General

Guideline Title

Bibliographic Source(s)

Guideline Status
This is the current release of the guideline.


Recommendations

Major Recommendations

The grades of recommendation (1A–2C) and the approach to rating the quality of evidence are defined at the end of the "Major Recommendations" field.

Pathologic Staging

When pathologically diagnosing patients with lung cancer, the synoptic reporting of histologic type, tumor size and location, tumor grade (if appropriate), lymphovascular invasion, pleural involvement, surgical margins, and status and location of lymph nodes is recommended (Grade 1B).

Malignant Mesothelioma vs Adenocarcinoma

In individuals with pleural-based tumors, a designated limited panel of histochemical and immunohistochemical assays or ultrastructural analysis is recommended to distinguish between pleural adenocarcinoma and malignant mesothelioma in order to increase diagnostic accuracy (Grade 1B).

Small Cell vs Non-small Cell Carcinoma

In individuals with parenchymal-based tumors, distinguishing between small cell carcinoma and non-small cell carcinoma of the lung is recommended. For challenging cases, a diagnostic panel of immunohistochemical assays or ultrastructural analysis is recommended to increase the diagnostic accuracy (Grade 1B).

Adenocarcinoma, Adenocarcinoma in situ (AIS) (Bronchioloalveolar Carcinoma), and Minimally Invasive Adenocarcinomas (MIAs)
For individuals with glandular producing tumors, distinguishing AIS and MIAs from invasive adenocarcinomas is recommended (Grade 1C).

**Remark**: Pathologic discrimination among these diagnostic entities are made on complete review of the tumor and not on needle biopsies.

**Adenocarcinoma vs Squamous Cell Carcinoma of the Lung**

In individuals with pathologically diagnosed non-small cell lung cancer (NSCLC), additional discrimination between adenocarcinoma and squamous cell carcinoma, even on cytologic material or small tissue samples, is recommended (Grade 1B).

**Remark**: The precise subclassification is achieved in most cases by conventional histo- and cytomorphology. Immunohistochemical assays are recommended in cases where routine histopathologic differentiation is difficult to ascertain.

**Primary vs Metastatic Lung Cancer**

For individuals with lung tumors whose differential includes primary lung carcinoma vs metastatic carcinoma, a directed panel of immunohistochemical assays is recommended to increase the diagnostic accuracy (Grade 1C).

**Definitions**

**Strength of the Recommendations Grading System**

<table>
<thead>
<tr>
<th>Grade of Recommendation</th>
<th>Benefit vs. Risk and Burdens</th>
<th>Methodologic Quality of Supporting Evidence</th>
<th>Implications</th>
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<td><strong>Strong recommendation, high-quality evidence, Grade 1A</strong></td>
<td>Benefits clearly outweigh risk and burdens or vice versa</td>
<td>Consistent evidence from randomized controlled trials (RCTs) without important limitations or exceptionally strong evidence from observational studies</td>
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<td>Benefits clearly outweigh risk and burdens or vice versa</td>
<td>Evidence for at least one critical outcome from observational studies, case series, or from RCTs with serious flaws or indirect evidence</td>
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<tr>
<td><strong>Weak recommendation, high-quality evidence, Grade 2A</strong></td>
<td>Benefits closely balanced with risks and burden</td>
<td>Consistent evidence from RCTs without important limitations or exceptionally strong evidence from observational studies</td>
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**Clinical Algorithm(s)**

None provided
Scope

Disease/Condition(s)
Lung cancer

Guideline Category
Diagnosis
Evaluation
Management

Clinical Specialty
Family Practice
Oncology
Pathology
Pulmonary Medicine
Radiation Oncology
Thoracic Surgery

Intended Users
Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Nurses
Patients
Physicians
Psychologists/Non-physician Behavioral Health Clinicians
Social Workers

Guideline Objective(s)
- To inform the clinical decisions that must be jointly made by physicians and patients in developing diagnostic, treatment, and management plans so that they can enhance the benefits and reduce the harms associated with various options
- To provide evidence-based background and recommendations for the development of American College of Chest Physicians guidelines for the diagnosis and management of lung cancer

