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ASCCP Clinical Guidance Document Standardization

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Abstract: The American Society for Colposcopy and Cervical Pathology (ASCCP) provides practice guidance for clinicians caring for patients with lower genital tract conditions. The ASCCP wants to ensure that its library of guidance documents is current, evidence based, and easy for clinicians to use. Guidance documents should present clear, actionable evidence-based management recommendations where the quality of the evidence and the strength of the recommendation are clearly identified. This document explains ASCCP's new standard document types and the processes for their development and maintenance, as well as the process for selecting new topics.

Key Words: ASCCP, clinical guidance, clinical documents, guidelines

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The American Society for Colposcopy and Cervical Pathology (ASCCP) educational mission is to improve clinician competence and performance outcomes through educational activities focused on the study, prevention, diagnosis, and management of anogenital and human papillomavirus (HPV)-related diseases. To accomplish this mission, ASCCP provides clinical practice guidance for clinicians caring for patients with lower genital tract concerns. The process for developing this guidance and the format in which it is presented continues to evolve.

Previous ASCCP guidance documents were developed in a wide array of formats including Management Consensus Guidelines, Practice Standards, Expert Opinions, Task-Force Endorsements/ Recommendations, and Practice Guidelines (Table 1). While the guidelines for the management of abnormal cervical screening tests and the colposcopy standards projects followed similar established processes and formats, other documents did not. The organization does not have a fully standardized process for determining when guidance documents are out of date and should be withdrawn or updated. The management guidelines have been periodically updated in a way that has kept them current and met the needs of patients and clinicians, but there has not been a clearly defined process for determining when they should be updated. The organization has also produced several "white papers" where a panel of authors is selected and tasked to write on a specific topic of interest. Authors are given general guidance regarding process and final format, but this guidance has not been consistent. There has not been a standardized approval process for the finished document, creating the potential for confusion as to whether the final document constitutes organizational guidance.

To address these issues, ASCCP is standardizing document types and their development process, consistent with the standards set by the Institution of Medicine (IOM 2011) and similar to those produced by other clinical professional organizations.[1–3] This document explains ASCCP's new standard document types and the processes for their development and maintenance, as well as the process for selecting new topics.

TYPES OF GUIDELINES

ASCCP Guidelines

These documents are meant to provide comprehensive evidence-based guidance on key clinical topics. They contain ASCCPS's most certain recommendations. They are developed using a rigorous process including thorough literature review and assessment, using systematic review methods whenever possible. To be a guideline document, adequate evidence must be available to address most covered clinical questions. Expert opinion may be used to fill key gaps, but this must be a small part of the document and clearly identified. Recommendations are made based on strength of evidence. The 2019 Risk-Based Management Consensus Guidelines for Abnormal Cervical Cancer Screening Tests and Cancer Precursors were created before the new document formats were established but meets the intent of the new guideline type in terms of comprehensiveness, evidence base, and actionable recommendations qualified by strength.[4]

ASCCP Clinical Consensus

These documents are developed when there is insufficient evidence for an ASCCP Guideline document. In general, these documents will cover specific topics or areas where recommendations are necessary but there is inadequate quality evidence. These documents will be developed with a systematic evidence review, but significant gaps in the evidence are anticipated and will be filled as necessary with evidence extrapolated from related areas or expert opinion. The ASCCP Clinical Consensus: Screening Recommendations for Clear Cell Adenocarcinomas in People Exposed to Diethylstilbestrol (DES) In Utero were developed in accordance with the new document types as our first ASCCP Clinical Consensus document.[5] This document format was appropriate for DES recommendations because it is a lower genital tract problem affecting a significant group of people where screening and management recommendations are clearly necessary. However, useful published direct evidence is lacking, leading to the need for supplementation with extrapolation and expert opinion in multiple areas.

