

Evidence-Based Consensus Recommendations for Colposcopy Practice for Cervical Cancer Prevention in the United States

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Abstract: The American Society for Colposcopy and Cervical Pathology (ASCCP) Colposcopy Standards recommendations address the role of colposcopy and directed biopsy for cervical cancer prevention in the United States (US). The recommendations were developed by an expert working group appointed by ASCCP's Board of Directors. An extensive literature review was conducted and supplemented by a systematic review and meta-analysis of unpublished data. In addition, a survey of practicing colposcopists was conducted to assess current colposcopy practice in the US. Recommendations were approved by the working group members, and the final revisions were made based on comments received from the public. The recommendations cover terminology, risk-based colposcopy, colposcopy procedures, and colposcopy adjuncts. The ASCCP Colposcopy Standards recommendations are an important step toward raising the standard of colposcopy services delivered to women in the US. Because cervical cancer screening programs are currently undergoing important changes that may affect colposcopy performance, updates to some of the current recommendations may be necessary in the future.

Key Words: colposcopy, biopsy, recommendations, cervical cancer, screening, evidence based

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Colposcopy is a centerpiece of cervical cancer prevention programs. Although initially developed to detect invasive cancers, colposcopy and biopsy have become diagnostic tools for women with abnormal cervical screening test results since the abandonment of immediate diagnostic conization more than half a century ago.¹ Colposcopy relies on visual characterization of the magnified cervix to guide biopsy sampling for histologic diagnosis to distinguish high-risk women who need treatment from lower-risk women who undergo surveillance according to management guidelines. Since the introduction of cytology screening followed by colposcopy, the incidence of cervical cancer in the United States (US) has decreased substantially.^{2,3}

Despite this success, the accuracy and reproducibility of colposcopy are limited.⁴ Important factors that may contribute to these limitations in the US include the following: (1) the lack of standardized terminology, (2) the lack of recommendations for colposcopy practice and procedures, and (3) the lack of quality assurance measures. Lack of standardized descriptive terminology for colposcopic practice within the US contributes to the inconsistent reporting and documentation of colposcopic findings, which in turn complicates clinical practice and makes the evaluation of colposcopy performance difficult.

Women referred to colposcopy after abnormal cervical cancer screening results have a wide range of underlying cervical

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precancer risks; however, there are currently no recommendations on how colposcopy should be performed in routine practice and modified based on an individual's risk profile. For example, the sensitivity of colposcopy for detecting prevalent precancers can be as low as 50%, especially in populations with borderline cytologic abnormalities that have been associated with small, early lesions.⁵ In these patients, traditional colposcopic findings associated with severe precancer, such as coarse vascular changes and dense acetowhitening, may not be present.⁶ Moreover, while traditional colposcopy teaching focused on grading criteria to identify the worst lesion(s) for biopsy, recent work has suggested that multiple biopsies of colposcopic abnormalities and even nontargeted biopsies of colposcopically normal cervix may improve accuracy.⁷⁻⁹ Changes in primary and secondary cervical cancer prevention are expected to further exacerbate the limitations of colposcopy accuracy and reproducibility.¹⁰ Although human papillomavirus (HPV) vaccination rates remain below the Healthy People 2020 goal of 80% in the US, HPV16 prevalence has decreased nationally among young women.¹¹ As HPV16 lesions tend to be the most visible colposcopic lesions, colposcopy performed on women with the remaining HPV types will be more difficult.^{8,12} Secondary prevention of cervical cancer in the US now includes the 3 different screening modalities: cytology, cytology-HPV co-testing, and primary HPV screening.¹³ Primary HPV screening may lead to even more challenging colposcopy, because lesions associated with persistent HPV infections without cytological abnormalities are likely to be small and harder to detect. Another area where colposcopy practice has been changing is related to a more conservative management approach for younger women, reducing colposcopy and treatment in this group.¹⁴