Target Population
Patients with lung cancer

Interventions and Practices Considered

1. Pathological diagnosis of lung cancer that includes staging information and biological behavior of the tumor
2. Distinguishing between pleural adenocarcinoma and malignant mesothelioma
3. Distinguishing between small cell carcinoma and non-small cell carcinoma
4. Distinguishing between adenocarcinoma in situ (AIS) and minimally invasive adenocarcinomas (MIAs)
5. Discrimination between adenocarcinoma and squamous cell carcinoma
6. Immunohistochemical assays

Major Outcomes Considered

Pathologic examination results

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

A systematic search of the medical and scientific literature using EMBASE, MEDLINE, and Cochrane Library search engines was performed for the years 1990 to 2011, and results were limited to literature on humans and articles written in English. The search was performed as a review and update of the "Diagnostic Surgical Pathology of Lung Cancer: ACCP Evidence-Based Clinical Practice Guidelines (2nd Edition)."

The searches were performed by an American College of Chest Physicians (ACCP) methodologist, and the authors supplemented these searches with a review of references from relevant reviews and other pertinent literature. The searches were performed to respond to the following population, intervention, comparison, and outcome questions:

1. Among patients with lung cancer, what pathologic findings should be reported?
2. Among pleural-based malignancies, what approach and tests should be performed for diagnostic accuracy?
3. Among lung cancers, what approach and tests should be performed to distinguish small cell and non-small cell carcinoma?
4. Among glandular malignancies, what diagnostic criteria should be performed to separate adenocarcinoma in situ (AIS), minimally invasive adenocarcinoma (MIA), and invasive adenocarcinoma?
5. Among non-small cell cancers, what approach and tests should be performed to distinguish squamous cell carcinoma from adenocarcinoma?
6. Among cancers of the lung, what approach and tests should be performed to distinguish primary vs metastatic cancers?

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Not Given)
Rating Scheme for the Strength of the Evidence
Not stated

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Assessment of Study Quality
Systematic reviews and meta-analyses were assessed using Documentation and Appraisal Review Tool (DART) (R. L. Diekemper; B. K. Ireland, MD; and L. R. Merz, PhD, MPH, DART, unpublished data, 2012), which was developed as an improved alternative to the existing tools for use in a clinical setting. However, this tool has been adopted for use in American College of Chest Physicians (ACCP) guidelines and consensus statements since 2011.

Quality was assessed for each study as well as for the body of relevant evidence. Based on the population, intervention, comparator, and outcome (PICO) questions and volume of available literature, multiple study designs were included in the systematic reviews of the literature. Randomized controlled trials (RCTs) primarily indicate benefits, but whenever observational studies met inclusion criteria they were often helpful in identifying harms. Observational studies were also examined when RCTs were not available to answer a particular PICO question. Allowing for multiple study designs resulted in the need for multiple quality assessment tools. Tools were chosen for assessing RCTs, observational studies, and diagnostic studies. The quality assessment tool for RCTs (R. L. Diekemper, B. K. Ireland, and L. R. Merz, unpublished data, 2012) was used for assessing the quality of RCTs, and a tool developed by the committee of the ninth edition of the Antithrombotics Guidelines was used for assessing the quality of observational studies. Diagnostic studies were assessed using the Quality Assessment Tool for Diagnostic Accuracy Studies (QUADAS).

