

Health Care Guideline
Diagnosis and Treatment of Respiratory Illness in
Children and Adults

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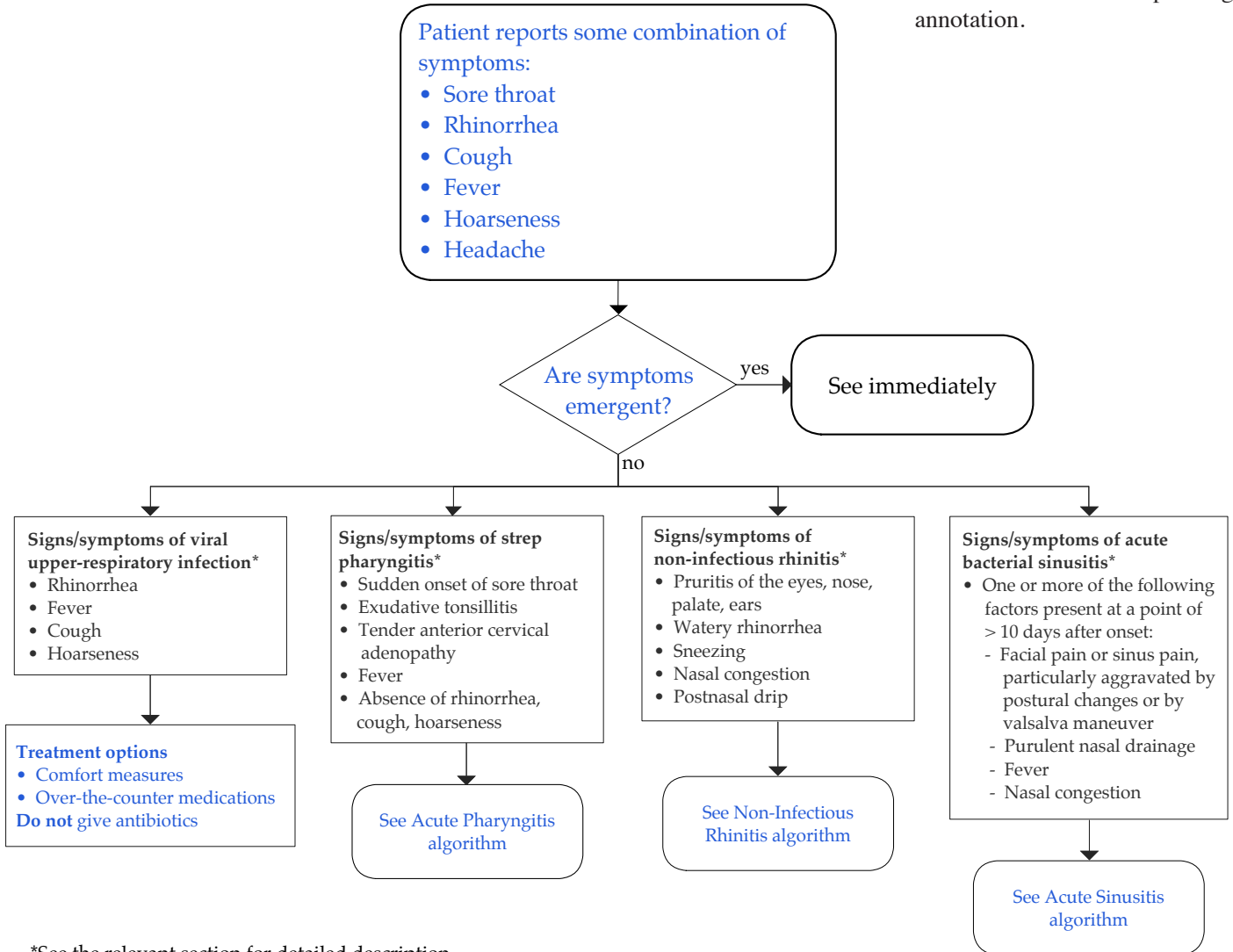
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Main Algorithm

**Fifth Edition
September 2017**

Text in blue in this algorithm indicates a linked corresponding annotation.

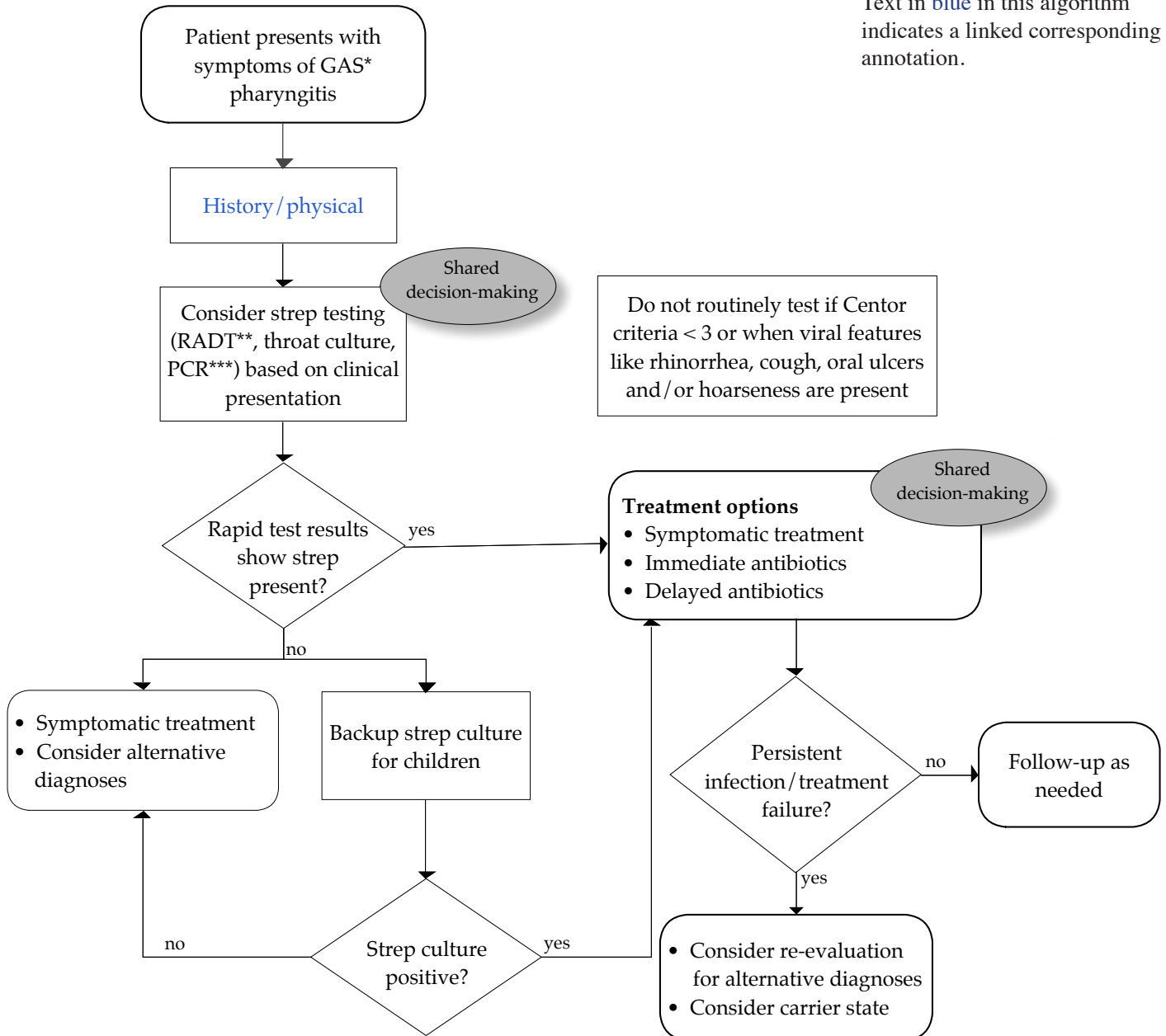


*See the relevant section for detailed description.

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Acute Pharyngitis Algorithm

Text in blue in this algorithm indicates a linked corresponding annotation.

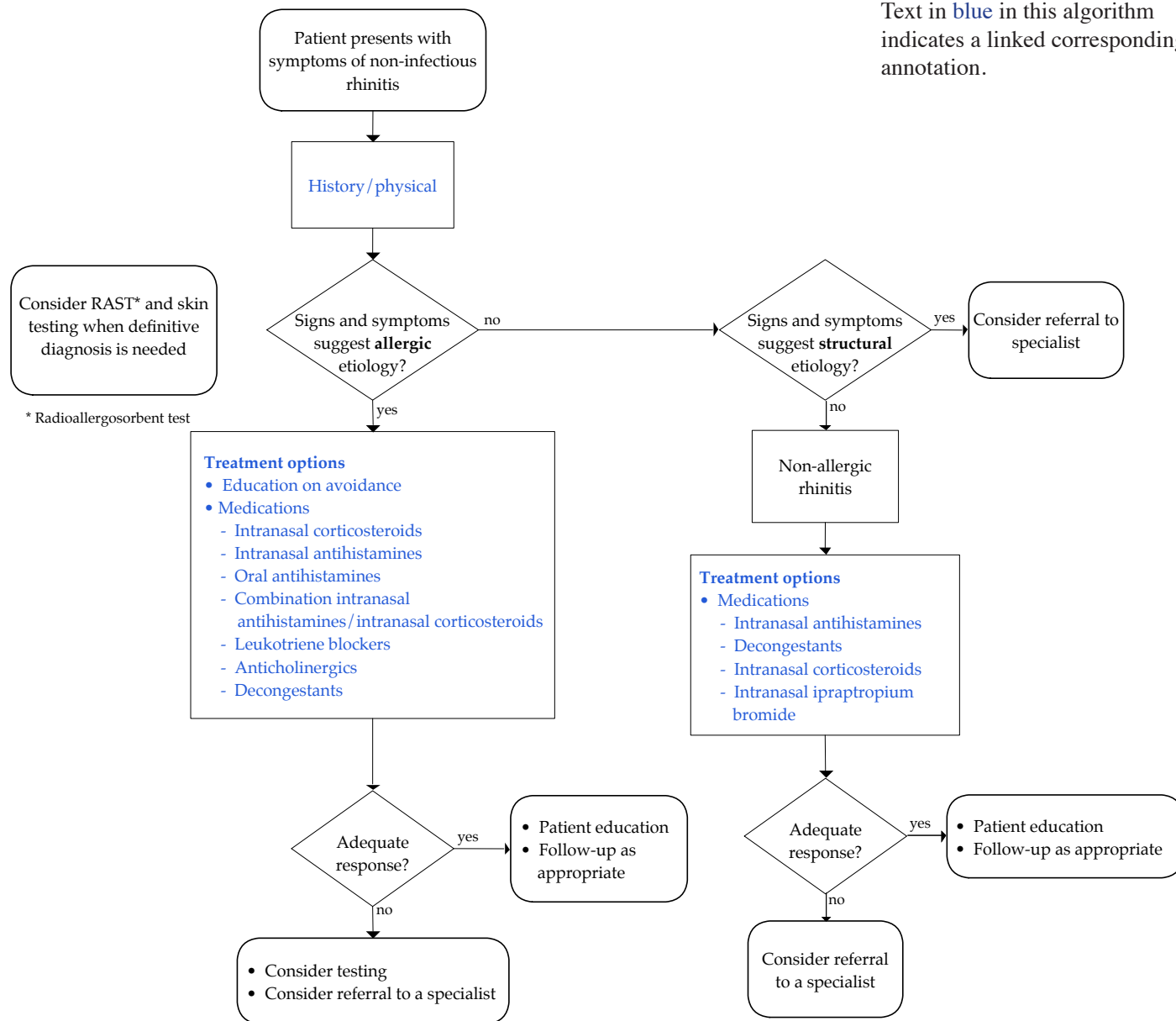


* Group A streptococcal
 ** Rapid antigen detection test
 *** Polymerase chain reaction

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Non-Infectious Rhinitis Algorithm

Text in blue in this algorithm indicates a linked corresponding annotation.



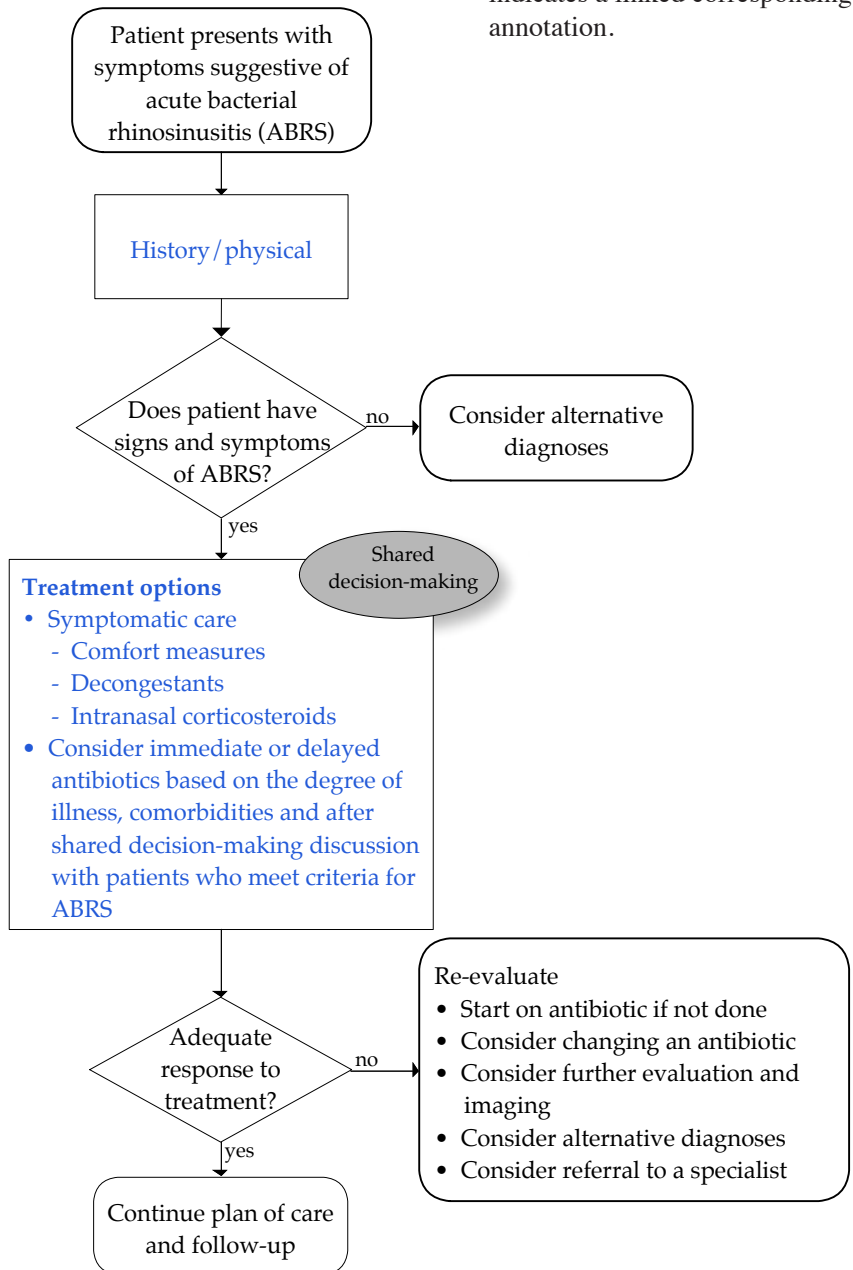
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Acute Sinusitis Algorithm

Text in blue in this algorithm indicates a linked corresponding annotation.

Diagnosis of ABRS
Two clinical presentations where ABRS have a higher likelihood of being present:

- Persistence of symptoms consistent with acute rhinosinusitis lasting 10 days or more without evidence of improvement
- Symptoms are worsening – new onset of fever, headache or increase in nasal discharge after a viral upper respiratory infection that lasted 5-6 days and the patient was initially improving (double worsening or double sickening)
- Severe symptoms and high fever of 102°F for at least 3-4 days from onset of illness should not routinely be used as criteria to diagnose ABRS. The diagnosis should be made on an individualized basis depending on the entire clinical scenario.



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Evidence Grading

Literature Search

A consistent and defined literature search process is used in the development and revision of ICSI guidelines. Literature searches for this guideline were done under following parameters:

- Time frame: May 2012 – February 2017 for all topics except antibiotic use for strep pharyngitis and pharmacologic treatment for allergic and non-allergic rhinitis. The time frame for these two topics included January 2005 – April 2017.
- Types of studies searched for: systematic reviews and meta-analysis, randomized controlled trials and observational studies (case-control, cohort and cross-sectional studies).
- Population: children and adults.
- All studies were published in English and included humans.

For detailed list of literature search terms by topic, see [Appendix A](#).

In addition to the literature searches, articles were obtained by work group members and ICSI staff. Those vetted by the work group were included in the guideline when appropriate.

Methodology

ICSI utilizes the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology system. GRADE involves systematically evaluating the quality of evidence (high, moderate, low, very low) and developing a strength of recommendation (strong, weak). For more detailed information on GRADE, please visit <http://www.gradeworkinggroup.org/>. In addition, when GRADE methodology could not be applied, the work group developed consensus recommendations.

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Recommendations Table

The following table is a list of evidence-based recommendations for the Diagnosis and Treatment of Respiratory Illness in Children and Adults.

