Complete Summary

GUIDELINE TITLE

Community-acquired pneumonia in adults.

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Community-acquired pneumonia in adults. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2006 May. 36 p. [37 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Community-acquired pneumonia in adults. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2005 May. 40 p.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse (NGC): This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- July 08, 2008, Fluoroquinolones (ciprofloxacin, norfloxacin, ofloxacin, levofloxacin, moxifloxacin, gemifloxacin): A BOXED WARNING and Medication Guide are to be added to the prescribing information to strengthen existing warnings about the increased risk of developing tendinitis and tendon rupture in patients taking fluoroquinolones for systemic use.

COMPLETE SUMMARY CONTENT

** REGULATORY ALERT **
SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
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IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY
DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Community-acquired pneumonia

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Risk Assessment
Treatment

CLINICAL SPECIALTY

Family Practice
Infectious Diseases
Internal Medicine
Pulmonary Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Health Plans
Hospitals
Managed Care Organizations
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To improve the assessment of need for hospitalization for patients with community-acquired pneumonia (CAP)
- To improve the selection of appropriate treatment for patients with pneumonia based on risk factors
- To increase the appropriate use of chest x-ray to improve the accuracy of diagnosis of community-acquired pneumonia

TARGET POPULATION

Patients 16 years and older with community-acquired pneumonia in an outpatient setting

This guideline excludes patients with human immunodeficiency virus (HIV) infection and pneumonia in immunocompromised patients.

INTERVENTIONS AND PRACTICES CONSIDERED

Evaluation/Diagnosis/Risk Assessment

1. Physical examination
2. Medical history
3. Chest x-ray
4. Assessment of patient risk for community-acquired pneumonia-related morbidity and mortality (pneumonia severity index) using a 2-step prediction rule based on patient age, comorbidities, physical exam, and laboratory findings
5. A three-step process to evaluate the initial site of treatment (inpatient vs. outpatient) including assessing co-existing conditions that require hospitalization, pneumonia severity index, and clinical judgment

Management/Treatment

1. First-line antibiotics for younger, previously healthy patients with no comorbidities:
    - Macrolides such as azithromycin alone or with amoxicillin-clavulanate
    - Respiratory fluoroquinolone, such as moxifloxacin or levofloxacin (if a macrolide has been recently received)
    - Cautious use of doxycycline (Note: increasing resistance to doxycycline in *Streptococcus pneumoniae* limits the usefulness of this agent)

    Note: The following drugs were considered, but not recommended as first-line antibiotics because of inefficacy, lack of sufficient data, and/or safety profile: gatifloxacin, gemifloxacin, ciprofloxacin, erythromycin, clarithromycin, and telithromycin.

2. First-line antibiotics for patients of older age and/or other comorbidities or risk factors
    - Amoxicillin/clavulanate + Azithromycin
    - Second-generation cephalosporin (cefuroxime axetil, cefpodoxime, cefprozil) + macrolide
    - Fluoroquinolones (e.g., moxifloxacin or levofloxacin)
3. Antibiotics for aspiration pneumonia:
    - Amoxicillin-clavulanate
    - Clindamycin
4. Antibiotics for nursing home patients:
    - Amoxicillin-clavulanate + azithromycin
    - Respiratory fluoroquinolone
5. Antibiotics for patients with recent influenza and possible superinfection:
    - Amoxicillin-clavulanate
    - Cefpodoxime, cefprozil, cefuroxime
    - Respiratory fluoroquinolone
    - Note: This empiric coverage recommendation does not cover methicillin-resistant *Staphylococcus aureus* (MRSA)
6. Patient education
7. Follow-up

MAJOR OUTCOMES CONSIDERED

Diagnosis

Diagnostic test performance, as measured by sensitivity, specificity, predictive value (positive and negative), and accuracy

Risk Stratification via Prediction Rule

- 30-day hospital mortality
- Overall mortality
- Length of hospital stay and need for intensive care unit admission
- Late admissions to hospital
- Functional status
- Time to return to work or normal routine
- Patient satisfaction

Treatment

- Erythromycin and clarithromycin interactions with drugs that can increase their serum levels
- Sudden cardiac death

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Key conclusions (as determined by the work group) are supported by a conclusion grading worksheet that summarizes the important studies pertaining to the conclusion. Individual studies are classed according to the system presented below, and are designated as positive, negative, or neutral to reflect the study quality.

