



Complete Summary

GUIDELINE TITLE

Clinical practice guideline: adult sinusitis.

BIBLIOGRAPHIC SOURCE(S)

Rosenfeld RM, Andes D, Bhattacharyya N, Cheung D, Eisenberg S, Ganiats TG, Gelzer A, Hamilos D, Haydon RC 3rd, Hudgins PA, Jones S, Krouse HJ, Lee LH, Mahoney MC, Marple BF, Mitchell CJ, Nathan R, Shiffman RN, Smith TL, Witsell DL. Clinical practice guideline: adult sinusitis. Otolaryngol Head Neck Surg 2007 Sep;137(3 Suppl):S1-31. [233 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

A scheduled review process will occur at 5 years from publication or sooner if new compelling evidence warrants earlier consideration.

COMPLETE SUMMARY CONTENT

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS EVIDENCE SUPPORTING THE RECOMMENDATIONS BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS CONTRAINDICATIONS QUALIFYING STATEMENTS IMPLEMENTATION OF THE GUIDELINE INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES IDENTIFYING INFORMATION AND AVAILABILITY DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Rhinosinusitis, defined as symptomatic inflammation of the paranasal sinuses and nasal cavity

GUIDELINE CATEGORY

Diagnosis Evaluation Management Prevention Treatment

CLINICAL SPECIALTY

Allergy and Immunology Emergency Medicine Family Practice Infectious Diseases Internal Medicine Nursing Otolaryngology Preventive Medicine Pulmonary Medicine Radiology

INTENDED USERS

Allied Health Personnel Nurses Physician Assistants Physicians

GUIDELINE OBJECTIVE(S)

- To improve diagnostic accuracy for adult rhinosinusitis, reduce inappropriate antibiotic use, reduce inappropriate use of radiographic imaging, and promote appropriate use of ancillary tests that include nasal endoscopy, computed tomography, and testing for allergy and immune function
- To create a guideline suitable for deriving a performance measure on rhinosinusitis and training participants in guideline methodology to facilitate future development efforts

TARGET POPULATION

Adults 18 years or older with a clinical diagnosis of uncomplicated rhinosinusitis

Note: *Uncomplicated rhinosinusitis* is defined as rhinosinusitis without clinically evident extension of inflammation outside the paranasal sinuses and nasal cavity at the time of diagnosis (e.g., no neurologic, ophthalmologic, or soft tissue involvement).

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Evaluation

- 1. Targeted history
- 2. Physical examination
- 3. Anterior rhinoscopy
- 4. Transillumination
- 5. Nasal endoscopy
- 6. Nasal swabs

- 7. Antral puncture
- 8. Culture of nasal cavity, middle meatus, or other site
- 9. Imaging procedures
- 10. Blood tests: complete blood count (CBC), others
- 11. Allergy evaluation and testing
- 12. Immune function testing
- 13. Gastroesophageal reflux
- 14. Pulmonary function tests
- 15. Mucociliary dysfunction tests

Treatment/Management

- 1. Watchful waiting/observation
- 2. Education/information
- 3. Systemic antibiotics
- 4. Topical antibiotics
- 5. Oral/topical steroids
- 6. Systemic/topical decongestants
- 7. Antihistamines
- 8. Mucolytics
- 9. Leukotriene modifiers
- 10. Nasal saline
- 11. Analgesics
- 12. Complementary and alternative medicine
- 13. Postural drainage/heat
- 14. Biopsy (excluded from guideline)
- 15. Sinus surgery (excluded from guideline)

Prevention

- 1. Topical steroids
- 2. Immunotherapy
- 3. Nasal lavage
- 4. Smoking cessation
- 5. Hygiene
- 6. Education
- 7. Pneumococcal vaccination
- 8. Influenza vaccination
- 9. Environmental controls

MAJOR OUTCOMES CONSIDERED

- Resolution or change of the signs and symptoms associated with rhinosinusitis
- Eradication of pathogens
- Recurrence of acute disease
- Complications or adverse events
- Cost
- Adherence to therapy
- Quality of life
- Return to work or activity
- Avoidance of surgery

- Return physician visits
- Effect on comorbid conditions (e.g., allergy, asthma, gastroesophageal reflux)

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Several literature searches were performed through November 30, 2006 by American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) staff. The initial MEDLINE search using "sinusitis OR rhinosinusitis" in any field, or "sinus* AND infect*" in the title or abstract, yielded 18,020 potential articles:

- Clinical practice guidelines were identified by limiting the MEDLINE search to 28 articles using "guideline" as a publication type or title word. Search of the National Guideline Clearinghouse (<u>www.guideline.gov</u>) identified 59 guidelines with a topic of sinusitis or rhinosinusitis. After eliminating articles that did not have rhinosinusitis as the primary focus, 12 guidelines met quality criteria of being produced under the auspices of a medical association or organization and having an explicit method for ranking evidence and linking evidence to recommendations.
- 2. Systematic reviews (meta-analyses) were identified by limiting the MEDLINE search to 226 articles using a validated filter strategy for systematic reviews. Search of the Cochrane Library identified 71 relevant titles. After eliminating articles that did not have rhinosinusitis as the primary focus, 18 systematic reviews met quality criteria of having explicit criteria for conducting the literature and selecting source articles for inclusion or exclusion.
- 3. *Randomized controlled trials* were identified by search of the Cochrane Controlled Trials Register, which identified 515 trials with "sinusitis" or "rhinosinusitis" as a title word.
- 4. Original research studies were identified by limiting the MEDLINE search to articles with a sinusitis (MeSH term) as a focus, published in English after 1991, not containing children age 12 years or younger and not having a publication type of case report. The resulting data set of 2039 articles yielded 348 related to diagnosis, 359 to treatment, 151 to etiology, and 24 to prognosis.

NUMBER OF SOURCE DOCUMENTS

- Clinical practice guidelines: 12
- Systematic reviews (meta-analyses): 18
- Randomized controlled trials: 515
- Original research studies: 348 related to diagnosis, 359 to treatment, 151 to etiology, and 24 to prognosis

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee) Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Evidence Quality for Grades of Evidence

Grade A: Well-designed randomized controlled trials or diagnostic studies performed on a population similar to the guideline's target population

Grade B: Randomized controlled trials or diagnostic studies with minor limitations; overwhelmingly consistent evidence from observational studies

Grade C: Observational studies (case control and cohort design)

Grade D: Expert opinion, case reports, reasoning from first principles (bench research or animal studies)

Grade X: Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit over harm

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses Systematic Review Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The guideline was developed using an explicit and transparent a priori protocol for creating actionable statements based on supporting evidence and the associated balance of benefit and harm. The multidisciplinary guideline development panel was chosen to represent the fields of allergy, emergency medicine, family medicine, health insurance, immunology, infectious disease, internal medicine, medical informatics, nursing, otolaryngology-head and neck surgery, and radiology.

Results of all literature searches were distributed to guideline panel members at the first meeting. The materials included an evidence table of clinical practice guidelines, an evidence table of systematic reviews, full-text electronic versions of all articles in the evidence tables, and electronic listings with abstracts (if available) of the searches for randomized trials and original research. This material was supplemented, as needed, with targeted searches to address specific needs identified in writing the guideline.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

In a series of conference calls, the working group defined the scope and objectives of the proposed guideline. During the 9 months devoted to guideline development ending in April 2007, the group met twice with interval electronic review and feedback on each guideline draft to ensure accuracy of content and consistency with standardized criteria for reporting clinical practice guidelines.

The Guidelines Review Group of the Yale Center for Medical Informatics used the Guideline Elements Module from the Conference on Guidelines Standardization (GEM-COGS), the guideline implementability appraisal and extractor software, to appraise adherence of the draft guideline to methodologic standards, to improve clarity of recommendations, and to predict potential obstacles to implementation. Panel members received summary appraisals in March 2007 and modified an advanced draft of the guideline.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Guideline Definitions for Evidence-Based Statements

Strong Recommendation: A strong recommendation means the benefits of the recommended approach clearly exceed the harms (or that the harms clearly exceed the benefits in the case of a strong negative recommendation) and that the quality of the supporting evidence is excellent (Grade A or B)*. In some clearly identified circumstances, strong recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms. *Implication*: Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.

Recommendation: A recommendation means the benefits exceed the harms (or that the harms exceed the benefits in the case of a negative recommendation), but the quality of evidence is not as strong (Grade B or C)*. In some clearly identified circumstances, recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms. *Implication*: Clinicians also should generally follow a recommendation but should remain alert to new information and sensitive to patient preferences.

Option: An option means that either the quality of evidence that exists is suspect (Grade D)* or that well-done studies (Grade A, B, or C)* show little clear advantage to one approach versus another. *Implication*: Clinicians should be flexible in their decision-making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role.

No Recommendation: No recommendation means that there is both a lack of pertinent evidence (Grade D)* and an unclear balance between benefits and harms. *Implication*: Clinicians should feel little constraint in their decision-making and be alert to new published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role.