Meta-analyses
If a recently published good-quality meta-analysis was available, then it was used to inform the recommendations. When a good-quality meta-analysis was not available, guideline authors were encouraged to perform their own meta-analyses. Meta-analyses were performed when the data were fairly homogeneous. If a study was deemed poor quality, then it was not included in the pooled analysis. Heterogeneity of the pooled results was assessed using a $\chi^2$ test and Higgins $I^2$, and a forest plot was examined for consistency of the results. The random effects model was chosen a priori as the appropriate model for pooling the data because it accounts for heterogeneity among the included studies. Results from the meta-analyses are available in the supplementary materials that can be downloaded from the Journal website under the corresponding article in the table of contents.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Panel Composition and Responsibilities
A call for applications to serve on the 3rd edition of the American College of Chest Physicians (ACCP) Lung Cancer Guidelines (LC III) panel was put forth to the ACCP membership, to past panelists, and to other organizations that have previously endorsed earlier editions of these guidelines or appointed representatives to serve on those panels. Guiding the team was the LC III Executive Committee, composed of a Panel Chair, Vice Chair, Liaison to the Guidelines Oversight Committee (GOC), and two staff members, one serving as an adviser and the other as the lead methodologist. The GOC appointed the Liaison and the Chair, who was required to be free of conflicts of interest (COI). This Executive Committee provided general oversight and guidance; multiple reviews of research questions, article outlines, manuscripts, evidence tables, and other supporting documents; and facilitation of the final conference discussions and voting. As the scope was defined, content experts in each...
Discussions generally resulted in agreement on both the quality of the evidence and strength of the recommendations. As the evidence reviews were completed and the tables and profiles prepared, the manuscripts and recommendations were drafted. Members of the Final Conference values and preferences likely would play an increasingly greater role in determining the best treatments or interventions for each patient. However, recommendations that do attain this score are those for which the panel could state with confidence that new studies would be unlikely to change the direction of the effect. These recommendations apply to most patients in most circumstances. But as the grades decline, patient values and preferences likely would play an increasingly greater role in determining the best treatments or interventions for each patient.

**Formulating the Recommendations**

In most cases the topic editors, along with the other completely non-conflicted members of the article committee, formulated the recommendations. The summarized evidence tables and profiles (where profiles existed) provided the foundation for the recommendations. In formulating the recommendations, panelists considered not only the body of evidence but also the balance between the benefits and harms and considerations of other factors, such as cost or resource availability considerations and patient values and preferences, which might vary widely for some recommendations. These additional considerations are described in a Remarks section, which appears just below the relevant recommendation in the publication, each time the recommendation appears.

**Grading the Recommendations**

Recommendations that are strong must be differentiated from those that are weak or weaker. Thus, the ACCP Grading System was used (see the "Rating Scheme for the Strength of the Recommendations" field), and the wording of the recommendations is explicit. This grading system has been used since 2005 and is based on two dimensions: the balance of benefits to harms and the quality of the evidence base. If the benefits clearly outweigh the harms or the harms clearly outweigh the benefits, the strength of the recommendation is considered strong and graded as a 1. In most cases, when there is strong confidence that the benefits outweigh the harms, most patients would choose the intervention endorsed in that recommendation. However, when the trade-offs between desirable and undesirable consequences are not as clear, variability in patient preferences and values often becomes germane to the decision-making conversation.

Weak recommendations are those for which the benefits and harms are more equally balanced, and thus a clear choice is not as obvious; these are graded with a 2. Strong recommendations are phrased, "the panel recommends," whereas weak recommendations are phrased "the panel suggests." Accompanying these indications of the strength of a recommendation is a letter score (A, B, or C) representing the grading of the body of relevant literature.

In grading the quality of the evidence, RCTs start with a high score but might be downgraded to moderate or even low based on the following criteria: limitations in the study design or conduct of the trial, imprecision, indirectness relative to the specifics of the PICO question, inconsistency in the results, and risk of reporting bias. Observational studies, on the other hand, start off as low-level evidence but can be upgraded to moderate or even high if exceptionally large and consistent treatment effects increase confidence in the findings, especially if there is a strong dose-response gradient.

The final grades are combinations reflecting the strength of the recommendation and the quality of the evidence. Strong recommendations with high quality evidence, grade of 1A, are less common than in past editions of these guidelines, since the evidence is assessed with greater rigor for most topics, and few studies without important limitations are available.

However, recommendations that do attain this score are those for which the panel could state with confidence that new studies would be unlikely to change the direction of the effect. These recommendations apply to most patients in most circumstances. But as the grades decline, patient values and preferences likely would play an increasingly greater role in determining the best treatments or interventions for each patient.