Colposcopy training and practice in the US are highly variable. Although limited data are available, it is likely that hundreds of thousands of colposcopies are performed in the US every year, by many different provider types including physicians, nurse midwives, nurse practitioners, and physician assistants in a number of specialties including gynecologic oncology, gynecology, family medicine, and internal medicine. Many colposcopists perform relatively few colposcopies annually, and limited experience may affect performance and outcomes.¹⁵ This is particularly important in many remote or sparsely populated areas in the US where colposcopy coverage is needed, but the number of procedures per provider is low. There is no nationwide integrated healthcare system, and there are no national screening or precancer registries, which makes implementation of program-level quality control measures and quality improvement strategies very difficult. In contrast with other regions,¹⁶ such as the United Kingdom,^{17,18} formal training, certification, and quality measurements are not in place to promote competence, and currently, there is no minimal set of colposcopic findings that must be recorded in medical records to ensure adequate documentation to help inform subsequent management.

Recognizing the limitations in accuracy and reproducibility of current colposcopy approaches in the US, and the likelihood that these limitations will continue to increase, the American Society for Colposcopy and Cervical Pathology (ASCCP), in collaboration with investigators from the US National Cancer Institute, set out to review and refine recommendations for US colposcopy practice. The goal was to develop evidence-based and expert consensus recommendations based on available evidence, focusing on the role of colposcopy in cervical cancer prevention. Emphasis was placed on approaches that provide clear objectives for training, which are feasible to implement in the current US setting, while serving as a foundation for future efforts in colposcopy training, certification, and continuing education. This article describes the approach of the Colposcopy Standards process and provides the executive summary of all recommendations, with supporting articles describing the rationale and evidence in more detail.¹⁹⁻²¹

APPROACHES AND METHODS

Development of Charges

In January 2015, ASCCP's Board of Directors initiated an effort to review current colposcopy approaches and develop recommendations to standardize colposcopy in the US. The charge was to develop evidence-based recommendations when possible and to rely on expert consensus in areas that lack supportive evidence. A steering committee was appointed, which recruited US experts in colposcopy for working groups. These groups were assigned charges in 3 areas: terminology, risk-based colposcopy, and colposcopy procedures and adjuncts.¹⁹⁻²¹

Review and Summary of Evidence, Member Survey

Literature search terms for these areas were generated at the National Cancer Institute, and reference lists were provided to the individual working groups. Between October 2015 and July 2016, working groups evaluated the literature and abstracted relevant results. For some questions related to risk-based colposcopy systematic review and meta-analysis of published and unpublished data was conducted. A survey was developed to evaluate current colposcopy practice in the US among ASCCP members and attendees of previous ASCCP meetings. The survey provided important information for the working groups focused on terminology and colposcopy procedures. The evidence review also included an in-depth assessment of international colposcopy standards^{16,18} with the goal to build on the work of other organizations and to harmonize with international standards when possible.

Development of Recommendations

Draft recommendations were developed based on the abstracted evidence and expert consensus. The recommendations were presented to the steering committee in October 2016 and reviewed for content and consistency. Revisions were presented to all working group members for discussion and further revision in January 2017, and a vote among working group members was held shortly after. Sixty-seven percent affirmative votes were required for approval of individual recommendations. All recommendations were approved at the first vote, and most were approved unanimously with only minor comments. After further editing and notification of stakeholder professional organizations, recommendations were posted on the ASCCP Web site for public comments between March 13 and 22, 2017, which resulted in additional modifications in response to the comments. Finally, recommendations were presented at the International Federation for Cervical Pathology and Colposcopy's (IFCPC) 16th World Congress in Orlando, Florida, on April 5, 2017, followed by a plenary discussion. Final revisions were made by the steering committee based on comments received at this meeting.

Guiding Principles

Several guiding principles were considered when developing the recommendations:

1. These recommendations address the role of colposcopy and directed biopsy, focusing on the cervix, for cancer prevention.
2. The recommendations were specifically developed for the US, where a wide range of healthcare professionals perform colposcopy and where some remote areas require colposcopy access for the examination of very few women per year.
3. Approaches were emphasized that could be implemented in current US settings and serve as a foundation for future improvements of colposcopy recommendations.

