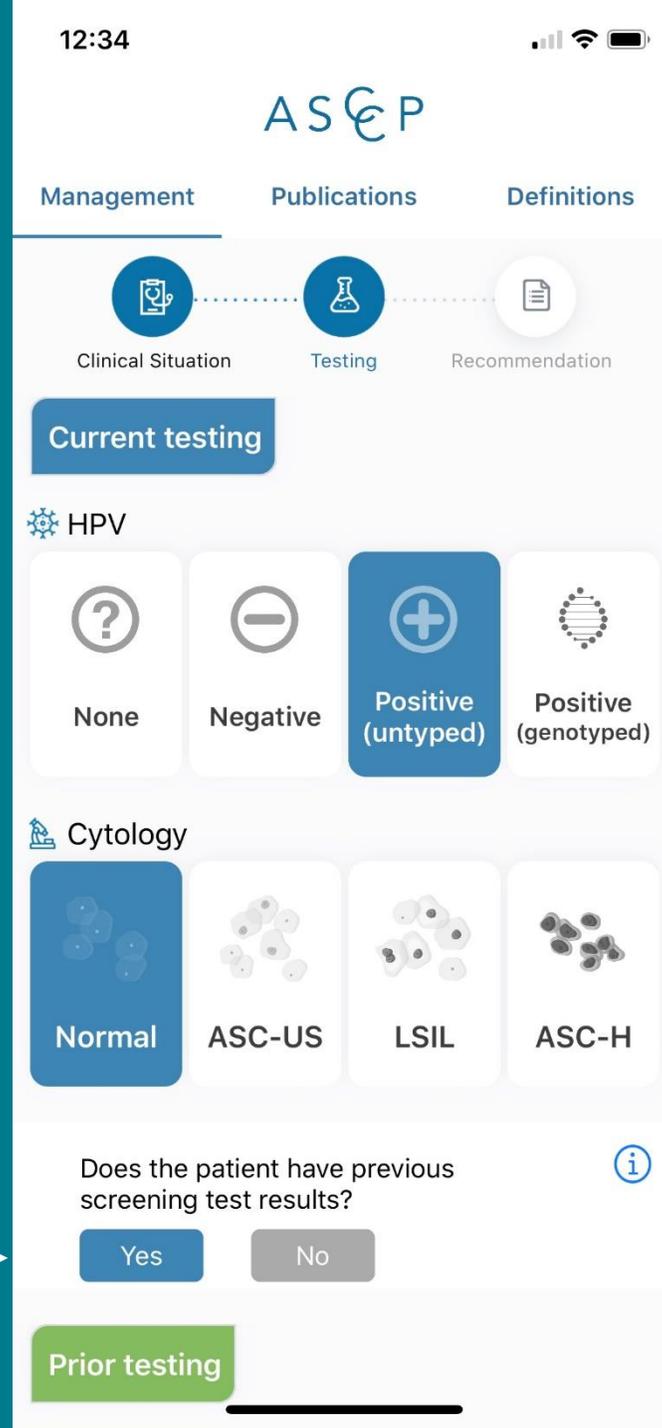
Special situation: Rarely screened patients >

Special situation: Symptomatic patients >

Special situation: Immunosuppressed patients >

Next →





Defaults to No.
If there are no prior results, click next. If there are prior results, click Yes and then add results

Management

Publications

Definitions

Does the patient have previous screening test results?



Yes

No

Prior testing



HPV

?
None

-
Negative

+
Positive



Cytology

None

Normal

ASC-US

LSIL

Does the patient have previous screening test results?



Yes

No

← Back

Next →



12:34



ASCP

Management

Publications

Definitions



Clinical Situation



Testing



Recommendation

Current testing



HPV



None



Negative



Positive
(untyped)



Positive
(genotyped)



Cytology



Normal



ASC-US



LSIL



ASC-H

Does the patient have previous screening test results?



Yes

No

Prior testing

If, at any time, you want to start over from the beginning click on management

Management

Publications

Definitions



Clinical Situation



Testing



Recommendation

Confirmation

Management of routine screening results

Age: 25 to 29

Current results

Cotest with positive HPV and normal cytology

Prior results

Cotest with negative HPV and normal cytology

← Back

Next →

Just a confirmation page



Clinical Situation



Testing



Recommendation

Recommendation

1-year follow-up¹

HPV-based screening at follow-up visit²

Risk



5 year risk of CIN3+ is **2.25%¹**

← Back

Start Over

References

It gives you a % risk and a recommendation

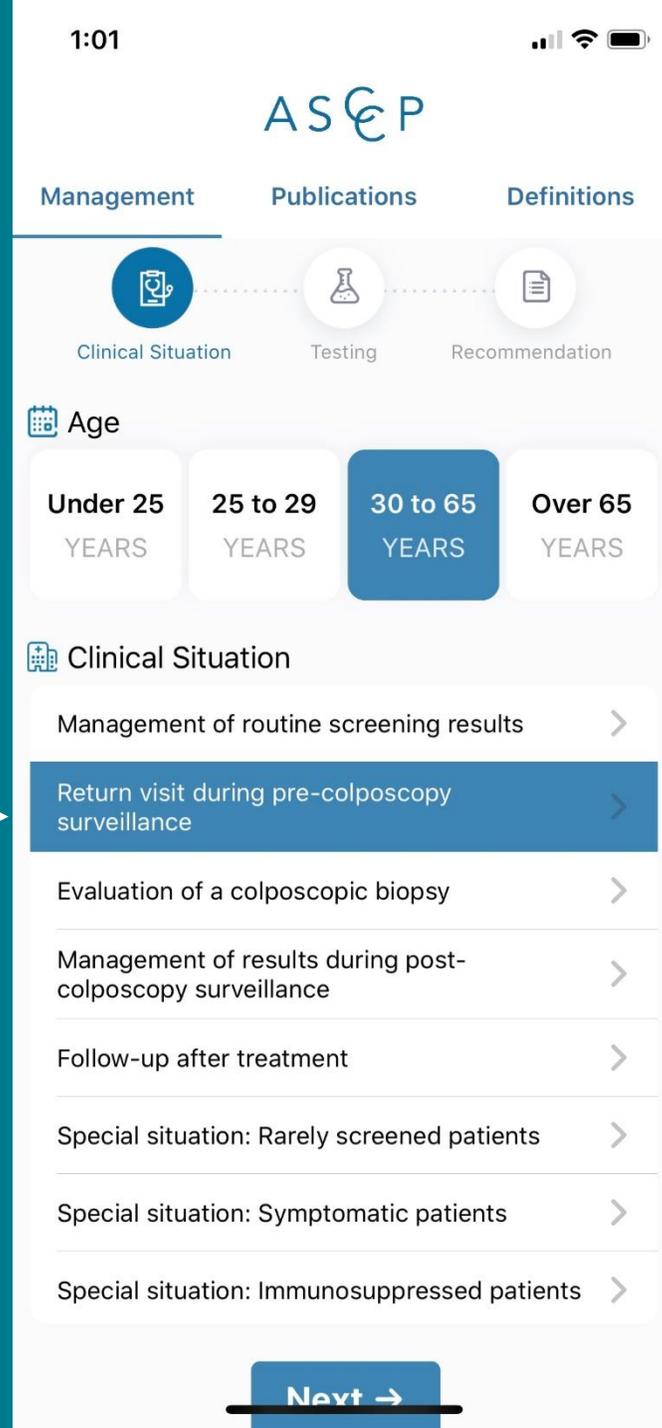
Risk

[← Back](#)[Start Over](#)

