FAQs: Colposcopy Standardization

Why did ASCCP and US NCI undertake colposcopy standardization?

Several paths converged to drive collaboration between ASCCP and US NCI on a program of colposcopy standardization.

a. ASCCP guidelines. ASCCP management guidelines have included colposcopy as a central strategy for assessing women at risk to identify CIN2+ lesions needed treatment to prevent cancer, but the contents of a colposcopy encounter have not been well defined.
b. Utility of standardization. Since 1998, NCI, ASCCP, and others have collaborated to standardize several components of the cervical cancer prevention process, including cytology terminology (the Bethesda system), screening (ACS/ASCCP/ASCP standards), management (ASCCP guidelines), and histology terminology (LAST). Recommendations for a standardized approach to the colposcopy/biopsy encounter in the US have been missing.
c. Limited accuracy of colposcopy. Several recent studies have indicated that current screening identifies precancers earlier than older approaches, and the accuracy of colposcopy appears more limited than previously thought. For these reasons, standardization of approaches to colposcopy and biopsy became important.
d. NCI Colposcopy Study results. Between 2009 and 2012, NCI collaborated with researchers at the University of Oklahoma on a study of colposcopy and biopsy procedures, and main results as well as informative sub analyses have become available to allow risk stratification to guide the colposcopy/biopsy encounter.
e. Limited uptake of IFCPC standards in the US. In 2011, Bornstein and colleagues in the IFCPC developed international terminology for colposcopy, but the template was not adopted in the US.

What are important components of the colposcopy standardization process?

There are four components to colposcopy standardization:

a. Terminology and documentation
b. Risk-based colposcopy/biopsy: Using risk information to guide biopsy selection
c. Colposcopy process: Aspirational and core components
d. Quality parameters

What are the elements of colposcopy?

The colposcopy standards process identified two sets of colposcopy elements:

a. The core set defines the minimum to ensure competent assessment of cancer/precancer. This includes documenting the indications for examination and the patient's pregnancy/menopause/hysterectomy status, obtaining written or verbal consent, examining the vulva and vagina during speculum insertion/removal, and examining the cervix using colposcopy and 3-5% acetic acid. Findings should be documented, including presence/absence of acetowhitening and lesions, visualization of the squamocolumnar junction, and a colposcopic impression (negative/normal, low grade, high grade, cancer), along with location of any biopsies and whether ECC was done.

b. The comprehensive set defines best practices in colposcopy. It includes the core components. In addition, the comprehensive set expands the pre-colposcopy evaluation by describing cervical disease history, parity, contraception, smoking, HIV status, and HPV vaccination status. Colposcopy includes assessment at multiple magnifications with use of white light and a red-free (blue or green) filter, with examination of the upper vagina. Documentation includes a diagram or photograph. Detailed description of colposcopic findings includes lesion size, location, color, contour, border, and vascular changes, and whether the entire lesion was seen. Documentation also includes how the patient will be informed of results and follow-up recommendations.

How does a risk-based colposcopy/biopsy approach modify the colposcopy encounter?

Several studies have reported increased sensitivity of the colposcopy biopsy encounter with increasing number of biopsies. Results from the Colposcopy Biopsy Study show that compared to a single biopsy of the worst lesion, performing at least two biopsies at a colposcopy encounter increases the sensitivity of colposcopy from 60% to 85%, while additional biopsies can improve sensitivity to more than 90%.

A sub analysis showed that women in the lowest risk group (Pap ASC-US or LSIL, colposcopy impression negative, known HPV16-) have such a low risk for precancer that biopsies aren't helpful—including random biopsies. At the high end of the risk spectrum, women with two of three risk factors (high grade colposcopic impression, HSIL Pap, HPV16+), risk of precancer is so high that immediate treatment is justifiable—although multiple negative biopsies in this setting result in good negative predictive value and are sufficiently reassuring to allow observation. Nondirected biopsies of colposcopically normal cervix are not useful. However, biopsy of minimal acetowhitening is indicated to obtain high sensitivity for precancer, as many modern CIN3+ lesions are small and lack the classic features of high grade lesions.

Can risk-based colposcopy be performed when HPV genotyping is not available?

Yes, combinations of cytology and colposcopy impression can achieve similar risk stratification, e.g. in women with HSIL cytology and high grade colposcopy impression, the risk is so high that immediate treatment is justified.