- There was a strong focus on generating clear and simple recommendations to facilitate training, implementation, and dissemination.
- For several recommendations, minimal practice recommendations as well as comprehensive practice recommendations are described. The minimal practice is a level necessary to adequately perform colposcopy in the US. The comprehensive practice is the level that should be achieved by most colposcopy practices in the US. The expectation is that providers currently operating below the comprehensive practice should strive to achieve the comprehensive practice level.

RECOMMENDATIONS

The following section includes the executive summary of recommendations from working groups in the areas of terminology, risk-based colposcopy, and colposcopy procedures and adjuncts. Comprehensive evidence reports from each working group supporting these recommendations are published in this issue.^{19–21}

The ASCCP Terminology for Colposcopic Practice

Approach

The ASCCP Colposcopy Standards Committee developed recommendations for standardized descriptive terminology for colposcopy practice within the US.¹⁹ The goal was to simplify and clarify reporting of colposcopic findings and to enhance standardized documentation of colposcopic appearances. An important objective of the recommendations was to have them widely adopted by US colposcopists in their diverse work environments. The 2011 IFCPC terminology was used as basis for the creation of the ASCCP terminology to allow as much consistency with international terminology as possible.²² Rather than directly adopting the full IFCPC terminology, it instead was adapted as necessary to fit colposcopic practice in the US with an additional emphasis on the facilitation of simple and clear provider-to-provider communication. The literature review focused on identifying studies that evaluated the accuracy, reproducibility, and usefulness of current terminology. The ASCCP membership survey included specific questions about the members' current use of terminology and preferences regarding updating the terminology. The survey results helped inform the modifications of the IFCPC terminology for application in the US.

1. Standardized terminology for colposcopic practice

Recommendation: The new ASCCP colposcopy terminology is summarized in Table 1. The 6 major areas include the following: (1) general assessment, (2) evaluation for presence of any acetowhite lesions, (3) description of normal colposcopic findings, (4) description of abnormal colposcopic findings, (5) description of other/miscellaneous findings, and (6) reporting of the colposcopic impression, defined as the highest-grade impression of any visible lesion on the cervix.

2. Reporting of comprehensive and minimal colposcopy criteria

Recommendation: A comprehensive colposcopic examination should include description of the cervix visibility, squamocolumnar junction visibility, presence of acetowhitening, presence and visualization of a lesion, color/contours/borders/vascular changes of lesions, the location and size(s) of lesion(s), other features, and the colposcopic impression. A diagram or marked image annotating the findings should also be included.

Minimum criteria for reporting findings at colposcopic examination should include the following: squamocolumnar junction visibility (fully/not fully), acetowhitening (yes/no), lesion (s) present (acetowhite or other) (yes/no), and colposcopic impression (normal/benign, low-grade, high-grade, cancer).

Risk-Based Colposcopy Practice

Approach

The ASCCP Colposcopy Standards Committee developed recommendations on how colposcopy practice should be modified based on “previous risk” (the severity of findings leading to colposcopic referral).²⁰ Women referred to colposcopy because of abnormal cervical cancer screening results have a wide range of underlying risk of cervical precancer. The risk can be estimated from screening and triage tests (e.g., cytology and HPV with HPV16/18 genotyping), and the colposcopic impression at the colposcopy visit. Risk markers can be combined to stratify the population and to guide how many biopsies should be taken.⁹

Many studies have shown that taking a single biopsy targeting the worst appearing lesion may miss up to one third of prevalent precancers and that taking multiple targeted biopsies substantially improves disease detection, whereas additional nontargeted biopsies (random biopsies) provide few additional benefits.^{9,23} To support the recommendations, an extensive literature review was conducted and data were pooled from published and unpublished studies for a systematic review and meta-analysis evaluating the incremental benefit of taking multiple targeted biopsies and evaluating the risk of precancer in various strata based on cytology, HPV testing, and colposcopy impression.²⁰

1. Adapting colposcopy practice to previous risk and colposcopy impression

Recommendation: Colposcopy practice may be modified based on the risk level (which can be viewed as the probability of finding precancer/cancer at the time of the procedure), based on reason for referral and colposcopy impression.

