

POLICY IMPLEMENTATION:

A NEW DOCUMENT TYPE – THE CLINICAL STATEMENT

The American Thoracic Society (ATS) has adopted a new document type, the “clinical statement”, to accompany its current portfolio of clinical practice guidelines, policy statements, research statements, technical statements, and workshop reports. A clinical statement is allowed to make clinical recommendations and, therefore, is the only document type other than clinical practice guidelines that is allowed to do so. Clinical recommendations refer to recommendations about which population to treat, which treatment to use, which population to test, and which diagnostic test to use.

All projects that seek to make clinical recommendations will be approved as clinical practice guidelines with the expectation that existing ATS rules for guideline development will be followed. However, each project intending to make clinical recommendations will be reviewed by the chair and vice-chair of the Documents Development and Implementation Committee (DDIC), Chief of Documents, Documents Editor, and chairs of the relevant assembly and assembly planning committee shortly after approval of the project for appropriateness for completion as a clinical practice guideline or as a clinical statement. Appropriateness for completion as a clinical practice guideline or a clinical statement will be determined on a case-by-case basis. Considerations will include the following:

- Goals – is the primary intent to influence payer reimbursement, to improve the uniformity of care, or something else? [Regulatory and payment implications favor a guideline]
- Scope – will several focused recommendations suffice or is a broader spectrum of recommendations necessary? [A broad scope favors a clinical statement, whereas a focused scope favors a guideline]
- Urgency – is there an urgent need for clinical guidance? [An urgent need favors a clinical statement, whereas lack of urgency favors a guideline]
- Progress made – Have most of the intended questions been addressed or only a few questions? [More progress to date favors completion as a guideline, whereas less progress favors rescue as a clinical statement]
- Severity and frequency of the problems – Is the disease being addressed rare and mild, or is it common and life threatening? [Common and/or severe diseases favor a guideline, whereas rare and/or mild diseases favor a clinical statement]
- Breadth and quality of available evidence – Is the evidence scarce and poor, or it abundant and robust? [Less evidence or poorer evidence favors a clinical statement, whereas more evidence or better evidence favors a guideline]
- Return on ATS investment – Are the potential benefits of the document appropriate for its cost so far? [A decreasing return on investment favors rescue as a clinical statement]

- Chair preferences – Do the chairs wish to finish quickly as a clinical statement or persist as a guideline? Are they willing to exert the effort and expend the time necessary to complete a guideline?

Clinical practice guideline projects will also be reviewed at the end of the first year and every six months thereafter. Clinical practice guidelines that at any of those stages are deemed subpar or unacceptably delayed (i.e., not submitted for peer review after two years) will be reviewed for transition to a clinical statement, facilitating less demanding and more rapid completion. The budgets for any guidelines that are transitioned to clinical statements will be appropriately curtailed.

The fundamental, non-negotiable requirement of a clinical statement will be that each clinical recommendation is accompanied by explicit descriptions of both the rationale for the recommendation and the evidence supporting the recommendation. Developers will not be expected to perform a systematic review of the evidence, pragmatic or otherwise, thus distinguishing the clinical statement from an Institute of Medicine Standards-adherent guideline. Recommendations will still be expected to be written and rated using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach, although exceptions may be made if approved by the DDIC. Any guideline project that is transitioned to a clinical statement will be closely overseen by the Documents Editor, with the goal of submission within six months of conversion from a guideline to a clinical statement. Clinical statements will include a sentence that indicates that the document is intended as a placeholder, not a substitute, for a clinical practice guideline.