National Family Planning & Reproductive Health Association

Highlights of 2019 ASCCP Risk-Based Management Guidelines

Implications for Family Planning Service Providers

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Introduction

In April 2020, the *2019 ASCCP Risk-Based Management Consensus Guidelines for Abnormal Cervical Cancer Screening Tests and Cancer Precursors were published*[1]. This is the 4th edition of management Guidelines, updating the 2001, 2006 and 2012 versions. While they are evolutionary, rather than revolutionary, the new guidelines were developed based on a greater amount of longitudinal data derived from a larger database than was previously available [2,3] and validated against several other databases. This resulted in significant changes in the content of the recommendations which are now consistently based on estimated risk for combinations of current and past results. Methods of accessing management recommendations have shifted in comparison to the earlier versions to facilitate access.

As before, the goal of screening and management is to discover pre-malignant cervical lesions and to treat them before invasion occurs. This is done by screening for cytologic abnormalities and/or the presence of one or more of 14 strains of high risk human papillomavirus (hereafter, referred to as HPV), followed by histologic (biopsy) diagnosis of histologic HSIL/cervical intraepithelial neoplasia (CIN) 2 or 3. Additionally, glandular cancer pre-cursor lesions can be detected (cytologically, as atypical glandular cells [AGC] and histologically, as adenocarcinoma-in situ [AIS]) and treated before invasion occurs. Consequently, the clinical endpoint that screening and evaluation seeks to identify is CIN 2/3+ (which includes CIN 2, CIN 2/3, CIN3, AIS, and cancer). Low grade lesions are highly likely to regress (or at least, not progress to CIN 3+), and therefore, *should not be treated* in most circumstances. There also is greater focus on specific HPV types, especially HPV-16 and HPV-18 infection, as conferring particularly high risk for precancerous lesions and cancer.

Family planning providers, women's health providers, and primary care providers who perform cervical cancer screening, those who perform colposcopy, and those treating pre-invasive lesions, will benefit from understanding important changes in the 2019 ASCCP Risk-Based Management Consensus Guidelines and taking note of advice regarding how to implement them. By using clinical action thresholds, the guidelines allow for future modifications and changes in recommendations going forward as new data and technologies emerge. Below is a listing of the eight most significant modifications in the guidelines. Quotations from the main 2019 ASCCP Risk-Based Management Consensus Guidelines article are indicated by indentation.

1. For the first time, an individual's prior test results and treatment history or lack of prior screening are used to estimate that individual's risk of currently having CIN3+ or developing CIN3+ over the next 5 years, including that information about past history now contributes to prospective management decisions, a step toward personalized health care.

Personalized risk-based management is possible with knowledge of current results and past history. The recognition that persistent HPV infection is necessary for developing precancer and cancer (defined as CIN 3+, which includes diagnoses of CIN 3, AIS, and cancer) underlies the 2019 guideline update.

Rather than consider screening test results in isolation, the new guidelines use current and past results, and other factors, to create individualized assessments of a patient's immediate risk of precancer (CIN3+), or 5-year risk of progressing to precancer or cancer. A "patient's screening history" includes any abnormal screening result in the last five years and any treatment in the proceeding 25 years. If no history is available, "past history unknown" is considered as a separate risk factor and included with the risk estimates. For patients with an unknown history, the minimum information required to make clinical decisions is patient age and current test result.

Comment:

It has been known for decades that the most important risk factor for CIN 2/3+ is a *persistent* high-risk HPV infection. When successive rounds of cervical screening are done with HPV-based testing (either HPV alone or HPV plus cytology co-testing), it is easier to determine whether persistent HPV infection is present. This information is then integrated into CIN 3+ risk estimations that determine management decisions. This improvement results in management decisions that are more tailored to the individual, rather than relying on the "generic" algorithms that were used in the earlier consensus management guidelines.

2. Equal management for equal risk.

History and current test results are used to calculate a patient's current and future risk of CIN 3+. Similar risks are managed similarly, regardless of the combination of results/history used to estimate the risk.

Recommendations of routine screening, 1-year or 3-year surveillance, colposcopy, or treatment correspond to a risk stratum, a range of risk for CIN 3+.