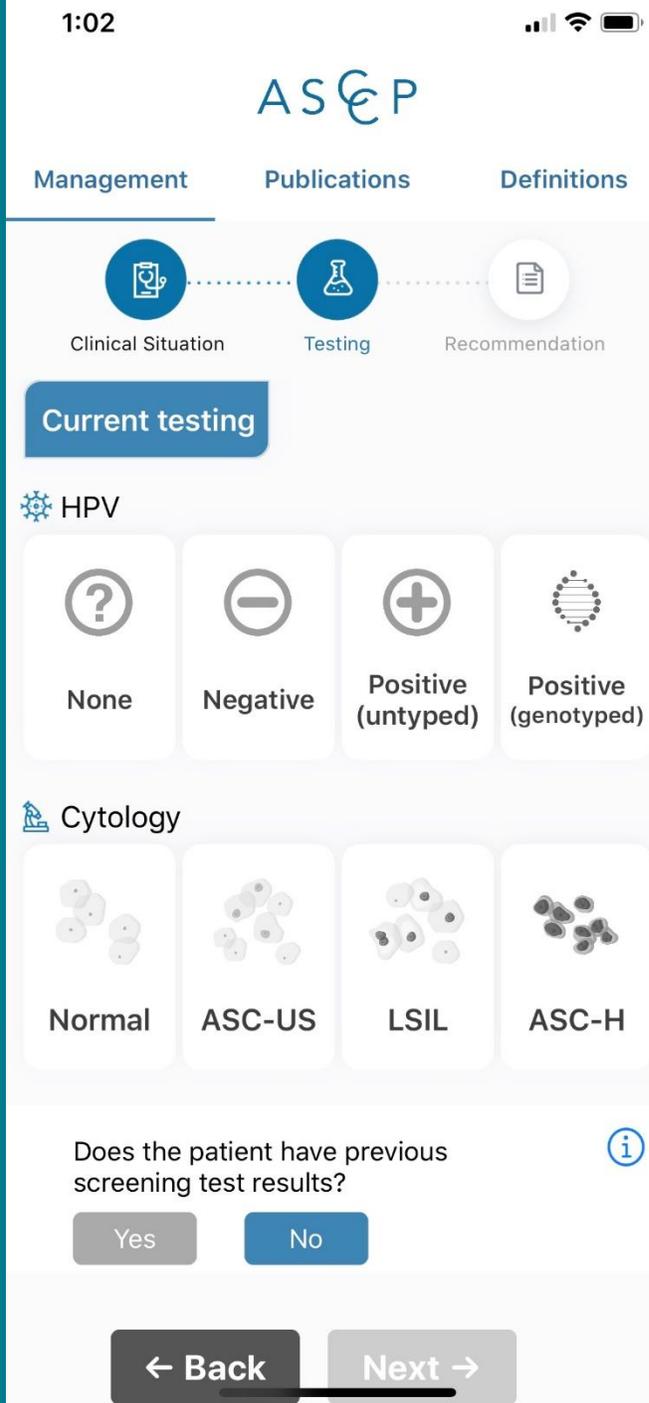
References

1. Risk estimates supporting the 2019 ASCCP Risk-Based Management Consensus Guidelines. <https://cervixca.nlm.nih.gov/RiskTables/>
2. Perkins RB, Guido RS, Castle PE, et al. 2019 ASCCP risk-based management consensus guidelines for abnormal cervical cancer screening tests and cancer precursors. *J Low Genit Tract Dis* 2020;24:102–31.

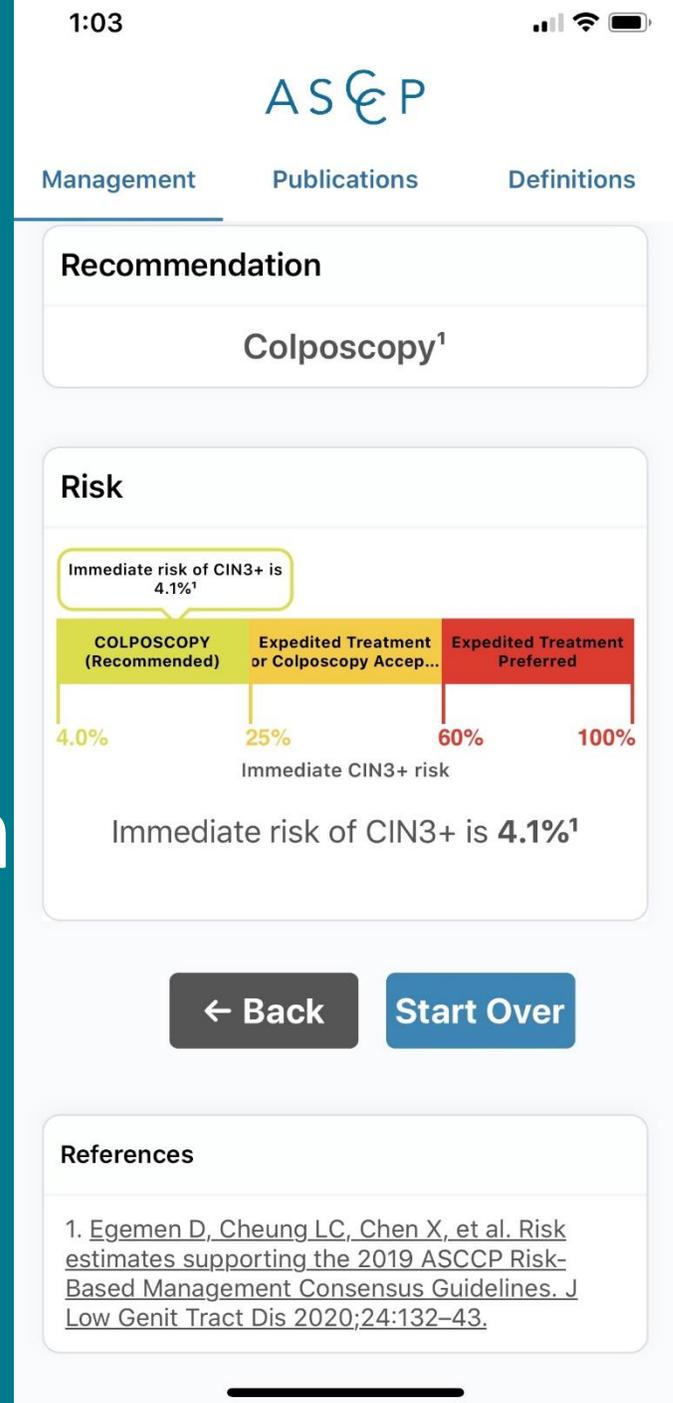
Hyperlink takes you to the article that contains the data that the guideline is based on

