

**Implementing the 2019 ASCCP Risk-Based Management Guidelines for
Abnormal Cervical Cancer Screening Tests in Your Practice
Q & A Document
July 23, 2020**

Questions for Mike Policar:

1. Does Medi-Cal cover HPV vaccines for those over 26 years old?

Yes. Medi-Cal fee-for-service and Medi-Cal Managed Care plans cover HPV-9 vaccine from 9-45 years of age. Links to the relevant Medi-Cal policies are as follows:

<https://files.medi-cal.ca.gov/pubsdoco/publications/masters-mtp/Part2/immun.pdf> (see page 12)

https://files.medi-cal.ca.gov/pubsdoco/medsupply/Medi-Cal_coverage_immunizations_faq.aspx

2. Does EWC cover genotype testing?

Yes. It is covered as of December 2018. The link to the relevant policy is:

https://files.medi-cal.ca.gov/pubsdoco/newsroom/newsroom_27397.aspx

3. Does FPACT cover the cost of HPV genotyping?

Yes, testing for HPV 16/18 is a Family PACT benefit as of Feb 27, 2019. Note that it is covered only when a hrHPV test is positive and the lab performs the 16/18 genotyping as a reflex test. It cannot be ordered as a “stand-alone” test. The link to the relevant policy is:

https://files.medi-cal.ca.gov/pubsdoco/newsroom/newsroom_27691.aspx

4. We have been told a limit of HPV testing because HPV testing is expensive. Is there a limit to how many tests can be done?

Family PACT has covered hrHPV (alone) testing since December 1, 2018. The cost of this test is the same as cervical cytology alone. However, this test is covered only for the purposes of primary cervical cancer screening in females 30-65 years of age and as indicated for surveillance in any of the circumstances listed in the 2012 ASCCP Guidelines. In the next few months, Family PACT policy in two sections of the Policies, Procedures and Billing Instructions manual (ben fam rel and lab) will be updated to reflect the 2019 ASCCP Guidelines.

The only limitation on the number of hrHPV tests a person can receive is that their use must be consistent with the USPSTF guidelines for screening and the ASCCP guidelines for management. When used for screening (hrHPV-alone or co-testing for women 30-65 years of age), if the screening result is negative, the next rescreening is in 5 years, and *not* earlier, even if requested by the client.

<https://files.medi-cal.ca.gov/pubsdoco/bulletins/artfull/fpact201811.aspx#a1>

Also see the Family PACT Clinical Practice Alert on Cervical Cancer Screening:

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

5. Does Medi-Cal cover LEEP procedure?

Yes. Medi-Cal covers LEEP excision (CPT: 57460), LEEP conization (CPT 57461) and LEEP (alone, without simultaneous colposcopy; CPT 57522). Family PACT covers LEEP excision only.

6. Is the p16 immunohistochemistry test covered by family pact?

No, not at the current time. However, adding this test, which is performed in the pathology lab on a cervical biopsy specimen, is under consideration.

7. Is it recommended for HPV to screen more in high risk HIV patients? Any difference in screening for HIV positive patients? If there is a difference, were can we find guidance for caring for the HIV positive patient?

The Panel on Opportunistic Infections in HIV-Infected Adults and Adolescents (2018) recommends that females who are infected with HIV should have age-based cervical cancer screening.

- HIV-positive individuals should begin screening with cytology alone within 1 year of onset of sexual activity or, if currently sexually active, within the first year after HIV diagnosis, but no later than 21 years of age. Repeating cytology in 6 to 12 months (without HPV testing) is recommended for HIV-infected females younger than 21 years with ASCUS test results.
- If the patient is younger than 30 years of age and the initial cytology screening result is normal, the next cytology screening should be in 12 months. After 3 consecutive normal annual screenings, follow-up screening should be every 3 years.
- Patients who are 30 years of age and older can be screened with cytology alone or co-testing. Once those screened with cytology alone have had 3 consecutive annual normal test results, or a single negative co-test result, screen every 3 years.