Recommendations of colposcopy, treatment, or surveillance will be based on a patient's risk of CIN 3+ determined by a combination of current results and past history (including unknown history). The same current test results may yield different management

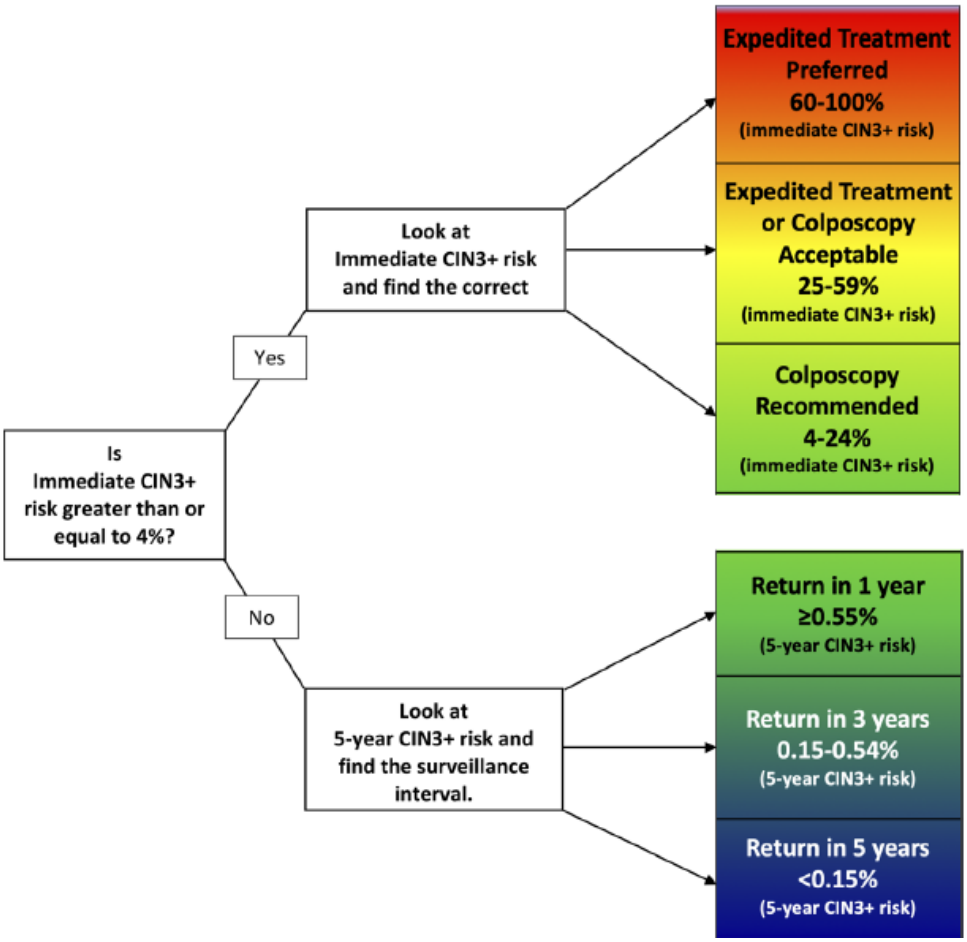
recommendations depending on the history of recent past test results.

Comment:

Guideline recommendations were based on risk estimates calculated with data from a large, prospective, longitudinal cohort of > 1.5 million patients at Kaiser Permanente Northern California (KPNC). With such a large database, it was possible to construct precise estimates for the risk of either acquiring or having CIN 3+ in the subsequent 5 years for a large number of clinical scenarios and combinations of past and current test results[2].

The applicability of these risk estimates to other United States regions and populations was validated by comparison with data sets from CDC NBCCEDP programs, the New Mexico Pap Registry, and two clinical trials. The wide variety of demographics represented in these additional data sets reassures us that the risk-based recommendations apply broadly[3].

Scenarios were categorized in one of six risk strata or clinical action thresholds, which in turn contained a management recommendation for either surveillance, colposcopy, colposcopy or treatment, or expedited treatment. Importantly, the immediate CIN 3+ risk threshold for **colposcopy is 4%**.