* Refer to "Rating Scheme for the Strength of the Evidence" field above for the definitions of evidence grades.

COST ANALYSIS

The direct annual health-care cost of sinusitis is \$5.8 billion, which stems mainly from ambulatory and emergency department services, but also includes 500,000 surgical procedures performed on the paranasal sinuses. The indirect costs of sinusitis include 73 million days of restricted activity per year.

Acute bacterial rhinosinusitis (ABRS) has significant socioeconomic implications. The cost of initial antibiotic treatment failure in ABRS, including additional prescriptions, outpatient visits, tests, and procedures, contributes to a substantial total rhinosinusitis related health-care expenditure of more than \$3.0 billion per year in the United States. Aside from the direct treatment costs, decreased productivity and lost work days contribute to an even greater indirect health-care cost associated with this condition.

Chronic rhinosinusitis (CRS) has significant socioeconomic implications. In 2001 there were 18.3 million office visits for CRS, most of which resulted in prescription medications. Patients with CRS visit primary care clinicians twice as often as those without the disorder, and have five times as many prescriptions filled. Extrapolation of these data yields an annual direct cost for CRS of \$4.3 billion.

The following cost considerations were addressed with the recommendations:

- Diagnosis of Acute Rhinosinusitis: not applicable
- Radiographic Imaging and Acute Rhinosinusitis: savings by not performing routine radiologic imaging
- Symptomatic Relief of Viral Rhinosinusitis (VRS): cost of medications
- Pain Assessment of Acute Bacterial Rhinosinusitis (ABRS): cost of analgesic medications
- Symptomatic Relief of ABRS: cost of medications
- Watchful Waiting for ABRS: antibiotics; potential need for follow-up visit if observation failure
- Choice of Antibiotic for ABRS: cost of antibiotics
- Treatment Failure for ABRS: medication cost
- Diagnosis of Chronic Rhinosinusitis or Recurrent Acute Rhinosinusitis: none
- Modifying Factors: variable based on testing ordered
- Diagnostic Testing: relates to the specific test or procedure
- Nasal Endoscopy: procedural cost
- Radiographic Imaging: procedural cost
- Testing for Allergy and Immune Function: procedural and laboratory cost
- Prevention: minimal

METHOD OF GUIDELINE VALIDATION

External Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The final draft practice guideline underwent extensive external peer review. Comments were compiled and reviewed by the group chairperson.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The evidence grades (**A-D**) and evidence-based statements (**Strong Recommendation, Recommendation, Option, and No Recommendation**) are defined at the end of the "Major Recommendations" field.

1a. Diagnosis of Acute Rhinosinusitis

Clinicians should distinguish presumed acute bacterial rhinosinusitis (ABRS) from acute rhinosinusitis caused by viral upper respiratory infections and noninfectious conditions. A clinician should diagnose ABRS when (a) symptoms or signs of acute rhinosinusitis are present 10 days or more beyond the onset of upper respiratory symptoms, or (b) symptoms or signs of acute rhinosinusitis worsen within 10 days after an initial improvement (double worsening).

Strong recommendation based on diagnostic studies with minor limitations and a preponderance of benefit over harm.

- Aggregate evidence quality: **Grade B**, diagnostic students with minor limitations regarding signs and symptoms associated with ABRS
- Value judgments: importance of avoiding inappropriate antibiotic treatment of viral or nonbacterial illness; emphasis on clinical signs and symptoms for initial diagnosis; importance of avoiding unnecessary diagnostic tests
- Policy level: strong recommendation

1b. Radiographic Imaging and Acute Rhinosinusitis

Clinicians should not obtain radiographic imaging for patients who meet diagnostic criteria for acute rhinosinusitis, unless a complication or alternative diagnosis is suspected.

Recommendation against based on diagnostic studies with minor limitations and a preponderance of benefit over harm.

- Aggregate evidence quality: **Grade B**, diagnostic studies with minor limitations
- Value judgments: importance of avoiding unnecessary radiation and cost in diagnosing acute rhinosinusitis
- Policy level: **recommendation**

2. Symptomatic Relief of Viral Rhinosinusitis (VRS)

Clinicians may prescribe symptomatic relief in managing VRS.

Option based on randomized trials with limitations and cohort studies with an unclear balance of benefits and harm that varies by patient.

- Aggregate evidence quality: **Grade B and C**, randomized controlled trials with limitations and cohort studies
- Value judgments: provide symptomatic relief, but avoid inappropriate use of antibiotics for viral illness
- Policy level: **option**

3a. Pain Assessment of Acute Bacterial Rhinosinusitis (ABRS)

The management of ABRS should include an assessment of pain. The clinician should recommend analgesic treatment based on the severity of pain.