Detailed information can be found at:

<https://aidsinfo.nih.gov/guidelines/brief-html/4/adult-and-adolescent-opportunistic-infection/343/human-papillomavirus>

8. How does these new guidelines transfer over to HIV patients with follow up with abnormal?

In Section K of the 2019 ASCCP Guidelines (Special Populations), there are important management recommendations for patients with immunosuppression, including those who are HIV positive. (Journal of Lower Genital Tract Disease 2020; 24(2), page 125). It's important to

enter this information into the APPor website tool, as being HIV positive or immunosuppressed will impact the management recommendation.

- In immunocompromised patients of any age, colposcopy referral is recommended for all results of HPV-positive ASC-US or higher.
- If HPV testing is not performed on ASC-US results, then repeat cytology in 6 to 12 months is recommended, with colposcopy referral for ASC-US or higher.
 - For any result of ASC-US or higher on repeat cytology or if HPV positive, referral to colposcopy is recommended.
- For all cytology results of LSIL or worse (including ASC-H, AGC, AIS, and HSIL), referral to colposcopy is recommended regardless of HPV test result if done.

9. Do we need to screen pregnant women? Can't we wait until they are postpartum? I hesitate to cause bleeding/friability. Can't it wait?

The screening intervals contained in the USPSTF recommendations apply equally to pregnant and non-pregnant females. For example, if a 32-year-old client seen for an initial prenatal visit had a negative screening 2 years ago by cytology-alone, hrHPV-alone, or co-test, she should not have cervical cancer screening at this visit. Re-screening after her delivery should occur only when 3 years have passed since her last cytology test or 5 years from her last hrHPV-alone or co-test.

There is no reason to *routinely* screen pregnant females for cervical cancer, either prenatally or post-partum, simply because they are pregnant.

10. Can we just bypass the pap smear and do an aceto-acid test then straight to biopsy?

No. The technique of VIA (visual inspection with acetic acid) is used in low resource countries where there is limited infrastructure for processing and reporting cervical cytology and biopsy results. While the VIA approach is as sensitive a cytology in the identification of pre-cancers, it is not nearly as specific, leading to a high rate of unnecessary treatment. There are no national guidelines in the United States (e.g., ASCCP, ACOG, USPSTF, or American Cancer Society) that recommend this approach. It is not covered by either Family PACT or Medi-Cal.

Questions for Patty Cason:

1. **How do you advise a patient who is positive asking about her boyfriend who may be positive regarding his plan of treatment?**

There is currently no recommended testing or treatment for male partners of patients testing positive for HrHPV.

2. **Which is the HPV test used for primary screening? We use HPV mRNA E6E8, could that be used for primary screening?**

The only tests licensed for primary screening are Cobas (Roche) and Onclarity (BD).

3. **Is there a way to have the app go further back than 2-3 years? For some patients who are in the "management of results during post-colposcopy surveillance" we have been following them for 5+ years however I have not found a way to input this. Would it change management?**

It can go back over a longer time span but only for a limited number of prior tests. You're correct that the number of prior test results you can input is determined by whether or not it would change the % risk and therefore management.

4. **Is there still a place for cytology with reflex HPV HR testing in screening?**

The new guidelines are about management not screening. Cytology with reflex HPV HR testing is still a valid screening option. There is no known advantage to this approach, but it is acceptable because there are a variety of individual circumstance/insurance/availability of tests etc. We expect new screening guidelines very soon.

5. **With the old guidelines, we were able to do cytology with reflex to HPV for women ages 21-29. How should we screen this population now, especially if my clinic doesn't have HPV alone screening available?**

The new guidelines are about management not screening. Cytology with reflex to HPV is still a valid screening option if necessary. There is no known advantage to this approach, but it is acceptable because there are a variety of individual circumstance/insurance/availability of tests etc.

6. **Would you recommend patients to get the HPV shot, when I attended HPV conference, they mentioned they are still protected for other strain.**

There are minimal downsides other than cost. The vaccine will prevent new infections of all 9 strains.