3. Guidance for expedited treatment is expanded (i.e., treatment without preceding colposcopic biopsy results).

> For non-pregnant patients 25 years or older, expedited treatment, defined as treatment without preceding colposcopic biopsy demonstrating CIN 2+, is preferred when the immediate risk of CIN 3+ is ≥60%, and is acceptable for those with risks between 25% and 60%. Expedited treatment is preferred for nonpregnant patients 25 years or older with high-grade squamous intraepithelial lesion (HSIL) cytology and concurrent positive testing for HPV genotype 16 (HPV 16) (i.e., HPV 16–positive HSIL cytology) and never or rarely screened patients with HPV-positive HSIL cytology regardless of HPV genotype. Shared decision-making should be used when considering expedited treatment, especially for patients with concerns about the potential impact of treatment on pregnancy outcomes.

Comment: The previous version of the ASCCP Consensus Management Guidelines[4] offered the option of expedited treatment (also known as "see-and-treat" LEEP). With this approach, if the cytology result is HSIL and the colposcopy reveals a lesion that has a high likelihood of requiring treatment, an excisional LEEP (CPT code 57460) or a LEEP conization (CPT code 57461) is done for the purpose of diagnosis and treatment in a single step, avoiding the need for 2 visits (one for colposcopy and biopsies and a second for the LEEP procedure itself). The 2019 Guidelines go further by offering specific high-risk scenarios for which expedited treatment is actually preferred such as HSIL with positive HPV 16 and HSIL with any positive HPV in someone who has been under screened.

When considering expedited treatment note that:

- If the colposcopic impression is consistent with a low-grade lesion or changes of uncertain significance, the advice is to biopsy first and await the pathology report before determining treatment.
- It is critical to ensure that the decision for expedited treatment is based on *only* the criteria from either the 2019 ASCCP Risk-Based Management Guidelines or the ASCCP Colposcopy Standards [5,6] and not extended to other situations, which could result in over-treatment.
- For those of reproductive age, the role of shared decision-making in weighing the benefits and harms of this approach is essential, especially regarding the potential impact of LEEP on future childbearing.

The 2019 Guidelines may result in a greater number of "see-and-treat" LEEP procedures, with the benefit of fewer people being lost to follow-up before the LEEP can be performed, as well as requiring fewer in-person visits for the patient.

4. The 2019 Guidelines are very comprehensive and include virtually every topic of interest regarding management of screening and biopsy results.

The guideline contains the following sections:

- Six clinical action thresholds, including surveillance (5-year, 3 year, or 1-year return visits), send to colposcopy, colposcopy, or treatment; and treatment preferred.
- Updates related to pathology reporting (the two-tier LAST recommendations) and laboratory tests (p16 IHC staining), management of Primary HPV Screening
- Rare cytology results (AGC, AIS, unsatisfactory for evaluation, absent transformation zone, benign endometrial cells in premenopausal patients or benign glandular cells in post-hysterectomy patients
- Colposcopy practice standards
- Managing histology (biopsy) results
- Surveillance after abnormalities
- Special populations: patients younger than 25 years, pregnancy, immunosuppression' after hysterectomy, older than 65 years with history of prior abnormalities

Comment: Before this guideline, a clinician had to refer to a variety of published guidelines for management advice (e.g., primary HPV screening; management of HIV positive and immunocompromised individuals). The fact that this Guideline integrates these other sources, and addresses so many common management dilemmas, is quite helpful.

Many clinicians are not familiar with the ASCCP Colposcopy Practice Standards [5,6] which are referenced in Section H1. The standards are comprehensive and based on the most current data. All colposcopists should read through the standards to ensure their colposcopy methods are consistent with best practices. The standards are also a helpful quality improvement tool to evaluate all colposcopists in your practice.

5. Rather than relying on a set of algorithms as in the past, use of the mobile device app (purchased) or website (free) is needed for determining next steps in patient management.

Clinicians can use the 2019 guidelines to manage their patients via the tables in Egemen et al[2] or by using an app or website designed to facilitate navigation of the tables available at http://www.asccp.org, including a no cost version.

Comment: For many clinicians, this will be the most profound change in how the guidelines are used. Think of it as moving from using a map to using GPS when driving. The use of the mobile device app or website app allows you to efficiently incorporate a considerable amount of clinical and demographic information when determining next steps in management and actualize personalized risk assessment. However, the downsides include the one-time cost of the mobile device app ($9.99) and if you are using the website version, having limited access to management recommendations in the absence of a working computer connected to the internet. Additionally, the guidelines and the evidence that support them are contained in 3 articles [1-3], each of which is

dense with information, making it impossible to reference management advice in a single easy-to-read article or set of algorithms as in the past.