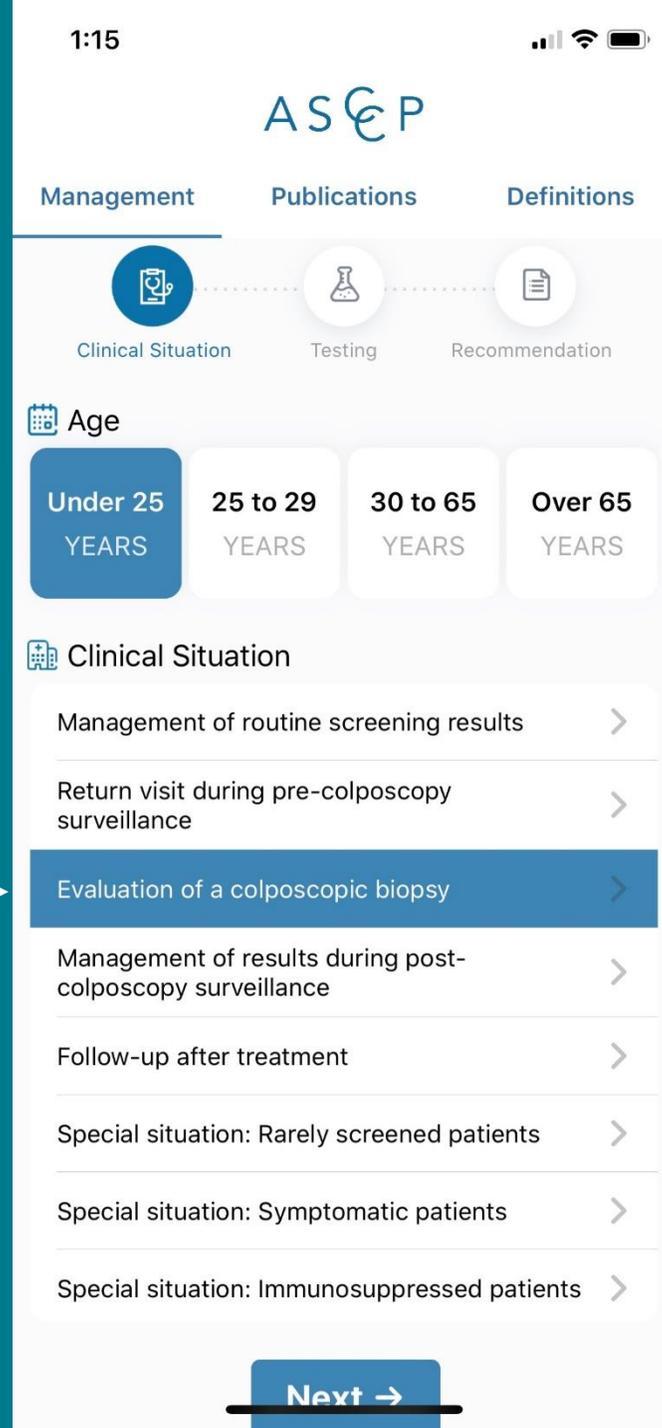


Use this when the person is being followed-up after an abnormal cytology &/or HPV result that did not (yet...) warrant colposcopy



It gives you a % risk and a recommendation





Use this once you know the pathology results from the colposcopy to get recommendation



Clinical Situation



Testing



Recommendation

Colposcopy

NO CIN

Histologic
LSIL (CIN 1)

Histologic
HSIL (CIN 2)

Histologic
HSIL (CIN 3)

Histologic
HSIL
(unspecified)

AIS

← Back

Next →

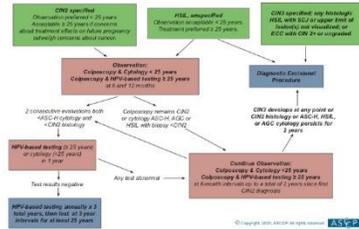
Recommendation

Refer to Algorithm¹

Consider colposcopy and HPV-based testing at 6 and 12 months, UNLESS lesion is unspecified HSIL, specified CIN3, is not fully visualized or is in the endocervical canal.¹

Figure

Figure 8: Management of CIN2 at age <25 years or for those concerned about the effects of treatment on future pregnancy



Special populations

Pregnancy

← Back

Start Over



Clinical Situation



Testing



Recommendation

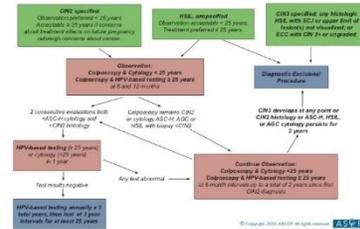
Recommendation

Treatment¹

Diagnostic excisional procedure is preferred and ablation is acceptable when the SCJ and the upper limit of lesion(s) are visible during colposcopy.¹

Figure

Figure 8: Management of CIN2 at age <25 years or for those concerned about the effects of treatment on future pregnancy



Special populations

Pregnancy



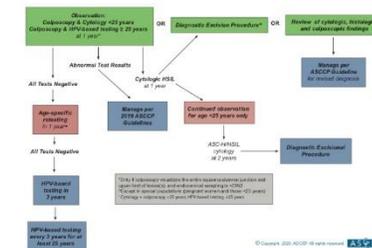
Recommendation

Refer to Algorithm¹

Observation, Treatment or Review¹

Figure

Figure 9: Management of Histologic LSIL (CIN1) or Less Preceded by HSIL Cytology



Special populations

Pregnancy

← Back

Start Over

References

1. Perkins RB, Guide PG, Quillen DF, et al. 2019

How were these updated guidelines for management of abnormal screening tests and cancer precursors developed and finalized?

19 Participating Organizations

Patient Advocacy Organizations

- American Sexual Health Association
- Cervivor
- Latino Cancer Institute
- Team Maureen

Federal Agencies

- Centers for Disease Control & Prevention
- National Cancer Institute

Medical Professional Societies

- ASSCP
- American Academy Of Family Physicians
- American Cancer Society
- American College Of Nurse-Midwives
- American College Of Obstetricians and Gynecologists
- American Society For Clinical Pathology
- American Society Of Cytopathology
- College Of American Pathologists
- Nurses For Sexual And Reproductive Health
- Nurse Practitioners In Women's Health
- Papanicolaou Society Of Cytopathology
- Society Of Gynecologic Oncology
- Women Veterans Health Strategic Healthcare Group

Screening distinguishes normal from abnormal



Colposcopy with biopsy detects CIN3 (“pre-cancer”)



