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# Acute sinusitis in children: Do antibiotics have any role?



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**Summary** Bacteria can be recovered from paranasal sinuses in the majority of patients given the diagnosis of acute bacterial sinusitis (ABS), and bacteriologic cure can be achieved with appropriate antibiotic treatment. The critical question is whether bacteriologic cure correlates with meaningful clinical endpoints such as clinical improvement, reduction in recurrent disease, or prevention of complications. Of the 4 pediatric placebo-controlled randomized clinical trials (PCRCTs), 2 suggest superiority of antibiotic treatment and 2 suggest lack of superiority. PCRCTs in adults are mixed as to clinical benefit. Pediatric and adult meta-analyses demonstrate modest benefit of antibiotic therapy and rates of spontaneous recovery without antibiotics of 60–65%. Although retrospective studies indicate that some patients who develop orbital or neurologic complications of sinusitis were pre-treated with antibiotic therapy, a low rate of complications precludes determination of whether antibiotic treatment prevents complications in some proportion of patients. Like the literature evidence, expert guideline recommendations are mixed. Although the evidence base is incomplete and conflicting, the limited data suggest that antibiotics probably do have a role in the treatment of pediatric ABS. The most compelling rationale is prevention of serious complications, but proof for this rationale is lacking.

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## Introduction

Sinusitis is a frequently diagnosed condition that adversely affects quality of life and can produce major complications that cause significant morbidity, and, occasionally, mortality. Sinusitis has important implications

from a societal perspective, also. In the United States, the estimated annual cost of sinusitis has been estimated at \$3.5–5.8 billion, including \$1.8 billion for children <12 years of age.<sup>1,2</sup> Sinusitis is a leading indication for antibiotic prescribing in the United States,<sup>3</sup> accounting for approximately 9% of pediatric and 21% of adult antibiotic

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prescriptions.<sup>2</sup> Thus, antibiotic therapy for sinusitis has a significant impact on medical expenditures and on the relationship between antibiotic consumption and antibiotic resistance.

## What is the rationale for antibiotic treatment of acute sinusitis?

Reasons to treat acute sinusitis include to hasten clinical improvement, prevent mucosal damage that predisposes to recurrent or chronic disease, and prevent complications. The rationale for antibiotic treatment is based on observations that (1) bacteria can be recovered from the paranasal sinuses in the majority of patients given the diagnosis of sinusitis and (2) bacteriologic cure can be achieved with appropriate antibiotic treatment. Of critical importance in determining whether antibiotics are an effective therapy for acute bacterial sinusitis (ABS), however, is an evaluation of the evidence that bacteriologic cure correlates with clinical endpoints, i.e., that antibiotic treatment makes the patient better.

## Definitions of acute bacterial sinusitis

Because culturing the infected site is not feasible in general practice, the diagnosis of sinusitis (and determination of disease resolution) is based on clinical definitions. These definitions provide a framework for both diagnosis and for investigation of treatment efficacy. The most commonly applied definition of ABS is an upper respiratory infection in which symptoms are *not improving* after 10–14 days and often worsening after 5–7 days. Symptoms in children may include nasal discharge, which may or may not be purulent and which may drain anteriorly or posteriorly; nasal congestion; cough, wet or dry and usually present in the daytime although often worse at night; fever, which is often absent and, when present, generally low-grade; halitosis; and, occasionally, periorbital edema, most prominent in the morning. This definition was derived from meticulous studies of the natural history of viral upper respiratory tract infections in children. These studies indicated that although children with uncomplicated viral infections may occasionally have symptoms lasting as long as 2–3 weeks, symptoms generally had resolved or improved by day 10 of illness.<sup>4</sup> Children whose symptoms were not improved by day 10 were considered to have ABS. When put to the test, this definition appears to be overly sensitive. Of children with non-improving symptoms by day 10, 65–75% had high densities of bacteria in maxillary sinus aspirates; clinical findings did not distinguish those who were culture-positive from the 25–35% who were culture-negative. In clinical practice, approximately 7–9% of children with upper respiratory tract infections fulfill this definition of ABS.

The second definition of ABS is the presence of severe symptoms out of proportion to those of a typical viral URI for more than 3–4 days at the beginning of illness. Symptoms may include high fever ( $\geq 39^\circ\text{C}$ ) and concurrent purulent nasal discharge, headache, facial pain or tenderness, and periorbital edema. These patients usually appear

ill. This presentation of ABS is less commonly observed in children than in adults.

The third definition of ABS consists of worsening symptoms after 5–6 days of a typical viral upper respiratory infection. This presentation may include new fever, worsening headache, increase in nasal discharge or cough, facial pain or tenderness, periorbital edema, and a more ill appearance than earlier in the course.

## Evaluation of the literature evidence

This review will examine 3 levels of evidence to assess whether the medical literature supports antibiotic treatment of ABS: pediatric placebo-controlled randomized clinical trials (PCRCTs), adult PCRCTs, and pediatric and adult meta-analyses.

### Pediatric placebo-controlled randomized clinical trials

Four PCRCTs evaluating the efficacy of antibiotic therapy for sinusitis have been performed in children. In 1986, Wald et al., reported a study of 2–16 year old children who had 10–30 days of non-improving symptoms of nasal discharge and cough (the first clinical definition described above) who also had abnormal maxillary sinus radiographs. Children with underlying disease, severe headache, or periorbital swelling were excluded. Subjects were randomized to receive 10 days of amoxicillin (40 mg/kg/day), amoxicillin–clavulanate (40 mg/kg/day of amoxicillin component) or placebo. No adjunctive medications such as decongestants or antihistamines were permitted. Ninety-three children were analyzed. Cure rates at day 3 were 43% in the amoxicillin group, 47% in the amoxicillin–clavulanate group, and 11% in the placebo group ( $p < 0.01$ ). At day 10, cure rates were 67%, 64%, and 43%, respectively ( $p < 0.05$ ). Conversely, rates of failure (lack of cure or improvement) were 16% and 25% in the antibiotic groups compared with 40% in the placebo group ( $p < 0.05$ ). The authors concluded that antibiotic treatment was associated with faster disease resolution and a higher cure rate, despite the 43% spontaneous cure rate and the 60% rate of cure or improvement observed in the placebo group.<sup>5</sup>

Fifteen years later, Garbutt et al, published the second PCRCT of pediatric sinusitis. Children 1–18 years of age with upper respiratory symptoms for 10–28 days who lacked underlying disease, recent antibiotic treatment, high fever, and facial swelling or pain were randomized to receive 14 days of amoxicillin (40 mg/kg/day), amoxicillin–clavulanate (45 mg/kg/day of amoxicillin component), or placebo. Adjunctive medications were allowed as per provider and parent discretion, and, overall, 50% of the 161 subjects received additional medications, including antihistamines, antitussives, intranasal steroids, decongestants, and expectorants. No differences among adjunctive medication use were observed among the study groups. Outcomes among the 3 treatment groups were virtually identical: improvement at day 14 in 79–81%, very good/excellent functional status at day 14 in 77–81%, relapse by day 21 or 28 in 12–13%, recurrence after day 28 in 9–13%, additional healthcare for sinus complaints in 12–14%,

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