Practice Advisory

These documents are meant to aid clinicians by providing awareness or guidance regarding emerging clinical issues, such as updates related to new health risks, release of relevant guidance from other organizations, new drugs or devices, or regulatory changes. These issues are typically time sensitive, so are drafted and released quickly. They include the most important evidence, but given the rapid cycle of their development, do not include exhaustive systematic reviews. They are typically 1-page documents and do not undergo public comment. They are meant to provide interim information while formal evidence-based guidance is created. Examples include Management Recommendations During the Coronavirus Pandemic, which provided guidance for modifying the evaluation of abnormal screening tests during the COVID-19 outbreak and the recent Practice Advisory on anal cancer screening.[6]

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TABLE 1. Past Clinical Documents Published by the ASCCP

Year published	Document title
2024	ASCCP Practice Advisory: Anal Cancer Screening
2024	ASCCP Clinical Consensus: Screening recommendations for cervical and vaginal clear cell adenocarcinomas in people exposed to DES in utero
2024	Cervical Cancer Prevention in Individuals With Criminal Legal System Involvement
2023	ASCCP Committee Opinion: Adjuvant Human Papillomavirus Vaccine for Patients undergoing Treatment for Cervical Intraepithelial Neoplasia
2023	Colposcopy Standards: Guidelines for Endocervical Curettage at Colposcopy
2023	Understanding Sexual and Gender Minority Populations and Organ-Based Screening Recommendations for Human Papillomavirus–Related Cancers
2021	ASCCP Cervical Cancer Screening Task Force Endorsement and Opinion on the American Cancer Society Updated Cervical Cancer Screening Guidelines
2020	A Systematic Review of Tests for Postcolposcopy and Posttreatment Surveillance
2019	2019 ASCCP Risk-Based Management Consensus Guidelines for Abnormal Cervical Cancer Screening Tests and Cancer Precursors
2019	Guidelines for Cervical Cancer Screening in Immunosuppressed Women Without HIV Infection
2017	Evidence-Based Consensus Recommendations for Colposcopy Practice for Cervical Cancer Prevention in the United States
2017	ASCCP Colposcopy Standards: Role of Colposcopy, Benefits, Potential Harms, and Terminology for Colposcopic Practice
2017	ASCCP Colposcopy Standards: How Do We Perform Colposcopy? Implications for Establishing Standards
2017	ASCCP Colposcopy Standards: Colposcopy Quality Improvement Recommendations for the United States
2017	ASCCP Colposcopy Standards: Risk-Based Colposcopy Practice
2016	A common clinical dilemma: Management of abnormal vaginal cytology and human papillomavirus test results
2013	The Lower Anogenital Squamous Terminology Standardization project for HPV-associated lesions: background and consensus recommendations from the College of American Pathologists and the American Society for Colposcopy and Cervical Pathology
2012	American Cancer Society, American Society for Colposcopy and Cervical Pathology, and American Society for Clinical Pathology screening guidelines for the prevention and early detection of cervical cancer
2012	2012 updated consensus guidelines for the management of abnormal cervical cancer screening tests and cancer precursors
2009	Update on ASCCP consensus guidelines for abnormal cervical screening tests and cervical histology
2007	2006 consensus guidelines for the management of women with abnormal cervical screening tests
2002	ASCCP Patient Management Guidelines: Pap Test Specimen Adequacy and Quality Indicators
2002	2001 Consensus Guidelines for the Management of Women with Cervical Cytological Abnormalities

Systematic Review

Systematic reviews may be performed during the development of ASCCP Guidelines and Clinical Consensus documents, particularly in areas where no prior systematic review has been conducted. These systematic reviews may be published as companion documents to support the recommendations. They will adhere to PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines. The ASCCP may choose to conduct systematic reviews separate from guideline document development in areas where a systematic summary of evidence may be of use to clinicians. Examples of potential areas could include efficacy of new diagnostic techniques and risk factor and epidemiology topics. See Table 2 for complete details on the types of ASCCP clinical documents.

NEW TOPIC SELECTION

Creation of new Guideline and Clinical Consensus documents and revision of existing ones will require significant time and resources, limiting the number of topics that can be completed each year. The number of new topics will be determined by ASCCP leadership based on available resources. The number of new topics will also depend on the number of existing topics needing revision.