Topic	Quality of Evidence	Recommendation	Strength of Recommendation	Relevant References
Viral Upper-Respiratory Infections (VURI)	Low	The ICSI work group does not recommend antibiotics for treatment of common cold symptoms in children and adults.	Strong	<i>Kenealy, 2013 (Systematic Review)</i>
Acute Pharyngitis – Testing for Group A Streptococcus (GAS)	Consensus Statement	It is the consensus of the ICSI work group <i>not</i> to test for Group A Streptococcal (GAS) pharyngitis in patients with modified Centor criteria scores < 3 or when viral features like rhinorrhea, cough, oral ulcers and/or hoarseness are present. Testing should generally be reserved for patients when there is a high suspicion for GAS and for whom there is intention to treat with antibiotics. This involves a shared decision-making conversation with patients and/or caregivers.	Not Applicable	<i>Hersh, 2013 (Clinical Report); Pelucchi, 2012 (Guideline); Shulman, 2012 (Guideline)</i>
Acute Pharyngitis – Treatment for Group A Streptococcus (GAS)	Moderate-High	It is the work group consensus that empirical antibiotic treatment of suspected Group A Streptococcal (GAS) pharyngitis is not recommended. There is inconclusive evidence regarding antibiotic treatment of GAS pharyngitis in low-risk patients (no history of rheumatic fever, no chronic or severe presentation of illness and/or immunocompromised). The work group recommends using shared decision-making with patients and/or caregivers to determine whether to test and treat with antibiotics.	Strong	<i>Little, 2014 (Observational Study); Spinks, 2013 (Systematic Review); Spurling, 2013 (Systematic Review); Kenealy, 2011 (Systematic Review); Robertson, 2005 (Meta-Analysis); Zwart, 2000 (Randomized Controlled Trial)</i>
Non-Infectious Rhinitis	High	The ICSI work group recommends intranasal corticosteroids as initial treatment for allergic rhinitis.	Strong	<i>Weiner, 1998 (Systematic Review)</i>

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Recommendations Table

Topic	Quality of Evidence	Recommendation	Strength of Recommendation	Relevant References
Acute Sinusitis – Diagnosis	Consensus Statement	<p>To diagnose acute bacterial rhinosinusitis (ABRS), the ICSI work group consensus is there are two clinical presentations where ABRS has a higher likelihood of being present:</p> <ul style="list-style-type: none"> • Persistence of symptoms consistent with acute rhinosinusitis lasting 10 days or more without evidence of improvement • Symptoms are worsening – new onset of fever, headache or increase in nasal discharge after a viral upper respiratory infection (VURI) that lasted five to six days and the patient was initially improving (double worsening or double sickening). <p>Clinical presentation of severe symptoms and high fever of 102°F for at least three to four days from onset of illness should not routinely be used as criteria to diagnose patients with bacterial sinusitis. The diagnosis of these patients should be made on an individualized basis depending on the entire clinical scenario.</p>	Not Applicable	<i>Rosenfeld, 2015 (Guideline); Wald, 2013 (Guideline); Chow, 2012 (Guideline)</i>
Acute Sinusitis – Treatment	Moderate-High	<p>Consider symptomatic care as initial treatment for patients with suspected acute bacterial rhinosinusitis (ABRS).</p> <p>Consider prescribing an immediate or delayed antibiotic based on degree of illness, comorbidities and after shared decision-making discussion with patients who meet criteria for ABRS.</p>	Strong	<i>Burgstaller, 2016 (Systematic Review); de la Poza Abad, 2016 (Randomized Controlled Trial); Sng, 2015 (Systematic Review); Ahovuo-Saloranta, 2014 (Systematic Review); Lemiengre, 2012 (Systematic Review)</i>

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Foreword

Introduction

Acute respiratory tract infections are the most common reason for antibiotic prescriptions in adults, comprising 41% of all antibiotic prescriptions (*Harris, 2016*). In children, more than one in five of ambulatory visits result in an antibiotic prescription (*Hersh, 2013*). Data from 2010-2011 national surveys on ambulatory care visits show that the antibiotic prescription rate was 506 per 1,000 population (total 184,032 visits), of which an estimated 353 antibiotic prescriptions were likely appropriate (*Fleming-Dutra, 2016*). Additionally, an observational study from the Netherlands found that 46% of antibiotic prescriptions were not indicated by the guidelines. Overprescribing was the highest for patients between ages 18 and 65 and those who had sore throat (*Dekker, 2015*).

The goal of this guideline is to provide evidence-based recommendations and supporting content regarding the appropriate care and antibiotic use for patients with the following acute upper-respiratory conditions:

1. Viral Upper-Respiratory Infections
2. Acute Pharyngitis
3. Non-Infectious Rhinitis
4. Acute Sinusitis

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Scope and Target Population

The age group included in this guideline is infants greater than three months, children, adolescents and adults.

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Aims

1. Decrease the percentage of patients with symptoms of acute pharyngitis but without confirmed Group A Streptococcal pharyngitis diagnosis who are prescribed an antibiotic. (*Annotation #3*)
2. Increase the percentage of patients diagnosed with allergic rhinitis who are prescribed intranasal corticosteroid therapy as initial treatment. (*Annotation #4*)

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Implementation Recommendation Highlights

Prior to implementation, it is important to consider current organizational infrastructure that addresses the system and process design; training, education and culture; and the need to shift values, beliefs and behaviors of the organization.

Antibiotic Stewardship Resources

Inappropriate antibiotic use can lead to antibiotic resistance. According to the Centers for Disease Control (CDC), antibiotic resistance can lead to an estimated 2 million infections and 23,000 deaths per year in the United States (*Sanchez, 2016*). Additionally, antibiotics can lead to medication-related adverse events for patients taking them. One of every five visits to the emergency departments is due to adverse antibiotic drug reactions (*Harris, 2016*). An estimated 5 to 25% of patients who use antibiotics have an adverse event with about 1 in 1,000 having a serious adverse event (*Harris, 2016*).

Antibiotic over-prescribing leads to the false perception that patients need antibiotics to feel well, while not taking into consideration the harms of overprescribing such as side effects and antibiotic resistance. The potential harms of antibiotic use make it especially important to use antibiotics judiciously.

The following resources on antibiotic stewardship in outpatient settings are available online:

- CDC's Get Smart: Know When Antibiotics Work in Doctor's Office at <https://www.cdc.gov/getsmart/community/improving-prescribing/core-elements/core-outpatient-stewardship.html>
- Minnesota OneHealth Antibiotic Stewardship Collaborative at <http://www.health.state.mn.us/onehealthabx/index.html>

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Algorithm Annotations

1. Initial Presentation

Patient Reports Some Combination of Symptoms

Patients may present for an appointment, call to schedule an appointment or call a nurse line presenting with respiratory illness symptoms. The symptoms of respiratory illness may include sore throat, rhinorrhea, cough, fever, headache and/or hoarseness and sneezing.

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Are Symptoms Emergent?

Patients with concern for upper-airway obstruction, lower-airway obstruction or severe headache should be seen immediately.

Recognizing the signs of a serious illness before it becomes life threatening is usually the clinician's key concern. Patients should be assessed for upper-airway obstruction, lower-airway obstruction, severe headache and the symptoms in Table 1, "Symptoms of Serious Illness." The purpose of Table 1 is to assist clinicians and triage personnel in distinguishing between respiratory illness and potentially more serious illness. The urgency increases with the number and severity of symptoms. Symptoms in Table 1 indicate which patients presenting with respiratory illness symptoms need to be seen immediately by a clinician.

Upper-airway obstruction

Stridor, air hunger, respiratory distress, toxic appearance, cyanosis and drooling are signs of upper-airway obstruction and may indicate diseases such as croup, peritonsillar/retropharyngeal abscess, and epiglottitis. Signs of upper-airway obstruction require immediate medical evaluation and possibly combined otolaryngology/anesthesia management in an emergency room or operating room setting.

Other severe symptoms – including inability to swallow liquids, trismus and drooling without respiratory distress – should receive prompt evaluation by a physician within a reasonable amount of time, depending on the symptoms.

Lower-airway obstruction

Signs of lower-airway obstruction may signal an underlying condition different from respiratory illness. If moderate to severe distress is present, evaluation for pneumonia, chronic obstructive pulmonary disease, asthma, foreign body, cardiac condition or other conditions may be warranted. Symptoms and exam findings like shortness of breath, wheezing, increased respiratory rate and retractions indicate the need for urgent evaluation and may indicate need for intensive treatment, supplemental oxygen and prolonged observation.

Severe headache

Severe headache (usually described as the worst headache of their life) could indicate subarachnoid hemorrhage, complications of sinusitis such as cavernous sinus thrombosis or sphenoid sinusitis, meningitis, encephalitis or other conditions. Such symptoms require prompt, intensive evaluation and care.

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Table 1. Symptoms of Serious Illness

Three months – three years	Four years – adult
Respiratory distress <ul style="list-style-type: none"> • Retractions • Cyanosis • Marked dyspnea • Rapid respiratory rate • Shallow respirations • Difficulty swallowing • Choking • Foreign body inhalation • Stridor with croup symptoms not relieved by conservative measures 	Respiratory distress <ul style="list-style-type: none"> • Retractions • Cyanosis • Moderate to severe dyspnea • Rapid respiratory rate • Shallow respirations • Difficulty swallowing • Choking • Foreign body inhalation • Drooling • Dysphonia • Feeling that throat is closing
Responsiveness and activity <ul style="list-style-type: none"> • Unresponsive • Decreased level of consciousness • Cannot awaken or keep awake • Markedly decreased activity • Very lethargic • Sleeps excessively • Inconsolable • Weak suck or weak cry (if infant) • Refuses feedings 	Responsiveness and activity <ul style="list-style-type: none"> • Altered mental state • Decreased level of consciousness • Markedly decreased activity • Refuses to eat • Very lethargic • Sleeps excessively • Cannot awaken or keep awake • Unresponsive
Dehydration and vomiting <ul style="list-style-type: none"> • No urination within 6-8 hours if younger than one year • No urination within 12 hours if older than one year 	Dehydration and vomiting <ul style="list-style-type: none"> • No urination in more than 12 hours
Meningeal signs <ul style="list-style-type: none"> • Stiff neck • Persistent vomiting 	Meningeal signs <ul style="list-style-type: none"> • Stiff neck • Persistent vomiting • Severe headache
Other <ul style="list-style-type: none"> • Petechial or purpuric rash 	Other <ul style="list-style-type: none"> • Petechial or purpuric rash

This table was created by the ICSI Diagnosis and Treatment of Respiratory Illness in Adults and Children guideline work group based on the information from medical textbooks and the following references: Simon, 1997; Ingraham, 1992; Nelson, 1992.

Complicating Factors

Patients with complicating factors should consult with a clinician. Potential complicating factors may include:

- Comorbidities (examples include but are not limited to congestive heart failure, asthma, chronic obstructive pulmonary disease, sickle-cell disease and diabetes)
- Elderly
- Immunocompromised/immunosuppressed (e.g., on chemotherapy, immune-modifying medications and HIV positive with or without AIDS)
- Pregnancy
- Under-immunized children

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2. Viral Upper-Respiratory Infections

Causes

Upper-respiratory tract infections (URIs) are commonly treated in primary care. Uncomplicated URIs account for 25 million visits and about 20 to 22 million days of absence from work or school each year in the United States. The majority of these infections are due to viral causes (*Zoorob, 2012*).

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History/Physical

A viral upper-respiratory infection (common cold) is a self-limited illness typically manifested by runny nose, fever, cough, sore throat, sneezing and nasal congestion (*Zoorob, 2012*). Children with viral upper-respiratory infections have some combination of the following symptoms: nasal congestion and discharge, fever, sore throat, cough, hoarseness, mild fussiness or irritability, decrease in appetite, sleep disturbance and mild eye redness or drainage. It is not unusual for a child to have five to eight colds a year (*Szilagyi, 1990*).

The symptoms of a common viral upper-respiratory infection usually peak in three to five days and should resolve within 14 days. A mild cough may persist for three or more weeks.

Table 2 was created based on the ICSI work group consensus to summarize the differential diagnoses for viral upper-respiratory infections. Treatment protocols for illnesses in this table are outside the scope of this guideline. Patients presenting with a constellation of symptoms suggestive of these illnesses need to be further evaluated.

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Table 2. Illnesses to Be Differentiated from Viral Upper-Respiratory Infection

Diagnosis	Signs and Symptoms
Otitis media	Otalgia (ear pain) Otorrhea (ear drainage) Hearing loss
Pneumonia/bronchitis	Deep cough Fever Pleuritic chest pain Wheezing Rhonchi Dyspnea Chest tightness
Epiglottitis	Alteration in voice Severe sore throat Severe dysphagia Stridor Drooling
Whooping cough (take history of exposure)	Cough spasms Vomiting with cough No fever Rhinorrhea
Croup	Hoarseness Barky seal cough or persistent hacky cough Inspiratory stridor
Influenza	Sudden onset General malaise Myalgia Fever Cough Hoarseness Conjunctival injection Decreased appetite Headache
Bronchiolitis (RSV and others)	Runny nose Stuffy nose Cough Slight fever Wheezing

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Diagnosis

Typical upper-respiratory illness is a clinical diagnosis, and confirmatory testing is not needed. Depending on symptoms, judicious laboratory and radiology testing may be utilized to rule out other illnesses or secondary infections (e.g., influenza, acute pharyngitis or mononucleosis).

Two recent systematic reviews looking at acute upper- and lower-respiratory infections have shown that the biomarkers procalcitonin and C-reactive protein (CRP), which aim to identify bacterial infections, may be useful in decreasing inappropriate antibiotic prescriptions (*Aabenhus, 2014; Schuetz, 2013*).

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Treatment

Comfort measures

- **Nasal suction for infants.** Use nasal saline before suctioning to help loosen secretions. To relieve nasal congestion, suction gently with a blunt-tipped bulb syringe before feedings and sleep. Using a bulb syringe to aspirate nasal secretions may promote drainage and comfort. Proper cleaning and air-drying of bulb syringe reduces the opportunity for growth of organisms inside the syringe (*Emerson, 1951*).
- **Steam or mist inhalation.** Mist inhalation has historically served as an effective comfort measure for some people. However, systematic review found that evidence is lacking on clear benefit of this measure (*Singh, 2013b*). Potential side effects include burns with use of steam vaporizers, nasal irritation and the potential for microorganism growth in vaporizers. If used, the recommended method for steam inhalation is standing in a hot shower or sitting in the bathroom when the hot shower is running. "Cool mist" vaporizers avoid the burn risk, though not the potential for growth of microorganisms (*Macknin, 1990; Tyrrell, 1989; Ophir, 1987*). The risks should be weighed against the potential benefits of using vaporizers/humidifiers and the parents' ability and willingness to use and clean the device properly.
- **Nasal irrigation.** Saline nose drops help loosen secretions, making it easier to clear nares (*Gadomski, 1992; Szilagyi, 1990*). Evidence shows that there may be some benefit for this remedy, but more studies are needed (*King, 2015*). Findings from one randomized controlled trial on nasal irrigation involving a total of 401 children (ages 6-10 years) with uncomplicated cold or flu showed faster resolution of some nasal symptoms during acute illness and less frequent reappearance of rhinitis subsequently in the saline group (*Slapak, 2008*).

Commercial or homemade saline nose drops/sprays may be used. FDA warns against use of tap water as it may increase risk of infections. The warning can be found at <https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm316375.htm>.

- **Honey.** Avoid using honey preparations for children under one year because of the risk of botulism (*Fashner, 2012; Paul, 2007*). A randomized controlled trial showed that honey was effective at reducing symptoms in a common cold during the first five days of illness (*Waris, 2014*).
- **Use hard candy or throat lozenge for sore throat or cough.** These are not recommended for children, age 4 and under (*Fashner, 2012*).
- **Vapor rubs.** Use in young children given once reduces symptoms (*Paul, 2010*). There have been case reports of complications when vapor rubs were applied directly under the nose in children. Patients should use caution when applying it to the face or on young children.
- **Elevate head of bed.**
- **Get adequate rest.** How a person feels is an indication of the amount of rest needed. When a person with a viral upper-respiratory infection is afebrile and feels like being up and about, normal activity should not prolong the illness.

Over-The-Counter (OTC) Medications

- **Children**

OTC Medicines (General). The ICSI work group does not recommend cough and cold medications for children under age 4.

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A 2014 systematic review evaluated the effectiveness of non-prescription, OTC medications for acute cough in children and adults. It included 29 trials (19 adults and 10 children) involving 4,835 people (3,799 adults and 1,036 children). It found no good evidence for or against the effectiveness of OTC medications for acute cough in children and adults. There were some serious limitations with the studies that were included in this review (*Smith, 2014*).

Decongestants and Antihistamines. There is no evidence of effectiveness of antihistamines in children (*De Sutter, 2015*). The Food and Drug Administration (FDA) has also issued a warning against use of cough and cold products containing decongestants or antihistamines in children under age 2. The warning can be found at <https://www.fda.gov/Drugs/ResourcesForYou/SpecialFeatures/ucm263948.htm>.

Fever reduction. The fever that frequently accompanies a viral upper-respiratory infection in children is not harmful and is usually gone in two to three days. Parents and/or caregivers should be educated on fevers, signs, symptoms and treatment of fevers. Fever can be evaluated only in the specific context of the whole illness and the accompanying circumstances. By itself, the magnitude of fever bears little or no relationship to the severity of the illness (*Schmitt, 1984*). If fever reduction is needed to reduce discomfort, acetaminophen or ibuprofen may be suggested for home use. A 2004 meta-analysis of 17 blinded-randomized controlled trials with children showed that ibuprofen and acetaminophen had safety similar as to analgesics and antipyretics, but that ibuprofen was a more effective antipyretic (*Perrott, 2004*). Another meta-analysis from 2010 that looked at 85 studies comparing ibuprofen and acetaminophen in adults and children found that ibuprofen is as efficacious as or more efficacious than acetaminophen for treatment of pain and fever and is equally safe (*Pierce, 2010*). Aspirin is not recommended for children because of the risk of Reye's syndrome (*Li, 2013*).

- **Adults**

OTC Medicines (General). For adults with a cold, OTC products such as nasal sprays, decongestants, saline nose drops and analgesics may provide temporary relief of sore throat, runny nose, coughing, minor aches and fever.

A 2014 systematic review evaluated the effectiveness of non-prescription, OTC medications for acute cough in children and adults. It included 29 trials (19 adults and 10 children) involving 4,835 people (3,799 adults and 1,036 children). It found no good evidence for or against the effectiveness of OTC medications for acute cough in adults. There were some serious limitations with the studies that were included in this review (*Smith, 2014*).

Decongestants. Decongestants include oral decongestants such as pseudoephedrine HCl or nasal sprays such as oxymetazoline, phenylephrine HCl. Topical decongestants should not be used for longer than 72 hours, owing to the potential for rebound congestion (*Aring, 2016*). Oral decongestants should be used with caution in patients with hypertension or cardiovascular disease (*Aring, 2016*). FDA has public health warning against the use of products containing phenylpropanolamine due to an increased risk of hemorrhagic stroke; it can be found at <https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm150763.htm>.

The evidence on the effectiveness of decongestants shows small benefit in the short term and unclear benefit of long-term use.

A 2015 systematic review of 15 randomized controlled trials (14 trials were in adults only) with 1,838 participants compared the effectiveness and adverse effects of nasal decongestants with placebo for treating the common cold in adults and children. The review found limited evidence to draw definitive conclusions on the effectiveness of single-dose nasal decongestants. However, multiple doses of nasal decongestants may have a small positive effect in adults with the common

cold, although evidence to draw any firm conclusions is insufficient. In addition, evidence was insufficient to make conclusions regarding the effectiveness of oral versus topical decongestants. Nasal decongestants do not seem to increase the risk of adverse events in adults in the short term (*Deckx, 2016*).

A 2011 systematic review found that nasal and oral decongestants reduce nasal congestion in common cold over 3 to 10 hours, but the effect in the longer term (> 10 hours) is unclear (*Arroll, 2011*).

Antihistamines. A 2015 systematic review of 18 randomized controlled trials evaluating the effectiveness of antihistamines as monotherapy compared to placebo for the common cold found antihistamines have short-term (days one and two of treatment) benefit on severity of the symptoms, but no long-term effect. There was no clinically significant effect on nasal obstruction, rhinorrhea or sneezing (*De Sutter, 2015*).

Intranasal corticosteroids. A 2015 systematic review of three trials (two trials included adults and one included children) with a total of 353 participants found no evidence to support the use of intranasal corticosteroids for symptomatic relief for the common cold. The included studies had methodological limitations (*Hayward, 2015*).

Fever reduction. A 2010 meta-analysis that evaluated 85 studies comparing ibuprofen and acetaminophen in adults and children found ibuprofen is as efficacious as or more efficacious than acetaminophen for treatment of pain and fever and is equally safe (*Pierce, 2010*). A 2013 systematic review on acetaminophen in adults with the common cold found that acetaminophen may help relieve nasal obstruction and rhinorrhea but did not appear to improve other cold symptoms. However, due to limitation in the studies, the data in that review did not provide sufficient evidence to inform practice (*Li, 2013*).

Aspirin, ibuprofen and naproxen should be avoided by persons who are not eating well (risk of gastrointestinal upset), have a history of peptic ulcer or related disorder, or have aspirin-sensitive asthma, coronary artery disease or have renal dysfunction.