7. **Could you clarify the difference between the first and second clinical situations listed on the ASCCP app (management of routine screening results vs return visit during pre-colposcopy surveillance)?**

The first is meant for the time when you have just gotten the abnormal screening test results and now need to plan next steps for follow up in 1, 3, 5 yrs., or colpo, or expedited treatment. With the second, the screening results had been abnormal enough to warrant sooner than 5 year follow up but not high risk enough for a colpo. So, you have already begun on the surveillance follow up and now have results from that follow up testing and need to know next steps.

8. When will the screening guidelines be updated to reflect the preference for HPV as primary screening?

Either co-testing or primary HPV screening are both “HPV based testing”. We hope the new screening guidelines will be outsoon.

And is cytology still preferred for people 21-29 as primary screening? Yes.

9. After a screening result of positive hrHPV with negative cytology (no h/o abnl), do we still offer the patient the two options, hrHPV typing, and if 16+ or 18+, then colpo OR no typing with f/u in 1 year? The app only recommends 1-year follow-up with this result. Should this screening result automatically have hrHPV typing done?

If you have the option to genotype, it is preferred.

10. Any changes in collection technique? What about screening guidelines for 21-29 years old?

No change in technique but I recommend reviewing the technique because many clinicians were not trained initially in such a way as to maximize the likelihood of submitting adequate cellular material to allow for both cytology and HPV testing (as needed).

11. You said any 2 positive HPV infections in a row should have colposcopy, but the app advised repeat 1 year in a 24-year-old with that scenario?

Just to clarify, it is not two infections in a row. If they are two infections, each would be an incident infection rather than one persistent infection which is the concerning situation. But we should not screen with HPV tests in persons under 30. You are referring to reflex testing after ASCUS, which is a different scenario. We wait two years after the first low grade screening abnormality in persons under 25 because they are so likely to represent incident infection that will be cleared by 2-3 years.

12. I like to use the Spirabrush as it gets more tissue and includes a larger surface area. What is your thought and advice on multiple bx?

The data I have read on soft biopsy technology is good. Not sure what the question is about multiple biopsy. Feel free to write to me: patty@maddala.com.

13. Is there any clinical value to include other HPV serotypes when screening besides 16 and 18?

Yes, screening begins with a test for any HrHPV which translates into increased risk.

My facility reflexes HPV positive testing to 16, 18 and "other". That is good.

Is the management different if a patient has + HPV non 16/18?

Yes, it is less risk if not 16 or 18 so, for example, normal cytology with positive HPV positive 16/18 goes to colpo whereas normal cytology with positive HPV negative 16/18 goes to 1 year follow up.

14. Can you review HPV ONLY screening? Why would that be a preference?

"HPV based" screening is what is preferred. That means either co-test or HPV only.

It seems that you need both the cytology and the HPV status. Many of our pts don't have "history" or they are confused about their Pap histories.

A negative co-test confers a 0.12 likelihood that the person will have CIN3+ in the next 5 years and a negative HrHPV test alone confers a 0.14 likelihood. Using the principle of equal management for equal risk, the two approaches confer similar risk. Note that cytology alone is never recommended for a 5-year return. If your patient is rarely or never screened, look at that particular line item in the app to advise if the calculated risk (hence recommended management) is different.

15. Given that you mentioned pap smear is not only a screening, more so looking for precancerous changes from HPV16, how would you approach the virginal patient -intact hymen? Let's add in w/ AUB. Would you recommend an EUA for a pap smear?

Someone who has never had any skin to skin genital contact is at exceedingly low risk of cervical cancer and it is a shared decision-making conversation. A great option for this person could be self-swabbing for HrHPV.

16. Given that Kaiser is an insulated integrated health system that is NOT representative of the non-integrated, diverse landscape of our health care in the US where many patients are under insured and access is a barrier, are you concerned about the impact of HPV Alone testing and missing disease in light of current cultural health equity disparities for example with women of color dying more from cervical cancer?