Members can nominate potential new topics through the ASCCP web site. Topic suggestions will also be solicited from the board and practice committee. The list of nominated topics will be reviewed annually by the Clinical Practice Committee. New topics will be prioritized based on several factors including:

- Aligns with the ASCCP mission.
- Addresses gaps in knowledge or management impacting individuals affected by anogenital and HPV-related diseases.
- Has the potential to mitigate or eliminate inequities in health care and remove barriers to improve health outcomes.
- Has the potential to affect clinical practice.

The Clinical Practice Committee will recommend the highest priority topics to the board for approval to move forward with Guideline and Clinical Consensus document creation.

Practice Advisory topics will be determined by the ASCCP president, who may obtain input from board members, stakeholders, or content experts to determine high impact topics of immediate interest to the membership.

DOCUMENT DEVELOPMENT AND APPROVAL

Guideline and clinical consensus document development is intended to adhere to National Academy of Medicine Standards for developing trustworthy clinical practice guidelines whenever possible.[1] Guideline and clinical consensus documents will follow similar development processes for areas where substantial data exist. The Practice Committee will outline the clinical questions to be covered in the document. The practice committee will recruit a writing team with skills in evidence review and requisite content expertise. Authors will determine PICO (patient/population, intervention, comparison, outcomes) criteria for performing a systematic search.[7] Clinical questions and PICO criteria will be posted for a 30-day public comment period. Authors will conduct the systematic review and develop recommendations. Recommendations and ratings will be presented in the format used in the 2019 ASCCP Risk-Based Management Consensus Guidelines for Abnormal Cervical Cancer Screening Tests and Cancer Precursors[4] (Table 3). When adequate direct data is not available, the authors will search and use indirect data and supplement with expert opinion as necessary. When this is done, it will be made clear in the

TABLE 2. ASCCP Clinical Documents

	ASCCP guideline	ASCCP clinical consensus	Practice advisory	Systematic review
Example(s)	Management guidelines	Incarcerated populations; DES	COVID-19 statement, USPSTF guideline release	
General description	Evidence-based guidance on key topics. Developed following process consistent with best practices (e.g., https://www.nationalacademies.org/our-work/standards-for-developing-trustworthy-clinical-practice-guidelines as possible)	Expert-based guidance when available evidence insufficient for evidence-based guideline, but guidance still necessary	Rapidly developed (ideally ready for dissemination approximately 4 wk after assignment to authors) document to raise awareness about time-sensitive clinical issue	Systematic review of relevant literature meeting PRISMA guidelines for process and publication. Does not include management recommendations, but may make recommendations for future research.
Topic selection process	Annual solicitation of potential topics from membership, practice committee, and exec board. Practice committee recommends topic list to board with modification/approval by board.	Annual solicitation of potential topics from membership, practice committee, and exec board. Practice committee recommends topic list to board with modification/approval by board.	President with advice of executive board as necessary.	Annual solicitation of potential topics from membership, practice committee, and exec board. Practice committee recommends topic list to board with modification/approval by board.
Development process	Practice committee outlines specific clinical questions to be covered in guideline. Authors/consensus panel follows guideline development (will need to define and create description for publication or posting on web site) process as close to https://www.nationalacademies.org/our-work/standards-for-developing-trustworthy-clinical-practice-guidelines as possible (COI management, public comment, systematic review, transparent recommendation statement development process, etc.). Develop targeted timeline for project completion.	Practice committee chooses authors to do full literature review of available direct and indirect evidence, draft recommendation, and provide guidance and rationale. Specific questions to be addressed in opinion outlined by practice committee. Develop targeted timeline for project completion.	Author(s) designated by president with option to delegate to practice committee	Practice committee outlines specific clinical questions to be covered in review. Authors/review panel follows process consistent with PRISMA guidelines to search, review, and summarize literature. When appropriate, meta-analysis may be performed. Draft document will be posted for public comment and final document reviewed and approved by practice committee and board.
Public comment	Completed document will be posted on ASCCP web site in draft format for 30 d after initial approval by practice committee and board. Public comments to be reviewed by practice committee and writing team with revisions as appropriate and general response to public comments summarized in brief "response to public comment" section in final document submitted to board for final approval.	Completed document will be posted on ASCCP web site in draft format for 30 d after initial approval by practice committee and board. Public comments to be reviewed by practice committee and writing team with revisions as appropriate and general response to public comments summarized in brief "response to public comment" section in final document submitted to board for final approval.	No public comment.	Completed document will be posted on ASCCP web site in draft format for 30 d after initial approval by practice committee and board. Public comments to be reviewed by practice committee and writing team with revisions as appropriate and general response to public comments summarized in brief "response to public comment" section in final document submitted to board for final approval.