Complementary and Integrative Medicine

The evidence on the efficacy of zinc, vitamin C, echinacea and carragenan nasal sprays is limited and insufficient. More studies are needed.

Some studies indicate that oral zinc may be beneficial at reducing URI length and symptoms, though side effects may be limiting.

Two large systematic reviews involving adults show some evidence that oral zinc gluconate may decrease the duration of a cold if started within 24 hours of onset. Adverse reactions include nausea and bad taste. However, the quality of studies overall is poor, and more research is needed (*Singh, 2013a; Science, 2012*). Intranasal zinc gluconate therapy has been associated with cases of anosmia and is not recommended (*Davidson, 2010*). A meta-analysis of three small randomized controlled trials of high-dose zinc gluconate lozenges for treating the common cold demonstrated reduced duration of symptoms such as nasal discharge, nasal congestion, cough, sneezing, sore throat, scratchy throat, hoarseness and muscle ache. There was no difference in the duration of headache and fever (*Hemilä, 2015*). A randomized controlled trial of zinc sulphate with 200 healthy children of efficacy found that the zinc sulphate group had a shorter mean duration of cold symptoms and decreased total severity scores for cold symptoms. Adverse effects were mild and similar in zinc sulphate and placebo groups (*Kurugöl, 2006*).

There are health risks associated with excessive intake of zinc. See the National Institutes of Health-Office of Dietary Supplements website on tolerable zinc intake levels: <https://ods.od.nih.gov/factsheets/Zinc-HealthProfessional/>.

Few therapeutic trials on the efficacy of vitamin C on the duration and severity of common cold symptoms are available. A single meta-analysis of seven trials involving 3,249 episodes examining the therapeutic

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effects of vitamin C compared with placebo found no consistent effect of vitamin C on the duration or severity of colds. No studies are available on children (*Hemilä, 2013*).

A 2014 systematic review of 15 randomized controlled trials of mixed quality found no benefits for treating colds with echinacea, although it is possible there is a weak benefit from some echinacea products (*Karsch-Völk, 2014*).

Two small randomized controlled trials did not find statistically significant benefit in using iota-carrageenan nasal spray versus placebo in early treatment of the common cold (*Eccles, 2015; Fazekas, 2012*).

Antibiotics

Recommendation	Quality of Evidence and Strength of Recommendation
<p>The ICSI work group does not recommend antibiotics for treatment of common cold symptoms in children and adults.</p>	<p>Quality of Evidence: Low Strength of Recommendation: Strong</p>
<p>Benefit Not treating with antibiotics eliminates the possible side effects of antibiotics such as nausea, vomiting, allergic reactions and <i>Clostridium Difficile</i> infection. In addition, better stewardship of antibiotics helps reduce potential for antibiotic resistance.</p> <p>Harms None</p> <p>Benefit-Harms Assessment Given that antibiotics do not help resolve viral infections, they are not indicated for treatment in viral infections such as common colds. There are no harms by not treating common colds with antibiotics.</p>	
<p>Relevant Resources <i>Kenealy, 2013 (Systematic Review)</i></p>	

Antibiotics are effective only for treating bacterial infections. Because the vast majority of respiratory illnesses are viral infections, antibiotic use will not cure or shorten their length (*Zoorob, 2012*).

A 2013 updated systematic review of randomized controlled trials involving 1,047 patients compared any antibiotic therapy against placebo in people with symptoms of acute upper-respiratory tract infection for less than seven days and found that participants receiving antibiotics for the common cold did no better in terms of lack of cure or persistence of symptoms than those on placebo. Adults receiving antibiotics had a significantly greater risk of adverse effects with antibiotics than with placebo; there was no greater risk in children (*Kenealy, 2013*). A 2011 systematic review found that antibiotics may be no more effective than placebo at increasing cure rate or general improvement at five to seven days in people with colds (*Arroll, 2011*).

Antibiotics often cause side effects such as gastrointestinal discomfort, diarrhea, diaper rash and yeast infections. More severe side effects may include life threatening allergic reactions and *Clostridium Difficile* infections. Additionally, unnecessary use of antibiotics can lead to the development of antibiotic-resistant strains of bacteria; cause millions of infections leading to an estimated 23,000 deaths in the United States annually (*Sanchez, 2016*). Finally, antibiotic use in infancy and childhood has been associated with allergic, autoimmune and infectious diseases (*Sanchez, 2016*).

Unfortunately, provider concerns regarding patient expectations may lead to unnecessary antibiotic prescriptions. It is important to educate patients about the nature of viral infections and the lack of benefit with antibiotics along with potential harms. Effective educations along with clear guidelines for follow-up help alleviate patient concerns and improve satisfaction (*Sanchez, 2016*). In addition, public displays of a commitment to antibiotic stewardship have been shown to reduce inappropriate antibiotic prescriptions (*Sanchez, 2016*).

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Codeine

Codeine is no more effective than placebo for cough in upper-respiratory illness and is not recommended for adults (*Fashner, 2012*). **The use of codeine may be dangerous in children.** Various organizations such as the World Health Organization, the Food and Drug Administration (FDA) and European health agencies have issued warnings against the use of codeine in children. Specifically, the FDA has a black box warning on codeine and codeine-containing preparations. The FDA warning can be found at <https://www.fda.gov/Drugs/DrugSafety/ucm549679.htm>.

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Follow-Up

The consensus of the ICSI work group is to contact a health care provider if:

- fever lasts for more than three days; or
- symptoms worsen after five days; or
- concerning symptoms appear (e.g., increasing symptoms of illness, lethargy, decreased responsiveness or difficulty breathing); or
- symptoms have not improved after 10 days; it is not unusual, however, for a mild cough and congestion to continue for several weeks.

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Prevention

Although the viral upper-respiratory infection is a respiratory illness, researchers have found that viral upper-respiratory infections are spread more by hands of the person with a cold and by very close contact than by droplets in the air. **Hand washing and use of hand sanitizers are the most effective ways to prevent the spread of the common cold (viral upper-respiratory infection)** (*Allan, 2014*). Viral upper-respiratory infection is most contagious at the onset of symptoms and while febrile (*Carabin, 1999*). Viral shedding continues for up to two weeks after the onset of initial upper-respiratory symptoms (*Szilagyi, 1990*).

A systematic review and meta-analysis of randomized placebo-controlled trials involving 11,306 participants found that vitamin C supplementation did not reduce the incidence of colds in the general population. In trials involving 598 participants who were exposed to periods of severe physical exercise (e.g., marathon runners, skiers and soldiers), the risk of developing a cold was significantly lower, indicating that vitamin C supplementation may be useful in this population (*Hemilä, 2013*).

Two randomized controlled trials on efficacy of vitamin D supplementation for preventing common cold show contradictory results. One randomized trial involving 164 voluntary young Finnish men undergoing military training found that the absence from duty due to respiratory tract infection was lower in the vitamin D supplementation group than it was in the control group (*Laaksi, 2010*). Another randomized trial conducted among 322 healthy adults in New Zealand found that monthly administration of 100,000 IU of vitamin D did not reduce the incidence or severity of upper-respiratory tract infections in healthy adults (*Murdoch, 2012*).

The evidence on the efficacy of probiotics, zinc, echinacea, gargling, yeast and cranberry polyphenols is limited. The studies are either small or of low quality, or the evidence is insufficient to make conclusions. More studies are needed (*Hao, 2015; Karsch-Völk, 2014; Auinger, 2013; McFarlin, 2013; Nantz, 2013; Singh, 2013a; Graubaum, 2012; Kurugöl, 2006; Satomura, 2005*).

Prevention Tips for Children

- Use and teach good hand washing.
- Ask visitors to wash their hands before holding a baby.

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- Make sure staff and children at day care centers are being taught good hand washing and other infection-control measures.
- Discourage visitors who have an acute illness, a fever or contagious disease.
- Prevent a child with viral upper-respiratory infection from sharing toys and pacifiers with other children, and clean these items with soap and hot water as feasible to reduce opportunities for viral transmission.
- Encourage mothers to continue breastfeeding as it may offer further protection from recurrent otitis and prolonged duration of upper-respiratory infections (*Duncan, 1993; Frank, 1982*).

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3. Acute Pharyngitis

Causes

Acute pharyngitis is one of the most common conditions encountered in primary care with 12 million ambulatory visits in the United States annually (*Harris, 2016*).

Viral causes of acute pharyngitis. Most cases of acute pharyngitis are viral in etiology. Viral pathogens can cause pharyngitis clinically indistinguishable from group A beta streptococcal pharyngitis and can also cause distinct clinical syndromes. These include adenovirus (pharyngoconjunctival fever), parainfluenza (hoarseness, croup), rhinovirus (coryza), herpes simplex type 1 and 2 (gingivitis and stomatitis), respiratory syncytial virus (hoarseness, wheezing), Epstein-Barr virus (infectious mononucleosis), influenza, coxsackievirus A (herpangina), enteroviruses (diarrhea), human immunodeficiency virus (HIV), coronavirus (viral upper-respiratory infection symptoms) and cytomegalovirus (mono-like illness) (*Paradise, 1992; Lang, 1990*).

Bacterial causes of acute pharyngitis. Group A streptococcus (GAS) accounts for approximately 5 to 15% of adults presenting with pharyngitis and up to 30% in children (*Van Brusselen, 2014*). Bacterial pathogens other than group A beta streptococcal that can cause pharyngitis include group C and group G strep, mixed anaerobes (Vincent's angina), *Fusobacterium necrophorum*, *Neisseria gonorrhoea*, *Corynebacterium diphtheriae* (diphtheria), *Yersinia pestis* (plague), *Treponema palladium* (secondary syphilis), *Francisella tularensis* (tularemia), *Mycoplasma pneumoniae* (atypical pneumonia), and several chlamydial species (*Paradise, 1992; Lang, 1990*).

Exclusion of Dangerous Conditions

Severe symptoms such as drooling, dysphonia, muffled or "hot potato" voice, or neck swelling especially with difficulty swallowing warrant evaluation for rare but serious infections, including, but not limited to:

- Epiglottitis
- Peritonsillar abscess
- Retropharyngeal space infections
- Submandibular space infections
- Infectious thrombophlebitis of the internal jugular vein (Lemierre's Syndrome)
- Diphtheria
- Acute retroviral syndrome

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History/Physical

History and physical findings may increase or decrease the likelihood of group A beta-hemolytic streptococcus (GAS) as the cause of pharyngitis. Also, close exposure to (especially familial exposure) should increase the suspicion of GAS pharyngitis.

Common signs and symptoms associated with GAS pharyngitis include:

- Sudden onset of sore throat
- Exudative tonsillitis
- Tender anterior cervical adenopathy
- History of fever
- Absence of rhinorrhea, cough and hoarseness

Additional signs and symptoms (often in the setting of the symptoms above) include:

- Headache
- Abdominal pain
- Vomiting
- Malaise
- Anorexia
- Rash (especially scarlet fever) or urticaria

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Diagnosis

Most cases of pharyngitis are viral and resolve on their own. Lack of physical findings and history suggesting GAS may eliminate the need to do testing and focus treatment instead on symptomatic measures.

Clinical scoring criteria have been developed to help determine the likelihood of a bacterial cause. The most extensively used are the modified Centor criteria, which include fever by history, tonsillar exudates, tender, anterior cervical adenopathy, absence of cough, and age (*Kalra, 2016; Choby, 2009*). Centor criteria have a low positive predictive value for determining the presence of GAS infection but can be used to identify patients who have a low probability of group A streptococcal pharyngitis and do not warrant further testing (*Harris, 2016*).

The ICSI work group was unable to identify recent primary literature on when to test for GAS. Therefore, ICSI work group reviewed recommendations from the Infectious Diseases Society of America (IDSA), the European Society for Clinical Microbiology and Infectious Diseases (ESCMID) and the American Academy of Pediatrics (AAP). The recommendations of these societies are summarized in Table 3.

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<p>Consensus Recommendation</p> <p>It is the consensus of the ICSI work group to NOT test for Group A Streptococcal (GAS) pharyngitis in patients with modified Centor criteria scores less than three or when viral features like rhinorrhea, cough, oral ulcers and/or hoarseness are present.</p> <p>Testing should generally be reserved for patients when there is a high suspicion for GAS and for whom there is intention to treat with antibiotics. This involves a shared decision-making conversation with patients and/or caregivers.</p>
<p>Benefits Judicious testing would reduce costs associated with over-testing. Shared-decision making discussions can help patients and/or caregivers understand the benefits and risks of testing and treatment.</p> <p>Harms Because fewer patients may be tested, there may be cases of GAS that are not diagnosed. It is unknown whether this would lead to increased complications.</p> <p>Benefit-Harms Assessment The benefit of more prudent testing and shared decision-making conversations about testing and/or treatment outweigh the possible harms.</p>
<p>Relevant Resources: <i>Hersh, 2013 (Clinical Report); Pelucchi, 2012 (Guideline); Shulman, 2012 (Guideline)</i></p>

GAS pharyngitis is uncommon in children younger than age 3 and rare in children younger than 18 months. Rheumatic fever is uncommon in children younger than age 3 (*Peter, 1992*). Diagnostic testing is not routinely indicated for children under age three. Children under age 3 who have risk factors such as an older sibling with GAS infection may be considered for testing (*Shulman, 2012*).

Table 3. Recommendations for Selection Criteria and Diagnosis for GAS Testing by IDSA, AAP and ESCMID

<p>IDSA Clinical Practice Guideline for the Diagnosis and Management of Group A Streptococcal Pharyngitis: 2012 Update by the Infectious Diseases Society of America (<i>Shulman, 2012</i>)</p>	<p>AAP Clinical Report: Principles of Judicious Antibiotic Prescribing for Upper-Respiratory Tract Infections in Pediatrics (<i>Hersh, 2013</i>)</p>	<p>ESCMID: Guideline for the Management of Acute Sore Throat (<i>Pelucchi, 2012</i>)</p>
<p>Swabbing the throat and testing for GAS pharyngitis by rapid antigen detection test (RADT) and/or culture should be performed because the clinical features alone do not reliably discriminate between GAS and viral pharyngitis except when overt viral features like rhinorrhea, cough, oral ulcers and/or hoarseness are present.</p> <p>In children and adolescents, negative RADT tests should be backed up by a throat culture. Positive RADTs do not necessitate a backup culture because they are highly specific.</p>	<p>Diagnosis of GAS pharyngitis requires confirmation by rapid testing or culture.</p> <p>Only test if two of the following are present: fever, tonsillar exudate/swelling, swollen/tender anterior cervical nodes, absence of cough.</p> <p>Testing should generally not be performed in children younger than age 3 in whom GAS rarely causes pharyngitis and in whom rheumatic fever is uncommon.</p>	<p>The Centor scoring system can help to identify those patients who have higher likelihood of group A streptococcal infection.</p> <p>In patients with high likelihood of streptococcal infections (e.g., 3-4 Centor criteria) physicians can consider the use of rapid antigen test (RAT). If RAT is performed, throat culture is not necessary after a negative RAT for the diagnosis of group A strep.</p>

If a patient is indicated for GAS testing, an appropriately performed throat swab touches both tonsillar pillars and the posterior pharyngeal wall. The tongue should not be included (although its avoidance is sometimes technically impossible).

Testing can be done through rapid antigen detection test (RADT), throat culture or polymerase chain reaction (PCR). Negative RADT tests should be backed up by a throat culture in children. This is not necessary in adults but may be done at clinician discretion (*Shulman, 2012*). Positive RADTs do not necessitate a backup culture (*Shulman, 2012*).

Polymerase chain reaction (PCR) may also be used for primary testing and does not require backup culture (*Pritt, 2016*).

Anti-streptococcal antibody titers reflect past rather than current events so are not recommended in the routine diagnosis of acute pharyngitis (*Shulman, 2012*).

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Treatment

Antibiotics

It has been estimated that 60% of adults seen in a United States clinic in 2010 for a complaint of sore throat received an antibiotic prescription, with a trend toward prescribing a broad spectrum of antibiotics (*Barnett, 2014*). Overtreatment of acute pharyngitis is a major cause of inappropriate antibiotic use that can be avoided through appropriate evaluation and treatment.

Currently, based on the same evidence, there are conflicting recommendations regarding treatment for GAS. In reviewing 17 international guidelines, Van Brusselen (2014) found that nine were pro-treatment (including a medical society from the United States), five favored no treatment and two had special considerations (*Van Brusselen, 2014*). The ESCMID guideline recommends that antibiotics should not be used in patients with less severe presentation of sore throat, e.g., 0-2 Centor criteria to relieve symptoms. Modest benefits of antibiotics, which have been observed in patients with 3-4 Centor criteria, have to be weighed against side effects, the effect of antibiotics on microbiota, increased antibacterial resistance, medicalization and costs (*Pelucchi, 2012*). The IDSA still advises antimicrobial treatment for adults and all children with GAS pharyngitis, given possible complications, although rare (*Shulman, 2012*). The AAP recommends antibiotic therapy for children with pharyngitis confirmed to be caused by GAS (*Hersh, 2013*).

In reviewing primary literature on treatment of GAS, the work group found several limitations. Many of the studies are on patients with sore throats and suspected but not confirmed GAS. In addition, the randomized controlled trials were all conducted prior to 2000, and several were conducted in the 1950s and 1960s before concerns of bacterial resistance.

Overall, the literature mostly shows that compared to no antibiotics, use of antibiotics with confirmed or suspected GAS may decrease non-suppurative and suppurative complications (*Little, 2014; Spinks, 2013; Kenealy, 2011; Robertson, 2005*). Evidence is not conclusive but does suggest antibiotics may improve symptoms in adults by one to three days (*Spinks, 2013; Kenealy, 2011; Zwart, 2000*).

There are no conclusive studies on children. The ones that are available are underpowered. A 2003 small randomized control trial among 156 children ages 4-15 years old found that antibiotics (penicillin) had no beneficial effect on the average duration of sore throat symptoms. Treatable strep complications (i.e., peritonsillar abscess, scarlet fever and impetigo) occurred more often in the placebo group. Given these findings, the authors concluded more prudent antibiotic use should be considered, such as limiting antibiotics to those severely ill or at high risk (*Zwart, 2003*).

There is some evidence that delayed antibiotics is a possible option that may be provided to patients and/or caregivers. A prospective observational cohort study of 12,829 adults with sore throat found that immediate antibiotic prescription was associated with fewer complications as delayed prescription of antibiotics. The risk of reconsultation was also reduced by either delayed or immediate antibiotic strategies (*Little, 2014*). A 2013 systematic review of four randomized controlled trials comparing no antibiotics, immediate antibiotics and delayed antibiotics found there was a small difference favoring immediate antibiotics for relieving fever and pain from sore throat (*Spurling, 2013*).

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Available data show the incidence of acute rheumatic fever (ARF) in the Western countries to be < 1/100,000 children while higher in the developing countries at 50/100,000 on average (Van Brusselen, 2014). It is not clear from research how much of the drop in acute rheumatic fever incidence is due to the increased use of antibiotics in GAS, improved living conditions or a different strain of GAS (Van Brusselen, 2014; Shulman, 2006; Robertson, 2005; Bisno, 1991). However, because the decline in rheumatic fever began before the antibiotic era, it is unlikely that antibiotics alone are responsible for the decreasing incidence (Bisno, 1991).