Treating CIN3 prevents cancer

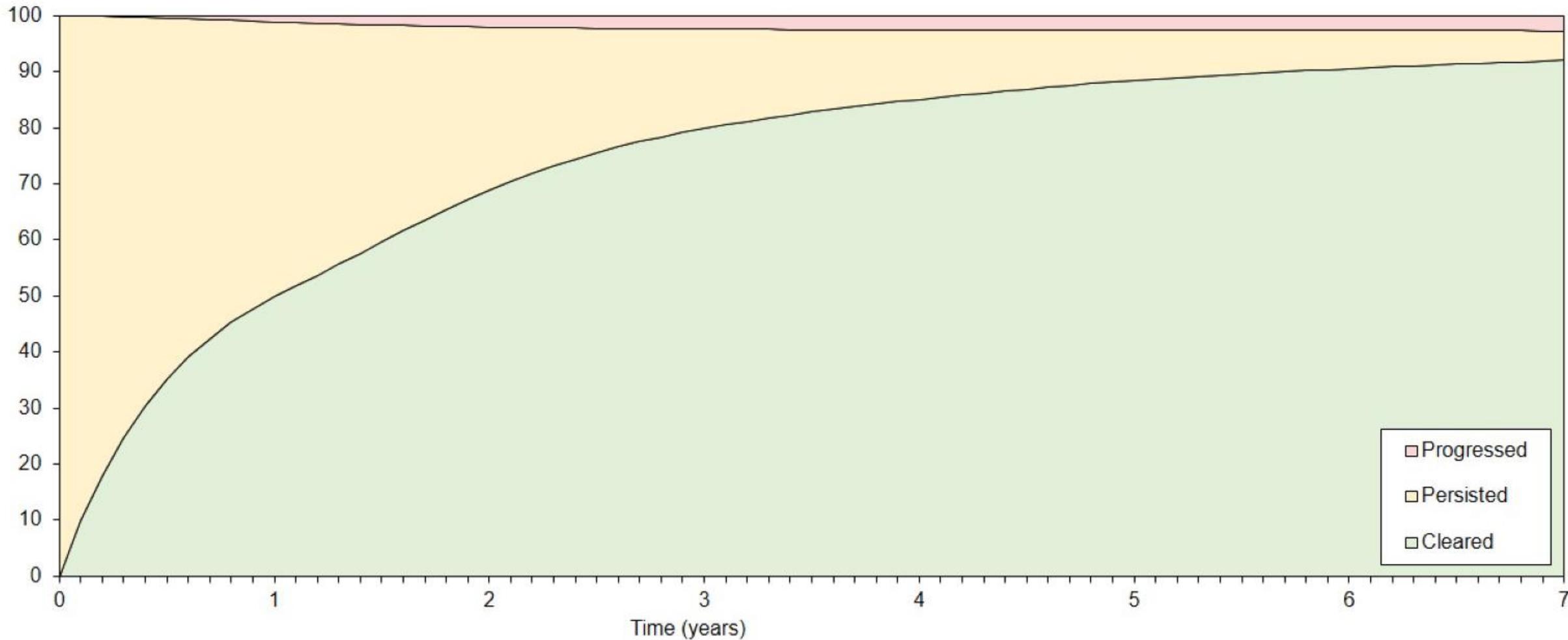


Goal of screening is to detect CIN3 and *prevent* cervical cancer

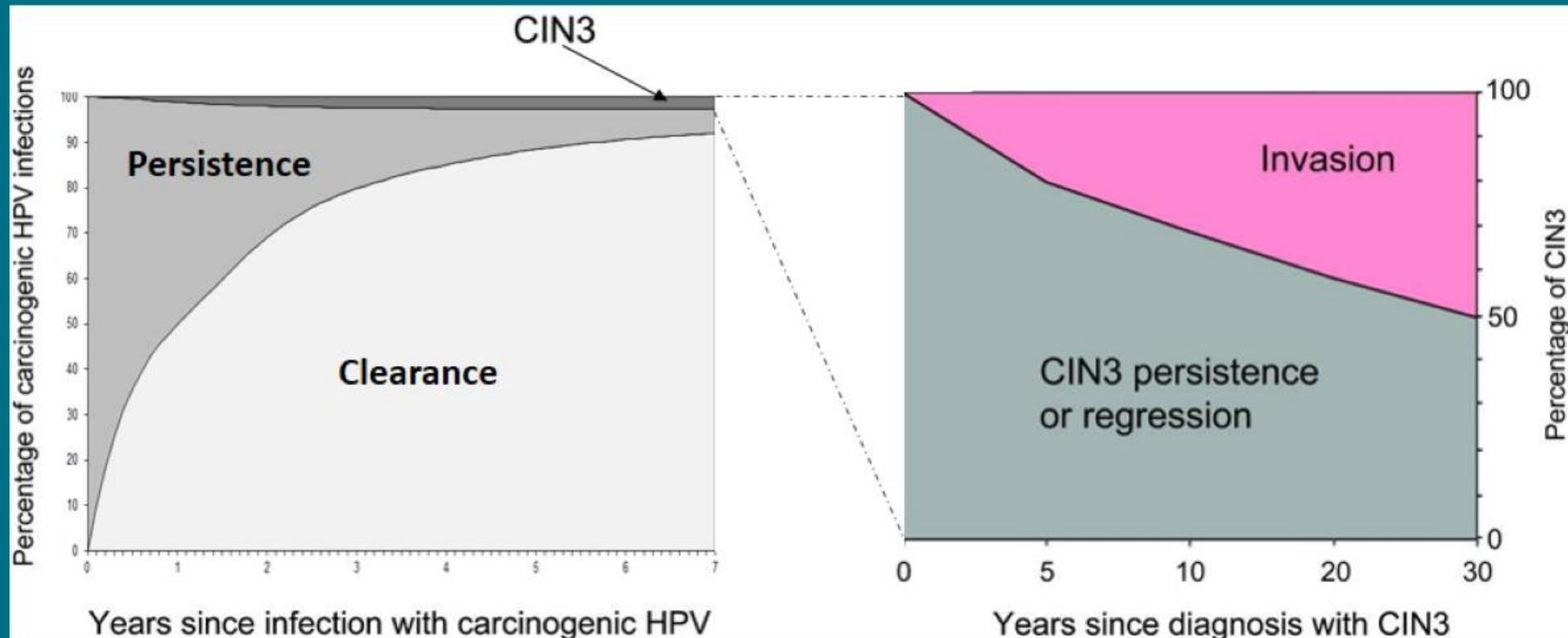
Fundamental Concept #1

- The longer an HPV infection has been present, the higher the risk of pre-cancer and cancer
 - *Time matters*
 - *Type matters (HPV 16 most dangerous)*
 - *Other patient factors don't matter if you know about HPV*
 - ***CLINICAL CORRELATE: Colposcopy is always needed following two consecutive positive HPV tests***

Most HPV infections become undetectable in 1-3 years those that persist cause CIN3+ over time



Precancer and cancer increase markedly when infections persist for 5 years or more



McCredie et al., . Lancet Oncol. 2008 May;9(5):425-34.

New guidelines prefer HPV testing for follow up

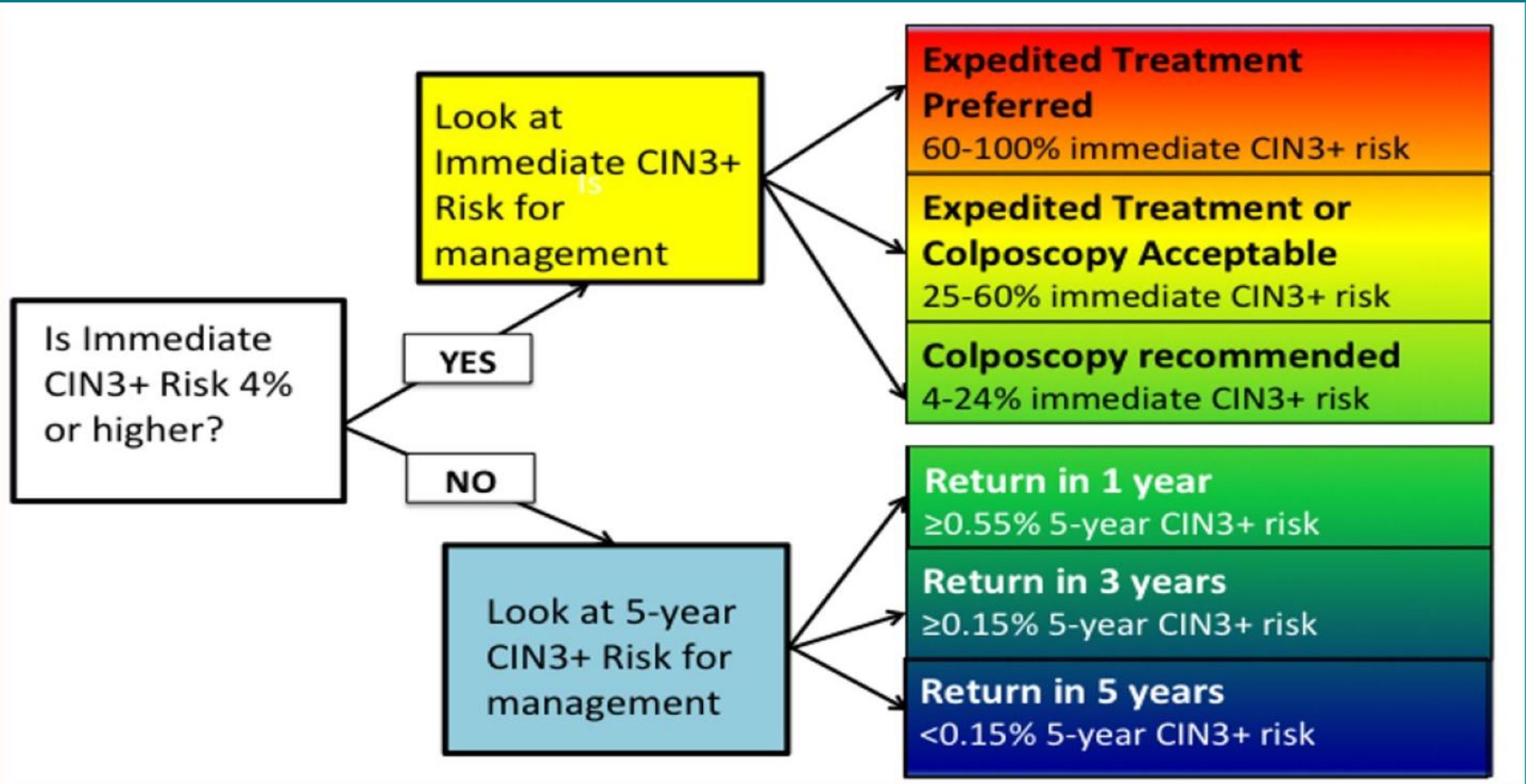
- Surveillance with cytology alone is acceptable only if testing with HPV or co-testing is not feasible.
- Cytology is less sensitive than HPV testing for detection of precancer, and is therefore recommended more often.
- **Cytology is recommended at 6-month intervals when HPV testing or cotesting is recommended annually.**
- **Cytology is recommended annually when 3-year intervals are recommended for HPV or cotesting.**

