ACUTE BACTERIAL SINUSITIS

EXECUTIVE SUMMARY

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PRIMARY OBJECTIVE

Develop a pathway for treating acute bacterial sinusitis in Children's Physicians and Children's Urgent Care clinics that standardizes first and second line antibiotic selection according to published literature taking into account local antibiotic resistance patterns.

RECOMMENDATIONS

Inclusion Criteria:

• Children ≥ 1-18 years of age

Exclusion Criteria:

• Toxic appearing

• Children with anatomic abnormalities of the paranasal sinuses (facial dimorphisms or trauma)

• Immunodeficiencies

• Cystic fibrosis

• Primary ciliary dyskinesia (immotile-cilia syndrome)

• Children with complications or suspected complications of acute bacterial sinusitis which include:

  o Preseptal orbital cellulitis or sympathetic edema

  o Subperiosteal abscess

  o Orbital abscess

  o Postseptal orbital cellulitis

  o Cavernous sinus thrombosis

  o Any neurologic changes

• Children less than 1 year old are excluded from this pathway. While "the maxillary and ethmoid sinuses are present and normally aerated at birth, pneumatization of the sphenoid is usually detectable at about 3 years of age and progresses throughout childhood. The frontal sinuses first extend above the roofs of the orbits at about 5 years, but may remain hypoplastic or aplastic into adulthood." [3] In addition there is not any published literature to support the diagnosis and treatment of sinusitis in children less than 1 year of age. "Although

bacterial sinusitis does occur rarely in children less than 1 year of age, their exclusion reflects in part, the difficulty in conducting clinical investigation into this age group."[2]

Diagnosis

• Acute bacterial sinusitis is a common complication of viral upper respiratory infection (URI) or allergic inflammation. Symptoms of acute bacterial sinusitis and uncomplicated viral URI overlap considerably, and therefore it is their persistence without improvement that suggests a diagnosis of acute bacterial sinusitis. The American Academy of Pediatrics (AAP) Clinical Practice Guideline for the Management of Sinusitis, (2001) recommends that clinicians make a presumptive diagnosis of acute bacterial sinusitis when a child presents with either a persistent illness, or a worsening course, or a severe onset of symptoms. When the patient does not meet the criteria of persistence, a diagnosis of viral URI should be considered.

• Although the triad of headache, facial pain, and fever is considered a classic presentation of ABRS in adults, it is uncommon. Onset with persistent symptoms is far more frequent. In children, the most common manifestations of bacterial sinusitis are cough (80%) followed by nasal discharge (76%) and fever (63%). Parents of preschoolers often report malodorous breath. Headache, facial pain, and swelling are rare.[1]

Presentation and Clinical Management:

Viral URI

• Nasal symptoms (discharge and congestion/obstruction) or both, typically peaking in severity by days 3 to 6, with improvement of symptoms by day 10.

o Provide symptom relief.

o Instruct parent to follow-up if symptoms don't improve within 10 days of onset, or worsen after initial improvement.

Acute Bacterial Sinusitis

• **Persistent illness**, i.e. nasal discharge (of any quality) or cough or both lasting more than 10 days without improvement

o For children with persistent illness, in shared decision making with child's caregiver(s), providers should either prescribe an antibiotic or offer observation for 3 days. If the patient does not improve

clinically during observation, or if there is clinical worsening of the child's condition at any time, provider should prescribe an antibiotic.[6]

o Although there are benefits to antibiotic therapy, some children improve on their own, and the risk of suppurative complications is low.[6]

o Factors that should be considered when choosing between observation and treatment with antibiotics include symptom severity, quality of life, recent antibiotic use, previous experience and outcomes with acute bacterial sinusitis, cost of antibiotics, ease of administration, caregiver concerns about potential adverse events, persistence of respiratory symptoms or development of complications.