Thank you so much for this question! There are two points here. 1) While the Kaiser database was huge at 1.5 million, it was directly compared with the NBCEDP databases and New Mexico registry which have more representative populations and the calculated risks produced the same action thresholds, so we feel reassured that the management recommendations are generalizable 2) This is a huge issue but part of this is an access to screening issue. If someone gets screening, the guidelines apply. If they don't, they are at much greater risk obviously and the most important step is to get them screened. We have no data suggesting that co-testing is vastly superior in the setting of underserved patients however if you see a patient who is never or rarely screened and you have the option to co-test, I would do that because you get more information.

- 17. What about adenocarcinoma, which is increasing in frequency in the US, and is less associated with HPV. Do these guidelines take this into account?**

Adenocarcinoma of the cervix is caused by HPV. In fact, it is harder to find with cytology since it is often in the canal, so we see more case-finding with HPV screening that would've been missed with cytology. It's a good example of the superiority of HPV testing to cytology.

- 18. How about the future of doing rectal pap with the regular pap?**

We are not there yet. In order to have a screening program (any screening – but this applies to anal CA), we need to: 1) Know the best way to screen and have clinicians trained in screening 2) have data showing that screening impacts disease 3) know what to do with screening results 4) have the manpower/capacity to manage abnormal results (clinicians trained in high resolution anoscopy (HRA) 5) have sufficient data suggesting that use of HRA and treatments impacts disease. We have none of these in place yet. Hopefully in the future. Maybe, if you are inspired, consider getting trained in HRA, it's an important and valuable skill.

- 19. I'm interested in training in colposcopy and have a preceptor. Do you know of an online training that is available now?**

We are in the process of getting the ASCCP course on-line. Hope to have it by the end of the year if not sooner. I don't know of anything right now.

- 20. I'm interested and intrigued why the app doesn't ask for the timing of last pap when entering past/historical results (because if >5 years ago may not be as relevant/useful).**

The technical considerations in creating the app are huge because there is so much data inherent in the guidance so timing wasn't included since it would not change the management except in unscreened or under screened people (which would be > 5 years). Otherwise it assumes timely screening. Use the line at the bottom of the first page for unscreened or under screened people to see their particular recommendation.

Also, I noticed that the option of listing HPV results wasn't always available.

Yes, in general, if a particular action is not recommended it is not given as an option in the app.

- 21. If someone is lost to follow-up for HSIL (LEEP), is a co-test 1 or 2 years later used as the "first" follow-up test, or is the time more important in tracking their future screening/risk?**

After LEEP? In general, once someone falls outside the guidelines we rely on expert opinion. You can present your case on the ASCCP list serve.

- 22. If you have a chance please comment on the brush-based biopsy techniques (Spirabrush, SoftBiopsy). Small studies show good correlation, our internal studies as well, but not addressed by ASCCP.**

Yes, the data I have read are good however the studies are small. It is an exciting option! Yes, ASCCP has not yet made a recommendation. Feel free to write to me and we can discuss if you like(patty@maddala.com).

23. How do I advise patients who are due for their pap but are leery of unnecessary exposure to Covid-19? How much leeway do we have?"

Routine screening can be postponed until the restrictions for the public health emergency have been loosened in your community and the client is comfortable being seen in-person.

Depending on the client's age and prior history, a postponement of 6-12 months is reasonable.

ASCCP have developed specific guidelines for females who were screened before or during the public health emergency and who have *abnormal* test results. These recommendations can be accessed at: <https://www.asccp.org//covid-19-resources>.

"In light of the current unprecedented COVID-19 pandemic, and in settings where all non-essential medical office visits and elective procedures have been suspended, ASCCP recommends the following:

- Individuals with low-grade cervical cancer screening tests may have postponement of diagnostic evaluations up to 6-12 months.
- Individuals with high-grade cervical cancer screening tests should have documented attempts to contact and diagnostic evaluation scheduled within 3 months.
- Individuals with high-grade cervical disease without suspected invasive disease should have documented attempts to contact and procedures scheduled within 3 months.
- Individuals with suspected invasive disease should have contact attempted within 2 weeks and evaluation within 2 of that contact (4 weeks from the initial report or referral)."