**The Final Conference**

As the evidence reviews were completed and the tables and profiles prepared, the manuscripts and recommendations were drafted. Members of the article committees convened by phone or e-mail to discuss the evidence and work on drafting and grading the recommendations. These discussions generally resulted in agreement on both the quality of the evidence and strength of the recommendations.
The manuscripts and supporting tables were then reviewed by members of the Executive Committee and, after several iterations, the revised versions were shared among all panelists and the representatives of invited organizations in advance of the conference. The other panelists and representatives were asked not only to provide feedback but also to review the recommendations to identify any controversies. A recommendation was deemed to be controversial if at least one person disagreed with the wording or the grading, if there was controversy in practice, if there were wide variations in practice, or if at least one person asked that it be discussed among the broader panel and association representatives. These identified controversies composed the main agenda for the conference.

See the "Methodology for Development of Guidelines for Lung Cancer" (see the "Availability of Companion Document field" for more information.

### Rating Scheme for the Strength of the Recommendations

#### Strength of the Recommendations Grading System

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### Cost Analysis

American College of Chest Physicians (ACCP) guidelines include consideration of resources in recommendations under selected circumstances. If it is likely that resource considerations would impact the direction or strength of a recommendation, a search for cost-effectiveness studies may have been conducted. Most recommendations in these guidelines do not include a full assessment of resource considerations. However, they can be adapted to middle- and low-income countries using the ADAPTE strategies.
Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Internal and External Peer Review

Once Executive Committee approval was received, the articles were submitted to American College of Chest Physicians (ACCP) staff for several layers of review. All reviewers were required to undergo a full conflict of interest (COI) appraisal before being approved. In the first round of reviews, the Thoracic Oncology NetWork reviewed the content of the manuscripts and the members of the Guidelines Oversight Committee (GOC) assessed the manuscripts for adherence to the methodology and conformance with the evidence. The ACCP President also appointed members of the Board of Regents to evaluate the guidelines in depth. All comments were collated into spreadsheets to ensure that they were appropriately answered. GOC and board reviewers discussed each comment and determined which should be mandatory for the authors to amend and which were provided as suggestions for improvement. All reviews and comments were anonymous, and authors were required to respond to all mandatory issues either by revising the manuscripts or providing written justification explaining why they did not agree with the reviewers' comments.

The revised manuscripts were submitted for round II review, simultaneously with the Journal peer review. Once the GOC and board reviewers approved the manuscripts, the ACCP President, President Elect, President Elect Designee, and Immediate Past President reviewed the guidelines. Approval was granted pending confirmation from the Board of Regents, before submission to the journal for final review by the Journal Editor. In addition to this extensive review process, which included nearly 30 individual reviewers from the ACCP leadership, external organizations were provided with opportunities to provide feedback before, during, and just after the conference. This final version was submitted for consideration for endorsement to all of the invited organizations, whether or not they sent representatives to the conference. However, once the guidelines were approved by the ACCP Board of Regents, no further changes were accepted. Organizations that provided endorsements are listed in each article.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate diagnostic surgical pathology in lung cancer

Potential Harms

Not stated

Qualifying Statements

- American College of Chest Physicians (ACCP) guidelines are intended for general information only, are not medical advice, and do not
replace professional medical care and physician advice, which always should be sought for any medical condition. The complete disclaimer for this guideline can be accessed at the CHEST Web site.

- Although the ACCP is moving toward the production of evidence profiles for all guideline recommendations, there were many recommendations for which profiles were not developed, mostly because of resource constraints. When possible, methodologists created evidence profiles, and all panelists were educated on how to read and interpret them. The population, intervention, comparator, and outcome (PICO)-based systematic literature review process was followed for most recommendations, but there were some that could have benefited from meta-analyses.

- One limitation of all guidelines today is that they are not able to adequately address complex patients with multiple morbidities. This is largely because these patients are generally excluded from clinical trials and are often not included in observational studies. Since guidelines are reliant on evidence published in the peer-reviewed literature, the scientific foundation impedes the process of providing good guidance for these patients and is a limitation in these guidelines. Therefore, the ACCP encourages funding agencies to ensure that topics with limited evidence are addressed in future research.