Peritonsillar abscesses are potential rare complications of GAS. The annual incidence of peritonsillar abscess (PTA) in the United States is approximately 30 per 100,000 persons (Galioto, 2017). Although PTA is generally a polymicrobial infection, GAS is considered a predominant pathogen (Galioto, 2017; Klug, 2017).

Taking into consideration the primary literature, the benefits and harms of antibiotics, as well as the differing recommendations among organizations internationally, the work group recommends taking a shared decision-making approach to the testing and treatment of GAS.

Recommendation	Quality of Evidence and Strength of Recommendation
<p>It is the work group consensus that empirical antibiotic treatment of suspected Group A Streptococcal (GAS) pharyngitis is not recommended.</p> <p>There is inconclusive evidence regarding antibiotic treatment of GAS pharyngitis in low-risk patients (no history of rheumatic fever, no chronic or severe presentation of illness and/or immunocompromised). The work group recommends using shared decision-making with patients and/or caregivers to determine whether to test and treat with antibiotics.</p>	<p>Quality of Evidence: Moderate-High</p> <p>Strength of Recommendation: Strong</p>
<p>Benefit Shared decision-making use will result in more prudent use of GAS testing and antibiotics.</p> <p>Harms Shared decision-making may lead to fewer patients being tested and/or treated. Those not treated may have longer symptom duration and increased risk of complications.</p> <p>Benefit-Harms Assessment Antibiotic treatment of GAS reduces symptoms by one to three days and reduces complications. However, dangerous complications of GAS such as acute rheumatic fever and abscesses are rare, and antibiotics have the risk of side effects as well as creating bacterial resistance. Given these considerations, judicious use of testing and antibiotics based on shared decision-making conversations with patients and/or caregivers is appropriate.</p>	
<p>Relevant Resources <i>Little, 2014 (Observational Study); Spinks, 2013 (Systematic Review); Spurling, 2013 (Systematic Review); Kenealy, 2011 (Systematic Review); Robertson, 2005 (Meta-Analysis); Zwart, 2000 (Randomized Controlled Trial)</i></p>	

In shared decision-making discussions with patients/caregivers, there are three options to present:

1. Observation (no antibiotics prescribed)
2. Immediate antibiotics prescribed
3. Delayed antibiotics (prescribed with instructions to delay filling the prescription to see if symptoms improve)

If a strategy of delayed antibiotics is chosen, the clinician must give the patient detailed instructions on what symptoms warrant filling the prescription and what symptoms necessitate returning to clinic for re-evaluation. It is important to avoid the situation where a patient fills the prescription for worsening symptoms that are actually indicative of a complication (e.g., abscess).

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The work group recommends reviewing the following points when deciding the appropriate treatment plan:

Benefits of antibiotic treatment

- Improve duration of symptoms by one to three days
- Decrease dangerous complications, including rheumatic fever

Harms of antibiotic treatment

- Complications such as rheumatic fever are very rare.
- Antibiotics have side effects including but not limited to gastrointestinal upset, *Clostridium difficile* infection and allergic reactions.
- Repeated antibiotic use may lead to antibiotic resistance.

Antibiotic Considerations

If treating with an antibiotic, it is the consensus of the ICSI work group that penicillin (PCN) is the drug of choice for treatment of culture-positive cases of GAS pharyngitis. In children and patients unable to swallow pills, amoxicillin is an acceptable alternative due to the poor palatability of the penicillin suspension (Lennon, 2008).

In penicillin-allergic patients, options include cephalosprins (for some types of allergies), macrolides and clindamycin. Although macrolides may be an acceptable alternative, clinicians should check their local resistance patterns.

The IDSA (Shulman, 2012), AAP (Hersh, 2013) and ESCMID (Pelucchi, 2012) recommends penicillin or amoxicillin as first-line antibiotics in treatment of GAS. For alternatives for penicillin-allergic patients, the IDSA recommends first-generation cephalosporin, clindamycin or clarithromycin, and azithromycin; the AAP and ESCMID do not list their recommendations.

Although the work group still recommends penicillin as first-line treatment, there is some literature suggesting other classes of antibiotics to be as efficacious as or more efficacious than penicillin (van Driel, 2016; Altamimi, 2012; Sakata, 2008; Pichichero, 2007). Further research is needed.

Duration of Antibiotic Treatment and Follow-Up

It is important to emphasize to the patient that completion of the course of antibiotic is important to reduce risk of recurrence. After initiating a course of an appropriate antibiotic, improvement in symptoms related to GAS pharyngitis should be seen within three to four days.

The IDSA recommends 10 days if treating with penicillin/amoxicillin, first-generation cephalosporin, clindamycin or clarithromycin – five days if treating with azithromycin. The ESCMID recommends two to three times daily dose for 10 days if treating with penicillin. The AAP Clinical Report did not list AAP recommendations.

A 2008 meta-analysis of 11 randomized controlled trials involving patients of any age with GAS diagnosis compared short-course (≤ 7 days) vs. long-course (at least two days longer than short course) treatment with the same antibiotics. It found that in the penicillin group, microbiological eradication rates of GAS were significantly higher with 10 days of treatment vs. five to seven days and that the difference was statistically nonsignificant with cephalosporin treatment. In trials involving children and adolescents (ages < 18 years), microbiological eradication was less likely with short-course treatment. Clinical cure rates were also inferior with the short-course treatment. Adverse events rates did not significantly differ between compared groups (Falagas, 2008).

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Return to School for Children

The two available studies on return to school had differing conclusions. A 1993 study of 47 children (ages 4 to 17) with pharyngitis and a positive throat culture for group A streptococci found that 17 (36.2%) of the 47 patients had a positive culture the morning after initiating antibiotic therapy. However, 39 (83%) of the patients became "culture negative" within the first 24 hours. The authors suggest that children with GAS should complete 24 hours of antibiotics before returning to day care or school (*Snellman, 1993*).

In a study of 111 children with confirmed GAS, 91% did not have detectable GAS on day two, regardless of whether they had received a second dose of amoxicillin that morning. The authors conclude that if treated by 5 p.m. on day one, it is reasonable for children with GAS to return to school on day two (*Schwartz, 2015*).

There is no evidence on children not treated with antibiotics.

The work group finds it reasonable for children with GAS pharyngitis to return to school 12-24 hours after first dose of antibiotic. If not treated with antibiotics, it is reasonable for children to return to school after they are 24 hours fever free without antipyretic treatment.

History of Rheumatic Fever

An individual with a previous history of rheumatic fever who develops GAS pharyngitis is at high risk for a recurrent attack of rheumatic fever. The infection does not need to be symptomatic to trigger a recurrence. Rheumatic fever recurrence can also occur when a symptomatic infection is optimally treated. Therefore, prevention of recurrent rheumatic fever requires continuous antimicrobial prophylaxis, and GAS infections in family members should be diagnosed and treated promptly (*Dajani, 1995*).

Symptomatic Care

Over-the-counter pain relievers such as acetaminophen or a non-steroidal anti-inflammatory agent (NSAID) may provide fast and effective relief of sore throat pain (*Kenealy, 2011*).

Additional treatments that may help with throat pain include lozenges, sipping warm or cold beverages, eating cold or frozen desserts and eating soft foods. Salt-water gargles are frequently used for throat pain. It is not clear that salt water works to relieve pain, but it is unlikely to be harmful.

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Reevaluation

Patients whose symptoms do not improve require reevaluation to determine if the treatment plan is appropriate, if a complication has occurred, or if an alternative diagnosis should be considered. Alternative diagnoses include but are not limited to infectious mononucleosis, peritonsillar/retropharyngeal abscess, and infectious thrombophlebitis of the internal jugular vein (Lemierre's Syndrome).

Mononucleosis

If clinically indicated, testing for mononucleosis may be appropriate. Infectious mononucleosis is most commonly associated with primary Epstein-Barr virus (EBV), which is usually transmitted through contact with the oropharyngeal secretions. Primary EBV infection is often manifested as non-specific illness in young children. Adolescents and adults are most commonly infected (*Luzuriaga, 2010*).

Newly infected patients typically present with fever, sore throat, pharyngitis, lymphadenopathy, malaise or fatigue. Patients may also have headache, hepatomegaly, splenomegaly, palatal petechiae, periorbital edema and rashes. Morbilliform rash is more common following the administration of ampicillin or amoxicillin (occurring in up to 95% of patients with such drug exposure) and other beta-lactam antibiotics (40-60%) (*Luzuriaga, 2010*).

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Peritonsillar Abscess

Peritonsillar abscess may be a complication of GAS, but it also may be part of the differential diagnosis for the pharyngitis itself, caused by a different pathogen. Patients with peritonsillar abscesses typically have progressive sore throat, pain on swallowing typically becoming unilateral, ear pain, malaise and trismus. Examination typically reveals tonsillar exudates and asymmetric, indurated peritonsillar swelling with deviation of the tonsil and uvula towards the midline. Other common findings are tender and enlarged cervical lymph nodes, trismus, muffled voice and fever. Significant upper airway obstruction is rare (*Galioto, 2017*).

Infectious Thrombophlebitis of the Internal Jugular Vein (Lemierre's Syndrome)

Lemierre's Syndrome is a potentially severe complication of pharyngitis caused by *Fusobacterium necrophorum* or mixed anaerobic flora. Recent evidence suggests that *Fusobacterium necrophorum* pharyngitis occurs as often as streptococcal pharyngitis in patients ages 15 to 30 (*Centor, 2009*). The infection begins in the oropharynx with thrombosis of the tonsillar veins followed by involvement of the parapharyngeal space and is associated with jugular venous thrombophlebitis and the dissemination of infection by septic emboli. Both children and adults with Lemierre's Syndrome almost always have pharyngitis at presentation. Patients typically present acutely ill with fever (> 39°C) and rigors, often accompanied by respiratory distress and worsening of pharyngitis symptoms with neck swelling (*Centor, 2009*).

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Carrier State

Patients who are chronically colonized with GAS are called carriers. These patients are at very low risk, if any, for developing suppurative (e.g., peritonsillar abscess) or non-suppurative (e.g., rheumatic fever) complications and are unlikely to spread GAS to close contacts. Therefore, most carriers require no medical intervention. A full discussion of management of patients who are carriers of GAS is beyond the scope of this guideline.

In the patient with recurrent culture-positive GAS pharyngitis, the patient is likely to be a streptococcal carrier if:

- clinical findings suggest a viral etiology,
- epidemiologic findings (e.g., age or season) suggest a viral etiology,
- there is little clinical response to antibiotic therapy,
- throat cultures done between episodes of acute pharyngitis (when the patient is asymptomatic) are also positive, or
- there is no serologic response to GAS antigens if measured (ASO, anti-DNAase B).

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Complications of GAS**Rheumatic Fever**

Rheumatic fever is a non-suppurative complication of GAS pharyngitis. Diagnosis is made using the Revised Jones Criteria (*Gewitz, 2015*). Major criteria include carditis, arthritis, chorea, erythema marginatum and subcutaneous nodules. Minor criteria include arthralgia, elevated erythrocyte sedimentation rate (ESR) and/or C-reactive protein (CRP), fever and prolonged PR interval (*Gewitz, 2015*). A detailed discussion on how to use these criteria to make the diagnosis is outside the scope of this guideline.

The risk of developing rheumatic fever is about 3% under epidemic conditions and approximately 0.3% under endemic conditions (*Dajani, 1995*). Acute rheumatic fever remains very rare in Western countries at less than 1 per 100,000 children (*Van Brusselen, 2014*). Non-rheumatogenic strains of GAS in children may be increasing. A 2006 observational study found a decline in rheumatogenic strains of GAS, but increase in

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non-rheumatogenic types in cases of acute streptococcal pharyngitis in children. The reasons are unclear (Shulman, 2006).

Peritonsillar Abscess

Peritonsillar abscesses are potential rare complications of GAS. The annual incidence of peritonsillar abscess (PTA) in the United States is approximately 30 per 100,000 persons (Galioto, 2017). Although PTA is generally a polymicrobial infection, GAS is considered a predominant pathogen (Galioto, 2017; Klug, 2017). Please see the "Reevaluation" section for more detailed discussion of the clinical presentation of peritonsillar abscess. Prompt recognition is important to prevent further complications such as airway obstruction, abscess rupture, extension of infection into the neck or mediastinum (Galioto, 2017).

Post-Streptococcal Glomerulonephritis

Post-streptococcal glomerular nephritis (PSGN) is the most common cause of acute nephritis worldwide. It primarily occurs in the developing world in areas in which the population has been exposed to poor nutritional support and inadequate general sanitation. These conditions likely result in an immunocompromised state and a dysregulated response to infections. The risk of PSGN is greatest in children between ages 5 and 12, and in older adults greater than age 60. Post-streptococcal glomerulonephritis is caused by prior infection with specific nephritogenic strains of group A beta-hemolytic streptococcus. These infections typically involve the skin or the throat. It can, however, occur after an infection at any site in the body. The clinical presentation varies from asymptomatic, microscopic hematuria to acute nephritic syndrome, characterized by red to brown urine, proteinuria edema, hypertension and acute kidney injury. The prognosis is generally favorable, especially in children (Kupin, 2012).

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4. Non-Infectious Rhinitis

Causes

Rhinitis is the presence of one or more of the following symptoms: nasal congestion, rhinorrhea (anterior and posterior), sneezing and nasal itching (Wallace, 2008).

Allergic rhinitis is an allergen-driven inflammation caused by inflammatory cells and other mediators, such as cytokines (Wallace, 2008). Examples of allergic rhinitis triggers include the following: pollen (tree, grass, weed), molds, house dust mites, animal dander and cockroaches.

Non-allergic rhinitis is characterized by perennial or periodic symptoms that are not from IgE-dependent events (Wallace, 2008). Examples of non-allergic rhinitis include hormonal (such as rhinitis of pregnancy), vasomotor rhinitis with sensitivity to smells and temperature changes, non-allergic rhinitic eosinophilic syndrome, rhinitis medicamentosa from regular use of topical nasal decongestants, and atrophic rhinitis. Other examples of triggers are smoke, fumes (such as from cleaning solutions, pool chlorine, car exhaust or other chemicals), strong odors (perfumes, hair sprays and some cleaners), medications (particularly antihypertensive agents), foods, alcohol, bright light, emotional upset, and snorting or inhaling illicit drugs or substances.

Atrophic rhinitis is characterized by foul-smelling nasal crusting and sinus pain, and is usually related to atrophy, excessive nasal and sinus surgery, radiation or one of several rare diseases such as Wegner's granulomatosis.

There are also a number of conditions that need to be included in the differential diagnosis. Structural abnormalities most often present with symptoms of obstruction. Deviated nasal septum, deformity of nasal bones, nasal turbinates or nasal cartilage may be detected on physical examination and may cause significant obstruction. Nasal polyps and adenoidal hypertrophy can cause obstruction. In the pediatric population, unilateral nasal obstruction and/or rhinorrhea require that an intranasal foreign body be ruled out.

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History/Physical

History of Present Illness:

- Congestion or obstruction
- Rhinorrhea (anterior nasal discharge)
- Pruritus of nose, eyes, palate and ears
- Sneezing
- Posterior nasal discharge with or without cough
- Sinus pressure/pain
- Snoring
- Episodic or seasonal or perennial symptoms
- Current medications such as topical decongestants, hormones and antihypertensives
- Current and previous treatments for rhinitis
- Vasomotor triggers such as foods, strong odors, weather changes, bright light and inhaled irritants

Past Medical History:

- History of trauma or facial/sinus surgery
- Relevant medical conditions: asthma, dermatitis, pregnancy, chronic sinusitis, chronic or recurrent otitis media.
 - Some research shows higher prevalence of autoimmune thyroid diseases in patients with rhinitis; however, more conclusive studies are needed on the relationship between rhinitis and thyroid diseases (*Degirmenci, 2015*).
- History of polyps and ASA/NSAID sensitivity
- Current and previous treatments for rhinitis
- Current medications such as topical decongestants, hormones and antihypertensives
 - Many antihypertensive agents – specifically, alpha-adrenergics, beta-blockers and ACE inhibitors – have been reported to induce rhinitis.

Family History:

- Asthma
- Rhinitis
- Atopic dermatitis

Social and Environmental History:

- Occupational exposures
- Home exposures
- Active and passive smoking exposures
- School exposures
- Illicit drug exposures

Algorithm Annotations

A structural etiology such as obstruction or a cerebrospinal fluid leak is more likely when previous trauma or surgery is present. Suspicion of a cerebrospinal fluid leak as the cause of nasal discharge can be confirmed by testing for glucose in the discharge. If cerebrospinal fluid leak is seriously being considered, this would fall in the realm of specialty diagnosis, and a consultation should be obtained as soon as possible.

In young children, foreign body in the nares and gastroesophageal reflux (in both children and adults) should also be considered as potential causes of rhinitis.

ICSI work group consensus on the signs and symptoms of allergic, non-allergic rhinitis etiology, and/or suggestive of either or both:

Signs and symptoms suggestive of an allergic etiology include:

- Pruritus of the eyes, nose, palate and ears
- Watery rhinorrhea
- Sneezing
- Seasonal symptoms
- Family history of allergies
- Symptoms triggered by specific allergens
- Asthma or eczema

Signs and symptoms suggestive of non-allergic rhinitis include:

- Sensitivity to smoke, perfume, weather changes and environmental irritants
- History of previous negative allergy testing
- Overuse of topical decongestants
- Adult onset of symptoms
- Nasal crusting or drying
- Facial pain

Signs and symptoms suggestive of either or both include:

- Perennial symptoms
- Episodic symptoms
- Nasal congestion
- History of frequent sinus infections/chronic sinusitis

Physical Examination

Swollen nasal turbinates (congestion), rhinorrhea and pruritus tend to be the most common.

Nose:

- Swollen nasal turbinates (may be boggy, bluish or pale, hyperemic or purplish red); note size and color
- Clear, cloudy or colored rhinorrhea
- Nasal septal deviation or structural abnormality

Algorithm Annotations

- Nasal polyps
- Nasal crease or "allergic salute"
- Sneezing
- Mouth breathing
- Unilateral obstruction
- Foreign body

Eyes:

- Conjunctivitis
- Allergic "shiners" (dark circles under the eyes from venous stasis)
- Dennie-Morgan lines (lower eyelid creases)
- Periorbital edema

Ears:

- Acute otitis media or otitis media with effusion (suggesting associated eustachian tube dysfunction)

Lungs:

- Wheezing or prolonged expiratory phase (suggesting associated asthma)

Skin:

- Atopic dermatitis

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Diagnosis

The clinician may recommend diagnostic testing at this point if the results would change management. A 2013 prospective observational study involving 108 patients found that patient symptoms, physical examination and nasal endoscopy are not reliable predictive tools for diagnosis of allergic rhinitis. This study demonstrated significant inter-rater variability of common nasal examination findings (*Eren, 2013*). While often the diagnosis is made clinically, specific diagnostic testing is recommended if a definitive diagnosis is needed.