Fundamental concept #2

Management is based on risk, not results

- Recommendations of colposcopy, treatment, or surveillance are based on a patient's risk of CIN3+ determined by a combination of **current results** and **past history** (*including unknown history*).
- The same current test results may yield different management recommendations depending on the history of recent/past test results and other risk factors.

Patients stratified into risk levels



What data were used/ how do we know they are representative?

Kaiser Permanente Northern California Data (KPNC)

- Largest/longest real clinical experience with HPV-based screening in the world
 - Over 1.5 million women with routine testing from 2003-2017
 - HPV genotyping for ~19,000 patients
- Provides risk-based evidence for most of the common decision points that occur in screening
 - Long length of follow-up allows use of past-history for more personalized management

Cheung LC et al J Low Genit Tract Dis 2020; 24(2): 90-101.

Validation of risk and risk-based management

- KPNC Cohort (~1.5 m)
- New Mexico HPV Pap Registry (450k, previous study)
- CDC NBCCEDP - well-screened (~200k)
- CDC NBCCEDP – rarely/never/unknown screened (~150k)
- BD Onclarity Trial (~30k with genotyping)

Which risk factors influence pre-cancer development?

HPV vaccination: important, but NOT included (yet)

- HPV vaccination prior to age 18 reduces the CIN3+ risk by 50%

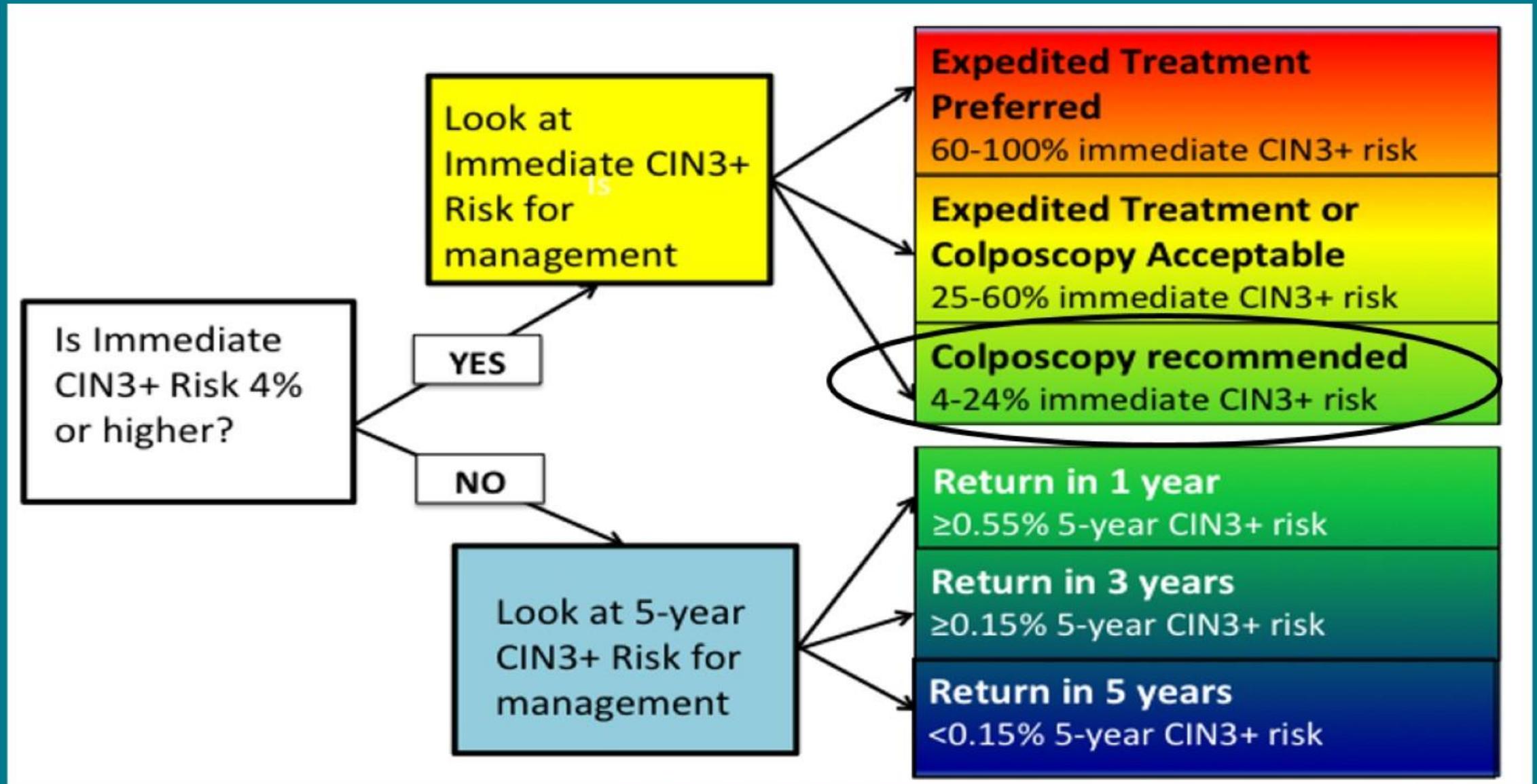
HOWEVER

- Current cohort is 21-24 years, a group already conservatively managed.
- 50% age eligible female first dose vaccine population coverage achieved 2015
- Documentation of vaccination and age at which vaccine is necessary to apply this factor correctly – *historically guidelines have not included factors clinicians can't document*
- Vaccination will impact age to start screening in the future
- Management will likely change as vaccinated cohorts age
- Target age 11-12 years, most not yet older than 25

2019 Management Guidelines Colposcopy Threshold

When individuals have an estimated immediate risk of diagnosis of CIN3+ of 4.0% or greater based on prior history and current results, referral to colposcopy is **recommended**.

