

Case 1

Your practice has decided to use primary HPV screening for cervical cancer. You tell this to a 45 y.o. new patient who says she has “always” had a yearly Pap test and doesn’t understand why she isn’t getting a Pap this visit.

Case 1

You reply:

- A. It's more effective to do the most sensitive test first
- B. HPV testing is more sensitive for risk of future disease
- C. HPV testing is more sensitive and reproducible than cytology alone
- D. All of the above

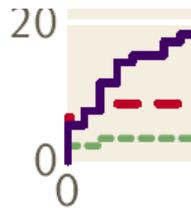
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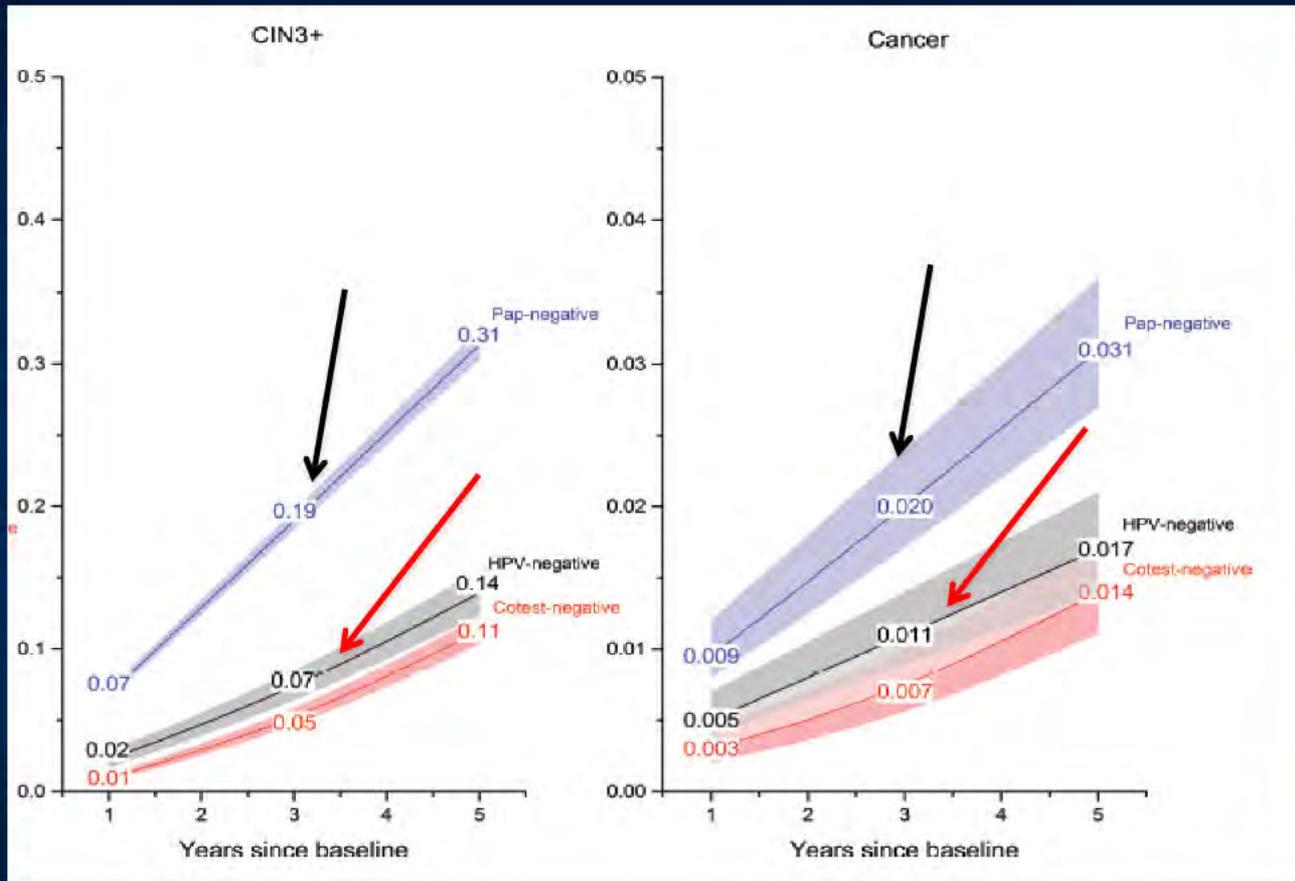
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Cumulative incidence of CIN3+ according to baseline test results in European sites (excluding Denmark and Tübingen)

Cumulative incidence of CIN3+
(per 10,000)



Time since initial testing (mos.)



Gage J *et al*, JNCI, 2014

Case 2

A 24 y.o. graduate student with limited student insurance has read about primary HPV screening. She would like to be screened with HPV alone. You are unsure if your lab uses the FDA-approved test for HPV primary screening.