• **Worsening Course**, i.e. worsening or new onset of nasal discharge, cough, or fever after initial improvement

o Antibiotic therapy is recommended for patients with a worsening course or severe onset of acute bacterial sinusitis because of the benefits revealed in randomized controlled trials and a theoretically higher risk of suppurative complications than for children who present with persistent symptoms.[6]

• **Severe Onset**, i.e. concurrent fever (temperature ≥ 39°C/102.2°F) and purulent nasal discharge for at least 3 consecutive days

Antimicrobial Therapy:

First Line Antibiotics:

• **Amoxicillin (high dose)** 90 mg/kg/day PO in two divided doses (usual adult dose 2000 mg/day divided two times a day) o In communities with a high prevalence of non-susceptible S. pneumoniae (>10% including intermediate and high-level resistance), treatment with high dose amoxicillin is recommended.6 The Omaha area does have a high prevalence of non-susceptible S. pneumoniae > 10%.

o Amoxicillin remains the antimicrobial of choice for first-line treatment of uncomplicated acute bacterial sinusitis in situations in which antimicrobial resistance is not suspected. This recommendation is based on amoxicillin's effectiveness, safety, acceptable taste, low cost, and relatively narrow microbiologic spectrum.[6]

o A recent guideline was published by the Infectious Diseases Society of America for acute bacterial rhinosinusitis in children and adults. Their recommendation for initial empirical antimicrobial therapy was amoxicillin-clavulanate based on the concern that there is an increasing prevalence of H. influenzae as a cause of sinusitis since introduction of the pneumococcal conjugate vaccines and an increasing prevalence of β-lactase production among these strains. In contrast the AAP allows either

amoxicillin or amoxicillin-clavulanate as first-line therapy. Unfortunately there is scant data available regarding the precise microbiology of acute bacterial sinusitis in the post-PCV-13 era.[6]

o Risk factors for the presence of organisms likely to be resistant to amoxicillin include attendance at child care, receipt of antimicrobial treatment within the previous 30 days, and age younger than 2 years.[6]

• **Amoxicillin Clavulanate (high dose)** 90 mg/kg/day PO in two divided doses (usual adult dose 2000 mg/day divided two times a day; dosing based on Amoxicillin component)

o For patients presenting with moderate to severe illness as well as those children with persistent illness < 2 years, attending child care, or who have recently been treated with an antimicrobial.

• **Ceftriaxone** 50 mg/kg/dose IM (max single dose of 1000 milligrams)

o For children who are vomiting, unable to tolerate oral medication, or unlikely to be adherent to the initial doses of antibiotic. If clinical improvement is observed at 24 hours, an oral antibiotic can be substituted to complete the course of therapy.

o Children who are still significantly febrile or symptomatic at 24 hours may require additional parenteral doses before switching to oral therapy

First Line Antibiotics for Patients Allergic to Penicillin:

• **Cefdinir** 14 mg/kg/day PO in one dose (usual adult dose 600 mg/day given once daily)

For Patients that Clinically Worsen After 72 Hours or Fail to Improve After 3-5 Days of Amoxicillin (high dose) Antimicrobial Therapy:

• **Amoxicillin Clavulanate (high dose)** 90 mg/kg/day PO in two divided doses (usual adult dose 2000 mg/day divided two times a day; dosing based on Amoxicillin component)

Second Line Antibiotic Therapy in Patients with or without Penicillin Allergies:

• **Cefdinir** 14 mg/kg/day PO in one dose (usual adult dose 600 mg/day given once daily) AND Clindamycin 30-40 mg/kg day PO in three divided doses (usual adult dose 1350 mg/day divided three times a day)

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Disclaimer: *Pathways are intended as a guide for practitioners and do not indicate an exclusive course of treatment nor serve as a standard of medical care. These pathways should be adapted by medical providers, when indicated, based on their professional judgement and taking into account individual patient and family circumstances*

• **Cefixime** 8 mg/kg/day PO in one dose (usual adult dose 400 mg/day given once a day) AND Clindamycin 30-40 mg/kg day PO in three divided doses (usual adult dose 1350 mg/day divided three times a day)

• **Ceftriaxone** 50 mg/kg/dose IM (max single dose of 1000 milligrams) AND Clindamycin 30-40 mg/kg/day PO in three divided doses (usual adult dose 1350 mg/day divided three times a day)

• **Doxycycline** 2-4 mg/kg/day PO in one dose (usual adult dose 200 milligrams given once daily) for patients > 8 years of age o For Patients that are < 8 years of age and cephalosporin allergic, providers should contact Infectious Disease.

Notes About Antimicrobial Therapy:

• Although dual therapy with third generation cephalosporins and clindamycin is suggested for first line therapy with allergies to penicillin; this is not currently an accepted practice in our local community. The efficacy of monotherapy with cefdinir as first line treatment of AOM will be followed and studied through the collection of data from this pathway's 4th metric.