Skin Tests and Radioallergosorbent Tests

Skin tests and serologic radioallergosorbent tests (RAST) identify the presence of IgE (immunoglobulin E) antibody to a specific allergen. Clinical relevance is established when exposure to an allergen to which the patient has evidence of allergen-specific IgE (e.g., skin tests) causes symptoms consistent with an allergic reaction. There are two major reasons to consider allergy testing: to differentiate allergic from non-allergic rhinitis, and to identify specific allergens causing allergic rhinitis. Skin tests are faster, more sensitive and more cost effective. Skin tests require experience in application and interpretation, and carry the risk of anaphylactic reactions. Therefore, only specially trained clinicians should perform them. The precise sensitivity of specific IgE immunoassays such as radioallergosorbent tests compared with prick/puncture skin tests is approximately 70-75% (*Wallace, 2008*). Therefore, skin tests are presently the preferred test for the diagnosing of IgE-mediated sensitivity.

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However, benefits to RAST include (*Seidman, 2015*):

- No risk of anaphylaxis
- Not affected by medications (e.g., antihistamines, beta blockers)
- Can be used for patients with severe skin problems (e.g., eczema)
- Can be used on patients taking beta blockers or with comorbid conditions for which skin testing is not safe

Other Tests:

Total serum IgG and/or IgE concentrations provide only modest information about the risk of allergic disease and are not routinely recommended (*Wallace, 2008*).

Nasal smear for eosinophil testing is not recommended as a routine test. It may be a useful adjunct if the diagnosis of allergic rhinitis is not straightforward from the history, physical and IgE testing (*Wallace, 2008*).

Serum eosinophilia has little diagnostic value in the evaluation of nasal allergies and is generally not helpful in the differential diagnosis.

Nasal endoscopy and/or rhinomanometry may be reserved for particular situations (*Wallace, 2008*).

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Treatment for Allergic Rhinitis

Education on Avoidance

If the clinical diagnosis is obvious, symptomatic treatment should be initiated. Symptomatic treatment includes both education on avoidance and medication therapy. Some avoidance activities require significant financial investment or substantial lifestyle changes by the patient. Before recommending such measures, it may be useful to recommend skin testing or limited radioallergosorbent testing to confirm the diagnosis and to identify the specific allergen.

Environmental control measures can reduce allergen level and/or reduce symptoms. Measures found to do both include removal of pets, acaridcides to kill dust mites and combined use of multiple control measures. Measures found to reduce allergen levels alone but not symptoms include washing pets twice a week, impermeable covers for bedding and air filtration (*Seidman, 2015*).

Nasal Saline

A 2016 review concluded that nasal saline alone is not more effective in reducing symptoms of allergic rhinitis in children than intranasal corticosteroids. Combination therapy maximizes the efficacy of intranasal corticosteroids and is effective in reducing symptoms (*Madison, 2016*).

Probiotics

Studies have demonstrated benefit of using probiotics, along with antihistamines, in children with perennial allergic rhinitis. Addition of probiotics did not provide acute symptomatic relief but led to improvement in symptoms that persisted for up to three months. Further studies with larger cohorts and longer follow-up periods are needed to further assess efficacy; however, probiotics may be considered as an adjunctive therapy (*Zajac, 2015; Lin, 2014; Lin, 2013b; Lue, 2012*).

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Medications

Recommendation	Quality of Evidence and Strength of Recommendation
The ICSI work group recommends intranasal corticosteroids as initial treatment for allergic rhinitis.	Quality of Evidence: High Strength of Recommendation: Strong
<p>Benefit Evidence shows that intranasal corticosteroids are very effective single agents for controlling the spectrum of allergic rhinitis symptoms in children and adults. They reduce the symptoms of nasal blockage, itching, sneezing and rhinorrhea.</p> <p>Harms The most common side effects of intranasal corticosteroids are nasal irritation (dryness, burning and crusting) and epistaxis. Nasal septal perforation has been reported.</p> <p>Benefit-Harms Assessment Given the efficacy and relative safety of intranasal corticosteroids in controlling the spectrum of allergic rhinitis symptoms and relative to harms, which can be decreased by use of the proper technique for administration, the ICSI work group recommends intranasal corticosteroids as initial treatment for allergic rhinitis in children and adults.</p>	
<p>Relevant Resources <i>Weiner, 1998 (Systematic Review)</i></p>	

- Intranasal corticosteroids.** Intranasal corticosteroids have been the most effective medication for managing rhinitis symptoms. However, these have a long onset of action. A 1998 systematic review of 16 randomized controlled trials conducted worldwide between 1966 and 1997 involving 2,267 individuals with allergic rhinitis concluded that intranasal corticosteroids should be used as first-line treatment for allergic rhinitis over oral antihistamines (*Weiner, 1998*). Furthermore, both the American Academy of Allergy, Asthma, and Immunology (AAAAI) and the American Academy of Otolaryngology (AAO) guidelines state that intranasal corticosteroids are very effective single agents for controlling the spectrum of allergic rhinitis symptoms in children and adults and are strongly recommended for treatment (*Seidman, 2015; Wallace, 2008*).

Intranasal corticosteroids reduce nasal blockage, itching, sneezing and rhinorrhea in allergic and non-allergic rhinitis. Regular daily use of the medications is required to achieve optimal results. It may be best to start treatment one week before the beginning of the allergy season for prophylactic use. Patients need to be carefully instructed on the correct method of administration. The clinical response does not appear to vary significantly between intranasal corticosteroids that are currently available (*Corren, 1999*).

Studies have demonstrated efficacy and safety in terms of growth velocity and lack of HPA suppression for topical triamcinolone and mometasone nasal sprays in children.

A 2016 systematic review of 40 studies on mometasone furoate nasal spray found no systemic effects on growth velocity and adrenal suppression, and no changes in epithelial thickness or atrophy have been observed after long-term administration of the drug (*Passali, 2016*). A small randomized, double-blind placebo-controlled trial involving 299 children ages 3 to 9 with perennial allergic rhinitis who were randomized between intranasal triamcinolone nasal spray and placebo groups found a small statistically significant but clinically insignificant effect of triamcinolone on growth velocity. But this effect was present only in the initial months of therapy and was not sustained after one year of treatment (*Skoner, 2015*). Children on corticosteroids should have height and weight checked at routine visits and plotted on the appropriate growth chart.

The most common side effects of intranasal corticosteroids are nasal irritation (dryness, burning and crusting) and epistaxis (*Seidman, 2015*). Nasal septal perforation has been reported (*Wallace, 2008*). The likelihood of these side effects can be decreased by use of the proper technique for administration (*Seidman, 2015; Wallace, 2008*). Intranasal corticosteroids when given in recommended doses are not generally associated with clinically significant systemic side effects (*Wallace, 2008*).

- **Oral corticosteroids.** A short course of oral corticosteroids may be appropriate for the treatment of very severe or intractable nasal symptoms or to treat significant nasal polyposis (*Wallace, 2008*). However, oral corticosteroids have not been shown to be more effective than intranasal corticosteroids (*Seidman, 2015*). The use of oral corticosteroids is discouraged as they have a greater potential for long-term corticosteroid side effects.
- **Intranasal antihistamines.** Intranasal antihistamines have a shorter duration of action but are not as effective in managing rhinitis symptoms as intranasal corticosteroids. Intranasal antihistamines can be used as therapy for management of rhinitis. In addition to blocking antihistamines, they have been shown to block other chemical mediators of inflammation (*Shah, 2009b; van Bavel, 2009*), which may explain the efficacy in managing nasal congestion as well as histamine-mediated symptoms (*Shah, 2009b*). Significant improvement in symptoms has been shown when compared to placebo (*Shah, 2009a; Shah, 2009b; van Bavel, 2009*). Most common adverse events include bitter taste and nasal irritation (*Shah, 2009a; Shah, 2009b*). Intranasal antihistamines have a quick onset of action with symptom relief noted as early as 30 minutes and sustained over 12 hours (*Patel, 2007*). Efficacy and safety of nasal antihistamines for treatment of allergic rhinitis has also been shown in pediatric studies (*Berger, 2009*).
- **Oral antihistamines.** Oral antihistamines are effective at controlling all symptoms associated with allergic rhinitis, with the exception of nasal congestion. They are somewhat less effective than intranasal corticosteroids, but they can be used either on a daily basis or on an as-needed basis. Common side effects of the first-generation antihistamines include somnolence, diminished alertness and anticholinergic effects such as dry mouth, blurred vision and urinary retention. The anticholinergic side effects are of more concern in people over age 65. Evidence supports that first-generation antihistamines cause central nervous system impairment even in the absence of overt symptoms. Some reports indicate that first-generation antihistamines clearly impair driving performances. The second-generation antihistamines are less sedating and cause less central nervous system impairment because they do not cross the blood brain barrier well. Both the AAAAI and the AAO recommend second-generation antihistamines over first-generation antihistamines for the treatment of allergic rhinitis due to its less sedative properties (*Seidman, 2015; Wallace, 2008*).

- **Combination Intranasal Antihistamines and Intranasal Corticosteroids**

Several studies have compared intranasal antihistamine/intranasal corticosteroids combination preparations (specifically fluticasone propionate and azelastine) against intranasal corticosteroid, intranasal antihistamine and placebo. Combination therapy was found to be more effective in treating rhinitis symptoms and had shorter onset of action when compared to both single agents and placebo. Combination therapy did not have a higher incidence of side effects or adverse effects when compared to single agents (*Meltzer, 2013; Carr, 2012; Meltzer, 2012*).

- **Leukotriene Blockers**

Montelukast is a leukotriene receptor antagonist that is as effective as loratadine and less effective than intranasal corticosteroids. The use of montelukast in combination with antihistamines such as loratadine or cetirizine has generally resulted in greater efficacy than when these agents were used alone, and in some studies has produced results comparable with intranasally applied corticosteroids. In patients with allergic rhinitis comorbid with asthma, montelukast treatment has resulted in significant improvements in both, compared with placebo (*Nayak, 2007*). It is generally well tolerated and is not associated with

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drowsiness. There have been some reports of rare drug-induced neuropsychiatric events such as aggression, depression, suicidal thinking and behavior (*Seidman, 2015*).

- **Cromolyn**

Intranasal cromolyn is effective in some patients in preventing and controlling symptoms of allergic rhinitis; however, it is less effective in most patients than corticosteroids. It is associated with minimal side effects (*Wallace, 2008*).

- **Anticholinergics**

Intranasal anticholinergics (ipratropium bromide) are effective in relieving anterior rhinorrhea in patients with allergic and non-allergic rhinitis, and improve quality of life (*Meltzer, 1992*). They have no effect on congestion, sneezing or itching. Most frequent side effects include epistaxis, blood-tinged mucus and nasal dryness (*Wallace, 2008*).

- **Topical decongestants.** Clinicians may consider using topical decongestants for short-term or intermittent/episodic therapy. Routine daily use is not recommended because of the risk for the development of rhinitis medicamentosa. A cross-sectional observational study documented overuse in 50% of patients despite being warned of the danger. Intranasal steroid use decreased the risk of nasal decongestant overuse (*Mehuys, 2014*).

- **Oral decongestants.** Two randomized controlled trials found no benefit to phenylephrine or modified-release phenylephrine compared to placebo for nasal congestion in patients with seasonal allergic rhinitis, although rates of side effects were low (*Meltzer, 2016; Meltzer, 2015*). No studies were found that examined use of pseudoephedrine alone, while two randomized controlled trials found benefit for nasal congestion scores in patients with seasonal allergic rhinitis from a combination of pseudoephedrine with desloratadine over either agent alone with minimal side effects (*Chervinsky, 2005; Pleskow, 2005*).

Safety. Topical decongestants should not be used for longer than 72 hours, owing to the potential for rebound congestion (*Aring, 2016*). Oral decongestants should be avoided in children under age 4. A review of multiple randomized placebo studies suggests that pseudoephedrine causes a slight increase in systolic blood pressure and heart rate (*Salerno, 2005*).

- **Immunotherapy**

Immunotherapy should be generally reserved for patients with significant allergic rhinitis for whom avoidance measures and pharmacotherapy are insufficient to control symptoms. Other candidates for immunotherapy include patients who cannot tolerate pharmacotherapy regimens or who develop complications such as recurrent sinusitis.

Subcutaneous immunotherapy (SCIT). SCIT is a series of injections of extracts of allergenic materials in an attempt to decrease the severity of allergic symptoms that may occur upon future exposure to the allergen. It consists of weekly incremental doses usually over four to six months, followed by maintenance injections of the tolerated maximum dose every two to four weeks. If successful, this treatment regimen is normally carried on for three to five years. According to a 2009 systematic review, SCIT is most effective for allergic rhinitis caused by pollens and dust mites. SCIT may be less effective for mold and animal dander allergies (*Calderon, 2009*).

Sublingual immunotherapy (SLIT). SLIT has been studied as an alternative to subcutaneous immunotherapy treatment for allergic rhinitis and is widely used in Europe. The treatment efficacy of SLIT was lower in North American studies than European studies, and the reasons are unclear. North American studies are more recent and have larger sample sizes, and are unaffected by study quality bias, which should provide a more reliable estimate of treatment effect. At the same time, North American studies

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have higher proportions of polysensitized patients in contrast to European studies, which may mask treatment effect, although researchers tried to control for that (*Di Bona, 2015*).

Sublingual treatment consists of daily tablets taken either seasonally for pollen allergies or perennially for dust mite allergies. Side effects are minimal and generally limited to oral itching or discomfort or nausea, and treatment can be self-administered at home. Currently FDA-approved treatment is available only for limited allergens.

There have not been adequate studies directly comparing the efficacy of SCIT to SLIT (*Lin, 2013a*). Some indirect comparisons have concluded that SCIT may be more effective than SLIT (*Di Bona, 2015; Dretzke, 2013; Di Bona, 2012*), while one study concluded that SCIT and SLIT are similar in their efficacy for grass pollen allergy (*Nelson, 2015*).

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Further Testing/Referral

When the patient has not experienced relief of symptoms within two to four weeks of adequate therapy, the clinician should:

- review obstacles to compliance with current medication, and discuss avoidance measures;
- consider a trial of another medication, or add another agent for targeted symptoms;
- consider allergen skin testing by a qualified physician – if there are positive skin tests to allergens that correlate with the patient's timing of symptoms, immunotherapy may be considered;
- consider complete nasal examination (rhinoscopy) by a qualified individual to rule out a mass or lesion, particularly if obstruction and congestion are the major symptoms; and
- consider alternative diagnosis of non-allergic rhinitis.

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Treatment for Non-Allergic Rhinitis

The following recommendations for the management of non-allergic rhinitis are based on work group consensus as well as the 2008 practice parameters jointly by the American Academy of Allergy, Asthma & Immunology, the American College of Allergy, Asthma, and Immunology, and the Joint Council of Allergy, Asthma and Immunology. Although a literature search was conducted spanning January 1, 2005 – May 1, 2017, primary evidence on the management of non-allergic rhinitis was not found.

Treatment of obstructive symptoms due to non-allergic rhinitis includes the following:

- Intranasal antihistamines (*Wallace, 2008*)

Intranasal antihistamines, in particular azelastine, have been associated with a clinically significant effect on nasal congestion from non-allergic rhinitis (*Wallace, 2008*).

- Oral and topical decongestants (*Wallace, 2008*)

The use of oral decongestants may cause central nervous system stimulation, hypertension and cardiac arrhythmias. However, some patients find them helpful in relieving symptomatic nasal obstruction secondary to non-allergic rhinitis. Oral decongestants, which have a relatively rapid onset of action, are particularly useful for sporadic symptoms. Patients using oral decongestants should be monitored for side effects, particularly hypertension. Topical decongestants may be considered for short-term relief but are not to be used daily because of the risk of rhinitis medicamentosa (*Wallace, 2008*).

- Intranasal corticosteroids (*Wallace, 2008*)

Intranasal steroid sprays can be used to treat chronic nasal congestion secondary to non-allergic rhinitis (*Daramola, 2016*), especially vasomotor rhinitis and non-allergic rhinitis and eosinophilia

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syndrome (NARES) (Wallace, 2008). Side effects seem to be related to application of the spray and are usually limited to intranasal dryness, crusting and bleeding. Documented systemic side effects are rare. Intranasal steroid sprays are better suited to patients with chronic, rather than sporadic, symptoms.

- Intranasal ipratropium bromide (Wallace, 2008)

Intranasal ipratropium bromide has been shown to be helpful for rhinorrhea (Wallace, 2008). It is generally well tolerated, with local irritation its only common side effect.

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Prevention

Rates of atopic diseases are rising in developing countries. Several associations have been identified between specific exposures and development of allergic disease. Exposure to traffic-related air pollution, second-hand cigarette smoke and pets have been studied. Secondhand cigarette smoke has been associated with atopic disease in both children and adults, while pet ownership has not been shown to be either beneficial in preventing atopy or associated with development of atopic diseases. Additional long-term studies are needed to quantify exposures while using validated methods to diagnose allergic rhinitis to better evaluate the relationship between exposures and development of allergic rhinitis (Hur, 2014; Saulyte, 2014; Lødrup Carlsen, 2012).

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5. Acute Sinusitis

Causes

Acute rhinosinusitis (ARS) is an inflammation of the paranasal sinuses and nasal cavity that is less than four weeks duration (Rosenfeld, 2015). Most often, acute sinusitis is the result of a viral etiology associated with upper-respiratory infection (Aring, 2016). Data on viral vs. bacterial etiology of acute sinusitis vary.

In adult patients with suspected acute maxillary sinusitis following a viral upper-respiratory infection, about one-half were found to have pus or mucopus in the sinus aspirate, and one-third had bacterial pathogens growing in culture (Aring, 2016). A review from 2014 states that after 10 days of upper-respiratory symptoms, the probability of a bacterial rhinosinusitis is at 60% (Van den Broek, 2014). A 2012 European Position Paper on Rhinosinusitis and Nasal Polyps states that only 0.5 to 2% of viral upper-respiratory tract infections are complicated by bacterial infection; however, the exact incidence is unknown, given the difficulty distinguishing viral from bacterial infection without invasive sinus-puncture studies. Bacterial culture results in suspected cases of acute community-acquired sinusitis are positive in only 60% of cases (Fokkens, 2012). In a small cohort study of 50 subjects with acute rhinosinusitis, 78% of the subjects had respiratory virus nucleic acid in their nasopharynx at enrollment in the study. At follow-up visit, a maxillary sinus puncture was performed on 40% of the participants, and 16% had positive cultures for nontypeable *H. influenzae* or bacterial ARS (Autio, 2015).

Typical bacterial organisms isolated from patients with acute sinusitis include *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Moraxella catarrhalis*, *Staphylococcus aureus*, other streptococci, anaerobes and (rarely) other gram-negative organisms. *S. Pneumoniae* and *H. influenzae* bacteria account for 76% of the isolates in adults (Gwaltney, 1992).

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History/Physical

A thorough history should inquire about the following:

- Purulent nasal discharge

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- Fever
 - Typically present at the beginning of a sinus infection and persisting approximately twice as long as with a viral upper-respiratory infection (*Wald, 2013; Chow, 2012*)
- Nasal congestion/fullness
- Change in sense of smell (reduced or absent)
- Facial pain/pressure
- Maxillary dental pain
- Ear pressure/fullness
- Fatigue

The following physical findings may be present:

- Purulent nasal drainage
- Purulent drainage in the posterior pharynx
- Focal facial pain with bending forward
- Unilateral sinus tenderness
- Halitosis

Note: Transillumination is of limited usefulness and is dependent on the skill level of the clinician performing the exam (*Williams, 1992*). Evidence suggests that it is an unreliable diagnostic tool and difficult to perform in children (*Wald, 2013*).