Conclusion Grades:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results of different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

Study Quality Designations:

The quality of the primary research reports and systematic reviews are designated in the following ways on the conclusion grading worksheets:

Positive: indicates that the report or review has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis.

Negative: indicates that these issues (inclusion/exclusion, bias, generalizability, and data collection and analysis) have not been adequately addressed.

Neutral: indicates that the report or review is neither exceptionally strong nor exceptionally weak.

Not Applicable: indicates that the report is not a primary reference or a systematic review and therefore the quality has not been assessed.

Classes of Research Reports:

A. Primary Reports of New Data Collection:

   Class A:

- Randomized, controlled trial

Class B:

- Cohort study

Class C:

- Nonrandomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

Class D:

- Cross-sectional study
- Case series
- Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports:

Class M:

- Meta-analysis
- Systematic review
- Decision analysis
- Cost-effectiveness analysis

Class R:

- Consensus statement
- Consensus report
- Narrative review

Class X:

- Medical opinion

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Clinical Validation-Pilot Testing
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Institute Partners: System-Wide Review

The guideline draft, discussion, and measurement specification documents undergo thorough review. Written comments are solicited from clinical, measurement, and management experts from within the member medical groups during an eight-week period of "Critical Review."

Each of the Institute's participating medical groups determines its own process for distributing the guideline and obtaining feedback. Clinicians are asked to suggest modifications based on their understanding of the clinical literature coupled with their clinical expertise. Representatives from all departments involved in implementation and measurement review the guideline to determine its operational impact. Measurement specifications for selected measures are developed by the Institute for Clinical Systems Improvement (ICSI) in collaboration with participating medical groups following general implementation of the guideline. The specifications suggest approaches to operationalizing the measure.

Guideline Work Group: Second Draft

Following the completion of the "Critical Review" period, the guideline work group meets 1 to 2 times to review the input received. The original guideline is revised as necessary, and a written response is prepared to address each of the suggestions received from medical groups. Two members of the Respiratory Steering Committee carefully review the Critical Review input, the work group responses, and the revised draft of the guideline. They report to the entire committee their assessment of two questions: (1) Have the concerns of the medical groups been adequately addressed? (2) Are the medical groups willing and able to implement the guideline? The committee then either approves the guideline for pilot testing as submitted or negotiates changes with the work group representative present at the meeting.

Pilot Test

Medical groups introduce the guideline at pilot sites, providing training to the clinical staff and incorporating it into the organization's scheduling, computer, and other practice systems. Evaluation and assessment occur throughout the pilot test

phase, which usually lasts for three months. Comments and suggestions are solicited in the same manner as used during the "Critical Review" phase.

The guideline work group meets to review the pilot sites' experiences and makes the necessary revisions to the guideline, and the Respiratory Steering Committee reviews the revised guideline and approves it for implementation.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse (NGC) and the Institute for Clinical Systems Improvement (ICSI): In addition to updating their clinical guidance, ICSI has developed a new format for all guidelines. Key additions and changes include: combination of the annotation and discussion section; the addition of "Key Points" at the beginning of most annotations; the inclusion of references supporting the recommendations; and a complete list of references in the Supporting Evidence section of the guideline. For a description of what has changed since the previous version of this guidance, refer to "Summary of Changes -- May 2006."

The recommendations for the management of community-acquired pneumonia in adults are presented in the form of algorithms, with 23 components, accompanied by detailed annotations. Algorithms are provided for: Community-Acquired Pneumonia in Adults and Outpatient Management. Clinical highlights and selected annotations (numbered to correspond with the algorithms) follow.

Class of evidence (A-D, M, R, X) and conclusion grade (I-III, Not Assignable) definitions are repeated at the end of the "Major Recommendations" field.