At the other end of the risk spectrum, risk-based colposcopy allows deferring biopsies in women with ASC-US or LSIL cytology who have entirely normal colposcopic examinations—that is, no acetowhitening, metaplasia, or other abnormality. Very few will be HPV16+. These women can be followed according to ASCCP guidelines with co-testing in 12 months. However, biopsies are required when the colposcopic impression is negative but any degree of acetowhitening, metaplasia, or other abnormality is present. In the past these women were considered to have benign changes, but thorough biopsy has revealed CIN3+ in enough to justify biopsy. In those women, multiple biopsies are required: failing to do so risks missing CIN3+ and allowing untreated progression.

What is the role of random biopsies in colposcopy-biopsy practice?

In many studies, “random” biopsies have not been well defined. They often refer to biopsies taken of normal-appearing cervix, but these colposcopically negative areas can include acetowhitening or metaplastic areas. It is more appropriate to differentiate targeted biopsies, i.e. biopsies targeting any visible change, including acetowhitening, metaplasia, and other changes within the normal and abnormal spectrum, from completely non-targeted biopsies.

Studies that have systematically evaluated the incremental yield of non-targeted biopsies in addition to targeted biopsies have shown very limited additional benefit for detection of CIN2+. In studies with images, review of cases where disease was found with non-targeted biopsies demonstrated that in many cases, minor abnormalities were biopsied demonstrating that these were not truly untargeted biopsies, but biopsies of visible changes on the cervix below a threshold of abnormality. In women with an increased risk of precancer (indicated by screening and triage markers such as high grade cytology, HPV16/18 positivity, etc.), biopsy targets are usually present.

Based on these data, we recommend multiple targeted biopsies at a low threshold of abnormality, including areas judged to be colposcopically normal but with acetowhitening, metaplasia, or similar nonspecific changes. In women with a low risk of precancer and a completely normal cervix without any biopsy targets, random biopsies are not recommended.

What is the role of colposcopic grading?

The key element of colposcopy in the Biopsy Study appears to be identification of any acetowhitening. With subtle, small lesions, colposcopic grading does not appear to discriminate among high grade and low grade lesions. Multiple biopsies are needed to do that. Colposcopic grading may still be useful in determining where to obtain 2-4 biopsies from large lesions with classical vascular and margin characteristics. It can also be useful in identifying high risk women who might benefit from immediate triage to LEEP without intervening biopsy.

In fact, women with a high grade colposcopic impression in the context of HPV16 infection or a prior HSIL Pap are at highest risk for CIN3+ and may merit immediate treatment (though observation is acceptable if multiple biopsies are negative or CIN1).

What is the role of ECC?

The colposcopy standards process did not address utility of ECC. The 2012 ASCCP standards for ECC remain in place: ECC is preferred when no lesion is present and when the squamocolumnar junction is not fully visualized. ECC is acceptable in other circumstances.

Do colposcopy standards change the 2012 ASCCP Guidelines for Management of Abnormal Cervical Cancer Screening Tests and CIN/AIS?

No, the colposcopy standards to not change the 2012 guidelines. Rather, they define what is in the box labeled “colposcopy” in algorithms. ASCCP and NCI are collaborating on data analysis that may structure another iteration of guidelines, but that process is incomplete. For now, the 2012 guidelines remain valid.

How should colposcopy quality indicators be integrated into practice?

Colposcopy standardization is of little value if critical elements are not adopted. The purpose of integrating quality indicators into colposcopy standards is to provide practice leaders and colposcopists with benchmarks against which they can assess performance in key measures of colposcopy. Areas of deficiency should be targeted for improvement. Interventions can include colposcopist education and construction of EMR templates. Colposcopy quality indicators should be tracked in practice, ideally through coordination with practice EMRs. This should be facilitated as ASCCP works with EMR vendors to standardize colposcopy templates.

How were quality indicators selected?

Quality indicators were selected to focus practice on the critical elements of the cancer prevention process incorporated into colposcopy and follow-up.

Critical colposcopy measures include documenting visualization of the SCJ, which can define treatment and suitability for observation without treatment; presence of any acetowhite lesion; colposcopic impression; visualization of the cervix; lesion extent; lesion location; and performance of multiple biopsies.

Quality indicators also include documenting efforts to contact and expeditiously schedule women with suspected cancer or precancer. The wording acknowledges that some patients may be unreachable and standards for adequate efforts vary, but the standards document notes that multiple attempts at patient contact should be undertaken.