Signs and symptoms of serious illness requiring further evaluation or emergency referral

- **Local**
 - External facial swelling/erythema over involved sinus evident on exam
- **Orbital**
 - Visual changes
 - Extraocular motion abnormal
 - Proptosis
 - Periorbital inflammation/soft tissue edema
 - Periorbital erythema/cellulitis
- **Intracranial, central nervous system complications**
 - Altered mental status
 - New changes in neurologic exam
 - Meningeal signs (stiff neck with inability to chin tuck, persistent vomiting and severe headache)

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Diagnosis

Clinical Presentations

The "gold standard" for the diagnosis of acute sinusitis is antral puncture and cultures. However, this is not clinically practical (*Herr, 1991; Gwaltney, 1981; Hamory, 1979*). Maxillary antrum aspiration for culture is indicated only when precise microbial identification is required. Therefore, the diagnosis of acute bacterial

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rhinosinusitis (ABRS) is based primarily on the patient's presenting symptoms and history, and is supported by the physical exam.

Table 5 summarizes the recommendations for the diagnosis of acute bacterial rhinosinusitis from the following societies and their guidelines:

- Infectious Disease Society of America (IDSA) Clinical Practice Guideline for Acute Bacterial Rhinosinusitis in Children and Adults (*Chow, 2012*)
- American Academy of Otolaryngology (AAO) Clinical Practice Guideline (Update): Adult Sinusitis (*Rosenfeld, 2015*)
- American Academy of Pediatrics (AAP) Clinical Practice Guideline for the Diagnosis and Management of Acute Bacterial Sinusitis in Children Aged 1 to 18 Years (*Wald, 2013*)

There is consensus among these three organizations and the ICSI work group, that there are two clinical presentations where acute bacterial rhinosinusitis (ABRS) has a higher likelihood of being present:

- Persistence of symptoms consistent with acute rhinosinusitis lasting 10 days or more without evidence of improvement
- Symptoms are worsening – new onset of fever, headache or increase in nasal discharge after a viral upper-respiratory infection (VURI) that lasted five to six days and the patient was initially improving (double worsening or double sickening)

Recommendations are mixed for patients with severe symptoms and high fever of 102°F for at least three to four days from onset of illness. The IDSA (*Chow, 2012*) and AAP (*Wald, 2013*) continue to recommend diagnosing these patients with bacterial sinusitis, while the AAO (*Rosenfeld, 2015*) has removed this indication for diagnosis. The ICSI work group was unable to identify primary literature discussing this clinical presentation in diagnosis of acute bacterial sinusitis. Therefore, the ICSI work group based its recommendation on whether to routinely use this clinical presentation as criteria to diagnose bacterial sinusitis upon the existing practice and the review of IDSA, AAO and AAP recommendations (summarized in Table 5).

<p>Recommendation</p> <p>To diagnose acute bacterial rhinosinusitis (ABRS), the ICSI work group consensus is there are two clinical presentations where ABRS has a higher likelihood of being present:</p> <ul style="list-style-type: none"> • Persistence of symptoms consistent with acute rhinosinusitis lasting 10 days or more without evidence of improvement • Symptoms are worsening – new onset of fever, headache or increase in nasal discharge after a viral upper-respiratory infection (VURI) that lasted five to six days and the patient was initially improving (double worsening or double sickening) <p>Clinical presentation of severe symptoms and high fever of 102°F for at least three to four days from onset of illness should not routinely be used as criteria to diagnose patients with bacterial sinusitis. The diagnosis of these patients should be made on an individualized basis depending on the entire clinical scenario.</p>
<p>Benefit</p> <p>Appropriately diagnosing ABRS based on clinical presentations decreases the likelihood of inappropriate treatment with antibiotics. Thus, side effects of antibiotic use and antibiotic resistance are avoided.</p> <p>Harms</p> <p>Patients could potentially be misdiagnosed and might not get appropriate treatment for their condition.</p> <p>Benefit-Harms Assessment</p> <p>Given the need for prudent antibiotic use, it is important that an appropriate diagnosis of ABRS is made.</p>
<p>Relevant Resources</p> <p><i>Rosenfeld, 2015 (Guideline); Wald, 2013 (Guideline); Chow, 2012 (Guideline)</i></p>

Table 5: Summary of Recommendations for Diagnosis of Acute Bacterial Rhinosinusitis by IDSA, AAO and AAP

<p>IDSA Clinical Practice Guideline for Acute Bacterial Rhinosinusitis in Children and Adults (Chow, 2012)</p>	<p>AAO Clinical Practice Guideline (Update): Adult Sinusitis (Rosenfeld, 2015)</p>	<p>AAP Clinical Practice Guideline for the Diagnosis and Management of Acute Bacterial Sinusitis in Children Ages 1 to 18 Years (Wald, 2013)</p>
<p>Conventional criteria for the diagnosis of sinusitis based on the presence of at least 2 major or 1 major and ≥ 2 minor symptoms:</p> <p>Major symptoms:</p> <ul style="list-style-type: none"> • Purulent anterior nasal discharge • Purulent or discolored posterior nasal discharge • Nasal congestion or obstruction • Facial congestion or fullness • Facial pain or pressure • Hyposmia or anosmia • Fever (for acute sinusitis only) <p>Minor symptoms:</p> <ul style="list-style-type: none"> • Headache • Ear pain or pressure, or fullness • Halitosis • Dental pain • Cough • Fever (for subacute or chronic sinusitis) • Fatigue 	<p>Acute rhinosinusitis (ARS) symptoms:</p> <ul style="list-style-type: none"> • Up to four weeks of purulent nasal drainage (anterior, posterior or both) accompanied by nasal obstruction, facial pain-pressure-fullness or both. • Purulent nasal discharge is cloudy or colored, in contrast to the clear secretions that typically accompany viral upper-respiratory infection, and may be reported by the patient or observed on physical examination. <p>Nasal obstruction may be reported by the patient as nasal obstruction, congestion, blockage or stuffiness, or may be diagnosed by physical examination.</p> <p>Facial pain-pressure-fullness may involve the anterior face or periorbital region, or manifest with headache that is localized or diffuse.</p>	<p>Symptom description is the same as recommendation.</p>
<p>Recommendation for diagnosing ABRs:</p> <p>The following clinical presentations (any of three) are recommended for identifying patients with acute bacterial vs. viral rhinosinusitis:</p> <p>(1) Onset with persistent symptoms or signs compatible with acute rhinosinusitis, lasting for 10 days without any evidence of clinical improvement</p> <p>(2) Onset with severe symptoms or signs of high fever (39°C [102°F]) and purulent nasal discharge or facial pain lasting for at least 3-4 consecutive days at the beginning of illness</p> <p>(3) Onset with worsening symptoms or signs characterized by the new onset of fever, headache or increase in nasal discharge following a typical viral upper-respiratory infection (URI) that lasted 5-6 days and were initially improving (“double sickening”)</p>	<p>Recommendation for diagnosing ABRs:</p> <p>Clinicians should distinguish presumed acute bacterial rhinosinusitis (ABRS) from acute rhinosinusitis (ARS) caused by viral upper-respiratory infections and noninfectious conditions. A clinician should diagnose ABRs when:</p> <p>(1) Symptoms or signs of acute rhinosinusitis (purulent nasal drainage accompanied by nasal obstruction, facial pain-pressure-fullness or both) persist without evidence of improvement for at least 10 days beyond the onset of upper-respiratory symptoms, or</p> <p>(2) Symptoms or signs of acute rhinosinusitis worsen within 10 days after an initial improvement (double worsening).</p>	<p>Recommendation for diagnosing ABRs:</p> <p>The diagnosis of acute bacterial rhinosinusitis (ABRS) is made when a child with an acute upper-respiratory tract infection (URI) presents with:</p> <p>(1) Persistent illness (nasal discharge [of any quality] or daytime cough or both lasting more than 10 days without improvement),</p> <p>(2) A worsening course (worsening or new onset of nasal discharge, daytime cough or fever after initial improvement), or</p> <p>(3) Severe onset (concurrent fever [temperature $\geq 39^\circ\text{C}/102.2^\circ\text{F}$] and purulent nasal discharge for at least three consecutive days).</p>

Imaging

Plain sinus x-rays and other imaging tests are not recommended in making the diagnosis of acute sinusitis.

The IDSA, AAO and AAP do not recommend obtaining imaging of any kind for patients who meet diagnostic for acute rhinosinusitis unless a complication or alternative diagnosis is suspected. If a complication or alternative diagnosis is suspected, then CT of the sinuses should be obtained (*Rosenfeld, 2015; Wald, 2013; Chow, 2012*). This recommendation is in alignment with the American College of Radiology (ACR) recommendation that most cases of uncomplicated acute and subacute rhinosinusitis are diagnosed clinically and should not require any imaging procedure. The ACR recommends that CT of the sinuses without contrast is the imaging method of choice in patients with recurrent acute sinusitis or chronic sinusitis, or to define sinus anatomy before surgery (*Cornelius, 2013*).

The ICSI work group conducted a literature search on this topic and did not find any new literature that contradicts the above recommendations.

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Treatment

The goal of treatment is to promote adequate drainage of the sinuses. This in turn will provide relief of symptoms associated with sinusitis. This may require a combination of home care and medical treatments.

Symptomatic Care

Many patient sources discuss the benefits of comfort measures even though few studies have been conducted on the sinusitis population to document the actual effects of these measures on the treatment of sinusitis. Therefore, non-pharmacologic measures are aimed at symptom relief and providing comfort. There is no evidence to determine whether the use of antihistamines, decongestants or nasal irrigation is efficacious in children with acute sinusitis (*Shaikh, 2014*). The sections below discuss the evidence for adults.

- **Comfort measures.** See the "[Viral Upper-Respiratory Infections](#)" section for information on comfort measures.
- **Topical decongestants.** One randomized controlled trial that included 60 patients evaluated the effects of topical agents of fluticasone propionate, oxymetazoline, and 3% and 0.9% sodium chloride solutions on mucociliary clearance in the therapy of acute bacterial rhinosinusitis in vivo. It found that oxymetazoline and 3% NaCl solution groups seemed to be more effective in mucociliary clearance, but there was no significant difference in improvement among the groups including those not receiving any treatment (*Inanli, 2002*). Topical decongestants should not be used for longer than 72 hours, owing to the potential for rebound congestion (*Aring, 2016*).
- **Oral decongestants.** No controlled trials have assessed the efficacy of oral decongestants for the treatment of acute sinusitis (*Aring, 2016*). The IDSA guideline does not recommend their use (*Chow, 2012*), while the AAP guideline states the data is insufficient, and the AAO guideline (*Rosenfeld, 2015*) supports their use while agreeing there is little data to document benefit. If used, oral decongestants should be recommended with caution to patients with hypertension or cardiovascular disease.
- **Intranasal corticosteroids.** Intranasal corticosteroid sprays are a reasonable option either alone or as adjunct to antibiotics. Evidence has shown modest benefit but low risk.

A 2012 systematic review and meta-analysis of six studies (five studies prescribed an antibiotic with the nasal steroid and one study did not) found modest benefit with a NNT of 13. The benefit was more pronounced with longer durations of treatment (21 days) and higher doses of medication. No serious adverse events were noted (*Hayward, 2012*).

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Similarly, a 2013 systematic review found that patients receiving intranasal corticosteroids were more likely to experience symptom improvement after 15 to 21 days compared with those receiving placebo. Higher doses of intranasal corticosteroids had a greater effect on symptom relief than lower doses. Additionally, no significant adverse events were reported, and there was no significant difference in dropout or recurrence rates for those receiving intranasal corticosteroids or placebo and for those receiving higher doses of intranasal corticosteroids (*Zalmanovici Trestioreanu, 2013*).

A different systematic review looked for evidence of benefit in patients with recurrent sinusitis (four or more episodes per year) and found only three trials, of which two had bias risks. That trial did find mild improvement in length of symptoms and possibly decreased recurrence, but more study is needed (*van Loon, 2013*).

- **Systemic corticosteroids.** Systemic corticosteroids have also been studied and have some advantage of lower cost and easier administration, but higher risk of adverse events. A 2014 systematic review of five trials studying oral steroids – one as monotherapy and four as adjunctive therapy – found in the monotherapy study no benefit while the adjunctive studies found modest benefit with a NNT of seven without significant adverse events. However, this review recommended against using oral steroids until more data are available (*Venekamp, 2014*). Due to high risk of side effects, systemic corticosteroids should be used judiciously.
- **Antihistamines**

Antihistamines are not recommended for the treatment of sinusitis in the absence of known allergic disease, because they cause further thickening of secretions (*Willett, 1994*).

Antibiotics

The controversy around use of antibiotics in sinusitis relates to the often self-limited nature of the disease and the relatively small benefits found in studies. It is currently controversial whether to start antibiotics at the time of diagnosis or use watchful waiting to determine if they are needed.

Since antral puncture on all patients suspected of bacterial sinusitis is clinically impractical, the diagnosis rests on clinical impression, and antibiotic therapy is empiric.

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Recommendation	Quality of Evidence and Strength of Recommendation
<p>Consider symptomatic care as initial treatment for patients with suspected acute bacterial rhinosinusitis (ABRS).</p> <p>Consider prescribing a delayed or an immediate antibiotic based on degree of illness, comorbidities and after shared decision-making discussion with patients who meet criteria for ABRS.</p>	<p>Quality of Evidence: Moderate-High</p> <p>Strength of Recommendation: Strong</p>
<p>Benefit Benefits of prudent antibiotic use decrease the possibility of serious side effects of antibiotic use and antibiotic resistance.</p> <p>Harms The recommendation leaves the treatment with antibiotics at clinician discretion. Not treating with antibiotics immediately or delaying treatment may prolong symptom duration and there is a possibility of complications from acute sinusitis.</p> <p>Benefit-Harms Assessment Considering small clinical benefit of antibiotic use (small reductions in duration of symptoms), the rarity of severe complications from acute rhinosinusitis and the potential for side effects of antibiotic use, antibiotics as initial treatment among immunocompetent adults with acute, uncomplicated rhinosinusitis may not be merited. Instead a delayed or an immediate antibiotic prescription strategy should be considered based on degree of illness, comorbidities and after shared decision-making discussion with patients who meet criteria for ABRS.</p>	
<p>Relevant Resources <i>Burgstaller, 2016 (Systematic Review); de la Poza Abad, 2016 (Randomized Controlled Trial); Sng, 2015 (Systematic Review); Ahovuo-Saloranta, 2014 (Systematic Review); Lemiengre, 2012 (Systematic Review)</i></p>	

In reference to other guidelines, Infectious Diseases Society of America (IDSA) Clinical Practice Guideline for Acute Bacterial Rhinosinusitis in Children and Adults (*Chow, 2012*) recommends starting an antibiotic at the time of diagnosis. American Academy of Otolaryngology (AAO) Clinical Practice Guideline (Update): Adult Sinusitis (*Rosenfeld, 2015*), and the American Academy of Pediatrics (AAP) Clinical Practice Guideline for the Diagnosis and Management of Acute Bacterial Sinusitis in Children Aged 1 to 18 Years (*Wald, 2013*) recommend considering watchful waiting using shared decision-making.

Overall, the literature shows consensus that immediate antibiotic use has small benefits in resolving acute rhinosinusitis symptoms or reducing clinical failure within approximately two weeks of treatment, although follow-up times vary across the included randomized controlled trials. Serious complications associated with acute rhinosinusitis were rare. Evidence on delayed treatment with antibiotics is small. More studies are needed on delayed strategies. Overall, the benefits of treating the symptoms of acute rhinosinusitis with antibiotics may not outweigh the harms of treatment such as serious side effects of antibiotic use and antibiotic resistance. One limitation of literature in general is that literature evaluated patients with clinical signs and symptoms and not definitive diagnosis of acute bacterial sinusitis. Finally, there is no conclusive evidence on merits of antibiotic use in children with acute rhinosinusitis. Individual studies have had the following findings:

- A 2016 systematic review including 6 randomized controlled trials (randomized controlled trials) that compared treatment of any antibiotic with placebo found a benefit of antibiotic treatment compared to placebo for the rate of improvement after 3 (odds ratio 2.78) and 7 days (odds ratio 2.29) after initiation of antibiotics in patients with symptoms and signs of acute rhinosinusitis lasting for seven or more days. After 10 days, improvement rates did not differ significantly between patients treated with or without antibiotics (odds ratio 1.36). Compared to placebo, antibiotic treatment relieves symptoms in a significantly higher proportion of patients within the first days of treatment (*Burgstaller, 2016*).

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- A 2015 systematic review of 31 randomized controlled trials on efficacy and side effects of antibiotics in the treatment of acute rhinosinusitis found only slight added benefit in the usage of antibiotics over placebo in the treatment of ARS (*Sng, 2015*).
- A 2014 systematic review of 63 studies (nine placebo-controlled trials with 1,915 participants) and 54 studies comparing different classes of antibiotics (10 different comparisons) (the trials in the review included clinically diagnosed acute sinusitis, confirmed or not by imaging or bacterial culture) found moderate-quality evidence that antibiotics provide a small benefit for clinical outcomes in immunocompetent primary care patients with uncomplicated acute sinusitis. However, about 80% of participants treated without antibiotics improved within two weeks (*Ahovuo-Saloranta, 2014*). In five studies at low risk of bias, penicillin or amoxicillin decreased the risk of clinical failure (a lack of full recovery or improvement for participants with symptoms lasting at least seven days) rate at 7 to 15 days follow-up (risk ratio 0.66) compared to placebo. After 15 days, there were no differences in clinical failure between the two groups. Cure or improvement rates, as opposed to clinical failure, at 7 to 15 days were 86% among placebo patients and 91% among antibiotic patients, indicating no differences between the two groups. When clinical failure was defined as a lack of full recovery, results were similar: antibiotics decreased the risk of failure (risk ratio 0.73) at 7 to 15 days follow-up. Adverse effects in seven of the nine placebo-controlled studies (comparing penicillin, amoxicillin, azithromycin or moxycillin to placebo) were more common in antibiotic than in placebo groups. However, dropouts due to adverse effects were rare in both groups (*Ahovuo-Saloranta, 2014*).
- A 2012 systematic review of 10 randomized controlled trials with 2,450 participants comparing antibiotic treatment to placebo in adult participants with uncomplicated acute rhinosinusitis-like signs and symptoms found that given antibiotic resistance and low incidence of serious complications, antibiotics should not be used in adult patients with clinically diagnosed, uncomplicated acute rhinosinusitis. The findings are not applicable to children, patients with a suppressed immune system and patients with severe disease since the trials did not include these populations (*Lemiengre, 2012*). Specifically, the findings showed that 47% of participants were cured after one week and 71% after 14 days irrespective of the treatment group; antibiotics shortened the time to cure, but only five more participants per 100 will cure faster at any time point between 7 and 14 days if they receive antibiotics instead of placebo (number needed to treat to benefit [NNTB] 18); purulent secretion resolved faster with antibiotics (odds ratio [OR] 1.58; NNTB 11) (*Lemiengre, 2012*). Participants who received antibiotics (7%) and those who received placebo (15%) experienced adverse events (OR 2.10; number needed to treat to harm [NNTH] 8). More participants in the placebo group needed to start antibiotic therapy because of an abnormal course of rhinosinusitis (OR 0.49; NNTH 20). Only one disease-related complication (brain abscess) occurred in a patient treated with antibiotics (*Lemiengre, 2012*).