Clinical Highlights

- All patients suspected of having pneumonia should have a chest x-ray to confirm this diagnosis. (*Annotation #3*)
- Use of a clinical prediction rule (a scoring system that determines a Risk Class level based on age, comorbidities, physical, and lab findings) is strongly encouraged to help determine whether or not hospitalization is indicated. (*Annotations # 6, 7*)
- Young and otherwise healthy patients who can be safely treated as outpatients will usually respond to azithromycin. Doxycycline should be used with caution because of increasing resistance to this agent, and reserved for use when other options are not available. Older patients, or those with substantial comorbidities, will usually respond well to combinations of a beta lactam agent (such as high dose amoxicillin/clavulanate) plus a macrolide. Newer generation recommended (so-called "respiratory") fluoroquinolones can be used as first-line agents but should be reserved for use in higher risk or drug intolerant patients in order to slow the emergence of resistance to this class of drugs. (*Annotations #10, 14, 18, 20, 22*)

Community-Acquired Pneumonia in Adults Algorithm Annotations

2. **Schedule Provider Visit**

An urgent provider visit should be scheduled if patient has two or more of the following complaints of lower respiratory tract infection:

- Rigors*
- Pleuritic chest pain*
- Shortness of breath*
- Chest tightness*
- Deep cough**
- Sputum production
- Fever over 100 degrees Fahrenheit lasting more than 72 hours
- Night sweats
- Wheezing

*The presence of any one of these symptoms may be reason enough for an emergency visit.

**Cough is the number one presenting complaint in outpatient medicine. In unselected ambulatory patients with acute cough, pneumonia is present in fewer than 10% of cases.

Supporting evidence is of class: C

3. **Obtain Chest X-Ray**

Key Points:

- A chest x-ray is essential in confirming the diagnosis of pneumonia.
- In circumstances in which a chest x-ray is not obtained, the recommendations in this guideline (Pneumonia diagnosed - Annotation #6) still apply.

A chest x-ray is essential in confirming the diagnosis of pneumonia. It is also helpful in assessing prognosis. Because of bacterial resistance and the need to avoid unnecessary use of antibiotics, it is important to try to confirm a diagnosis of pneumonia whenever possible. A chest x-ray may also assist the hospitalization decision.

The work group agrees with the expert opinion of the Infectious Disease Society of America (IDSA) and American Thoracic Society (ATS) that favors obtaining a chest x-ray for confirmation of pneumonia. At a minimum, it is prudent to obtain a chest x-ray in patients over 40 years old, patients with chronic obstructive pulmonary disease, asthma, and other comorbid illnesses, and in smokers. In the event a chest x-ray is not obtained and a presumptive diagnosis of pneumonia is made based on a clinical judgment, then the recommendations outlined in "Pneumonia Diagnosis" (Algorithm Annotation # 6) still apply.

If a pleural effusion is present on the initial chest x-ray, then a decubitus film should be considered to determine the amount of the effusion. Pleural

effusions in patients with community-acquired pneumonia (CAP) should be followed. Thoracentesis should be considered if clinically indicated, especially when the effusion layers out to more than 2 cm on a decubitus film.

Evidence supporting this recommendation is of classes: C, M

4. **Chest X-Ray Shows Infiltrate or Strong Clinical Suspicion of Pneumonia?**

A chest radiograph is considered the gold standard for pneumonia diagnosis.

In the event a chest x-ray is not obtained and a presumptive diagnosis of pneumonia is made based on clinical judgment, then the recommendations outlined in "Pneumonia Diagnosis" (Annotation #6) still apply.

False negative chest x-ray results can be seen in some patients with dehydration, *Pneumocystis carinii* pneumonia, pneumonia with profound neutropenia, or patients evaluated during the first 24 hours.

Evidence supporting this recommendation is of class: M

6. **Pneumonia Diagnosed, Calculate Pneumonia Severity Index (PSI)**

The decision to hospitalize a patient with community-acquired pneumonia is one of the most important decisions early in the course of a patient's illness. There is a prediction rule that can help the clinician identify patients with CAP who are at low risk for morbidity and mortality and who may be candidates for outpatient treatment. *[Conclusion Grade II: See Conclusion Grading Worksheet A -- Annotation # 6 (Prediction Rule for Classifying Risk) in the original guideline document]*.