2. Number and type of biopsies taken at colposcopy

Recommendation: Multiple biopsies targeting all areas with acetowhitening, metaplasia, or higher abnormalities are recommended. Usually, at least 2 and up to 4 targeted biopsies from distinct acetowhite lesions should be taken.

3. Biopsy practice in women with low risk of precancer

Recommendation: Nontargeted biopsies are not recommended for women referred to colposcopy at the lowest end of risk, i.e., those with less than high-grade squamous intraepithelial lesion cytology, no evidence for HPV16/18, and a completely normal colposcopic impression (i.e., no acetowhitening, metaplasia, or other visible abnormality).

4. Biopsy practice in women with very high risk of precancer

Recommendation: In nonpregnant women 25 years and older with very high risk of precancer (at least 2 of the following: high-grade squamous intraepithelial lesion cytology, HPV16 and/or HPV 18 positive, high-grade colposcopy impression) either immediate excisional treatment without biopsy confirmation, or colposcopy with multiple targeted biopsies is acceptable. Endocervical sampling should be conducted according to the 2012 ASCCP Management Guidelines.¹⁴ If biopsies are taken and do not show precancer, management according to the 2012 ASCCP Management Guidelines is recommended.¹⁴

Colposcopy Procedures and Adjuncts

Approach

The ASCCP Colposcopy Standards Committee developed recommendations on how colposcopy should be performed in routine practice and on the use of adjuncts to aid colposcopy.²¹ An extensive literature review did not reveal quality evidence for or against individual elements of the colposcopy examination. Literature was also reviewed for studies on adjuncts to colposcopy, including but not limited to fluorescence, reflectance and electrical impedance spectroscopy, dynamic spectral imaging, and optical

TABLE 1. The ASCCP Terminology for Colposcopic Practice

Category	Features/criteria	Details
General assessment	Visualization of the cervix	Fully visualized/not fully visualized
	Visualization of the SCJ	Fully visualized/not fully visualized
Acetowhite changes	Any degree of whitening after application of 3%–5% acetic acid	Yes/no
Normal colposcopic findings	Original squamous epithelium: mature, atrophic	
	Columnar epithelium	
	Ectopy/ectropion	
	Metaplastic squamous epithelium	
	Nabothian cysts	
	Crypt (gland) openings	
	Deciduous in pregnancy	
	Submucosal branching vessels	
Abnormal colposcopic findings	Lesion(s) present (acetowhite or other)	Yes/no
	Location of each lesion	<ul style="list-style-type: none"> • Clock position • At the SCJ (yes/no) • Lesion visualized (fully/not fully) • Satellite lesion
	Size of each lesion	<ul style="list-style-type: none"> • No. cervical quadrants the lesion involves • Percentage of surface area of TZ occupied by the lesion
	Low-grade features	Acetowhite <ul style="list-style-type: none"> • Thin/translucent • Rapidly fading Acetowhite <ul style="list-style-type: none"> • Fine mosaic • Fine punctuation Acetowhite <ul style="list-style-type: none"> • Irregular/geographic border Acetowhite <ul style="list-style-type: none"> • Condylomatous/raised/papillary • Flat
	High-grade features	Acetowhite <ul style="list-style-type: none"> • Thick/dense • Rapidly appearing/slowly fading • Cuffed crypt (gland) openings • Variegated red and white Acetowhite <ul style="list-style-type: none"> • Coarse mosaic • Coarse punctuation Acetowhite <ul style="list-style-type: none"> • Sharp border • Inner border sign (internal margin) • Ridge sign • Peeling edges Contour <ul style="list-style-type: none"> • Flat Fused papillae
	Suspicious for invasive cancer	<ul style="list-style-type: none"> • Atypical vessels • Irregular surface • Exophytic lesion • Necrosis • Ulceration • Tumor or gross neoplasm • May not be acetowhite
	Other (nonspecific)	<ul style="list-style-type: none"> • Leukoplakia • Erosion • Contact bleeding • Friable tissue
	Lugol's staining	<ul style="list-style-type: none"> • Not used • Stained • Partially stained • Nonstained

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TABLE 1. (Continued)

Category	Features/criteria	Details
Miscellaneous findings	Polyp (ectocervical or endocervical)	
	Inflammation	
	Stenosis	
	Congenital TZ	
	Congenital anomaly	
Colposcopic impression (highest grade)	Post-treatment consequence (scarring)	
	Normal/benign	
	Low grade	
	High grade	
	Cancer	

SCJ, squamocolumnar junction; TZ, transformation zone.

coherence tomography. No high-quality randomized controlled trials or observational studies comparing colposcopy alone with colposcopy using an adjunct were found.

In the absence of any strong evidence in the literature, recommendations on colposcopy procedures and adjuncts were, therefore, developed based on expert consensus and the ASCCP member survey. The responses of those colposcopists who self-identified as performing at least 6 colposcopy examinations per month were used to form the framework for the recommendations on the elements of colposcopy practice. This framework was further developed after discussion among members of the ASCCP Colposcopy Standards Committee and after considering comments from a national electronic bulletin board and those suggested during the plenary discussion at the 2017 IFCPC meeting. The resultant components, based on expert opinion, formed the recommended elements for comprehensive colposcopic practice and the minimum practice for a colposcopy examination.

1. *Colposcopy procedures for minimally acceptable and comprehensive practice*

Recommendation: Recommended minimally acceptable and comprehensive colposcopy procedures are summarized in Table 2. Five major areas of colposcopy procedures were covered, including the following: (1) precolposcopy evaluation, (2) examination, (3) documentation, (4) biopsy sampling, and (5) postcolposcopy procedures.

2. *Evaluation of colposcopy adjuncts*

Recommendation: Current evidence is insufficient to recommend for or against the use of any adjunct in colposcopic practice.

SUMMARY AND FUTURE DIRECTIONS

The ASCCP Colposcopy Standards provide a core set of recommendations for US providers who perform colposcopy, taking into account current variations in practice settings, training, and experience. They provide guidance for colposcopy terminology, practice, and documentation and lay the groundwork for future quality improvement efforts. They are not management guidelines and are not intended to replace or update the 2012 ASCCP Guidelines for Management of Abnormal Cervical Cancer Screening Tests and cervical intraepithelial neoplasia/adenocarcinoma in situ.¹⁴ Rather, they expand on these guidelines and elucidate colposcopy practice, when it is recommended.

These recommendations were developed based on a thorough review of evidence regarding colposcopy practice, including an extensive evaluation of international colposcopy standards. An important limitation of the current effort is that for many aspects of colposcopy, very little evidence is available, preventing

recommendations for or against many specific approaches. This especially limits recommendations on requirements for biopsy instruments and on colposcopy adjuncts, areas where future research is needed.

Several approaches will be taken to accelerate implementation of the ASCCP Colposcopy Standards recommendations. The recommendations will be integrated into the ASCCP comprehensive colposcopy courses and various other colposcopy training programs. To facilitate implementation in clinical practice, the ASCCP seeks to collaborate with electronic medical record software providers to establish templates incorporating components of the recommendations. Outreach to other professional societies for general adoption is underway. Ongoing efforts will be required to monitor adherence to these recommendations, to identify barriers to implementation, and to evaluate their impact on the quality of US colposcopy practice.

While it is currently not feasible to have complete coverage with comprehensive colposcopy units across the US, identifying and facilitating retraining for clinicians who fail to follow minimum practice recommendations outlined here will ensure more consistent quality in colposcopy services. Related to that, quality indicators based on the new Colposcopy Standards have been developed in parallel.²⁴ Standardization of colposcopic practice is also an important prerequisite for developing a certification of competence. As part of ongoing efforts, the ASCCP plans to explore possible methods and opportunities for implementation of certification in colposcopy.