TABLE 2. *(Continued)*

	ASCCP guideline	ASCCP clinical consensus	Practice advisory	Systematic review
Authorship	Practice committee chooses authorship team, ranging from small group to full consensus process. Authors should have no significant financial or intellectual COI, and any potential COI needs disclosure. Some (preferably all) authors need expertise in evidence review. Authors would preferably be ASCCP members except for joint documents with other societies.	Practice committee chooses authorship team, typically a small group. Authors should not have significant financial COI, and any potential COI needs disclosure. Some (preferably all) authors need expertise in evidence review. Content expertise needs to be assessed carefully by committee to minimize bias. Authors would preferably be ASCCP members except joint documents with other societies.	Single author or small group of ASCCP members, with management/ disclosure of COI.	Practice committee chooses authorship team, with size depending on scope of review. Authors should have no significant financial or intellectual COI, and any potential COI needs disclosure. Some (preferably all) authors need expertise in evidence review. Authors would preferably be ASCCP members except for joint reviews with other societies.
Document format	Introduction; methods (if we have a consistent process, could post on web site to shorten this section); clear recommendations statements with summary of strength of evidence and recommendation (GRADE or management guideline format) followed by summary of relevant evidence and discussion of evidence and implementation considerations.	Introduction; methods (if we have a consistent process, could post on web site to shorten this section); clear recommendations statements with GRADE or other summary of strength of evidence and recommendation followed by summary of any direct or indirect evidence and discussion of implementation considerations. When recommendation is largely expert opinion-based, clear discussion of rationale for recommendation.	Generally 1-page document with references as appropriate.	To meet PRISMA guidelines for publication of systematic reviews (PRISMA statement [prisma-statement.org]).
Approval process	Reviewed and revised by practice committee (some consensus and joint documents may not allow revision). Recommendation for approval made to board. Final approval or return to practice committee by board. Acknowledgement of board's review and acceptance within the document.	Reviewed and revised by practice committee (some consensus and joint documents may not allow revision). Recommendation for approval made to board. Final approval or return to practice committee by board. Acknowledgement of board's review and acceptance within the document.	Approved by exec committee, with notification of board.	Reviewed and revised by practice committee. Recommendation for approval made to board. Final approval or return to practice committee by board. Acknowledgement of board's review and approval within the document.
Maintenance/review process	Review by practice committee every 2 y with determination of withdrawal/ revision/reaffirmation. Reaffirmations noted on web site.	Review by practice committee every 2 y with determination of withdrawal/revision/ reaffirmation. Reaffirmations noted on web site.	Periodic review with removal from web site when determined to be no longer relevant/correct	Review by practice committee every 2 y with determination of withdrawal/ revision/reaffirmation. Reaffirmations noted on web site. Withdrawn documents referred back to practice committee for assessment of whether update should be performed.
Dissemination	JLGTD - possibly open/free access. Ideally, posted on web site.	JLGTD - possibly open/free access. Ideally, posted on web site.	E-mail to membership/ No expectation to publish in Journal. Posted on website.	JLGTD - possibly open/free access. Ideally, posted on web site.