At initial assessment of the patient with pneumonia, if they are under age 50 and without the specified comorbidities and physical exam findings (see original guideline), they are considered to be very low risk for morbidity and mortality and could be considered for outpatient therapy.

The Pneumonia Severity Index (PSI) can be calculated according to the details provided in the original guideline document.

7. **Evaluation of Inpatient vs. Outpatient Management**

The guideline group concurs with the recommendation of the Infectious Disease Society of America (IDSA) for a three-step process to evaluate the initial site of treatment.

> Step 1: Assess for any pre-existing conditions that would preclude outpatient management. Examples include active co-existing conditions that require hospitalization, hypoxia, or inability to take oral medications.

Step 2: PSI score: greater than 90 suggests the patient is at increased risk for mortality and inpatient management should be considered.

Step 3: Clinical judgment suggests inpatient management is appropriate. Examples could include frail condition, history of substance abuse, or unstable living situation.

If any of these steps suggests patient should be treated as an inpatient, then inpatient admission should be strongly considered. Clinical judgment should take precedence.

The IDSA guideline supports use of the PSI score, and this guideline work group continues to support its use. This is a well validated instrument and has now been studied in the United States and Canada and shown to decrease low-risk admissions to the hospital without increased complications. See Appendix B, "PSI Scoring Tool" in the original guideline document.

Outpatient Management Algorithm Annotations

9. **Outpatient Management**

Key Points:

- Most CAP is treated empirically based on host risk factors and expected pathogens.
- Supplement patient education with written materials. Patient education should include information on the causes, transmissibility, duration of CAP, self help tips at home, and the importance of taking the antibiotics.
- Barring complications, a follow-up chest x-ray at 6 to 8 weeks is recommended. Unresolved cases will warrant further work up.

Treatment Based on Patient Characteristics

Most CAP is treated empirically based on host risk factors and expected pathogens. Thus, consistent with IDSA guidelines, the treatment algorithm has been organized by patient type and expected pathogens. Other patient specific factors may be considered depending on a patient's demographic characteristics, recent travel, underlying disease states, previously identified etiologies or history of treatment failures. Further diagnostic studies may be needed in these settings and treatments based on this may differ from the algorithm.

Table 1 in the original guideline document displays epidemiological and underlying conditions related to specific pathogens in selected patients with community-acquired pneumonia.

Evidence supporting this recommendation is of class: R

Patient Education

Much of the information can be provided directly by the physician. However, a discussion should be supplemented with written materials. See the original guideline document for details regarding questions raised in patient focus group sessions and for key education messages to patients.

Evidence supporting this recommendation is of classes: B, D

Follow-Up

Criteria for follow-up include:

- Difficulty breathing
- Worsening cough
- Worsening or onset of rigors
- Fever persisting more than 48 hours
- Medication intolerance

Common clinical practice is to obtain a follow-up chest x-ray in patients with pneumonia to ensure resolution of the infiltrate, especially in patients who are 40 years of age and older and/or smokers. The benefit of this practice has not been established, but a convalescent follow-up chest x-ray will be reasonable in many clinical situations. Barring complications, a follow-up x-ray is recommended at 6 to 8 weeks. Patients with multilobar involvement should at least show improvement, if not resolution, by then. A non-resolving infiltrate at 6 to 8 weeks requires further evaluation. Lung cancer is often suspected with non-resolving infiltrates.

It is suggested that patients treated as outpatients should be contacted by the health care team within 24 to 48 hours after commencing therapy to assess their progress.

Evidence supporting this recommendation is of class: D

10. **Previously Healthy Patients Without Comorbidities**

Key Points:

- Azithromycin is usually adequate therapy for younger and otherwise healthy patients who have not received these antimicrobials in the previous 3 months.
- Erythromycin and clarithromycin are not recommended as first-line drugs, and safer and better tolerated antimicrobials should be used.
- Doxycycline, although effective against the "atypical" pathogens, is increasingly less useful in *Streptococcus pneumoniae* infections due to resistance.
- For previously healthy patients without comorbidities who have received antimicrobials in the previous 3 months, the possibility of resistance to those antimicrobials is a potential concern. Thus, if the patient has recently received a macrolide, a recommended respiratory fluoroquinolone is a good option.

