

American College of Emergency Physicians Clinical Policy Development

Clinical policies are Board-approved documents describing the College's policy on the clinical management of specific topics. Clinical policies are evidence-based with evidence grading and weighting according to a rating scheme. There is a systematic review of the evidence with evidence tables.

Funding for ACEP's clinical policies is provided by ACEP, or in some instances, under contract from such entities as the Centers for Disease Control and Prevention, or the Emergency Medical Services for Children Program. Companies* are not permitted to participate in nor provide direct support for the development, or initial publication, or distribution of ACEP's clinical policies.

ACEP's clinical policies are developed based on the best available scientific evidence. When the medical literature does not contain enough quality information to answer a critical question, a statement is added to alert the reader of the lack of evidence.

Suggestions for a clinical policy topic can come from individual members, internal groups or staff, external constituencies, or in response to the external environment.

The Board of Directors approves topics for future clinical policy development, taking into consideration the potential for major impact on health care outcomes, such as areas of high risk, high frequency, or high cost, available resources, and existing and future College activities and priorities. Assignment of the task of developing a clinical policy is achieved through the normal committee process.

Once a topic has been approved and assigned, the Clinical Policies Committee posts the approved topics for open comment from the membership on areas to focus on within the topics. Pertinent critical questions are drafted in PICO (Patient, Intervention, Comparison, Outcome) format by an assigned Clinical Policies Subcommittee with input from ACEP's Quality and Patient Safety Committee and the Board of Directors. The critical questions are then approved by the Clinical Policies Committee.

A Clinical Policies Subcommittee consists of committee members and noncommittee members ideally with expertise in the topic. The Clinical Policies Committee has a process for identifying and managing conflicts of interest for committee and subcommittee members. The subcommittee provides criteria for the literature search. The literature search is conducted by a professional librarian. The subcommittee reviews the search results and selects articles for further review. Staff obtains the selected articles and makes them available to the subcommittee. The subcommittee reviews the articles and determines if the articles are pertinent to the question and should be graded or used as background material. The articles selected for grading are sent to the methodologists. The subcommittee prepares an initial draft evidentiary table without the Class of evidence noted. The methodologists finalize the drafting of the evidentiary table after grading is completed. All articles used in the formulation of a clinical policy are independently graded by at least two methodologists and assigned a Class of Evidence. The methodologists assign design classes to each article, with design 1 representing the strongest study design and subsequent design classes (eg, design 2, design 3) representing respectively weaker study designs for therapeutic, diagnostic, or prognostic studies, or meta-analyses. Articles are then graded on dimensions related to the study's methodological features, such as randomization processes, blinding, allocation concealment, methods of data collection, outcome measures and their assessment, selection and misclassification biases, sample size, generalizability, data management, analyses, congruence of results and conclusions, and conflicts of interest. Using a predetermined process combining the study's design, methodological quality, and applicability to the critical question, articles receive a Class of Evidence grade. An adjudication process involving discussion with the original methodologist graders and at least one additional methodologist is then used to address any discordance in original grading, resulting in a final Class of Evidence assignment (ie, Class I, Class II, Class III, or Class X). Articles identified with fatal flaws or ultimately determined to not be applicable to the critical question receive a Class of Evidence grade "X" and are not used in formulating recommendations in a policy. However, content in these articles may have been used to formulate the background and to inform expert consensus in the absence of robust evidence. Grading is done with respect to the specific critical questions; thus, the Class of Evidence for any one study may vary according to the question for which it is being considered. As such, it is possible for a single

article to receive a different Class of Evidence rating when addressing a different critical question. Question-specific Class of Evidence grading is included in the Evidentiary Table with each policy.

The results of the evidence grading are provided to the subcommittee. The subcommittee then reviews the evidence grading and if there is disagreement, the methodologists and subcommittee members collaborate to reach an agreement. Based on the strength of the evidence grading for each critical question, the subcommittee drafts the recommendations and the supporting text synthesizing the evidence using the following guidelines:

Level A recommendations. Generally accepted principles for patient care that reflect a high degree of clinical certainty (ie, based on evidence from 1 or more Class of Evidence I or multiple Class of Evidence II studies).

Level B recommendations. Recommendations for patient care that may identify a particular strategy or range of strategies that reflect moderate clinical certainty (ie, based on evidence from 1 or more Class of Evidence II studies or strong consensus of Class of Evidence III studies).

Level C recommendations. Recommendations for patient care that are based on evidence from Class of Evidence III studies or, in the absence of any adequate published literature, based on expert consensus. In instances where consensus recommendations are made, “consensus” is placed in parentheses at the end of the recommendation.

The recommendations and evidence synthesis are then reviewed and revised by the Clinical Policies Committee, which are informed by additional evidence or context gained from reviewers.

There are certain circumstances in which the recommendations stemming from a body of evidence should not be rated as highly as the individual studies on which they are based. Factors such as consistency of results, uncertainty about effect magnitude, and publication bias, among others, might lead to a downgrading of recommendations.

When possible, clinically oriented statistics (eg, likelihood ratios, number needed to treat) are presented to help the reader better understand how the results may be applied to the individual patient.

Once the Clinical Policies Committee has approved the subcommittee draft, it is distributed for expert review and open comments to emergency physicians, external health providers, professional medical associations with knowledge in the subject area, ACEP’s Quality and Patient Safety Committee, ACEP’s Medical Legal Committee, any other internal committees or groups to which the topic is pertinent, and the ACEP Board of Directors and Council Officers. It is also posted for a 60-day period of open public comments. Comments from the expert review/open comment period are carefully reviewed by the committee and changes made in the draft when there is quality evidence to support a change.

The finalized draft is submitted to the Board of Directors for approval. Once approved, the clinical policy is posted to the ACEP Web site and submitted for publication in *Annals of Emergency Medicine*. The availability of the clinical policy is announced in an ACEP publication, such as *ACEP Now*. The approved clinical policy is also submitted to the ECRI Institute for abstraction.

Additional implementation tools, such as mobile applications, are developed for clinical policies as appropriate.

Clinical policies are scheduled for review every 3 years; however, interim reviews are conducted when technology or the practice environment changes significantly.

ACEP’s clinical policies are not intended to represent a legal standard of care for emergency physicians. Recommendations offered are not intended to represent the only diagnostic or management options available to

the emergency physician. ACEP recognizes the importance of the individual physician's judgment and patient preferences. The guideline provides clinical strategies for which medical literature exists to answer the critical questions addressed in the policy.

*Company: A company is a for-profit entity that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, and alleviate health conditions.