Patients stratified into risk levels



Immediate CIN3+ Risk by Co-test(KPNC)

HPV	Pap	N	%	Immediate risk (%)	Colposcopies per CIN3+ diagnosis
Pos	HSIL+	3980	0.3%	48.86	2.1
Pos	ASC-H	3766	0.2%	25.73	2.8
Neg	HSIL+	183	0.0%	25.21	2.8
Pos	ASC-US	30506	2.0%	4.45	8.6
Pos	LSIL	23659	1.5%	4.27	11.3
Pos	NILM	63541	4.1%	2.13	18.3
Neg	LSIL	3300	0.2%	1.05	19.0
Neg	ASC-US	25331	1.6%	0.04	22.6
Neg	NILM	1388153	89.8%	0.002	219.4

Documented prior negative HPV (KPNC)

HPV	Pap	Immediate risk (%) after prior HPV neg	Immediate risk (%) no prior HPV test
Pos	HSIL+	32.28	48.86
Pos	ASC-H	13.56	25.73
Neg	HSIL+	13.80	25.21
Pos	ASC-US	2.10	4.27
Pos	LSIL	2.03	4.45
Pos	NILM	0.74	2.13
Neg	LSIL	0.44	1.05
Neg	ASC-US	0.014	0.04
Neg	NILM	0.001	0.002

LSIL/ASCUS
no longer
meets
colposcopy
threshold

Key change in 2019 Guidelines

Colposcopy can be deferred for certain patients.

- Repeat HPV testing or cotesting at 1 year is recommended for patients with minor screening abnormalities indicating HPV infection with low risk of underlying CIN3+ (e.g., low-grade cytologic abnormalities following a documented negative screening HPV test or cotest).

Impact of HPV type with prior negative HPV test (KPNC)

HPV Type	PAP Category	CIN3+ Immediate risk (%)	Cancer Immediate risk (%)
HPV 16+	ASC-US	5.34	0.33
HPV 16+	LSIL	6.70	0.89

**HPV-16 positive ASC-US and LSIL still exceed 4% threshold*

<https://CervixCa.nlm.nih.gov/RiskTables>

Safer: Define high risk patients to focus resources

High-risk concepts similar to 2012 guidelines:

- Histologic HSIL (CIN2+) on biopsy remains the threshold for treatment in the general population
- CIN3 should always be treated (except in pregnancy)
- CIN2 has the option of treatment or observation with colposcopy/biopsy for those concerned with treatment effects on future pregnancy

Safer: Define high risk patients so resources can be focused on them

- High-grade cytology with HPV 16 infections are highest risk
 - >75% risk of any precancer (histologic HSIL or CIN2+)
 - >60% risk of highest-grade precancer (CIN3+)

Demarco M. et al. J Low Genit Tract Dis. 2020;24(2):144-147.

Clinical Action Thresholds for Expedited Treatment (without confirmatory colposcopic biopsy)

Immediate Risk of pre-cancer (CIN 3+)

<25%

Level below which colposcopy and biopsy is preferred

≥25-59%

Immediate excisional treatment or treatment after colposcopy with biopsy confirmation are acceptable

>60%

Immediate excisional treatment is preferred, treatment after colposcopy with biopsy confirmation is acceptable

**Not recommended for patients age <25 and pregnant women*

2019 Management Guidelines

Highest risk patients receive expedited treatment

- Excisional treatment for patients at high risk of pre-cancer without requiring confirmatory biopsy

Changes to follow-up after treatment of CIN2/3

- HPV-based testing at 6 months, then annually for 3 years
- Continued surveillance with HPV testing or co-testing **at 3-year intervals for at least 25 years**
- Continued surveillance at 3-year intervals beyond 25 years is acceptable for as long as the patient's life expectancy and ability to be screened are not significantly compromised by serious health issues.

Note: 2012 guidelines recommended return to 5-yr screening intervals and did not specify when screening should cease. New evidence indicates that risk remains elevated for at least 25 yrs, with no evidence that treated patients ever return to risk levels compatible with 5-yr intervals.

Additional Key Changes in 2019 Guidelines

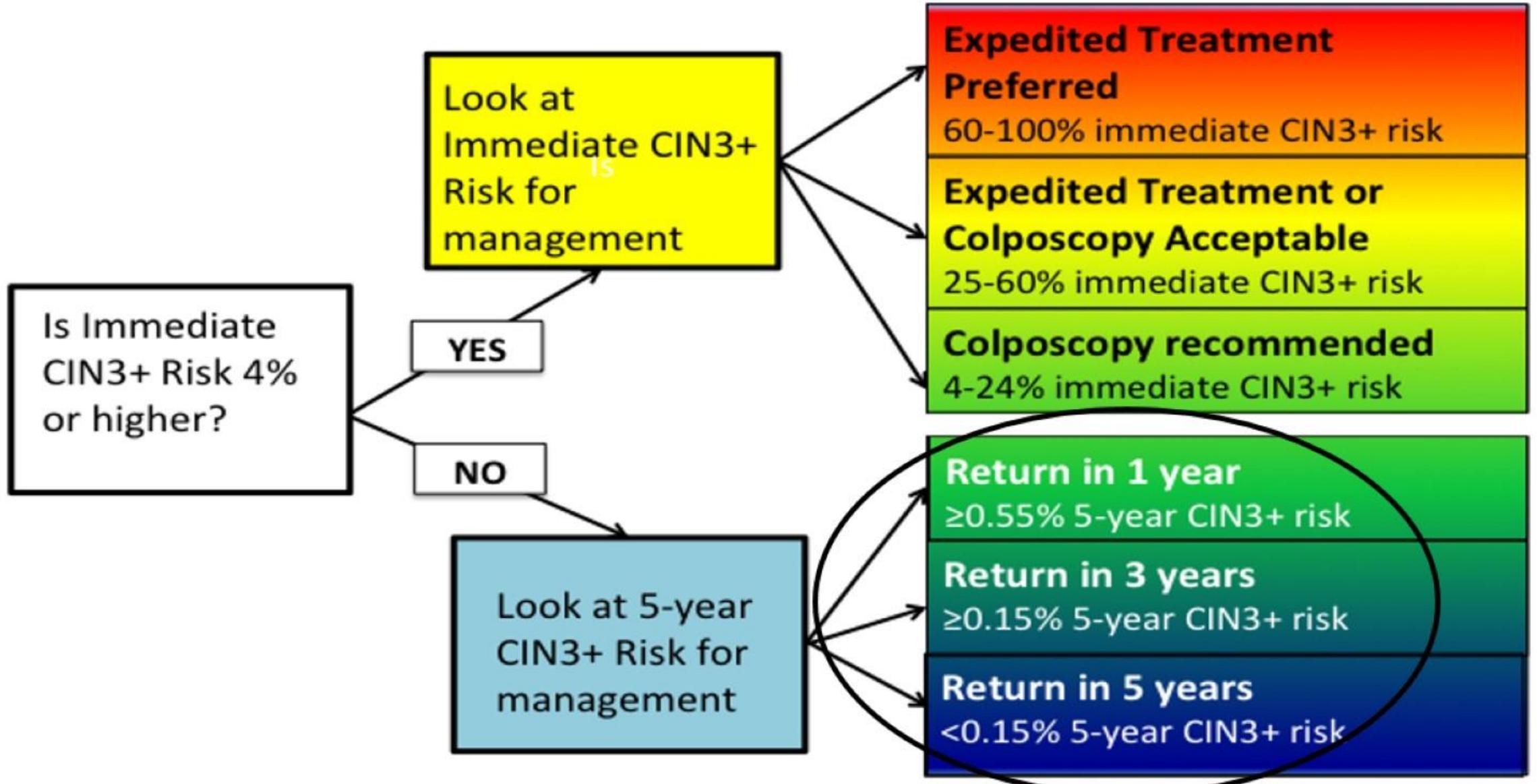
- 1) Excisional treatment is preferred to ablative treatment for histologic HSIL (CIN2 or CIN3) in the United States.
 - Excision is recommended for adenocarcinoma *in situ* (AIS).
- 2) Observation is preferred to treatment for CIN grade 1 (CIN1).
 - Treatment remains acceptable for patients with repeat diagnoses of CIN1 persisting 2 years or more.