More studies are needed on the merits of antibiotic use in children with acute rhinosinusitis.

A 2013 systematic review and meta-analysis of four randomized controlled trials on efficacy of antibiotics in the treatment of acute rhinosinusitis in children found symptoms improved at 10-14 days of antibiotic use (odds ratio 2.0). There were substantial methodological differences between the included randomized controlled trials to conclusively determine whether antibiotic use in children is merited (*Cronin, 2013*).

Delayed vs. immediate antibiotic prescription strategies. A 2016 randomized controlled trial involving 405 adults with acute, uncomplicated respiratory infections compared the efficacy and safety of two delayed antibiotic prescription strategies (a delayed patient-led prescription strategy and a delayed prescription collection strategy requiring patients to collect their prescription from the primary care center) with immediate prescription and no antibiotic strategies. In this trial 19.8% of the participants had uncomplicated acute rhinosinusitis, while the rest had other uncomplicated acute

respiratory tract infections. It found that use of antibiotics does not lead to a clinically significant improvement in symptom resolution compared to the placebo group. But for patients who do want antibiotics, a delayed prescription approach may be more appropriate as it significantly reduces antibiotic use (*de la Poza Abad, 2016*).

Antibiotic Considerations

A 2014 systematic review of 63 randomized controlled trials of patients with clinically diagnosed acute sinusitis, confirmed or not by imaging or bacterial culture that included 54 studies comparing different classes of antibiotics (10 different comparisons), found that in the 10 head-to-head comparisons, none of the antibiotic preparations was superior to another. However, amoxicillin-clavulanate had significantly more dropouts due to adverse effects than cephalosporins and macrolides (*Ahovuo-Saloranta, 2014*).

The ICSI work group did not specifically search for primary literature on first-line vs. alternative antibiotic treatments for acute bacterial sinusitis. Instead, the IDSA (*Chow, 2012*), AAO (*Rosenfeld, 2015*) and AAP (*Wald, 2013*) antibiotic recommendations are listed.

First-line treatment. The IDSA recommends amoxicillin-clavulanate combination. Per the IDSA, high-dose amoxicillin-clavulanate should be considered in situations where the patient has higher risk of resistance: age < 2 or > 65, day care participation, hospitalization within the past five days, prior antibiotics within the past month, immunocompromised, comorbidities, a local rate of *S. pneumoniae* resistance > 10%, or severe disease (*Chow, 2012*). The AAO and AAP recommend amoxicillin with or without clavulanate.

Alternatives to first-line

- Doxycycline is an alternative in adults who are allergic to penicillin. It is not suitable for children (IDSA and AAO).
- Respiratory fluoroquinolone (Levofloxacin or Moxifloxacin) in children and adults who are allergic to penicillin (IDSA, AAO and AAP) – **FDA warns fluoroquinolones should be used only in serious bacterial infections and reserved for use in patients who have no other treatment options for acute bacterial sinusitis.** There may be serious adverse events associated with these medications that outweigh the benefits. The warning can be found at <https://www.fda.gov/Drugs/DrugSafety/ucm511530.htm>.
- Second- or third-generation cephalosporins as monotherapy or in combination
 - The IDSA does not recommend it as monotherapy due to lack of coverage of penicillin-resistant *S. pneumoniae*.
 - The IDSA recommends combination therapy with a third-generation oral cephalosporin (cefixime or cefpodoxime) plus clindamycin as second-line therapy for children with non-type I penicillin allergy or from geographic regions with high endemic rates of PNS *S. pneumoniae*.
 - The AAO recommends combination therapy with a third-generation oral cephalosporin (cefixime or cefpodoxime) plus clindamycin in adults with a history of non-type I hypersensitivity to penicillin.
 - The AAP recommends their use if allergic to penicillin or amoxicillin or combination of clindamycin (or linezolid) and cefixime in young children (age < 2) with a serious type I hypersensitivity to penicillin and moderate or more severe sinusitis.
 - Trimethoprim-sulfamethoxazole and macrolides are no longer recommended as alternatives due to increasing resistance (IDSA, AAO and AAP).

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Duration of initial antibiotic treatment

A 2014 systematic review involving adult patients found that penicillin or amoxicillin decreased the risk of clinical failure rate at 7 to 15 days follow-up compared to placebo (*Ahovuo-Saloranta, 2014*). Another systematic review involving adult patients found that antibiotics can shorten the time to cure, but only five more participants per 100 will cure faster at any time point between 7 and 14 days if they receive antibiotics instead of placebo. Number needed to treat to benefit was 18 (*Lemiengre, 2012*).

A 2013 systematic review and meta-analysis of 4 randomized controlled trials on efficacy of antibiotics in the treatment of acute rhinosinusitis in children found symptoms improved at 10-14 days of antibiotic use (*Cronin, 2013*).

IDSA, AAO and AAP recommendations:

- 5-7 days in adults; 10-14 days in children (IDSA)
- 5-10 days for most adults (AAO)
- No recommendation (AAP)

Antibiotic Treatment Response

Complete response. Patient is symptomatically improved to near normal.

Failure or no response. IDSA, AAO and AAP guidelines on acute bacterial rhinosinusitis all agree that patients who worsen in 48-72 hours after starting treatment or who are not responsive within seven days warrant reevaluation. During reevaluation, consider whether the diagnosis is correct and if there is an underlying abnormality (*Rosenfeld, 2015; Wald, 2013; Chow, 2012*). They recommend the following for these patients:

- Consider switching to an alternative antibiotic
- Consider referral to a specialist (e.g., ENT or ID)
- Consider imaging with sinus CT

An antibiotic that offers better coverage-resistant bacteria, such as high-dose amoxicillin/clavulanate, should be prescribed if ABRIS is confirmed as the diagnosis (*Chow, 2012*). A substantial minority of patients will have infection from bacteria that are resistant in vitro to first-line therapy. Several studies have suggested that failure of therapy may be due to β -lactamase-producing organisms, anaerobes or staphylococci. It would seem reasonable, therefore, to give a trial of a broader spectrum antibiotic in the setting of clinical failure (*Rosenfeld, 2015*).

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Phone/Virtual Care Management

Phone care management, with treatment typically via protocol by a triage nurse, or virtual care with electronic communication, typically between a provider and patient, is increasingly being used for initial treatment of sinusitis. Patients who are in generally good health and only mildly ill may be appropriate candidates for home care/phone management of presumed acute rhinosinusitis. In addition, patients recently seen by a care clinician who call back to the office to report symptoms of sinusitis are appropriate candidates for phone management, as the physician is already familiar with the patient.

Both the patient and the clinician should be comfortable with home care/phone management.

One study evaluating phone care found phone treatment increased the likelihood of use of first-line antibiotic therapy and did not increase antibiotic use (*Chauhdry, 2006*). Another study compared e-visits to conventional visits and found that more antibiotics were prescribed (99% vs. 94%), although both types

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Algorithm Annotations

of visits had a high degree of antibiotic prescribing (*Mehrotra, 2013*). There is not enough evidence on the outcomes of phone/virtual care management. Further studies are needed. In the meantime, virtual care should be limited to a select group of patients with follow-up in the office if the patient does not respond to first-line antibiotics.

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Prevention

Appropriate treatment of allergies and avoidance of viral upper-respiratory infections can prevent the development of sinusitis. Environmental factors that affect the sinuses include cigarette smoke, pollution, swimming in contaminated water and barotrauma.

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Complications

Complications of sinusitis are rare but include orbital or intracranial abscess, encephalitis and meningitis. One retrospective case series in the Netherlands found a complication rate of 1:12,000 pediatric and 1:32,000 adult cases (*Hansen, 2012*). Another retrospective study found that decreased use of antibiotics for URI led to a slight increase in pneumonia and peritonsillar abscess but no increase in mastoiditis, intracranial abscess or Lemierre's Syndrome (*Gulliford, 2016*).

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The Aims and Measures section is intended to provide protocol users with a menu of measures for multiple purposes that may include the following:

- population health improvement measures,
- quality improvement measures for delivery systems,
- measures from regulatory organizations such as Joint Commission,
- measures that are currently required for public reporting,
- measures that are part of Center for Medicare Services Physician Quality Reporting initiative, and
- other measures from local and national organizations aimed at measuring population health and improvement of care delivery.

This section provides resources, strategies and measurement for use in closing the gap between current clinical practice and the recommendations set forth in the guideline.

The subdivisions of this section are:

- Aims and Measures
- Implementation Recommendations
- Implementation Tools and Resources
- Implementation Tools and Resources Table

Aims and Measures

1. Decrease the percentage of patients with symptoms of acute pharyngitis but without confirmed Group A streptococcal pharyngitis diagnosis who are prescribed antibiotics. (*Annotation #3*)

Measures for accomplishing this aim:

- a. Percentage of patients with symptoms of acute pharyngitis but without confirmed Group A streptococcal pharyngitis diagnosis who are prescribed an antibiotic.
2. Increase the percentage of patients diagnosed with allergic rhinitis who are prescribed intranasal corticosteroid therapy as initial treatment. (*Annotation #4*)

Measures for accomplishing this aim:

- a. Percentage of patients diagnosed with allergic rhinitis who are prescribed intranasal corticosteroids as initial treatment.

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Measurement Specifications

Measurement #1a

Percentage of patients with symptoms of acute pharyngitis but without confirmed Group A streptococcal pharyngitis diagnosis who are prescribed an antibiotic.

Population Definition

Children and adult patients with a visit to primary care (general internal medicine, pediatrics, family practice, urgent care) presenting with symptoms of acute pharyngitis but without confirmed Group A streptococcal pharyngitis diagnosis. Confirmed refers to positive test result by either RADT or backup culture.

Data of Interest

of patients who are prescribed an antibiotic who have symptoms of acute pharyngitis

of patients with symptoms of acute pharyngitis but without confirmed Group A streptococcal pharyngitis diagnosis

Numerator and Denominator Definitions

Numerator: Patients who are prescribed an antibiotic who have symptoms of acute pharyngitis.

Denominator: Patients with symptoms of acute pharyngitis but without confirmed Group A streptococcal pharyngitis.

Method/Source of Data Collection

Query EMR for patient population that fit criteria in the population definition and the denominator. Out of that number, determine the number that fits numerator criteria.

Time Frame Pertaining to Data Collection

Monthly.

Notes

This is a process measure on overuse, and improvement is noted as a decrease in the rate.

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Aims and Measures

Measurement #2a

Percentage of patients diagnosed with allergic rhinitis who are prescribed intranasal corticosteroids as initial treatment.

Population Definition

Children and adult patients with a visit to primary care (general internal medicine, pediatrics, family practice, urgent care) diagnosed with allergic rhinitis.

Data of Interest

$$\frac{\# \text{ of patients who are prescribed intranasal corticosteroids as initial treatment}}{\# \text{ of patients diagnosed with allergic rhinitis}}$$

Numerator and Denominator Definitions

Numerator: Patients who are prescribed intranasal corticosteroids as initial treatment.

Denominator: Patients with diagnosis of allergic rhinitis.

Method/Source of Data Collection

Query EMR for patient population that fit criteria in the population definition and the denominator. Out of that number, determine the number that fits numerator criteria.

Time Frame Pertaining to Data Collection

Monthly.

Notes

This is a process measure, and improvement is noted as an increase in the rate.

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Implementation Recommendations

Prior to implementation, it is important to consider current organizational infrastructure that addresses the system and process design; training, education and culture; and the need to shift values, beliefs and behaviors of the organization.

Antibiotic Stewardship Resources

Inappropriate antibiotic use can lead to antibiotic resistance. According to the Centers for Disease Control (CDC), antibiotic resistance can lead to an estimated 2 million infections and 23,000 deaths per year in the United States (*Sanchez, 2016*). Additionally, antibiotics can lead to medication-related adverse events for patients taking them. One of every five visits to the emergency departments is due to adverse antibiotic drug reactions (*Harris, 2016*). An estimated 5 to 25% of patients who use antibiotics have an adverse event with about 1 in 1,000 having a serious adverse event (*Harris, 2016*).

Antibiotic over-prescribing leads to the false perception that patients need antibiotics to feel well, while not taking into consideration the harms of overprescribing such as side effects and antibiotic resistance. The potential harms of antibiotic use make it especially important to use antibiotics judiciously.

The following resources on antibiotic stewardship in outpatient settings are available online:

- CDC's Get Smart: Know When Antibiotics Work in Doctor's Office at <https://www.cdc.gov/getsmart/community/improving-prescribing/core-elements/core-outpatient-stewardship.html>
- Minnesota OneHealth Antibiotic Stewardship Collaborative at <http://www.health.state.mn.us/onehealthabx/index.html>

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Implementation Tools and Resources

Criteria for Selecting Resources

The following tools and resources specific to the topic of the guideline were selected by the work group. Each item was reviewed thoroughly by at least one work group member. It is expected that users of these tools will establish the proper copyright prior to their use. The types of criteria the work group used are:

- The content supports the clinical and the implementation recommendations.
- Where possible, the content is supported by evidence-based research.
- The author, source and revision dates for the content are included where possible.
- The content is clear about potential biases, and conflicts of interests and/or disclaimers are noted.

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Implementation Tools and Resources Table

Author/Organization	Title/Description	Audience	Web Sites/Order Information
Centers for Disease Control and Prevention (CDC)	Get Smart: Know When Antibiotics Work in Doctor's Office	Patients and Families; Health Care Professionals	https://www.cdc.gov/getsmart/community/improving-prescribing/core-elements/core-outpatient-stewardship.html
Minnesota Department of Health (MDH)	Minnesota OneHealth Antibiotic Stewardship Collaborative	Patients and Families; Health Care Professionals	http://www.health.state.mn.us/onehealthabx/index.html

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The subdivisions of this section are:

- References
- Appendices

References

Links are provided for those new references added to this edition (author name is highlighted in blue).

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Appendix A – Literature Search Terms by Topic

Presentation

Respiratory illness infections; risk of infections in underimmunized children.

Viral Upper-Respiratory Infections

Infections (common cold); diagnosis of common cold and use of procalcitonin guided algorithm; prevention and treatment for common cold; yeast and cranberry for prevention and treatment of viral upper-respiratory infections (common cold); use of humidifiers/vaporizers as comfort measures in treatment of common cold; vapor rubs in young children for treatment; essential oils for treatment; honey preparation products for treatment; over-the-counter medications for children for treatment; antihistamines, decongestants and intranasal steroids for treatment; respiratory infection and antibiotic overuse; vitamin D for prevention; nasal irrigation for prevention; echinacea.

Pharyngitis

At home testing for acute respiratory pharyngitis; strep testing: rapid test vs. use of PCR; Centor scoring criteria for testing and treatment in children under three years old; strep throat culture testing in children under three years of age; risk(s) of no treatment of group A strep; rheumatic fever complications; return to school after strep treatment started (timeframe/waiting period); Carrier status for group A strep; pharyngitis and antibiotic overuse; strep pharyngitis and antibiotic use; virtual treatment for pharyngitis.

Non-Infectious Rhinitis

Testing for allergic and non-allergic rhinitis (skin tests for allergic rhinitis, radioallergosorbent tests – RAS, blood eosinophilia and rhinitis; blood eosinophilia and allergic rhinitis, total IgE and allergic rhinitis, total IgE and rhinitis); pets and allergic rhinitis; environment and allergic rhinitis; treatment for allergic rhinitis; nasal strips and rhinitis; nasal strips and rhinitis; medications (corticosteroids, nasal antihistamines for rhinitis; effectiveness of 2nd generation antihistamines for allergic rhinitis, effectiveness of 2nd generation antihistamines for non-allergic rhinitis, leukotriene blockers and allergic rhinitis; leukotriene blockers and non-allergic rhinitis, decongestants for rhinitis); corticosteroids and growth suppression; corticosteroids and bone suppression; monitoring of children on corticosteroids; pharmacologic treatment/medications for non-allergic rhinitis; leukotriene blockers for rhinitis; cromolyn for rhinitis; anticholinergics for rhinitis; ophthalmic medications for rhinitis; rhinitis and antibiotic overuse; sleep conditions and allergic rhinitis.

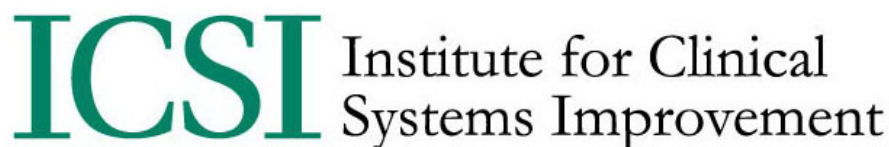
Acute Sinusitis

Imaging and sinusitis; sinusitis and computerized tomography (CT); antibiotics and other treatments for sinusitis (neti-pot and sinusitis, treatment for acute sinusitis, antibiotics and acute sinusitis, antibiotic treatment and acute sinusitis, sinusitis and nasal irrigation); sinusitis and antibiotic overuse; duration of antibiotic and acute sinusitis; virtual treatment for sinusitis.

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BACK

Appendix B – ICSI Shared Decision-Making Model



The Collaborative Conversation™ Shared Decision-Making and the Translation of Evidence into Practice

A consistent finding from clinical and health services research is the failure to translate research into practice. The translation of evidence into practice can be advanced through the use of shared decision-making since shared decision-making results in evidence being incorporated into patient and clinician consultations.

Shared decision-making (SDM) is a process in which patient and clinicians collaborate to clarify all acceptable options, ensure that the patient is well-informed and chose a course of care consistent with patient values and preferences and the best available medical evidence. (Minnesota Shared Decision-Making Collaborative [MSDMC], 2011).

Evidence-based guidelines may recommend the use of shared decision-making for decisions in instances where the evidence is equivocal, when patient action or inaction (such as medication adherence or lifestyle changes) can impact the potential outcome, or when the evidence does not indicate a single best recommendation.

SDM is a patient-centered approach that involves a conversation between the patient and the clinician. It is ideal to involve caregivers and family members in these conversations as well. Family members and caregivers can participate in discussions, ask questions, hear content the patient may miss and provide invaluable support in decision follow-through. Although only patients and clinicians are specifically mentioned throughout this document for brevity purposes, this does not diminish the importance of caregivers and families in patient-centered care.

Both the patient and the clinician bring expertise to the shared decision-making conversation. Clinicians' expertise includes disease etiology, prognosis, options for treatment including the burden and benefit to the patient, and outcome probabilities. Patients' expertise lies in their knowledge of their risk tolerance, body, priorities, family and financial issues, as well as their daily experience with the condition (adapted from Making Shared Decision-Making a Reality. No decision about me, without me. Coulter, A., Collins, A., The King's Fund 2011).

Treatment options vary in their burden on a patient. SDM offers an opportunity to help the patient select a treatment to which they can adhere. When conversations discussing options occurs, patients and clinicians are actively engaged while considering the attributes and issues of the available options. This empathic approach results in the clinician and patient co-creating a decision and a plan of care (adapted from Montori, V., the Mayo Clinic KER UNIT, April 2015). Decision aids can be supportive of this conversation when they communicate the best available evidence to inform the patient and clinician discussion.

Without a conversation, clinicians may make assumptions about what the patient prefers. This creates the potential for discrepancies between what clinicians assume and what patients want, resulting in a “preference misdiagnosis” (adapted from Health Policy Publishing, LLC, May 2013).