Azithromycin is usually adequate therapy for younger and otherwise healthy patients who have not received these antimicrobials in the previous 3 months. Azithromycin provides adequate coverage for most *Streptococcus pneumoniae, Haemophilus influenzae*, and the "atypical" pathogens: Mycoplasma, *Chlamydia pneumoniae*, and Legionella. Consistent with IDSA guidelines, the workgroup recommends use of azithromycin rather than a fluoroquinolone in this setting, to minimize overuse and development of quinolone resistance.

Erythromycin has been used for CAP in the past, but requires more frequent dosing and has a higher degree of gastrointestinal side effects than the newer agents. Because of a large number of drug interactions and a recent report suggesting an increased risk of sudden cardiac death (presumably due to QT prolongation) when used in combination with drugs that can increase their serum levels, erythromycin and clarithromycin are not recommended as first-line drugs, and safer and better tolerated antimicrobials should be used. *[Conclusion Grade II: See Conclusion Grading Worksheet B -- Annotation #10 (Erythromycin and Clarithromycin) in the original guideline document]*.

Doxycycline, although effective against the "atypical" pathogens, is increasingly less useful in *S. pneumoniae* infections due to resistance. It can be used, but caution should be exercised and another agent substituted if the patient does not show prompt response.

For previously healthy patients without comorbidities who have received antimicrobials in the previous 3 months, the possibility of resistance to those antimicrobials is a potential concern. Thus, if the patient has recently received a quinolone, azithromycin plus high dose amoxicillin or amoxicillin-clavulanate would be a good treatment option. Similarly, if the patient has recently received a macrolide, a respiratory quinolone (moxifloxacin or levofloxacin) is a good option.

Among the quinolones, this work group suggests moxifloxacin may be preferred over levofloxacin. Pharmacodynamic parameters (AUC/MIC) favor moxifloxacin for *S. pneumoniae*; additionally, moxifloxacin concentrations exceed the mutant prevention concentration and may be less likely to cause resistance. There is evidence that levofloxacin-induced first-step mutants of *S. pneumoniae* may not be detected with current susceptibility testing methods and use of levofloxacin in this setting can potentially lead to high level resistance with cross-resistance to other quinolones.

Due to a lack of randomized comparative trials demonstrating clear superiority of moxifloxacin and the availability of several studies supporting levofloxacin efficacy, levofloxacin has been included in the guideline as an option. Note that ciprofloxacin does not have adequate coverage for *S. pneumoniae* and should not be used in this setting. Gemifloxacin was recently U.S. Food and Drug Administration (FDA) approved but has a higher incidence of rash and has been less studied than other options. Gatifloxacin is contraindicated in diabetic patients due to reports of hypo and hyperglycemia. Thus, the use of gemifloxacin and gatifloxacin has not been included in the guideline.

If the patient has recently received a recommended respiratory fluoroquinolone, azithromycin plus high dose amoxicillin or amoxicillin-clavulanate would be good treatment options. High dose amoxicillin or amoxicillin-clavulanate used for respiratory infections can overcome intermediate resistance seen in *S. pneumoniae*, while the macrolide conveys activity for atypical organisms.

Telithromycin is a new ketolide antibiotic recently approved by the FDA for treatment of mild-moderate community-acquired pneumonia, including macrolide resistant strains of *S. pneumoniae*. It also has activity against *H. influenzae, Moraxella catarrhalis*, and atypical organisms. Similar to erythromycin, it has numerous drug interactions and should be avoided in patients predisposed to prolongation of the QT interval. In addition, it can cause visual disturbances in some patients and should be avoided in patients with myasthenia gravis. It is also fairly expensive and for now should be reserved as a second-line agent where intolerance to alternatives exists or resistant organisms are suspected. Until further safety and efficacy data are available, the workgroup did not include it in the algorithm.

Most recently the FDA issued a statement that it is continuing to evaluate the issue of liver problems in association with use of telithromycin in order to determine if labeling changes or other actions are warranted. As a part of this, the FDA is continuing to work to better understand the frequency of liver-related adverse events reported for approved antibiotics, including telithromycin.

See Appendix A, "Pneumonia Antibiotics," in the original guideline document for detail on doses and comparative costs.

Comment: Antibiotic therapy may need to be tailored to known local antibiotic resistance patterns.

Evidence supporting this recommendation is of classes: C, D, R

14. **Patients with Other Comorbidities (Chronic Obstructive Pulmonary Disease, Diabetes, Congestive Heart Failure, Renal Failure, Malignancies)**

For patients who have comorbidities such as cardiopulmonary disease, diabetes, renal failure, malignancies, alcohol abuse, elderly age group, or corticosteroid use, antibiotic recommendations are generally more broad-spectrum than in previously healthy young adults. The antibiotics chosen should be active against *S. pneumoniae* as well as *H. influenzae, M. catarrhalis, Mycoplasma*, *C. pneumoniae* and *Legionella*. Staphylococcus aureus and gram-negative aerobes may be less frequent etiologic agents in this group. Residence in a nursing home, underlying cardiopulmonary disease, and multiple comorbidities may increase the risk of Gram negative enteric organisms.

A combination of antibiotics can be used to cover these possible etiologies. Choices include high dose amoxicillin/clavulanate or second generation cephalosporin (cefuroxime axetil, cefpodoxime, cefprozil), with the addition of

azithromycin to cover atypical agents. A recommended respiratory fluoroquinolone (moxifloxacin or levofloxacin) can also be used and provides coverage for typical and atypical pathogens in this setting.

If there has been recent antimicrobial use, the potential for resistance to these antimicrobials should be considered. If a recommended respiratory fluoroquinolone has been used in the previous 3 months, the beta lactam plus advanced generation macrolide option is preferred. Likewise, if there is recent macrolide use, a respiratory fluoroquinolone would be preferred.

18. **Aspiration Suspected**

Microaspiration often causes chemical pneumonitis, which can be difficult to distinguish from pneumonia. When the cause is infectious, etiologies of aspiration pneumonia are often polymicrobial and include anaerobic and aerobic organisms. For treatment of aspiration pneumonia in the community setting, clindamycin or high dose amoxicillin-clavulanate are generally preferred over the previously recommended penicillin due to enhanced anaerobic coverage. For aspiration in patients with comorbidities or in the nursing home setting, high dose amoxicillin-clavulanate would be preferred to clindamycin.

20. **Nursing Home Patient**

Pathogens causing pneumonia in nursing home patients often include the usual CAP organisms. However, less commonly, Gram negative, atypical organisms, and staphylococci cause infection in this patient group. Thus, recommended treatment options are more broad-spectrum and include a combination of high dose amoxicillin-clavulanate plus azithromycin or a recommended respiratory fluoroquinolone.

22. **Recent Influenza, Possible Superinfection**

Empiric treatment of suspected bacterial superinfection of influenza should provide activity against *S. pneumoniae, Staphylococcus aureus*, and *H. influenzae*. Suggested antimicrobial therapy in this setting includes high dose amoxicillin-clavulanate, cefpodoxime, cefprozil, cefuroxime, or a recommended respiratory fluoroquinolone.

Note: This empiric coverage recommendation does not cover methicillin-resistant *Staphylococcus aureus* (MRSA). If patient is not responding, MRSA should be considered.

Deviations from the IDSA guideline

The workgroup deviated from the IDSA guideline in the following instances:

- Macrolide choice: Because of safety and microbial coverage reasons, only azithromycin is recommended from this class.
- Respiratory quinolones: Gatifloxacin is not included in the algorithm due to recent reports of serious hypo and hyperglycemia and the

subsequent change in labeling indicating that it is contraindicated in diabetic patients and should be used with caution in other patients with risk factors for dysglycemia.
- With recent influenza recommendations, the work group dropped the recommendation for high-dose amoxicillin, given its decreased performance against *Staphylococcus aureus*.
- The work group left in the recommendation for high-dose amoxicillin-clavulanate for certain infections. However, there are concerns that supportive outcome studies are not available.