### Implementation of the Guideline

#### Description of Implementation Strategy

**Dissemination and Implementation**

These guidelines are widely disseminated through the CHEST journal publication, National Guidelines Clearinghouse, and Guidelines International Network library. Additional clinical resources will soon be available to users of CHEST Evidence, an upcoming tool for searching the content of America College of Chest Physicians (ACCP) guidelines.

As the expanding research into diagnostic techniques and treatment options continues to evolve, the guidelines must be updated and kept current. This edition of the ACCP Lung Cancer Guidelines will be the last to be published as a complete collection, as the ACCP is now embarking on a new living guidelines model (LGM) for revising existing recommendations and developing new recommendations as the literature evolves. This will include a continual assessment of the currency of these recommendations relevant to new research studies as they are published. The review cycle for the ACCP Lung Cancer Guidelines will begin 1 year after publication unless the content experts who monitor the literature bring a recommendation or set of related recommendations to the attention of the Guideline oversight Committee (GOC), suggesting that those recommendations are in need of updating sooner. The new LGM will permit a more nimble approach to guideline development but also requires a point-of-care accessible vehicle, CHEST Evidence, for the users to readily search for the most current version. These features will be described in greater detail in upcoming publications. As a step in this direction, these guidelines will be published primarily online with a printed version of the Executive Summary, containing all of the recommendations, the introduction, and this article on methodology. All narratives for each article with their supporting tables, figures, and algorithms will be available online at [journal.publications.chestnet.org](http://journal.publications.chestnet.org).

#### Implementation Tools

**Mobile Device Resources**

**Patient Resources**

**Quick Reference Guides/Physician Guides**

**Resources**

For information about availability, see the Availability of Companion Documents and Patient Resources fields below.

### Institute of Medicine (IOM) National Healthcare Quality Report Categories

**IOM Care Need**
Identifying Information and Availability

Bibliographic Source(s)


Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2007 Sep (revised 2013 May)

Guideline Developer(s)

American College of Chest Physicians - Medical Specialty Society

Source(s) of Funding

- The development of this guideline was supported primarily by the American College of Chest Physicians (ACCP). The lung cancer guidelines conference was supported in part by a grant from the Lung Cancer Research Foundation. The publication and dissemination of the guidelines was supported in part by a 2009 independent educational grant from Boehringer Ingelheim Pharmaceuticals, Inc.
- Role of sponsors: The ACCP was solely responsible for the development of these guidelines. The remaining supporters played no role in the development process. External supporting organizations cannot recommend panelists or topics, nor are they allowed prepublication access to the manuscripts and recommendations. Further details on the Conflict of Interest (COI) Policy are available online at http://chestnet.org.
- See the methodology companion (see the "Availability of Companion Documents" field) for a complete discussion of the source of funding for this guideline.

Guideline Committee

American College of Chest Physicians (ACCP) Expert Panel on Lung Cancer Guidelines

Composition of Group That Authored the Guideline

Authors: Arnold M. Schwartz, MD, PhD, FCCP; M. Katayoon Rezaei, MD
Financial Disclosures/Conflicts of Interest

- Conflicts of Interest (COI) grids reflecting the conflicts of interest that were current as of the date of the conference and voting are posted in the online supplementary materials.
- Financial/nonfinancial disclosures: The authors have reported to CHEST that no potential conflicts of interest exist with any companies/organizations whose products or services may be discussed in this article.
- See the methodology companion (see the "Availability of Companion Documents" field) for a complete discussion of the conflict of interest procedures and requirements for the guideline panel.

Guideline Endorser(s)

American Association for Bronchology and Interventional Pulmonology - Medical Specialty Society
European Society of Thoracic Surgeons - Professional Association
Oncology Nursing Society - Professional Association
Society of Thoracic Surgeons - Medical Specialty Society

Guideline Status

This is the current release of the guideline.

Guideline Availability

Available to subscribers of Chest - The Cardiopulmonary and Critical Care Journal. Also available to Chest subscribers through the Chest app for iPhone and iPad.

Print copies: Available from the American College of Chest Physicians, Products and Registration Division, 3300 Dundee Road, Northbrook IL 60062-2348.

Availability of Companion Documents

The following are available:


