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# ASCCP Colposcopy Standards: Colposcopy Quality Improvement Recommendations for the United States

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## Abstract

**Objectives—**The ASCCP Colposcopy Standards recommendations address the role of and approach to colposcopy and biopsy for cervical cancer prevention in the United States. The recommendations were developed by an expert working group appointed by ASCCP's Board of Directors. The ASCCP Quality Improvement Working Group developed evidence based guidelines to promote best practices and reduce errors in colposcopy and recommended indicators to measure colposcopy quality.

**Methods—**The working group performed a systematic review of existing major society and national guidelines and quality indicators. An initial list of potential quality indicators was developed and refined through successive iterative discussions and draft quality indicators were proposed. The draft recommendations were then reviewed and commented on by the entire Colposcopy Standards Committee, posted online for public comment, and presented at the IFCPC 2017 World Congress for further comment. All comments were considered, additional adjustments made, and the final recommendations approved by the entire Task Force.

**Results—**Eleven quality indicators were selected spanning documentation, biopsy protocols, and time intervals between index screening tests and completion of diagnostic evaluation.

**Conclusions—**The proposed quality indicators are intended to serve as a starting point for quality improvement in colposcopy at a time when colposcopy volume is decreasing and individual procedures are becoming technically more difficult to perform.

### Keywords

cervical cancer; colposcopy; cervical intraepithelial neoplasia; quality assurance; quality improvement; quality of care; health care quality assessment; health care quality assurance; healthcare quality indicators; cervical squamous intraepithelial lesions

## Introduction

Variability in healthcare delivery has led to inconsistent outcomes in the United States. In 1966, Donabedian [1] published a sentinel article that proposed measuring the quality of health care through the examination of its structure, processes, and outcomes, setting into

motion multiple movements to address quality improvement and patient safety. The healthcare industry has broadened its approach to improve patient care by following quality improvement processes initiated by other industries. One major example is that of aviation, [2] which uses a collaborative approach to improve safety. The Institute of Medicine's (IOM) report "To Err is Human: Building a Safer Health System" [3] stated that up to 98,000 Americans die each year as a direct result of medical errors. In addition to morbidity and mortality, medical errors cost as much as $29 billion annually. The IOM recognized that this level of healthcare delivery related patient harm is unacceptable in the US. In response, agencies and professional societies develop and implement evidence based guidelines to promote best practices and reduce errors in medical care.

A core concept of quality improvement is the measurement of relevant outcomes, including the evaluation of outliers and the iterative refinement of contributing processes. While many countries and groups, including the United Kingdom [4], Australia [5], the European Union [6], and Canada [7] have quality improvement guidelines and measures in place for colposcopy, there are no recognized standards in the United States. To achieve these goals for colposcopy, the American Society for Colposcopy and Cervical Pathology (ASCCP) organized the ASCCP Colposcopy Standards Committee, which represented multiple disciplines (including physicians, advanced practice providers, and researchers in the disciplines of obstetrics and gynecology, family medicine, gynecologic oncology, preventive medicine, and pathology) all involved in cervical cancer screening, diagnosis, and prevention. The Standards Committee initiated a process to develop comprehensive, evidence-based recommendations to address colposcopy quality, documentation, and practice. The quality improvement working group was charged with developing guidelines for quality assurance to serve as a starting point for developing quality improvement programs in the United States.

Recognizing the limitations of current colposcopy approaches in the U.S., the American Society for Colposcopy and Cervical Pathology (ASCCP), in collaboration with investigators from the U.S. National Cancer Institute (NCI), set out to review evidence and develop recommendations for U.S. colposcopy practice. ASCCP leadership formed a steering committee, who selected additional working group members with expertise in colposcopy and guideline development.

## Methods

In developing quality indicators, the Quality Improvement Working Group performed a systematic review of existing major society and national guidelines. [8] The completed systematic review was supplemented with input from the steering committee to develop a list of proposed US quality measures and guidelines. The list of proposed US quality measures was refined through successive iterative discussions by the working group members in collaboration with the other working groups of the ASCCP Colposcopy Standards Committee. Because of the paucity of evidence and the volume of potential measures, a Delphi style method [9] augmented with group conference calls was used to derive specific proposed quality indicators for the United States. Guiding principles were created by the working group to inform the key values in guideline development (Table 1).

Specific quality indicators were chosen based on the guiding principles, availability of necessary informatics infrastructure, and anticipated ability of U.S. clinical practice settings to implement the required changes. The working group considered all of the indicators in the identified international guidelines (enumerated in the companion systematic review) as well as recommendations of the other working groups. [10] When there was no evidence to support a recommendation and international guidelines varied, criteria were selected based on expert opinion. In general, the working group began with consideration of the varying international recommendations, but was not limited to them. Expert opinion was used most frequently to determine follow-up time intervals.

The output of the working group was regularly reviewed by the steering committee for appropriateness and direction. After multiple cycles of revision, draft quality indicators were proposed by the working group 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 website for public comments between March 13–22, 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, FL on April 5, 2017, followed by a plenary discussion. Final revisions were made by the steering committee based on comments received at this meeting. Colposcopy terminology defined by the ASCCP Colposcopy Standards Committee for the U.S. was used for reporting quality indicators.

## Results

Table 2 presents the ASCCP Colposcopy Standards Committee's quality indicator recommendations. All of these indicators fall into the process category of the Donabedian model. Each indicator is presented along with a brief rationale for its inclusion and a summary of other organizations that are already using it. A total of 11 quality indicators were chosen. Both minimum and comprehensive standards are presented for most indicators. The minimum value represents the lowest performance measure that the working group determined was acceptable for a provider or colposcopy unit. The comprehensive goal was felt to be reasonably attainable and an appropriate measure for a quality colposcopy provider or unit. Instructions for determining numerators and denominators for calculating the measure are included. There are no specific minimum denominator values specified.

## Discussion

Colposcopy has been performed in the U.S. for decades without formal standards. This is at odds with many other parts of the world, where standards for colposcopy are widely implemented, measured, and enforced by professional societies and payors. [8] A number of

forces are at work that promise to make maintenance of colposcopy skills notably more difficult in the future, as procedure volume drops and difficulty increases. Procedure volume has already started to fall with the implementation of the 2012 ASCCP/ACS/ASCP Screening Guidelines [20], which increased the testing intervals and consequently, decreased the number of abnormal tests. At the University of Alabama, average monthly colposcopy volume dropped to nearly one third of its peak from 2010 to 2015. [21] With increased uptake of HPV vaccination, numbers of abnormal screening tests will decline further. Predictive values of cytology for CIN3+ already appear to be dropping in vaccinated populations.[22] Lesions associated with HPV 16 are typically more acetowhite and easier to visualize. [23] As vaccination will prevent many of these infections, lesions from the remaining HPV types will be harder to visualize at colposcopy. The ASCCP Colposcopy Standards Working Group 3 found that 32% of respondents to the ASCCP survey indicated they did fewer than 6 colposcopies per month. [24] In the setting of lower volumes of harder to perform procedures, training new providers and maintaining proficiency of existing providers will be more challenging, and quality measurement much more important.

Maintaining quality is further challenged by the varied practice settings in which colposcopy is currently performed, and the geographically and socioeconomically diverse population of women undergoing the procedure. In developing the standards we defined a set that would be applicable across practice settings, including public and private clinics, low or high volume, and insured and uninsured patients. These factors were particularly relevant to setting thresholds for follow-up, which needed to encompass both easy to reach patients with resources for follow-up testing, and potentially difficult to reach uninsured populations in public settings and rural communities.

The proposed minimum and comprehensive quality measures for colposcopic practice can be divided into two general categories. The first has to do with the documentation of minimum elements of a technically complete and clinically well-performed colposcopic evaluation. At a minimum these must include documentation of the visualization (or not) of the cervix. Additional documentation of the entire squamocolumnar junction, the presence (or absence) and location of acetowhite lesion(s) as well as whether biopsies were performed and how many must also be included. These standards should be achievable by any type of provider with any patient population in any practice setting. Efforts to incorporate these elements into templates in the electronic medical record (when available) should facilitate clinicians’ ability to meet these standards.

The second category sets minimum standards for patient follow-up in the setting of the management of cervical disease. The expectation is for documented attempts at contacting a patient with high-grade cervical cancer screening within four weeks of reported results, and to be scheduled for evaluation within four weeks of that contact. Likewise women with suspected invasive disease on laboratory report or referral should have contact attempted within two weeks, and evaluation scheduled within two weeks of that contact. Like many of the quality improving standards from other countries, the working group put a differential in the urgency of follow up based upon cytology results to allow clinics with high volumes to prioritize more severe cases. We based our goals mostly on the New Zealand recommendations, but the British, the Canadians, and others have a similar differential in

follow up scheduling. [4, 7, 13] This should help to not unduly burden high-volume safety net clinics while still increasing and measuring the quality being delivered. The guideline group appreciated that achieving these targets would be profoundly affected by the adherence of the patient population and the resources of the provider and practice setting; it accounted for this by focusing on the process of patient contact and evaluation rather than on the events. In this instance, time intervals were determined by the risk of underlying invasive cancer and the natural course of HPV disease and rather than the particulars of the range of practice settings.

The guidelines group did not set minimum numbers of procedures to review in assessing adherence with the quality measures. The guidelines groups appreciated that some units and providers may have sophisticated electronic medical records allowing global review of all colposcopy procedures performed. Other practices may still use paper charts or have electronic medical records that do not allow summary review, requiring individual records review to determine adherence with quality measures. In this setting, review of a minimum of approximately 30 procedures is likely adequate. The group was also not specific about whether the measures should be applied to individual providers or entire units. It was felt that the measures could be calculated either way depending on the organization of the practice or unit. The working group also did not make recommendations about frequency with which the indicators should be reviewed. For stable practices with minimal staff turnover, intervals of one to three years may be reasonable. For new practices or practices undergoing staff or provider changes, more frequent assessment may be required.

This iteration of the ASCCP Colposcopy Standards Committee and its working groups did not assess or address types and uses of particular colposcopy instruments or colposcopes. We only assessed the colposcopy procedures and documentation, not screening tests or treatments. It is expected that these will be addressed by future committees.

There were no patients or patient advocates on the working group. It is anticipated that when providers and clinics develop or continue to develop their quality improvement program, that there will be patients and/or patient advocates involved in the process as recommended by quality groups such as the Agency for Healthcare Research and Quality (AHRQ.) [25]

For the purposes of these quality indicators, follow up could be either with the original provider or with a provider who can continue providing care at the same or a more advanced level. The goal is to make sure patients get appropriate continuity of care. This could be with the original provider who performed testing, a partner within a practice, or with other providers who provide services that the original provider does not.

The working group examined the question of how many quality indicators to adopt. In the United States, quality improvement program is often carried out in the form of continuous quality improvement which is a process that continually assesses, improves, reassesses, and further adjusts the system (Plan, Do, Study, Act or PDSA cycles) to produce a steady and constant flow of improvement to the system. High yield, high impact quality measures are often first chosen to focus considerable resources to devote to improving outcomes. The working group decided to assume this paradigm and selected 11 measures as a starting point

for quality improvement for colposcopy. This contrasts with some national society programs where comprehensive programs with numerous quality indicators are employed. To produce a limited list of desirable indicators that would be feasible to implement in clinical settings not currently practicing quality improvement, it was necessary to exclude some potentially useful international measures. These guidelines are intended to be a starting point, especially for those clinical settings without a strong clinical quality improvement focus. The authors anticipate that as infrastructure is developed and practices and health care systems become more adept at conducting colposcopy quality improvement activities, additional helpful indicators will be added.

Other national and society guidelines included a number of standards that we chose not to include. The U.S. does not have any national data repository for cytology or histologic findings, so we did not include any indicators that required a national registry. The U.S. also does not have a unique patient identifier for its citizens, so any indicators that require cross-linking of results across health care systems were also not included. Because of the high mobility of the U.S. population, indicators that require repetitive cytology or histology data points over time to determine long term treatment and colposcopist outcomes were not included. As information systems continue to develop in the United States, future efforts may be able to reasonably include such quality indicators as have already been implemented in other countries, particularly the United Kingdom and Australia.

Although we included measures of time to first contact for women with HSIL and cancer, we did not define what should constitute adequate attempts to make contact. Systems to ensure pending tests are tracked and patients notified of results have been described. [26] Multiple efforts should be undertaken and documented in the medical record, as discussed in a 1997 guideline from the ASCCP Practice Committee; secure electronic messaging may be a component of contemporary systems for patient notification. [27]

We also did not specifically address issues related to colposcopy training. In the United States, training is not regulated by the government and there is no certification. Standards in many other countries do include training. [8] These standards generally stipulate that all clinicians who perform colposcopic examinations should have completed a formal colposcopic training program conducted by expert trained personnel whose clinical competence and teaching abilities are well-documented. This training typically included objective demonstration of core knowledge of the evaluation and management of HPV-related neoplasia and related lower genital tract disease, as well as the demonstration of clinical skills and competence based on a practical preceptored experience. This training generally occurred under the direct supervision of a competent colposcopist preceptor and should be evidence-based and include at a minimum four core components: diagnoses and management, therapeutic modalities, documentation, and maintenance of competence. We did not include training requirements in our standards. In the US, training in the traditional settings of residency, informal proctoring, or through courses put on by major societies has been considered adequate in the past, although structured curricula have been proposed and variably adopted. [28, 29] As procedural volume decreases, this is likely to change, and future iterations of these guidelines may incorporate training and maintenance of certification requirements.

We view these indicators as the first step of a set of measures that will evolve, and anticipate that ASCCP will monitor them and refine them over time. During the implementation, we anticipate that some measures, particularly documentation requirements, will be easy to comply with and over time no longer reflect quality. As electronic medical records mature, it may become easier to monitor a broader array of indicators, and tie them to outcomes on a larger scale.

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Dr. Einstein has advised, but does not receive an honorarium from any companies. In specific cases his employer has received payment for his consultation from Photocure, Papivax, Inovio, PDS Biotechnologies, Natera, and Immunovaccine. If travel is required for meetings with any industry, the company pays for Dr. Einstein's travel-related expenses. Also, his employers have received grant funding for research related costs of clinical trials that Dr. Einstein has been the overall PI or local PI for the past 12 months from Astra Zeneca, Baxalta, Pfizer, Inovio, Fujiboro, and Eli Lilly. Dr. Choma reports she is on a speaker's bureau and advisory board for Hologic, Inc. and an Advisory Board for Symbiomix Therapeutics.

## Abbreviations and acronyms

| | |
|---|---|
| **AHRQ** | Agency for Healthcare Research and Quality |
| **ASCCP** | The American Society for Colposcopy and Cervical Pathology |
| **ACS** | American Cancer Society |
| **ASCP** | American Society of Clinical Pathology |
| **CIN** | cervical intraepithelial neoplasia |
| **CQI** | continuous quality improvement |
| **HPV** | human papillomavirus |
| **HSIL** | high grade squamous intraepithelial lesion |
| **IARC** | International Agency for Research on Cancer |
| **IFCPC** | International Federation of Cervical Pathology and Colposcopy |
| **IOM** | Institute of Medicine |
| **PDSA** | Plan, Do, Study, Act |
| **WHO** | World Health Organization |

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**Table 1**

Guiding principles for colposcopy standards development

| | |
|---|---|
| **1** | Greater enforced provider record-keeping results in less time for providers to directly interact with patients. In choosing quality measures, we emphasized relevant routinely recorded clinical data that can be captured and retrieved from an electronic medical record to minimize burden on the provider and staff. |
| **2** | The minimum number of measures should be used to minimize burden on providers. A minimum number of measures should be adequate for a number of reasons. There is likely to be a high degree of correlation between quality measures. Providers who do well on 5–6 key measures will probably do well on others. There is no data that increasing the number of measures would improve outcomes compared to a smaller number of measures. A number of potentially important measures were considered, but not included to ensure the total number of measures was manageable. |
| **3** | Outcome measures should be reliably "measurable" and reinforce optimal clinical outcomes. |
| **4** | At present, the measures are intended for self-monitoring and improvement, and were not developed with public reporting in mind. In the future, there may be a need for reporting of quality measures to outside entities such as healthcare payers including the Center for Medicare and Medicaid Services, and the measure proposed here may be used to inform future requirements. |
| **5** | The list of measures will not be static, and there will be opportunities to revise them in the future as some measures become routinely complied with and new ones become relevant. |

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**Table 2**

Proposed Minimum and Comprehensive Quality Measures for the Colposcopic Examination

| Recommendation | Context/background | Calculation for provider or unit | Minimum Target | Comprehensive Target | References and notes |
|---|---|---|---|---|---|
| 1. Document that squamo-columnar junction is visualized (fully visualized/ not fully visualized) | Adequate visualization at the time of colposcopy is important in managing abnormal screening tests. Lack of documentation may impact current or future management. | Numerator: Number colposcopy notes with documentation of visualized (fully/ not) Denominator: Number total colposcopies performed by individual provider or group | 90% | 100% | European Federation of Colposcopy 2013 [6], Massad et al. [11], WHO/ IARC 2003 [12], New Zealand 2013 [13] Germany 2015 [14] |
| 2. Documentation of whether any acetowhite lesion is present (yes/no) | Documentation of the presence of a lesion is important in correlating cytology, histology, clinical impression and clinical management. Lack of documentation can alter management and lead to suboptimal outcomes | Numerator: Number colposcopy notes with documentation of lesion present Denominator: Number total colposcopies performed by individual provider or group | 90% | 100% | Massad et al. [11], British 2016, New Zealand 2013 [13], Italy 2006 [15] |
| 3. Documentation of colposcopic impression (normal/benign; low grade; high grade; cancer) | Documentation of colposcopic impression is clinically important and is a quality assurance and precision metric for colposcopy | Numerator: Number colposcopy notes with documentation of colposcopic impression Denominator: Number total colposcopies performed by individual provider or group | 80% | 100% | Massad et al. [11], WHO/ IARC 2003 [12], New Zealand 2013 [13] Germany 2015 [14] |
| 4. Documentation of cervix visibility (fully visualized, not fully visualized) | Adequate visualization of the cervix at the time of colposcopy is important in management of abnormal screening tests. Lack of documentation may result in over or under treatment of abnormal findings. | Numerator: Number colposcopy notes with documentation of adequate visualization of the cervix at the time of colposcopy Denominator: Number total colposcopies performed by individual provider or group | 70% | 100% | Britain 2016 [4] WHO/ IARC 2003 [12], New Zealand 2013 [13], |
| 5. Documentation of extent of lesion visualized (fully/partial) | Adequate visualization of the extent of the lesion(s) at the time of colposcopy is important in management of abnormal screening tests. Partial visualization of the lesion(s) can alter management. Lack of documentation may result in over or under treatment of abnormal findings. | Numerator: Number colposcopy notes with documentation of visualization of extent of any/all lesion(s) or no lesion Denominator: Number total colposcopies performed by individual provider or group | 70% | 100% | Britain 2016 [4] WHO/ IARC 2003 [12], New Zealand 2013 [13], |
| 6. Documentation of location of lesion(s) | Knowledge of the location of the cervical lesions and size of the lesion allows the practitioner to tailor any necessary extirpative procedure to the abnormal pathology. Lack of documentation may result in overly large or inadequate cervical excision. | Numerator: Number colposcopy notes with documentation of location of the lesion(s) or no lesion Denominator: Number total colposcopies performed by individual provider or group | 0% | 100% | New Zealand 2013 [13] |
| 7. Provider should take multiple biopsies targeting all areas with acetowhitening, metaplasia or higher abnormalities (at least two and up to four biopsies) | A single biopsy, targeting the worst appearing lesion may miss up to a third of prevalent precancers. | Numerator: Number colposcopy notes with documentation of any acetowhite lesion and 2 to 4 biopsies taken OR a biopsy and endocervical sampling taken. Denominator: Number colposcopy notes with documentation of any acetowhite lesion | 85% | 100% | Britain 2016 [4], Canada 2012 [7], Gage JC, et al [16] Stoler MH, et al. [17], Pretorius RG, et al. [18] Wentzensen N, et al. [19] |
| 8. An attempt should be made to contact a patient with suspected | Optimally a patient with suspected invasive disease should be seen as soon as possible after the | Numerator: Number of patients with suspected invasive disease with | 60% | 90% | New Zealand 2013 [13], Expert/committee opinion. |

| Recommendation | Context/background | Calculation for provider or unit | Minimum Target | Comprehensive Target | References and notes |
|---|---|---|---|---|---|
| invasive disease * within 2 weeks of receipt of report or referral. | diagnosis has been confirmed. Multiple factors may impact the ability to complete that contact among patients with a high acuity abnormality were identified including: 1) screening environment 2) insurance status 3) health literacy 4) social/cultural/ language barriers | attempted contact within 2 weeks Denominator: Number of patients with suspected invasive disease | | | |
| 9. Patients with suspected invasive disease * should be seen within 2 weeks of contact. | Time to definitive treatment for invasive cervix cancer is associated with improved outcomes. Therefore, timely evaluation, diagnosis and referral is integral to appropriate care and patients should be provided prompt treatment. | Numerator: Number of patients with suspected invasive disease seen within 2 weeks of contact Denominator: N of patients with suspected invasive disease | 60% | 90% | New Zealand 2013 [13], Expert/committee opinion. |
| 10. An attempt should be made to contact a patient with high grade cytology results ** within 4 weeks of receipt of report or referral. | Patients with high grade cytology results ** have a risk of CIN2+ of >10%. Therefore, timely evaluation is critical for diagnosis and management of dysplastic disease. | Numerator: Number of patients with high-grade cytology results ** with attempted contact within 4 weeks Denominator: Number of patients with high grade cytology results | 60% | 90% | New Zealand 2013 [13], Expert/committee opinion. |
| 11. Patients with high grade cytology results ** should be seen within 4 weeks of contact. | See #9. | Numerator: Number of patients with high-grade cytology results ** seen within 4 weeks of contact Denominator: N of cytology tests with high grade disease | 60% | 90% | New Zealand 2013 [13], Expert/committee opinion. |

* Suspected invasive disease includes cytology tests with neoplasia or suspected neoplasia or with clinical suspicion for invasive disease.

** A high grade cytology result includes any of the following cytology results: High-grade Squamous Intraepithelial Lesion, Atypical Squamous Cells: Cannot Exclude High-grade Squamous Intraepithelial Lesion, Atypical Glandular Cells

Contact is defined as communications by any HIPAA compliant means for the purpose of informing the patient of the status of their clinical investigation and the plan for their continued follow up. The communication should document a response from the patient acknowledging the future plan, acknowledging understanding of the information being discussed, and documentation of the interaction.