Definitions:

Classes of Research Reports:

A. Primary Reports of New Data Collection:

Class A:

- Randomized, controlled trial

Class B:

- Cohort study

Class C:

- Nonrandomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

Class D:

- Cross-sectional study
- Case series
- Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports:

Class M:

- Meta-analysis
- Systematic review
- Decision analysis
- Cost-effectiveness analysis

Class R:

- Consensus statement
- Consensus report
- Narrative review

Class X:

- Medical opinion

Conclusion Grades:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results of different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade IV: The support for the conclusion consists solely of the statements of informed medical commentators based on their clinical experience, unsubstantiated by the results of any research studies.

CLINICAL ALGORITHM(S)

Detailed and annotated clinical algorithms are provided for:

- Community-Acquired Pneumonia in Adults
- Outpatient Management

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is classified for selected recommendations (see "Major Recommendations").

In addition, key conclusions contained in the Work Group's algorithm are supported by a grading worksheet that summarizes the important studies pertaining to the conclusion. The type and quality of the evidence supporting

these key recommendations (i.e., choice among alternative therapeutic approaches) is graded for each study.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Patients with community-acquired pneumonia may be accurately diagnosed and appropriately treated.
- Patients at low risk may be treated as outpatients, rather than hospitalized.
- Patients may have a shorter duration of symptoms and may return to work or normal routines sooner.

Subgroups Most Likely to Benefit

Patients who are low risk (based on Pneumonia Severity Index)

POTENTIAL HARMS

- False-negative chest x-ray results can be seen in some patients with dehydration, *Pneumocystis carinii* pneumonia, pneumonia with profound neutropenia, or patients evaluated during first 24 hours.
- Caution is urged against unnecessary use of fluoroquinolones and macrolides to avoid the development of microbial resistance.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These clinical guidelines are designed to assist clinicians by providing an analytical framework for the valuation and treatment of patients, and are not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition. A guideline will rarely establish the only approach to a problem.
- This clinical guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients are urged to consult a health care professional regarding their own situation and any specific medical questions they may have.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Once a guideline is approved for general implementation, a medical group can choose to concentrate on the implementation of that guideline. When four or more groups choose the same guideline to implement and they wish to collaborate with others, they may form a guideline action group.

In the guideline action group, each medical group sets specific goals they plan to achieve in improving patient care based on the particular guideline(s). Each medical group shares its experiences and supporting measurement results within the action group. This sharing facilitates a collaborative learning environment. Action group learnings are also documented and shared with interested medical groups within the collaborative.

Currently, action groups may focus on one guideline or a set of guidelines such as hypertension, lipid treatment, and tobacco cessation.

Detailed measurement strategies are presented in the original guideline document to help close the gap between clinical practice and the guideline recommendations. Summaries of the measures are provided in the National Quality Measures Clearinghouse (NQMC).

IMPLEMENTATION TOOLS

Clinical Algorithm
Pocket Guide/Reference Cards
Quality Measures
Resources

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

RELATED NQMC MEASURES

- Community-acquired pneumonia (CAP) in adults: percentage of patients with a diagnosis of CAP that had a chest x-ray to confirm diagnosis.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Community-acquired pneumonia in adults. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2006 May. 36 p. [37 references]

ADAPTATION

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

DATE RELEASED

1999 Aug (revised 2006 May)

GUIDELINE DEVELOPER(S)