Difficulty in initiating a conversation is cited by patients and clinicians as one of the barriers to shared decision-making. To address this impediment, ICSI worked with patients, practicing clinicians, and other stakeholders to develop the Collaborative Conversation™ model for use across the care continuum.

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Collaborative Conversation™

A collaborative approach towards decision-making is a fundamental tenet of Shared Decision-Making (SDM). The Collaborative Conversation™ is an interprofessional approach that nurtures relationships; enhances patients' knowledge, skills and confidence as vital participants in their health; and encourages them to manage their health care. Within a Collaborative Conversation™, the perspective is that the patient, rather than the clinician, knows which course of action is most consistent with the patient's values and preferences.

Use of Collaborative Conversation™ elements and tools is even more necessary to support patient, care clinician and team relationships when patients and families are dealing with high stakes or highly charged issues. A diagnosis of a life-limiting illness is one example of such a circumstance.

The overall objective for the Collaborative Conversation™ approach is to create an environment in which the patient, family and care team work collaboratively to reach and carry out a decision that is consistent with the patient's values and preferences, along with the best available evidence. A rote script, completed form or checklist does not constitute this approach. Rather it is a set of skills employed appropriately for the specific situation. These skills need to be used artfully to address all aspects of the person involved in making a decision: cognitive, affective, social and spiritual.

Key communication skills help build the collaborative conversation approach. These skills include (Adapted from O'Connor, Jacobsen Decisional Conflict: Supporting People Experiencing Uncertainty about Options Affecting their Health [2007], and Bunn H, O'Connor AM, Jacobsen MJ Analyzing decision support and related communication [1998, 2003])

1. Listening skills

Encourage patient to talk by providing prompts to continue such as *go on, and then? and uh huh* or by repeating the last thing a person said, *It's confusing*.

Paraphrase content of messages shared by patient to promote exploration, clarify content and to communicate that the person's unique perspective has been heard. The clinician should use their own words rather than just parroting what they heard.

Reflection of feelings usually can be done effectively once trust has been established. Until the clinician feels that trust has been established, short reflections at the same level of intensity expressed by the patient without omitting any of the message's meaning are appropriate. Reflection in this manner communicates that the clinician understands the patient's feelings and may work as a catalyst for further problem solving. For example, the clinician identifies what the person is feeling and responds back in his or her own words like this: *“So, you're unsure which choice is the best for you.”*

Summarize the person's key comments and reflect them back to the patient. The clinician should condense several key comments made by the patient and provide a summary of the situation. This assists the patient in gaining a broader understanding of the situation rather than getting mired down in the details. The most effective times to do this are midway through and at the end of the conversation. An example of this is *“You and your family have read the information together, discussed the pros and cons, but are having a hard time making a decision because of the risks.”*

Perception checks ensure that the clinician accurately understands a patient or family member perspective, and may be used as a summary or reflection. They are used to verify that the clinician is interpreting the message correctly. The clinician can say, *“So you are saying that you're not ready to make a decision at this time. Am I understanding you correctly?”*

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2. Questioning Skills

Open and closed questions are both used, with the emphasis on open questions. Open questions ask for clarification or elaboration and cannot have a yes or no answer. An example would be, *“What else would influence you to choose this?”* Closed questions are appropriate if specific information is required, such as *“Does your daughter support your decision?”*

Other skills such as summarizing, paraphrasing, and reflection of feeling can be used in the questioning process so that the patient doesn't feel pressured by questions.

Verbal tracking, referring back to a topic the patient mentioned earlier, is an important foundational skill (Ivey & Bradford-Ivey). An example of this is the clinician saying, *“You mentioned earlier...”*

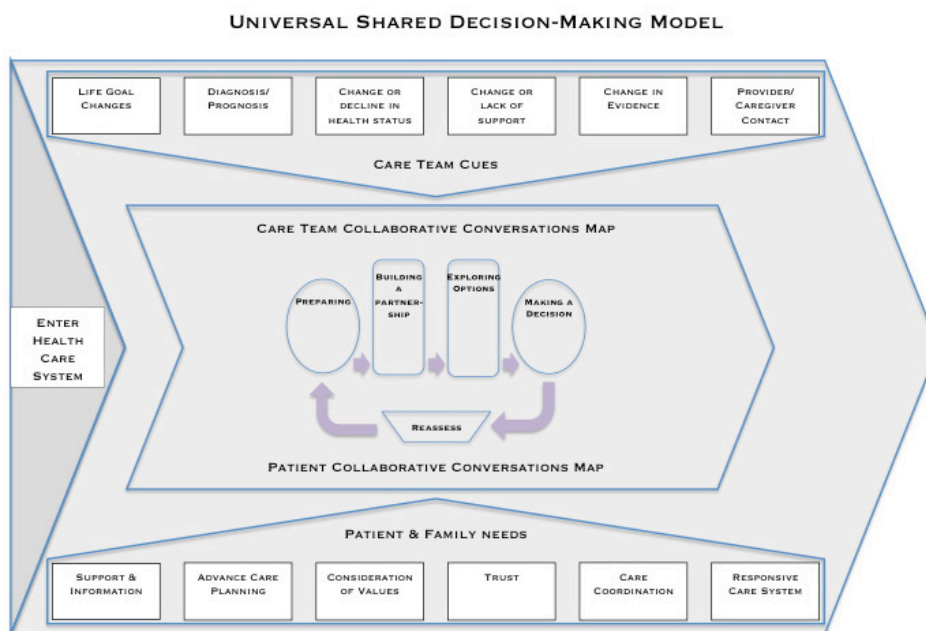
3. Information-Giving Skills

Providing information and **providing feedback** are two methods of information giving. The distinction between providing information and giving advice is important. Information giving allows a clinician to supplement his or her knowledge and helps to keep the conversation patient centered. Giving advice, on the other hand, takes the attention away from the patient's unique goals and values, and places it on those of the clinician.

Providing information can be sharing facts or responding to questions. An example is *“If we look at the evidence, the risk is...”* **Providing feedback** gives the patient the clinician's view of the patient's reaction. For instance, the clinician can say, *“You seem to understand the facts and value your daughter's advice.”*

When to Initiate a Collaborative Conversation™

Certain seminal events occur along the care continuum, creating especially opportune times for collaborative conversations. More than one of these opportunities may present at a time, and they will occur in no specific order.



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Table 1

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Cues for the Care Team to Initiate a Collaborative Conversation™:

- Life goal changes: *Patient's priorities change related to things the patient values such as activities, relationships, possessions, goals and hopes, or things that contribute to the patient's emotional and spiritual well-being.*
- Diagnosis/prognosis changes: *Additional diagnoses, improved or worsening prognosis.*
- Change or decline in health status: *Improving or worsening symptoms, change in performance status or psychological distress.*
- Change or lack of support: *Increase or decrease in caregiver support, change in caregiver, change in caregiver status, change in financial standing, difference between patient and family wishes.*
- Disease progression: *Change in physical or psychological status as a result of the disease progression.*
- Clinician/caregiver contact: *Each contact between the clinician/ caregiver presents an opportunity to reaffirm with the patient that the care plan and the care he or she is receiving are consistent with his or her values.*

Patient and Family Needs within a Collaborative Conversation™

- Request for support and information: *Decisional conflict is indicated by, among other things, the patient verbalizing uncertainty or concern about undesired outcomes, expressing concern about choice consistency with personal values, or exhibiting behavior such as wavering, delay, preoccupation, distress or tension. Support resources may include health care professionals, family, friends, support groups, clergy and social workers. When patient expresses a need for information regarding options and their potential outcomes, the patient should understand the key facts about the options, risks and benefits, and have realistic expectations. The method and pace with which this information is provided to the patient should be appropriate for the patient's capacity at that moment.*
- Advance Care Planning: *With the diagnosis of a life-limiting illness, conversations around advance care planning open up. This is an opportune time to expand the scope of the conversation to other types of decisions that will need to be made as a consequence of the diagnosis of a life-limiting illness.*
- Consideration of Values: *The personal importance a patient assigns potential outcomes must be respected. If the patient is unclear how to prioritize his or her preferences, value clarification can be achieved through the use of decision aids, detailing the benefits and harms of potential outcomes in terms of how they will directly affect the patient, and through collaborative conversations with the clinician.*
- Trust: *The patient must feel confident that his or her preferences will be communicated to and respected by all caregivers.*
- Care Coordination: *Should the patient require care coordination, this is an opportune time to discuss the other types of care-related decisions that need to be made. These decisions will most likely need to be revisited often. Further, the care delivery system must be capable of delivering coordinated care throughout the continuum of care.*
- Responsive Care System: *The care system needs to support the components of patient- and family-centered care so the patient's values and preferences are incorporated into the care he or she receives throughout the care continuum.*

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ICSI Shared Decision-Making Model

The Collaborative Conversation™ Map is the heart of this process. The Collaborative Conversation Map™ can be used as a stand-alone tool that is equally applicable to clinicians and patients, as shown in Table 2. Clinicians use the map as a clinical workflow. It helps get the shared decision-making process initiated and provides navigation for the process. Care teams can use the Collaborative Conversation™ to document team best practices and to formalize a common lexicon. Organizations can build fields from the Collaborative Conversation™ Map in electronic medical records to encourage process normalization. Patients use the map to prepare for decision-making, to help guide them through the process and to share critical information with their loved ones.

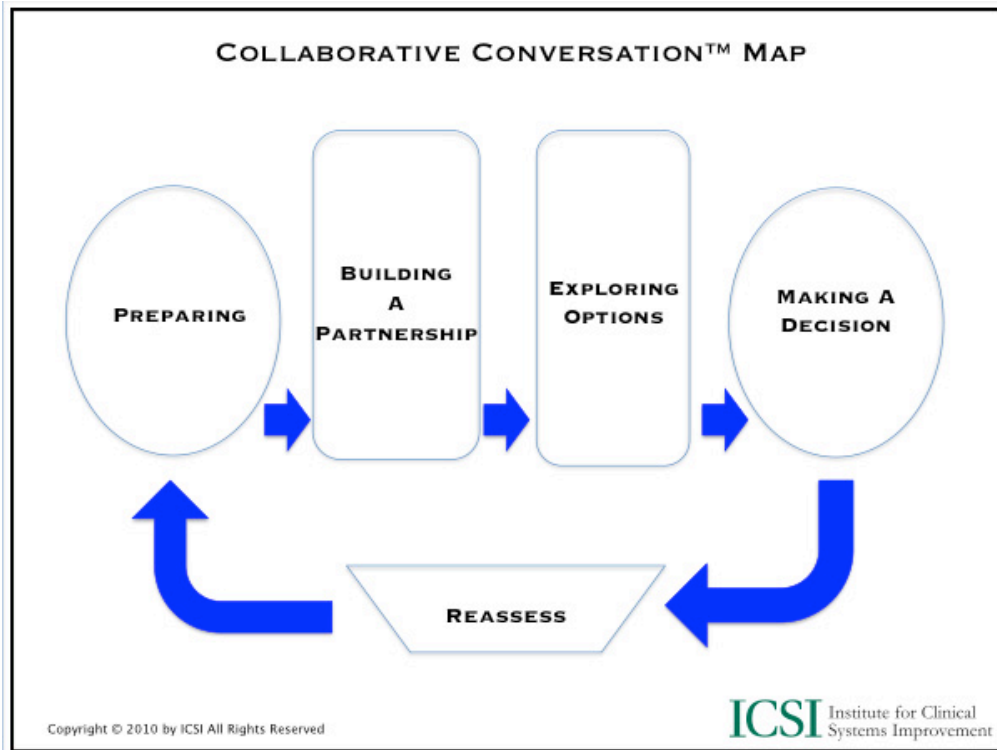


Table 2

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Evaluating Shared Decision-Making

It has proven challenging to assess shared decision-making. Measuring shared decision-making remains important for continued adoption of shared decision-making as a mechanism for translating evidence into practice; promoting patient-centered care; and understanding the impact of shared decision-making on patient experience, outcomes and revenues. Many assessments exist, but they are often proxy measures.

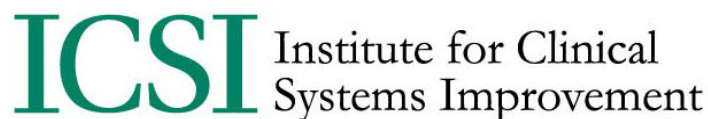
Two suggested methods for measuring shared decision-making are the CollaboRATE tool and the SURE Test. These two tools measure different aspects of shared decision-making, as described below.

The **CollaboRATE tool** measures the level of shared decision-making in the clinical encounter from the patient's perspective. It is a brief patient-reported measure of shared decision-making. The tools and guidance on their use can be found at <http://www.collaboratescore.org/>.

The **SURE Test** is a brief screening questionnaire the patient uses to assess his or her readiness and capacity to make a decision or to determine whether he or she is comfortable with the choice that was made. In other words, it provides information on how likely a patient may be experiencing decisional conflict. If the SURE Test indicates decisional conflict may exist, the **Decisional Conflict Scale** should be completed in order to assess clinically significant decisional conflict.

Shared decision-making is a useful mechanism for translating evidence into practice. While research on the impacts of shared decision-making continues to grow, there is mounting evidence that both patients and clinicians benefit from SDM. Shared decision-making offers the opportunity to bring evidence and the patient's values into the patient/clinician discussion of health choices.

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ICSI has long had a policy of transparency in declaring potential conflicting and competing interests of all individuals who participate in the development, revision and approval of ICSI guidelines and protocols.

In 2010, the ICSI Conflict of Interest Review Committee was established by the Board of Directors to review all disclosures and make recommendations to the board when steps should be taken to mitigate potential conflicts of interest, including recommendations regarding removal of work group members. This committee has adopted the Institute of Medicine Conflict of Interest standards as outlined in the report, *Clinical Practice Guidelines We Can Trust* (2011).

Where there are work group members with identified potential conflicts, these are disclosed and discussed at the initial work group meeting. These members are expected to recuse themselves from related discussions or authorship of related recommendations, as directed by the Conflict of Interest committee or requested by the work group.

The complete ICSI policy regarding Conflicts of Interest is available at <http://bit.ly/ICSICOI>.

Funding Source

The Institute for Clinical Systems Improvement provided the funding for this guideline revision. ICSI is a not-for-profit, quality improvement organization based in Bloomington, Minnesota. ICSI's work is funded by the annual dues of the member medical groups and three sponsoring health plans in Minnesota. Individuals on the work group are not paid by ICSI but are supported by their medical group for this work.

ICSI facilitates and coordinates the guideline development and revision process. ICSI, member medical groups and sponsoring health plans review and provide feedback but do not have editorial control over the work group. All recommendations are based on the work group's independent evaluation of the evidence.

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Diagnosis and Treatment of Respiratory Illness in Children and Adults

ICSI seeks review from members and the public during the revision process.

Member Review

All ICSI documents are available for member review at two points in the ICSI revision process. The ICSI Response Report is sent to members at the beginning of a document revision. The goal of this report is to solicit feedback about the guideline, including but not limited to the algorithm, content, recommendations, and implementation. At the end of the revision process, members are invited to provide feedback on the guideline.

The work group would like to thank all those who took time to thoughtfully and thoroughly review the draft and submitted comments for the Diagnosis and Treatment of Respiratory Illness in Children and Adults guideline.

Public Comment

ICSI makes a draft of the guideline available to the public on the ICSI website. The public is invited to comment in an effort to get feedback prior to its finalization. All comments will be reviewed by the ICSI facilitator and work group members when needed. ICSI work group may or may not make changes to the guideline based on public comment responses.

The work group would like to thank all those who took time to thoughtfully and thoroughly review the draft and submitted comments for the Diagnosis and Treatment of Respiratory Illness in Children and Adults guideline.

Invited Reviews

For some guidelines, ICSI will invite experts in the community to comment on a guideline draft prior to finalization. This is done during the public comment period.

No invited review was done for the Diagnosis and Treatment of Respiratory Illness in Children and Adults guideline.

ICSI Patient Advisory Council (PAC)

The ICSI Patient Advisory Council responds to any guideline review requests put forth by ICSI facilitators and work groups. The PAC members may be involved at the beginning, middle, and/or end of the revision process. Patient advisors who serve on the council consistently share their experiences and perspectives in either a comprehensive or partial review of a document.

The work group would like to acknowledge the work done by the ICSI Patient Advisory Council in reviewing the Diagnosis and Treatment of Respiratory Illness in Children and Adults and thank them for their input.

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Document History

In October 2006, a merger of four ICSI guidelines began in order to create the current guideline, Diagnosis and Treatment of Respiratory Illness in Children and Adults. The documents merged were Acute Pharyngitis, last released in 2005; Acute Sinusitis, and Viral Upper-respiratory Infections, both last released in 2004; and Chronic Rhinitis, last released in 2003.

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◀ The next revision will be no later than September 2022.

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ICSI Document Development and Revision Process

Overview

Since 1993, the Institute for Clinical Systems Improvement (ICSI) has developed more than 60 evidence-based health care documents that support best practices for the prevention, diagnosis, treatment or management of a given symptom, disease or condition for patients.

Audience and Intended Use

The information contained in this ICSI health care guideline is intended primarily for health professionals and other expert audiences.

This ICSI health care guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients and families are urged to consult a health care professional regarding their own situation and any specific medical questions they may have. In addition, they should seek assistance from a health care professional in interpreting this ICSI health care guideline and applying it in their individual case.

This ICSI health care guideline is designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and is not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition.

Document Development and Revision Process

The development process is based on a number of long-proven approaches and is continually being revised based on changing community standards. The ICSI staff, in consultation with the work group and a medical librarian, conduct a literature search to identify systematic reviews, randomized clinical trials, meta-analysis, other guidelines, regulatory statements and other pertinent literature. This literature is evaluated based on the GRADE methodology by work group members. When needed, an outside methodologist is consulted.

The work group uses this information to develop or revise clinical flows and algorithms, write recommendations, and identify gaps in the literature. The work group gives consideration to the importance of many issues as they develop the guideline. These considerations include the systems of care in our community and how resources vary, the balance between benefits and harms of interventions, patient and community values, the autonomy of clinicians and patients and more. All decisions made by the work group are done using a consensus process.

ICSI's medical group members and sponsors review each guideline as part of the revision process. They provide comment on the scientific content, recommendations and implementation strategies. This feedback is used by and responded to by the work group as part of their revision work. Final review and approval of the guideline is done by ICSI's Committee on Evidence-Based Practice. This committee is made up of practicing clinicians and nurses, drawn from ICSI member medical groups.

Implementation Recommendations and Measures

These are provided to assist medical groups and others to implement the recommendations in the guidelines. Where possible, implementation strategies are included that have been formally evaluated and tested. Measures are included that may be used for quality improvement as well as for outcome reporting. When available, regulatory or publicly reported measures are included.

Document Revision Cycle

Scientific documents are revised every 12-24 months as indicated by changes in clinical practice and literature. ICSI staff monitors major peer-reviewed journals every month for the guidelines for which they are responsible. Work group members are also asked to provide any pertinent literature through check-ins with the work group midcycle and annually to determine if there have been changes in the evidence significant enough to warrant document revision earlier than scheduled. This process complements the exhaustive literature search that is done on the subject prior to development of the first version of a guideline.

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