Cervical cancer screening programs are currently undergoing major changes. The following 3 different primary screening modalities are available in the US: cytology alone, cytology-HPV co-testing, and HPV testing alone. The choice of primary screening and triage strategies has an important impact on the populations that are referred to colposcopy, particularly regarding the previous risk of precancer and the size of lesions, which influence the ability of colposcopy to detect precancerous lesions. Importantly, current recommendations are largely based on practice from populations screened with cytology alone. In HPV-based screening programs, women referred to colposcopy with persistent HPV positivity but normal cytology may have smaller lesions that are more challenging to find during colposcopy. Going forward, it will be important to determine how new biomarkers that are being evaluated for triage of HPV-positive women, such as p16/Ki-67 and methylation,²⁵ will affect detectability of precancer at colposcopy. Similarly, increasing vaccination coverage in the population will lead to reductions of disease prevalence overall and particularly of HPV16-related precancers,²⁶ shifting the disease spectrum in colposcopy populations to precancers that are smaller and more difficult to detect. As more

TABLE 2. Colposcopy Procedures

	Comprehensive colposcopy practice	Minimum colposcopy practice
Precolposcopy evaluation	Evaluate and document at least the following: <ul style="list-style-type: none"> • Indications for colposcopy • History of cervical cytology, colposcopy, treatment • Parity • Contraception • Pregnancy status • Menopausal status • Hysterectomy status • Smoking history • HIV status • HPV vaccination status 	Evaluate and document at least the following: <ul style="list-style-type: none"> • Indications for colposcopy • Pregnancy status • Menopausal status • Hysterectomy status
Examination	Obtain informed consent Examine vulva and vagina grossly Examine the cervix with multiple magnifications after application of 3%–5% acetic acid. Examine cervix with both white light and a red-free (blue or green) filter. Examine upper vagina with magnification.	Obtain informed consent Examine vulva and vagina grossly Examine the cervix with magnification after application of 3%–5% acetic acid
Documentation	Document findings using a diagram or photograph, annotated if possible. Findings should be imported into electronic medical record. Document cervix visibility (fully/not fully visualized) Document SCJ visibility (fully/not fully visualized), and whether cervical manipulation is needed, to completely visualize the SCJ, e.g., using an applicator stick or endocervical speculum. Document colposcopic findings. <ul style="list-style-type: none"> • Acetowhitening present (yes/no) • Lesion(s) present (yes/no) • If lesion(s) present, document extent of lesion(s) visualized (fully/not fully), lesion size and location, description (color, contour, border, vascular changes). 	Document findings at least in text format. Document SCJ visibility (fully/not fully visualized). Document colposcopic findings. <ul style="list-style-type: none"> • Acetowhitening present (yes/no) • Lesion(s) present (yes/no)
Biopsy	Document a colposcopic impression (benign normal/low grade/high grade/cancer). If biopsies are indicated, take biopsies at the SCJ and document their location Document whether endocervical sampling performed and method: curette vs brush or both	Document a colposcopic impression (benign-normal/low-grade/high-grade/cancer). If biopsies are indicated, take biopsies at the SCJ Document whether endocervical sampling performed
Postprocedure	Document how patient will be notified of results and management plan	Make arrangements to notify patient of results

HPV, human papillomavirus; SCJ, squamocolumnar junction.

data become available from vaccinated women, as well as populations screened with HPV and new biomarkers, updates to some of the current recommendations may be needed.

Our extensive literature review identified important evidence gaps, highlighting the need for future research in the following areas^{19–21}:

1. Evaluation of the impact of the new colposcopy recommendations on colposcopy performance and patient outcomes.
2. Evaluation of colposcopy equipment and biopsy instruments.
3. Continued, frequent re-evaluation of the performance of new colposcopy adjuncts.
4. Re-evaluation of the indications for and performance of endocervical sampling.
5. Evaluation of colposcopy performance in women screened with HPV and cytology co-testing or HPV alone, as well as in HPV-vaccinated women.
6. Prospective evaluation of the reassurance of reduced risk of precancer from a negative colposcopy result with a multi-biopsy protocol per the recommendations.
7. Evaluation of the role of immediate excision over multiple biopsy sampling in women at highest risk of precancer.

The ASCCP, together with other stakeholders, will continue to address these issues as extensions to the current Colposcopy Standards and as part of the next screening and management guidelines.²⁷ The current recommendations represent an important step toward raising the standard of colposcopy services delivered to women in the US, thereby improving cervical cancer screening programs as a whole.

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