Special Situations:

HPV18, HPV-negative AGC, and ASC-H

- Disproportionately important for invasive cancer
- Using medium-term risk of CIN3+ does not lead to colposcopy using Clinical Action Threshold of 4% risk.
- Consider absolute risk of cancer in addition to risk of precancer for **safety**

Patients stratified into risk levels



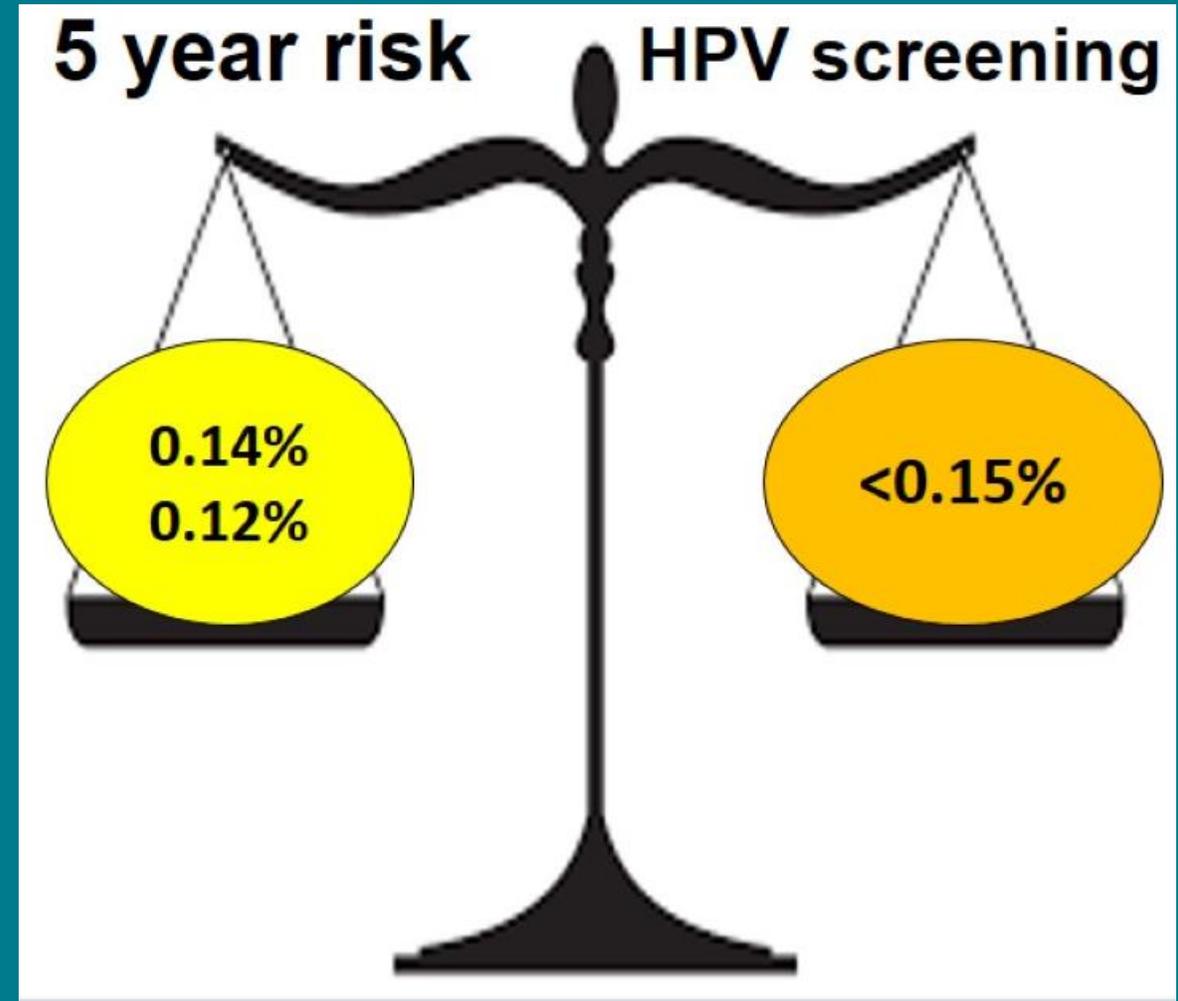
Surveillance intervals in 2019 Management Guidelines

- Goal = simplicity and excellent care
- No compelling reason to change intervals
- Providers are familiar with 1, 3, and 5-year follow up intervals.
- Health systems/tracking features built around these intervals



5-year Return Clinical Action Threshold

- Risk should be similar to that of negative HPV test or cotest in a screening population
- 5 year CIN3+ risk based on the general population at KPNC
 - HPV screening alone = 0.14%
 - Co-testing = 0.12%