Strong recommendation based on randomized controlled trials of general pain relief in non-ABRS populations with a preponderance of benefit over harm.

- Aggregate evidence quality: **Grade B**, randomized controlled trials demonstrating superiority of analgesics over placebo for general pain relief, but not trials specifically regarding patients with ABRS.
- Value judgments: pain relief is important
- Policy level: strong recommendation

3b. Symptomatic Relief of Acute Bacterial Rhinosinusitis (ABRS)

Clinicians may prescribe symptomatic relief in managing ABRS.

Option based on randomized trials with heterogeneous populations, diagnostic criteria, and outcome measures with a balance of benefit and harm.

- Aggregate evidence quality: Grade B, randomized controlled trials with heterogeneous populations, diagnostic criteria, and outcomes measures; Grade D, for antihistamines (in nonatopic patients) and guaifenesin
- Value judgments: provide symptomatic relief while minimizing adverse events and costs
- Policy level: **option**

4. Watchful Waiting for Acute Bacterial Rhinosinusitis (ABRS)

Observation without use of antibiotics is an option for selected adults with uncomplicated ABRS who have mild illness (mild pain and temperature <38.3°C or 101°F) and assurance of follow-up.

Option based on double-blind randomized controlled trials with heterogeneity in diagnostic criteria and illness severity, and a relative balance of benefit and risk.

- Aggregate evidence quality: **Grade B**, randomized controlled trials with heterogeneity in diagnostic criteria and illness severity
- Value judgments: minimize drug-related adverse events and induced bacterial resistance
- Policy level: **option**

5. Choice of Antibiotic for Acute Bacterial Rhinosinusitis (ABRS)

If a decision is made to treat ABRS with an antibiotic agent, the clinician should prescribe amoxicillin as first-line therapy for most adults.

Recommendation based on randomized controlled trials with heterogeneity and noninferiority design with a preponderance of benefit over harm.

- Aggregate evidence quality: **Grade B**, randomized controlled trials with heterogeneity and noninferiority design
- Value judgments: promote safe and cost-effective initial therapy
- Policy level: recommendation

6. Treatment Failure for Acute Bacterial Rhinosinusitis (ABRS)

If the patient worsens or fails to improve with the initial management option by 7 days after diagnosis, the clinician should reassess the patient to confirm ABRS, exclude other causes of illness, and detect complications. If ABRS is confirmed in the patient initially managed with observation, the clinician should begin antibiotic therapy. If the patient was initially managed with an antibiotic, the clinician should change the antibiotic.

Recommendation based on randomized controlled trials with limitations supporting a cut point of 7 days for lack of improvement and expert opinion and first principles for changing therapy with a preponderance of benefit over harm.

- Aggregate evidence quality: Grade B, randomized controlled trials with limitations supporting a cut point of 7 days for lack of improvement; Grade
 D, expert opinion and first principles for changing therapy
- Value judgments: avoid excessive classification as treatment failures because of a premature time point for assessing outcomes; emphasize importance of worsening illness in definition of treatment failure
- Policy level: recommendation

7a. Diagnosis of Chronic Rhinosinusitis or Recurrent Acute Rhinosinusitis

Clinicians should distinguish chronic rhinosinusitis and recurrent acute rhinosinusitis from isolated episodes of acute bacterial rhinosinusitis and other causes of sinonasal symptoms.

Recommendation based on cohort and observational studies with a preponderance of benefit over harm.

- Aggregate evidence quality: **Grade C**, cohort and observational studies
- Value judgments: importance of accurate diagnosis
- Policy level: recommendation

7b. Modifying Factors

Clinicians should assess the patient with chronic rhinosinusitis or recurrent acute rhinosinusitis for factors that modify management, such as allergic rhinitis, cystic fibrosis, immunocompromised state, ciliary dyskinesia, and anatomic variation.

Recommendation based on observational studies with a preponderance of benefit over harm.

- Aggregate evidence quality: **Grade C**, observational studies
- Value judgments: consensus that identifying and managing modifying factors will improve outcomes
- Policy level: recommendation

8a. Diagnostic Testing

The clinician should corroborate a diagnosis and/or investigate for underlying causes of chronic rhinosinusitis and recurrent acute rhinosinusitis.

Recommendation based on observational studies with a preponderance of benefit over harm.

- Aggregate evidence quality: **Grade C**, observational studies
- Value judgments: identifying and managing underlying conditions will improve outcomes
- Policy level: recommendation

8b. Nasal Endoscopy

The clinician may obtain nasal endoscopy in diagnosing or evaluating a patient with chronic rhinosinusitis or recurrent acute rhinosinusitis.

Option based on expert opinion and a preponderance of benefit over harm.

- Aggregate evidence quality: **Grade D**, expert opinion
- Value judgments: importance of a detailed, complete intranasal examination
- Policy level: **option**

8c. Radiographic Imaging

The clinician should obtain computed tomography (CT) of the paranasal sinuses in diagnosing or evaluating a patient with chronic rhinosinusitis or recurrent acute rhinosinusitis.

Recommendation based on diagnostic and observational studies and a preponderance of benefit over harm.

- Aggregate evidence quality: **Grade C**, diagnostic and observational studies
- Value judgments: minimize radiation exposure and avoid unnecessary intravenous contrast
- Policy level: **recommendation**

8d. Testing for Allergy and Immune Function

The clinician may obtain testing for allergy and immune function in evaluating a patient with chronic rhinosinusitis or recurrent acute rhinosinusitis.

Option based on observational studies with an unclear balance of benefit versus harm.

- Aggregate evidence quality: **Grade C**, observational studies
- Value judgments: need to balance detecting allergy in a population with high prevalence vs. limited evidence showing benefits of allergy management on rhinosinusitis outcomes
- Policy level: **option**

9. Prevention

Clinicians should educate/counsel patients with chronic rhinosinusitis or recurrent acute rhinosinusitis regarding control measures.

Recommendation based on randomized controlled trials and epidemiologic studies with limitations and a preponderance of benefit over harm.

- Aggregate evidence quality: **Grade B**, randomized controlled trials and epidemiologic studies with limitations
- Value judgments: importance of prevention in managing patients with CRS or recurrent acute rhinosinusitis
- Policy level: **recommendation**

Definitions:

Guideline Definitions for Evidence-Based Statements

Strong Recommendation: A strong recommendation means the benefits of the recommended approach clearly exceed the harms (or that the harms clearly exceed the benefits in the case of a strong negative recommendation) and that the quality of the supporting evidence is excellent (Grade A or B)*. In some clearly identified circumstances, strong recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms. *Implication*: Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.

Recommendation: A recommendation means the benefits exceed the harms (or that the harms exceed the benefits in the case of a negative recommendation), but the quality of evidence is not as strong (Grade B or C)*. In some clearly identified circumstances, recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms. *Implication*: Clinicians also should generally follow a recommendation but should remain alert to new information and sensitive to patient preferences.

Option: An option means that either the quality of evidence that exists is suspect (Grade D)* or that well-done studies (Grade A, B, or C)* show little clear advantage to one approach versus another. *Implication*: Clinicians should be flexible in their decision-making regarding appropriate practice, although they

may set bounds on alternatives; patient preference should have a substantial influencing role.

No Recommendation: No recommendation means that there is both a lack of pertinent evidence (Grade D)* and an unclear balance between benefits and harms. *Implication*: Clinicians should feel little constraint in their decision-making and be alert to new published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role.

Evidence Quality for Grades of Evidence

Grade A: Well-designed, randomized, controlled trials or diagnostic studies performed on a population similar to the guideline's target population

Grade B: Randomized, controlled trials or diagnostic studies with minor limitations; overwhelmingly consistent evidence from observational studies

Grade C: Observational studies (case-control and cohort design)

Grade D: Expert opinion, case reports, or reasoning from first principles (bench research or animal studies)

Grade X: Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit over harm

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations contained in this practice guideline were based on the best available published data through January 2007. Where data were lacking a combination of clinical experience and expert consensus was used. The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Diagnosis of acute rhinosinusitis: decrease inappropriate use of antibiotics for non bacterial illness; distinguish noninfectious conditions from rhinosinusitis
- Radiographic imaging and acute rhinosinusitis: avoid unnecessary radiation exposure; avoid delays in diagnosis from obtaining and interpreting imaging studies
- Symptomatic relief of viral rhinosinusitis (VRS): reduction of symptoms; avoidance of unnecessary antibiotics

- Pain assessment of acute bacterial rhinosinusitis (ABRS): pain reduction
- Symptomatic relief of ABRS: symptom relief
- Watchful waiting for ABRS: increase in cure or improvement at 7 to 12 days (number needed to treat [NNT] 6), and improvement at 14 to 15 days (NNT 16); reduced illness duration
- Choice of antibiotic for ABRS: demonstrated superiority of amoxicillin over placebo, with clinical outcomes comparable to broader-spectrum antibiotics for initial therapy; potential reduced bacterial resistance by using a narrow-spectrum antibiotic as first-line therapy; cost-effectiveness of amoxicillin versus other antibiotic choices
- Treatment failure for ABRS: prevent complications, detect misdiagnosis, institute effective therapy
- Diagnosis of chronic rhinosinusitis (CRS) or recurrent acute rhinosinusitis: distinguish conditions that might benefit from additional diagnostic evaluation and management from isolated cased of ABRS
- Modifying factors: identify modifying factors that would alter management of CRS or recurrent acute rhinosinusitis; identify conditions that require therapy independent of rhinosinusitis
- Diagnostic testing: corroborate diagnosis and identify underlying causes that may require management independent of rhinosinusitis for symptom relief
- Nasal endoscopy: confirm diagnosis of CRS; detect structural abnormalities, masses, lesions; perform biopsy or culture
- Radiographic imaging: confirm diagnosis of CRS; detect structural abnormalities, masses, lesions
- Testing for allergy and immune function: identify allergies or immunodeficient states that are potential modifying factors for CRS or recurrent acute rhinosinusitis
- Prevention: reduce symptoms and prevent exacerbations

POTENTIAL HARMS

- Diagnosis of acute rhinosinusitis: risk of misclassifying bacterial rhinosinusitis as viral, or vice-versa
- Radiographic imaging and acute rhinosinusitis: delayed diagnosis of serious underlying condition
- Symptomatic relief of viral rhinosinusitis (VRS): adverse effects of decongestants, antihistamines, topical steroid sprays
- Pain assessment of acute bacterial rhinosinusitis (ABRS): side effects of analgesic medications; potential for masking underlying illness or disease progression
- Symptomatic relief of ABRS: side effects of medication, which include local and systemic adverse reactions
- Watchful waiting for ABRS: adverse effects of specific antibiotics (number needed to harm [NNH] 9), especially gastrointestinal; societal impact of antibiotic therapy on bacterial resistance and transmission of resistant pathogens; potential disease progression in patients initially observed who do not return for follow-up
- Choice of antibiotic for ABRS: potential increased gastrointestinal adverse effects with amoxicillin compared to other antibiotics; adverse effects from penicillin allergy
- Treatment failure for ABRS: delay of up to 7 days in changing therapy if patient fails to improve

- Diagnosis of chronic rhinosinusitis (CRS) or recurrent acute rhinosinusitis: potential misclassification of illness because of overlapping symptomatology with other illnesses
- Modifying factors: identifying and treating incidental findings or subclinical conditions that might not require independent therapy; morbidity related to specific tests
- Diagnostic testing: related to the specific test or procedure
- Nasal endoscopy: adverse effects from topical decongestants, anesthetics, or both; discomfort; hemorrhage; trauma
- Radiographic imaging: radiation exposure
- Testing for allergy and immune function: procedural discomfort; instituting therapy based on test results with limited evidence of efficacy for CRS or recurrent acute rhinosinusitis; very rare chance of anaphylactic reactions during allergy testing
- Prevention: local irritation from saline irrigation

CONTRAINDICATIONS

CONTRAINDICATIONS

Patients with penicillin allergy may receive a macrolide antibiotic or trimethoprimsulfamethoxazole.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- This clinical practice guideline is not intended as a sole source of guidance for managing adults with rhinosinusitis. Rather, it is designed to assist clinicians by providing an evidence-based framework for decision-making strategies. It is not intended to replace clinical judgment or establish a protocol for all individuals with this condition, and may not provide the only appropriate approach to diagnosing and managing this problem.
- As medical knowledge expands and technology advances, clinical indicators and guidelines are promoted as conditional and provisional proposals of what is recommended under specific conditions, but they are not absolute. Guidelines are not mandates and do not and should not purport to be a legal standard of care. The responsible physician, in light of all the circumstances presented by the individual patient, must determine the appropriate treatment. Adherence to these guidelines will not ensure successful patient outcomes in every situation. The American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS), Inc. emphasizes that these clinical guidelines should not be deemed inclusive of all proper treatment decisions or methods of care, or exclusive of other treatment decisions or methods of care reasonably directed to obtaining the same results.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Implementation Considerations

The complete guideline is published as a supplement to *Otolaryngology–Head and Neck Surgery* to facilitate reference and distribution. The guideline will be presented to American Academy of Otolaryngology-Head and Neck Surgery Foundation (AAO-HNSF) members as a miniseminar at the annual meeting following publication. Existing brochures and publications by the AAO-HNSF will be updated to reflect the guideline recommendations.

An anticipated barrier to the diagnosis of rhinosinusitis is the differentiation of viral rhinosinusitis (VRS) from acute bacterial rhinosinusitis (ABRS) in a busy clinical setting. This may be assisted by a laminated teaching card or visual aid summarizing diagnostic criteria and the time course of VRS. When diagnosed with VRS, patients may pressure clinicians for antibiotics, in addition to symptomatic therapy, especially when nasal discharge is colored or purulent. Existing educational material from the Centers for Disease Control and Prevention (CDC) Get Smart Campaign can be used by clinicians to help clarify misconceptions about viral illness and nasal discharge.

Anticipated barriers to using the "observation option" for ABRS are reluctance of patients and clinicians to consider observing a presumed bacterial illness, and misinterpretation by clinicians and lay press of the statement regarding observation of ABRS as a "recommendation" instead of an "option." These barriers can be overcome with educational pamphlets and information sheets that outline the favorable natural history of nonsevere ABRS, the moderate incremental benefit of antibiotics on clinical outcomes, and the potential adverse effects of orally administered antibiotics (including induced bacterial resistance).

Some patients and clinicians might object to amoxicillin as first-line therapy for ABRS, based on assumptions that newer, more expensive alternatives "must be" more effective. Most favorable clinical outcomes for nonsevere ABRS, however, result from natural history, not antibiotics, and randomized trials of comparative efficacy do not support superiority of any single agent for initial empiric therapy. Pamphlets may help in dispelling myths about comparative efficacy.

Barriers may also be anticipated concerning guideline statements for chronic rhinosinusitis (CRS) and recurrent acute rhinosinusitis. The diagnostic criteria for these entities are unfamiliar to many clinicians, who might benefit from a summary card or teaching aid that lists these criteria along with those for ABRS and VRS. Performance of nasal endoscopy, allergy evaluation, and immunologic assessment, when appropriate, may be hindered by access to equipment and by procedural cost. Last, successfully achieving smoking cessation in patients with CRS or recurrent acute rhinosinusitis will require patient cooperation and clinician access to education materials and support services.

IMPLEMENTATION TOOLS

Patient Resources

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

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better Living with Illness Staying Healthy

IOM DOMAIN

Effectiveness Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Rosenfeld RM, Andes D, Bhattacharyya N, Cheung D, Eisenberg S, Ganiats TG, Gelzer A, Hamilos D, Haydon RC 3rd, Hudgins PA, Jones S, Krouse HJ, Lee LH, Mahoney MC, Marple BF, Mitchell CJ, Nathan R, Shiffman RN, Smith TL, Witsell DL. Clinical practice guideline: adult sinusitis. Otolaryngol Head Neck Surg 2007 Sep;137(3 Suppl):S1-31. [233 references] PubMed

ADAPTATION

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

DATE RELEASED

2007 Sep

GUIDELINE DEVELOPER(S)

American Academy of Otolaryngology - Head and Neck Surgery Foundation - Medical Specialty Society

SOURCE(S) OF FUNDING

American Academy of Otolaryngology--Head and Neck Surgery Foundation

GUIDELINE COMMITTEE

American Academy of Otolaryngology--Head and Neck Surgery Guidelines Development Task Force

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Primary Authors: Richard M. Rosenfeld, MD, MPH, David Andes, MD, Neil Bhattacharyya, MD, Dickson Cheung, MD, MBA, MPH-C, Steven Eisenberg, MD, Theodore G. Ganiats, MD, Andrea Gelzer, MD, MS, Daniel Hamilos, MD, Richard C. Haydon III, MD, Patricia A. Hudgins, MD, Stacie Jones, MPH, Helene J. Krouse, PhD, Lawrence H. Lee, MD, Martin C. Mahoney, MD, PhD, Bradley F. Marple, MD, Col. John P. Mitchell, MC, MD, Robert Nathan, MD, Richard N. Shiffman, MD, MCIS, Timothy L. Smith, MD, MPH, David L. Witsell, MD, MHS

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Richard M Rosenfeld, Nothing to disclose. David Andes, Speaking and grant support for non-sinusitis related research: Schering Plough, Pfizer, Merck, Astellas, Peninsula. Dickson Cheung, Nothing to disclose. Neil Bhattacharyya, Grant support from ArthroCare Corporation. Steven Eisenberg, Employed by BC/BS of Minnesota, Phoenix Healthcare Intelligence, and UnitedHealthcare; consultant to the Minnesota DHHS, Pfizer Healthcare Solutions, Pharmetrics, Inc. and ProfSoft, Inc.; editor Disease Management. Ted Ganiats, Nothing to disclose. Andrea Gelzer, Employed by CIGNA HealthCare. Daniel Hamilos, Consultant for Sinexus, Accentia, Isis, Novartis, Schering, and Genentech; speakers' bureau for Merck and Genentech. Richard C. Haydon III, Speakers bureau Sanofi-Aventis/Merck; advisory board for Alk-Abello, Alcon, Altara & Glaxo-Smith Klein. Patricia A. Hudgins, Nothing to disclose, Stacie Jones, Nothing to disclose, Helene J Krouse, PhD, Grant support Schering-Plough, speakers bureau Sanofi-Aventis, consultant Krames Communication; stockholder - Alcon, Merck, Medtronic, Schering-Plough, Pfizer, Genentech, and Viropharma. Lawrence H. Lee, Employed by United-Healthcare. Martin C. Mahoney, Nothing to disclose. Bradley F. Marple, Speaker's bureau-Glaxo Smith Kline, Sanofi Aventis, Merck, Alcon, Bayer, Altana, Pfizer, Abbott; Advisory Board - Abbott, Glaxo-Smith-Kline, Sanofi-Aventis, Alcon, Bayer, Schering, Altana, Novacal, Allux, Xomed-Medtronics, Replidyne, Greer, ALK-Abello, Critical Therapeutics, MedPoint; Consultant-Alcon, Xomed-Medtronic, Accentia; Stock options- Allux, Novacal. John P. Mitchell, Nothing to disclose. Robert Nathan, Consultant/Scientific Advisor: Amgen, AstraZeneca, Aventis, Genentech, GlaxoSmith, Merck, Novartis, Pfizer, Schering/Key, Sepracor, Viropharm; Grant/Research Support: 3-M Pharmaceuticals, Abbott, AstraZeneca, Aventis, Bayer, Berlex, Bohringer Ingelheim, Bristol-Myers Squibb, Ciba-Geigy, Dura, Forest, GlaxoSmithKline, Immunex, Janssen, Parke-Davis, Pfizer, Proctor & Gamble, Roberts, Sandoz, Sanofi Schering/Key, Sepracor, Sterling, Tap Pharmaceuticals, Wallace, Wyeth. Richard N. Shiffman, Nothing to disclose. Timothy L. Smith, Research grant from NIH, consultant for Acclarent. David L Witsell, Nothing to disclose.

GUIDELINE STATUS

This is the current release of the guideline.

A scheduled review process will occur at 5 years from publication or sooner if new compelling evidence warrants earlier consideration.

GUIDELINE AVAILABILITY

Electronic copies: Available to subscribers of the <u>Otolaryngology - Head and Neck</u> <u>Surgery journal</u>. Print copies: Available from Richard M. Rosenfeld, MD, MPH, Department of Otolaryngology, 339 Hicks Street, Brooklyn, NY 11201-5514; E-mail: richrosenfeld@msn.com

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

• Rosenfeld RM. Executive summary. Clinical practice guideline on adult sinusitis. Otolaryngol Head Neck Surg 2007. Electronic copies: Available to subscribers of the <u>Otolaryngology - Head and Neck Surgery journal</u>.

PATIENT RESOURCES

The following is available:

• Fact sheet: Do I have sinusitis? Electronic copies available from the <u>American</u> <u>Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) Web site</u>.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This NGC summary was completed by ECRI Institute on August 5, 2008. The information was verified by the guideline developer on August 7, 2008.

COPYRIGHT STATEMENT

Permission is granted to reproduce the aforementioned material in **print and electronic format** at no charge subject to the following conditions:

- 1. If any part of the material to be used (for example, figures) has appeared in our publication with credit or acknowledgement to another source, permission must also be sought from that source. If such permission is not obtained then that material may not be included in your publication/copies.
- 2. Suitable acknowledgement to the source must be made, either as a footnote or in a reference list at the end of your publication, as follows:

"Reprinted from Publication title, Vol number, Author(s), Title of article, Pages No., Copyright (Year), with permission from American Academy of Otolaryngology – Head and Neck Surgery Foundation, Inc."

3. Reproduction of this material is confined to the purpose for which permission is hereby given.

4. This permission is granted for non-exclusive world **<u>English</u>** rights only. For other languages please reapply separately for each one required.

DISCLAIMER

NGC DISCLAIMER

The National Guideline Clearinghouse[™] (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria which may be found at http://www.guideline.gov/about/inclusion.aspx.

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.

© 1998-2008 National Guideline Clearinghouse

Date Modified: 11/3/2008