Case 2

You reply:

- A. Yes, this is a good test for someone in your financial circumstances
- B. Yes, our lab does HPV testing so it must be able to do HPV primary screening
- C. No, you are not a candidate for this test
- D. No, I prefer co-testing for cervical cancer screening

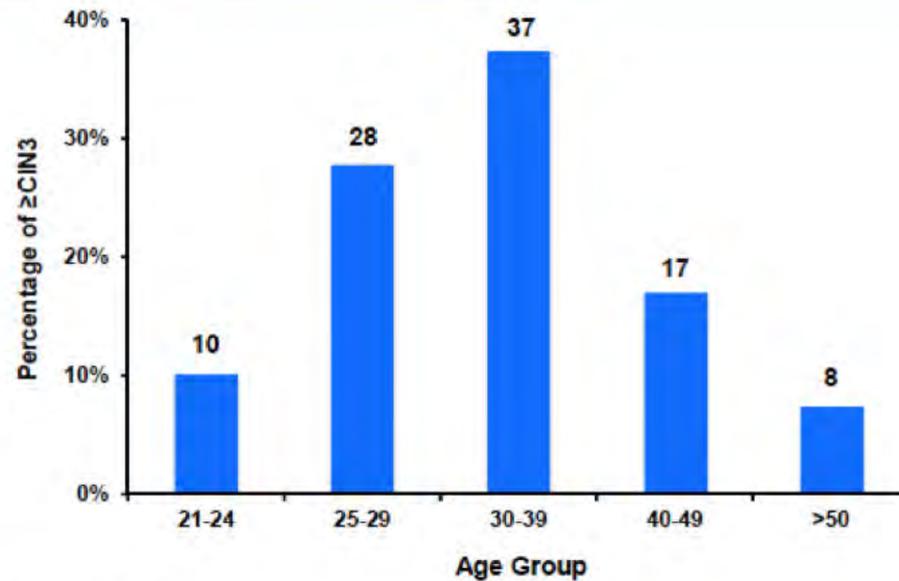
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Why Start at 25 years of Age?

≥CIN3 by Age Group ATHENA



Data not reviewed by FDA
Wright et al. *Am J Obst Gynecol*, 2011.

CC-28

From 3/12/2014 FDA Panel Materials

Age To Initiate Primary HPV Screening

Primary HPV screening should not be initiated prior to age 25.

Starting at age 25, the number of colposcopies increased but found 54% more CIN 3

However, progression to cancer is uncommon in this age group and it is uncertain if identification of CIN 3 before age 30 will reduce cervical cancer

Case 2

This patient is not age appropriate for primary HPV screening and the test the lab uses is not FDA approved for this indication.

Co-testing is recommended only for women 30 and older

Case 3

A 30 y.o. comes in for contraception. Her last cervical cancer screen was cytology at age 28. She asks about screening at this visit. Your lab uses the FDA- approved test.

Case 3

You reply:

- A. Yes, you are now 30 and due for co-testing
- B. Yes, we can offer you primary HPV screening
- C. No, you are not due for screening
- D. A or B

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Optimal Interval for Primary HPV Screening

Rescreening after a negative screen should occur no sooner than every 3 years

There are limited prospective US data to determine the best interval for Primary HPV Screening. In the ATHENA trial, the incidence of CIN 3 over 3 years was less than 1%. European trials have used 3 year screening intervals. Until further US data is available, screening no sooner than 3 years is recommended.

Case 4

Your practice utilizes Primary HPV Screening. A 36 y.o. woman s/p BTL has a positive HPV 16 result. You call her to recommend:

Case 4

- A. Perform co-testing
- B. Repeat HPV test one year
- C. Perform colposcopy
- D. Perform LEEP

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Case 4

The risk of high grade disease with a positive HPV 16 test is too great to delay further testing and colposcopy is recommended, just as it is with co-testing when genotyping finds HPV 16 or 18.

However, treatment with any modality is not recommended unless high grade disease is found.

Case 5

A 47 y.o. woman sees you for screening. She has just recently obtained health insurance and is trying to “catch up” on her preventive care. She thinks her last Pap was over 10 years ago and states that none have ever been abnormal. Your lab uses the FDA-approved HPV test for primary screening. Her result returns negative for 16 and 18 but positive for the other pooled high risk types.

What do you recommend?

Case 5

What do you recommend?

- A. Perform co-testing now
- B. Perform cytology now
- C. Perform colposcopy now
- D. Perform co-testing at 12 months

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- A. Perform co-testing now
- B. Perform cytology now**
- C. Perform colposcopy now
- D. Perform co-testing at 12 months

Case 5

According to the algorithm proposed in the Interim Clinical Guidance, “reflex” cytology can be performed and subsequently managed according to the appropriate ASCCP Guideline.

The best scenario is somewhat unknown for this situation but it puts it into the realm of co-testing, for which we do have data.