Institute for Clinical Systems Improvement - Private Nonprofit Organization

GUIDELINE DEVELOPER COMMENT

Organizations participating in the Institute for Clinical Systems Improvement (ICSI): Affiliated Community Medical Centers, Allina Medical Clinic, Altru Health System, Aspen Medical Group, Avera Health, CentraCare, Columbia Park Medical Group, Community-University Health Care Center, Dakota Clinic, ENT Specialty Care, Fairview Health Services, Family HealthServices Minnesota, Family Practice Medical Center, Gateway Family Health Clinic, Gillette Children's Specialty Healthcare, Grand Itasca Clinic and Hospital, HealthEast Care System, HealthPartners Central Minnesota Clinics, HealthPartners Medical Group and Clinics, Hutchinson Area Health Care, Hutchinson Medical Center, Lakeview Clinic, Mayo Clinic, Mercy Hospital and Health Care Center, MeritCare, Mille Lacs Health System, Minnesota Gastroenterology, Montevideo Clinic, North Clinic, North Memorial Care System, North Suburban Family Physicians, Northwest Family Physicians, Olmsted Medical Center, Park Nicollet Health Services, Pilot City Health Center, Quello Clinic, Ridgeview Medical Center, River Falls Medical Clinic, Saint Mary's/Duluth Clinic Health System, St. Paul Heart Clinic, Sioux Valley Hospitals and Health System, Southside Community Health Services, Stillwater Medical Group, SuperiorHealth Medical Group, University of Minnesota Physicians, Winona Clinic, Ltd., Winona Health

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GUIDELINE COMMITTEE

Respiratory Steering Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Work Group Members: John Degelau, MD (Work Group Leader) (HealthPartners Medical Group) (Internal Medicine); Garrett Trobec (Family HealthServices Minnesota) (Family Medicine); Michael Briggs, MD (Dakota Clinic) (Pulmonology); Salim Kathawalla, MD (Park Nicollet Health Services) (Pulmonology); David Thomas (Sioux Valley Health System) (Pulmonology); James Hargreaves, DO (Altru Health System) (Infectious Disease); Stephen Kolar, MD (HealthEast Clinics) (Internal Medicine); Mark Nyman, MD (Mayo Clinic) (Internal Medicine); Lynn Estes, PharmD (Mayo Clinic) (Pharmacy); Teresa Hunteman, RRT, CPHQ (Institute for Clinical Systems Improvement) (Measurement Advisor); Brent Metfessel, MD, MPH (Institute for Clinical Systems Improvement) (Evidence Analyst); Linda Setterlund, MA (Institute for Clinical Systems Improvement) (Facilitator)

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

In the interest of full disclosure, the Institute for Clinical Systems Improvement (ICSI) has adopted a policy of revealing relationships work group members have with companies that sell products or services that are relevant to this guideline topic. The reader should not assume that these financial interests will have an adverse impact on the content of the guideline. Readers of the guideline may assume that only work group members listed below have potential conflict of interest to disclose.

No work group members have potential conflicts of interest to disclose.

ICSI's conflict of interest policy and procedures are available for review on ICSI's website at www.icsi.org.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Community-acquired pneumonia in adults. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2005 May. 40 p.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Institute for Clinical Systems Improvement (ICSI) Web site.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org; e-mail: icsi.info@icsi.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Community-acquired pneumonia in adults. Executive summary. Bloomington (MN): Institute for Clinical Systems Improvement, 2006 May. 1 p. Electronic

copies: Available from the Institute for Clinical Systems Improvement (ICSI) Web site.

- ICSI pocket guidelines. April 2006 edition. Bloomington (MN): Institute for Clinical Systems Improvement, 2006. 298 p.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org; e-mail: icsi.info@icsi.org.

Additionally, the Pneumonia Severity Index (PSI) scoring tool can be found in Appendix B of the original guideline document.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on July 10, 2000. The information was verified by the guideline developer on April 25, 2001. This summary was updated on December 4, 2002. The updated information was verified by the guideline developer on December 24, 2002. This summary was updated on May 12, 2004, and July 29, 2005. This summary was updated by ECRI on January 27, 2006 following the U.S. Food and Drug Administration (FDA) advisory on Ketek (telithromycin). This summary was updated by ECRI on February 21, 2006 following the U.S. Food and Drug Administration (FDA) advisory on Tequin (gatifloxacin). This NGC summary was updated by ECRI on June 27, 2006. This summary was updated by ECRI on March 6, 2007 following the updated FDA advisory on Ketek (telithromycin). This summary was updated by ECRI Institute on July 28, 2008 following the U.S. Food and Drug Administration advisory on fluoroquinolone antimicrobial drugs.

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