• The dosing for clindamycin varies between conditions because of the tissue being treated. Children's infectious disease physicians recommend a higher dose of clindamycin to treat sinusitis and otitis media due to the need to penetrate biofilm. Additionally the organisms associated with acute bacterial sinusitis infections and otitis media are generally not as susceptible as those of Group A Streptococcus.

• Second and third-generation oral cephalosporins are no longer recommended for empiric monotherapy due to variable rates of resistance among S. pneumoniae. Combination therapy with a third-generation oral cephalosporin plus clindamycin is recommended to cover penicillin-resistant S. Pneumoniae. [1, 6]

• Macrolides (clarithromycin & azithromycin) are not recommended for empiric therapy due to high rates of resistance of S. pneumoniae (~30%). "The prevalence of macrolide-resistant S. pneumoniae in the United States has escalated dramatically since the 1990's. Studies reveal that whereas only 5% of S. pneumoniae clinical isolates in the United States were resistant to macrolides in 1993, >30% had become resistant by 2006. During 2005-2007, 43% of invasive S. pneumoniae isolates were macrolide-resistant." [1]

• Trimethoprim-sulfamethoxazole (TMP/SMX) is not recommended for empiric therapy because of high rates of resistance among both S. pneumoniae and Haemophilus influenzae (~30-40%). "Surveillance of recent respiratory isolates in the United States indicates a variable, but significant increase in penicillin–intermediate and macrolide or TMP/ SMX-resistant S. pneumoniae and β-lactamase-

producing H. influenzae. Accordingly, antimicrobial agents previously recommended as an alternative to amoxicillin or amoxicillin-clavulanate, such as macrolides, TMP-SMX, or secondor third-generation oral cephalosporins, can no longer be recommended because of increasing resistance among S. pneumoniae and/or H. influenzae."

Duration of Therapy:

• Duration of antibiotic therapy may range from 10-21 days or longer. "The optimal duration of therapy for patients with acute bacterial sinusitis has not received systematic study. Recommendations based on clinical observations have varied widely, from 10-28 days of treatment. An alternative suggestion has been made that antibiotic therapy be continued for 7 days after the patient becomes free of signs and symptoms. This strategy has the advantage of individualizing the treatment of each patient, results in a minimum course of 10 days, and avoids prolonged antimicrobial therapy in patients who are asymptomatic and therefore unlikely to adhere to the full course of treatment." [6]

Referrals to consider:

• When patients fail to respond despite a change in antimicrobial therapy to broaden coverage for presumed bacterial resistance, prompt referral to a specialist such as an otolaryngologist, allergist, or infectious disease specialist should be based on the indication for referral, and whether the suspected cause of treatment failure is primarily surgical, medical, or of an immunologic/allergic nature. A confirmation of diagnosis is probably best determined by an otolaryngologist, who may assist in obtaining cultures by sinus puncture or middle meatus endoscopy. Severe infection, particularly in the immunocompromised host, or patients with multiple medical problems that complicate appropriate dosing or predispose to unusual microorganisms, should be referred to an infectious disease specialist. Patients with recurrent infection or suspected to have an underlying hypersensitivity or immunologic disorder should be referred to an allergist. Patients with rapid deterioration and manifestations suggestive of orbital or intracranial suppurative complications require urgent consultation and a multidisciplinary approach.[1]

• Severe infection (high persistent fever with temperature > 39°C [102°F]; orbital edema, severe headache, visual disturbance, altered mental status, meningeal signs) (Emergency Department [ED], Infectious Disease [ID], or Ear, Nose & Throat [ENT])

• Recalcitrant infection with failure to respond to extended courses of antimicrobial therapy (ID or ENT)

• Immunocompromised host (ID)

• Multiple medical problems that might compromise response to treatment (e.g., hepatic or renal impairment, hypersensitivity to antimicrobial agents, organ transplant) (ID)

• Unusual or resistant pathogens (ID)

• Fungal sinusitis or granulomatosis disease(ID or ENT)

• Nosocomial infection (ID)

• Anatomic defects causing obstruction requiring surgical intervention (ENT)

• Multiple recurrent episodes of acute bacterial rhinosinusitis suggesting chronic sinusitis (ENT)