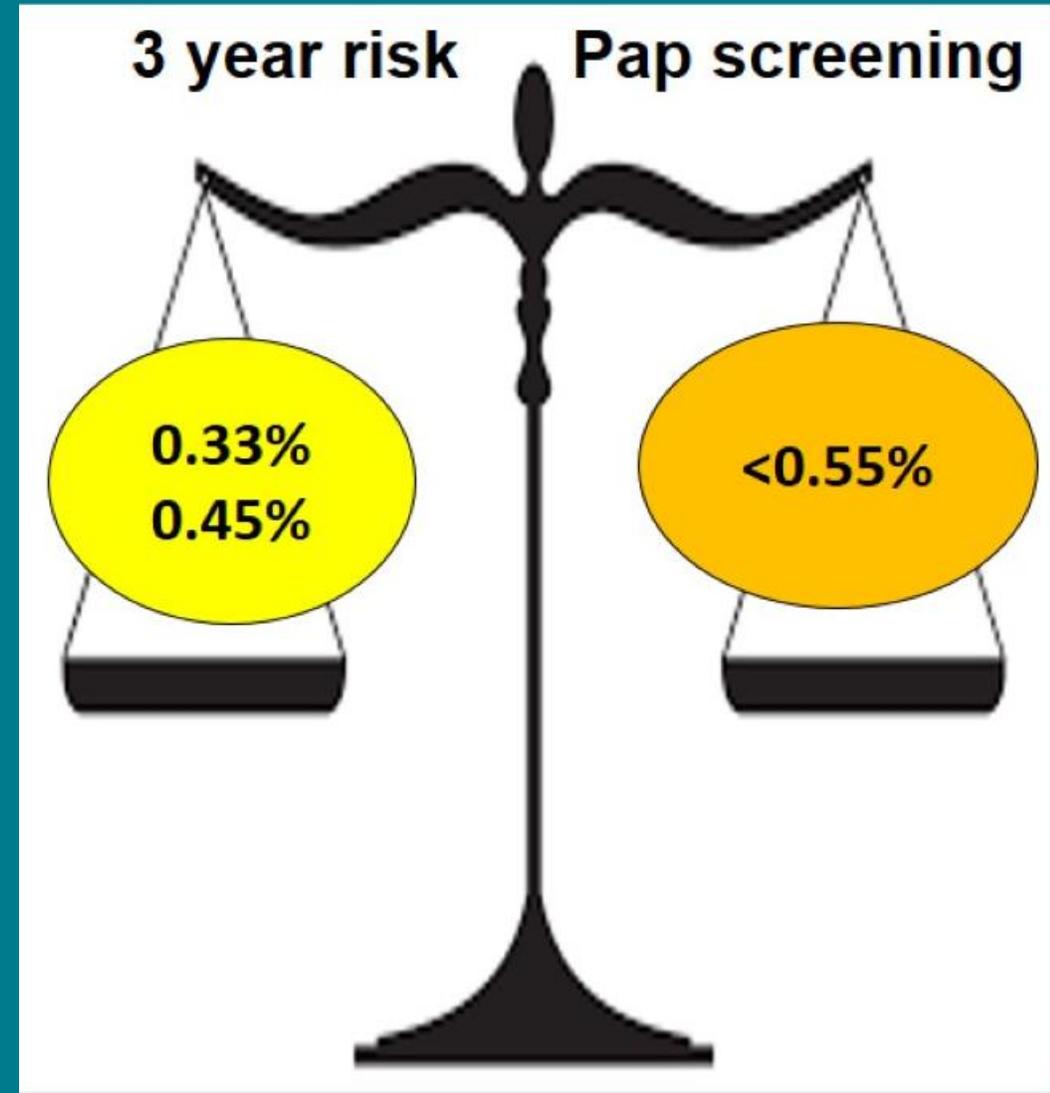
5-year Return Clinical Action Threshold

Guideline:

- When patients have an estimated 5-year CIN3+ risk of $<0.15\%$ based on past history and current test results, return to routine screening at 5-year intervals using HPV-based testing is recommended.
- *Note: HPV-based testing is cotesting or primary HPV testing*

3-year Return Clinical Action Threshold

- Risk should be similar to that of negative Pap test in a screening population
- Five-year CIN3+ risks:
 - **0.33%** estimated in KPNC
 - **0.45%** projected in CDC breast and cervical cancer screening program



3-year Return Clinical Action Threshold

Guideline:

- When patients have an estimated 5-year CIN3+ risk $\geq 0.15\%$ but $< 0.55\%$ based on past history and current test results, repeat testing in 3 years with HPV-based testing is recommended.
- *Note: HPV-based testing is cotesting or primary HPV testing*

Clinical examples of 3-year return

Result	CIN3+ risk at 5 years
HPV-negative ASC-US screening result	0.40%
HPV-negative LSIL → HPV-negative NILM cotest	0.40%
Low-grade cotest → Colposcopy CIN1 → HPV-negative NILM follow-up	0.42%
CIN2/3 treated with LEEP → 3 negative cotests	0.35%

1-year Return Clinical Action Threshold

Guideline:

- When patients have an estimated risk of CIN3+ based on past history and current results that is below the threshold for immediate colposcopy (4.0% immediate risk) and above the 3-year follow-up threshold ($\geq 0.55\%$ at 5 years), repeat testing in 1 year with HPV-based testing is recommended.
- *Note: HPV-based testing is cotesting or primary HPV testing*

Screening results leading to *1-year Return*

Result	CIN3+ immediate risk %
HPV-positive NILM	2.1%
HPV-negative LSIL	1.0%

Post-colposcopy results leading to 1-year return

Pre-colposcopy test result	Colposcopy result	Post-colposcopy test result	Immediate CIN3+ risk
Low-grade*	<CIN2	HPV-positive NILM	2.0%
Low-grade*	<CIN2	HPV-positive ASCUS/LSIL	3.1%

**Low-grade defined as HPV+/NILM, ASC-US, or LSIL cytology*

Key changes to 2015 primary HPV testing interim guidance

All positive HPV tests, regardless of genotype, should have additional reflex triage testing performed from the same laboratory specimen (e.g., reflex cytology).

- Additional testing from the same laboratory specimen is recommended because the findings may inform colposcopy practice. For example, those with HSIL cytology and concurrent positive testing for HPV genotype 16 qualify for expedited treatment.
- HPV 16 or 18 infections have the highest risk for CIN3 and occult cancer, so additional evaluation (e.g., colposcopy with biopsy) is necessary even when cytology results are negative.
- If HPV 16 or 18 testing is positive, and additional laboratory testing of the same sample is not feasible, the patient should proceed directly to colposcopy.

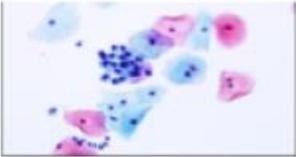
Enduring: defined risks for referral to colposcopy and treatment based on successful historical standards

- 2019 Guidelines Framework designed to preserve cancer prevention while decreasing unnecessary colposcopy in the setting of
 - Decreasing CIN3+ prevalence as vaccinated populations age into screening cohorts
 - Decreasing CIN3+ prevalence as populations undergo multiple rounds of HPV-based screening

Enduring: accommodates new tests in development

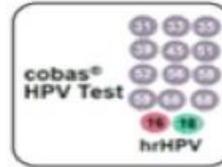
Cytology-based

Cytology / Automation



Molecular

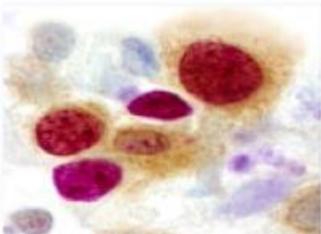
HPV genotyping



Methylation



p16/Ki-67 / Automation

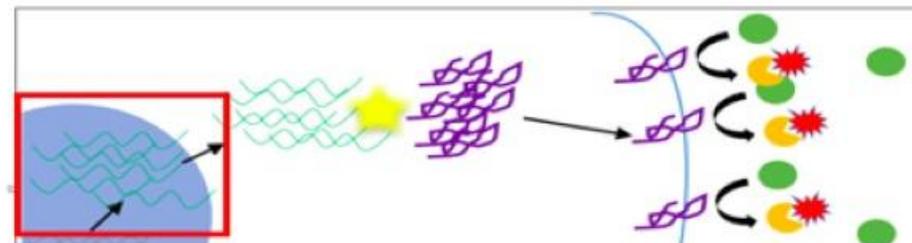


Visual

VIA / Automation



In-vivo imaging



Enduring: accommodates new tests in development

- Establishment of risk-based thresholds means that new tests can be elevated against existing thresholds instead of making new algorithms for each new test
 - Test characteristics will be objectively compared to existing Clinical Action Thresholds
 - Standardized, transparent clinical guidance will logically follow from test characteristics and existing consensus thresholds
 - Reduces the need for interim guidance and frequent consensus conferences

With tremendous thanks to:

- ASCCP
- Consensus voting participants
- KPNC team
- NCI statistical team
- Steering committee members
- Working group participants

How Should Providers Implement the Guidelines?

- Clinicians and staff doing client follow-up: obtain the ASCCP APP
- Update your clinic protocols for screening and colposcopy
- In-service staff regarding the 2019 guidelines
- Inform clients who are under surveillance that they will be managed based on updated guidelines
- Watch for updated coding and billing policies from your payers (Family PACT, Medi-Cal, EWC, commercial health plans)

Questions and Answers