At a minimum, a provider will need to know a patient's age and current screening test result to make a clinical decision.

6. The 2019 Guideline development was a consensus process that included a "who's-who" of health, professional, scientific, governmental, and patient advocacy organizations, making it the North American benchmark guideline on this topic.

> The ASCCP Risk-Based Management Consensus Guidelines represented a consensus of 19 professional organizations and patient advocates.

Comment: This creates a new national "benchmark" guideline that addresses special populations and scenarios previously requiring multiple searches. In addition, the development process included stakeholder feedback from providers (survey and public comment period) and patients (survey) to ensure that the guidelines met the needs of those who would be using them[7].

7. Implementation of the 2019 Guidelines will not require any new technology or lab testing not already used for cervical cancer screening, but the guidelines are designed to allow new technologies to be added in the future .

Comment: Other than primary HPV screening and p16 immunohistochemistry (p16 IHC) staining of certain biopsies in the pathology lab, there are no new technologies included in the 2019 Guidelines when compared to the 2012 Guidelines. However, recognizing that many new technologies are in development, the guidelines were specifically designed to allow new tests to be incorporated without requiring interim guidance or frequent consensus conferences. The clinical action thresholds, which recommend management based on risk estimation, allow for new tests to be incorporated into the existing framework by estimating the risk associated with each result. An ongoing risk estimation program will continue for this purpose.

8. Recommended implementation action items for family planning clinics.

Comment: Here are some ideas about implementing the 2019 Guidelines in your practice.

- Watch the "QuickStart Guide" video on the ASCCP website at https://www.asccp.org/quickstart.
- Download the Perkins and Guido et al, and Egemen et al articles from the Journal of Lower Genital Tract Disease on the 2019 Guidelines from the ASCCP website at https://www.asccp.org/management-guidelines.
- Clinicians and staff doing follow-up should obtain the ASCCP app (iPhone, iPad, Android) or try out the tool on the ASCCP.org website.
- Update your clinic or office protocols for cervical cancer screening and colposcopy to reflect the 2019 ASCCP Risk-Based Management Guidelines.
- In-service staff regarding the 2019 ASCCP Risk-Based Management Guidelines.
- Inform patients who are under surveillance following abnormal results that they will be managed based on updated guidelines.
- Watch for the publication of updated coding and billing policies from your payers (Medicaid, state family planning programs, Title X, commercial health plans).

References

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Other Frequently Asked Questions

1. How do I advise patients who are due for screening 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 has developed specific guidelines for females who were screened before or during the public health emergency and who have *abnormal* test results.

"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).

These recommendations can be accessed at: https://www.asccp.org//covid-19-resources

2. 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

3. How do these new guidelines transfer over to HIV patients with follow up with abnormals?

In Section K (Special Populations) of the 2019 ASCCP Guidelines, there are important management recommendations for patients with immunosuppression, including those who are HIV positive[1, pg 125]. This patient information can be entered into the app and the tool at the ASCCP website.

- In immunocompromised patients of any age, colposcopy referral is recommended for all results cytology 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.

4. 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.

5. Any changes in collection technique?

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).

6. How about the future of doing rectal cytology with the routine (cervical) cytology test?

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 training 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.

7. 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 HPV.

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".

On July 20, 2020, the American Cancer Society (ACS) published a new screening guideline entitled "Cervical cancer screening for individuals at average risk: 2020 guideline update from the American Cancer Society". It can be accessed at https://acsjournals.onlinelibrary.wiley.com/doi/full/10.3322/caac.21628

These new screening recommendations differ in 4 important respects compared with the 2012 ACS recommendations:

1. The *preferred* screening strategy is primary HPV testing every 5 years, with co-testing and cytology alone acceptable where access to US FDA-approved primary HPV testing is not yet available;
2. The recommended age to *start screening is 25 years* rather than 21 years;
3. Primary HPV testing, as well as co-testing or cytology alone when primary testing is not available, is recommended starting at age 25 years rather than age 30 years; and
4. The guideline is transitional, ie, options for screening with co-testing or cytology alone are provided but should be phased out once full access to primary HPV testing for cervical cancer screening is available without barriers.

As of this time, the current cervical cancer screening guidelines of the US Preventative Services Task Force, ASCCP, and the American College of Obstetricians and Gynecologists (ACOG) have not been modified or updated to match the 2020 guideline update of the American Cancer Society.

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