• Chronic rhinosinusitis (with or without polyps or asthma) with recurrent ABRS exacerbations (ENT)

• Evaluation of immunotherapy for allergic rhinitis (allergist)

Imaging:

• "The high prevalence (30-50%) of incidental sinus opacification in infants and children without apparent asymptoms has been documented by x-ray film studies and confirmed by computed tomography (CT). Some authors have ascribed this finding to crying during radiographic examinations or even stated that it may represent the normal condition in infants and young children. A recent study suggests that most asymptomatic sinus opacification in children older than 1 year is actually secondary to apparently uncomplicated upper respiratory infection. These findings may persist as long as 2 weeks after symptoms have resolved."[3] For these reasons as well as the increased radiation associated with CT, and the high cost associated with MRI and often the need for sedation in the pediatric population, imaging tests are not necessary in children with uncomplicated bacterial sinusitis. The AAP, the American College of Radiology, the Sinus and Allergy Health Partnership, and the Infectious Diseases Society of America all agree with not imaging patients with suspected acute bacterial sinusitis. However, CT scans of the paranasal sinuses should be considered for patients in whom surgery is being considered as a management strategy after discussion with ENT and/or radiology.

Adjuvant Therapy

• "Potential adjuvant therapy for acute sinusitis might include intranasal corticosteroids, saline nasal irrigation or lavage, topical or oral decongestants, mucolytics, and topical or oral antihistamines." 6 A recent Cochrane review on decongestants, antihistamines, and nasal irrigation for acute sinusitis in children "found no evidence supporting the use of antihistamines or decongestants. Furthermore, there is growing evidence from observational studies and from randomized trials of these medications in

children with other upper respiratory tract infections, which shows that the use of antihistamines and decongestants can lead to significant adverse events, especially in young children. Similarly there was no evidence to support the use of irrigation in children with acute sinusitis. Although irrigation in general is well tolerated, without data to support its efficacy its routine use cannot be recommended." [5]

RATIONALE

• **Safety:** Shall be improved by selecting the appropriate antibiotics to treat acute bacterial sinusitis and by eliminating unnecessary radiology procedures.

• **Quality**: Will be improved by instituting consistent antibiotic selection, dosing and care between providers.

• **Cost:** Will be improved by decreasing the cost associated with doing unnecessary testing and prescribing unnecessary or inappropriate antibiotics.

• **Delivery:**

  o Providing appropriate antibiotic therapy for acute bacterial sinusitis should reduce complications associated with the infection.

  o Not performing sinus imaging will reduce the amount of time patients are in the clinic and/or eliminate the need for them to visit the hospital for sinus imaging.

  o Providing appropriate therapy to patients with acute bacterial sinusitis will help reduce antibiotic resistance.

• **Engagement:** Is created and supported by the involvement of a multidisciplinary team in the development and maintenance of the pathway.

• **Patient/Family Satisfaction:** Shall be improved by providing the highest quality care based on established guidelines and the latest evidence available in the literature. For children with persistent symptoms, there is also an opportunity for shared decision making regarding the initiation of antibiotic therapy versus further observation between provider and care givers in the treatment of acute bacterial sinusitis.

IMPLEMENTATION ITEMS

• Algorithm

• Sinusitis SmartSet and SmartText

METRICS PLAN

1. Decrease the number of prescriptions written for azithromycin, clarithromycin, and trimethoprim-sulfamethoxazole (TMP/SMX) for the treatment of acute bacterial sinusitis by 90%. A total of 13,089 prescriptions were given out for the treatment of acute bacterial sinusitis in 2015 by Children's Physicians providers. Of those 1,255 or 9.59% were a zithromycin, clarithromycin, or trimethoprim-sulfamethoxazole (TMP/SMX).

2. Monitor the number of sinus imaging studies ordered to diagnose acute bacterial sinusitis.

3. Increase the percentage of patients who are not penicillin allergic that receive either high dose amoxicillin or high dose Amoxicillin Clavulanate as first line treatment for acute bacterial sinusitis.

4. Monitor monotherapy use with cephalosporins and associated response rates.

SUPPORTING DOCUMENTS (Pathway, inclusion/exclusion criteria, definitions, algorithm)

• Algorithm

TEAM MEMBERS

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EVIDENCE

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