TABLE 3. Rating the Recommendations

Strength of recommendation
A. Good evidence for efficacy and substantial clinical benefit support recommendation for use.
B. Moderate evidence for efficacy or only limited clinical benefit supports recommendation for use.
C. Evidence for efficacy is insufficient to support a recommendation for or against use, but recommendations may be made on other grounds.
D. Moderate evidence for lack of efficacy or for adverse outcome supports a recommendation against use.
E. Good evidence for lack of efficacy or for adverse outcome supports a recommendation against use.
Quality of evidence
I. Evidence from at least 1 randomized, controlled trial.
II. Evidence from at least 1 clinical trial without randomization, from cohort or case-controlled analytic studies (preferably from more than 1 center), or from multiple time-series studies, or dramatic results from uncontrolled experiments.
III. Evidence from opinions of respected authorities based on clinical experience, descriptive studies, or reports of expert committees.
Terminology used for recommendations
Recommended. Good data to support use when only 1 option is available
Preferred. Option is the best (or one of the best) when there are multiple options
Acceptable. One of multiple options when there is either data indicating that another approach is superior or when there are no data to favor any single option
Not recommended. Weak evidence against use and marginal risk for adverse consequences
Unacceptable. Good evidence against use

summary of the quality of evidence and strength of recommendation. Guideline documents will rely on systematic reviews whenever possible. When published systematic reviews are not available, the development team will conduct them in a manner that will satisfy PRISMA requirements for publication.[8] Systematic reviews done for document development will be published as separate articles or on-line appendices. Systematic reviews may also be developed separate from guidance document development. In this instance, the reviews will be conducted to meet PRISMA guidelines for publication.

Given the rapidity with which a Practice Advisory must be developed and short document length, systematic reviews will not be feasible. Authors are expected to do a literature review as part of the document development and ensure that the final document includes any highly relevant publications.

Draft Guideline and Clinical Consensus documents will undergo an initial review by the Practice Committee. Drafts may be revised by the Practice Committee or returned to the author team with comment for revision. After approval by the Practice Committee the document will be sent to the ASCCP Board of Directors for review and preliminary approval. The Board may approve the document or return it to the Practice Committee with comments for further revision. After initial approval by the Board of Directors, Guideline and Clinical Consensus documents will be posted for public comment. Comments will be reviewed by the Practice Committee, who may make revisions based on the public comment or refer the document to the original authors for revision. The revised document will be reviewed and given final approval by the ASCCP Board. Documents developed jointly with other organizations will be reviewed under the conditions of the document development agreement. Any document that is not acceptable to the Practice Committee or Board will not be published as an ASCCP guidance document.

Practice advisories will undergo an expedited approval process by the ASCCP Executive Committee who will notify the Board of Directors. The Executive Committee may work with the authors regarding necessary revisions.

MAINTENANCE

The ASCCP guidance documents will be reviewed regularly to ensure that they remain current and accurate. Guideline and Clinical Consensus documents will be reviewed every 2 years by the Practice Committee. The review will include an interim literature search, and based on this, the Practice Committee will determine if the document should be reaffirmed, withdrawn, or revised. Should a revision be necessary, the Practice Committee will determine whether the existing document can stay in place while the new document is developed, or whether it should be withdrawn. Documents may be withdrawn without being revised if it is determined that the topic is no longer of sufficient relevance. Documents may be reviewed ahead of schedule if the Practice Committee becomes aware of relevant new studies, new guidelines, or disruptive new technologies that may make substantive information in the document out of date. Practice Advisories will be withdrawn 1 year after posting.

DISSEMINATION OF DOCUMENTS

It is ASCCP's goal to ensure that members have easy access to guidance documents and that these documents are available to all clinicians. Practice advisories will be emailed to the membership and posted on the ASCCP web site. The ASCCP guidelines, systematic reviews, and clinical consensus documents will be published in the Journal of Lower Genital Tract Disease. These documents will also be posted on the clinical document section of the ASCCP web site. The web site will contain the entire library of active documents including the timing of their last review and reaffirmation. Withdrawn documents will be removed from the web site.

CONCLUSION

ASCCP has significantly revised their guidance document format and standardized their development process to achieve several aims:

- Standardized document types that correspond to the breadth and quality of evidence and recommendations.

- Standardized document formats and recommendation statements for ease of clinician use.
- Regular review process to ensure documents remain current and outdated documents are withdrawn.
- Standardized new topic selection process to ensure the library of documents is expanded to encompass the full range of high impact clinical areas.

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