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PediaNews

The Official Newsletter of RxPups - Student Society of Pediatric Advocates

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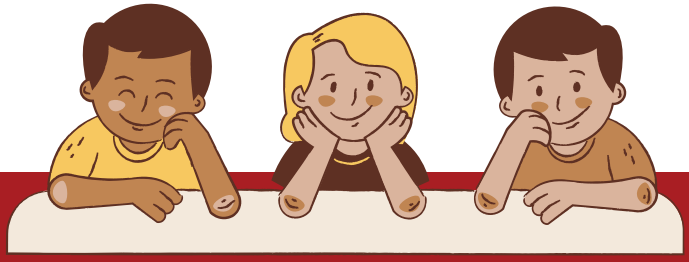

Inside this issue:

Our Mission

The Student Society of Pediatric Advocates is a student organization affiliated with the University of Georgia College of Pharmacy. We are a student group associated with the Pediatric Pharmacy Advocacy Group. The Mission of the SSPA is to bring awareness to the proper use of medication therapy in pediatric populations through various service and education- based initiatives. Service activities center around lending our medication-based knowledge to pediatric patients and their parents in our community. Educational activities are directed toward student members in an effort to safely and effectively extend pharmacy practice to pediatric populations by building relationships with mentors and professionals in the health care community, as well as supplementing didactic coursework with lectures by specialists and our peers. Overall, SSPA advocates for the safety and happiness of young patients while learning and having fun along the way. The purpose of our newsletter is to educate pharmacy students about pediatric pharmacy and advocate for pediatric patients within the University of Georgia College of Pharmacy.

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FDA Approval of Alirocumab for Children with Heterozygous Familial Hypercholesterolemia

Written by Christopher Barry, PharmD Candidate 2026

Familial Hypercholesterolemia (HeFH) is an autosomal dominant disorder characterized by elevated low-density lipoprotein (LDL-C) concentrations. [1] The disease exists in two genotypes, either homozygous or heterozygous. While the homozygous form of the disease is associated with more severe symptoms, the heterozygous form is more prevalent with 1 in 313 affected individuals in the United States and globally. [1] The disorder results from genetic mutations that alter the function of LDL receptors resulting in either an interruption in cholesterol binding to the receptor, or hindered uptake of the LDL receptor-cholesterol complex. [2] Heterozygotes have one functioning wild type allele and one mutated allele; therefore, they have half the number of normal LDL receptors relative to the general population. [2] Hypercholesterolemia at an early age means these individuals are at a higher risk of premature cardiovascular events in adulthood. [1] Consequently, early diagnosis and treatment of this disorder is critical to prevent atherosclerosis and related complications in early adulthood.

The ACC/AHA guidelines recommend an LDL-C of less than 110 mg/dL in children and adolescents. [1] Current treatment guidelines for children with HeFH include diets high in fiber and low in saturated fats, regular physical activity, and the use of statins in children as young as 8 years. [2] In children unable to achieve a 50% reduction in LDL-C on a maximally tolerated statin therapy, ezetimibe and bile acid sequestrants are recommended as an adjunct therapy. [2] PCSK9 inhibitors, such as alirocumab and evolocumab, are additional options for treatment. These monoclonal antibodies function in LDL-C reduction by binding PCSK9, a protein that binds LDL receptors to prevent their recycling to the hepatocyte surface. [3] Alirocumab has been approved since 2015 for use in adults as an adjunct to statin therapy. As of March 2024, the FDA extended approval of alirocumab for children 8 years or older with inadequate LDL-C reduction on a maximally tolerated statin following a phase 3 randomized clinical trial published in JAMA Pediatrics. [4]

This Phase 3, randomized, double-blind, placebo-controlled, multicenter trial was conducted with 153 patients ages 8-17 across 24 countries. [1] These HeFH patients were eligible if they had an LDL-C of 130 or greater while on a maximally tolerated statin or non-statin lipid lowering therapy. Patients were excluded from the study if they weighed less than 25 kg, had signs of delayed puberty, or had uncontrolled diabetes among other conditions including abnormal kidney or liver function. The experimental group was randomized into two groups that were each given alirocumab using weight-based dosing. One group was administered alirocumab every 2 weeks (Q2W) while the other received alirocumab every 4 weeks (Q4W). Both the experimental and placebo groups continued their lipid lowering therapies during the trial. Blood samples were retrieved from both the experimental and placebo arms of the trial at week 0, 8, 12, and 24. The primary endpoint was the percent change in LDL-C over the course of the 24 weeks. [1] The investigators assessed safety by monitoring adverse effects, vital signs, and Tanner staging. [1] In addition, they monitored for the development of anti-alirocumab antibodies. [1]

In the Q2W group, alirocumab reduced LDL-C versus placebo, with a -43.3% least squares mean difference. Likewise, there was a similar LDL-C reduction in the Q4W group, with a -33.8% least squares mean difference. In the Q2W group, adverse events were reported by 26 patients receiving alirocumab and 13 receiving the placebo. In the Q4W group, adverse events were reported by 26 patients receiving alirocumab and 16 receiving the placebo. Over 75% of participants achieved an LDL-C less than 130 mg/dL and about a third of participants achieved a 50% or more reduction in LDL-C. [1] Overall, adverse events were mild to moderate in nature with two patients reporting syncope as a result of treatment. None of the participants developed anti-alirocumab antibodies. [1] The phase 3 trial outlined above was important for the FDA approved extension of alirocumab for children of 8 years and older that are unable to achieve adequate lipid values on a statin alone. This patient population can significantly benefit from the addition of new medication options and alternatives. The trial demonstrated alirocumab's safety and efficacy in this population; therefore, it is a reasonable option pharmacists can consider recommending for this patient population.

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An Overview Concerning the Overprescribing of Antibiotics in Pediatric Patients

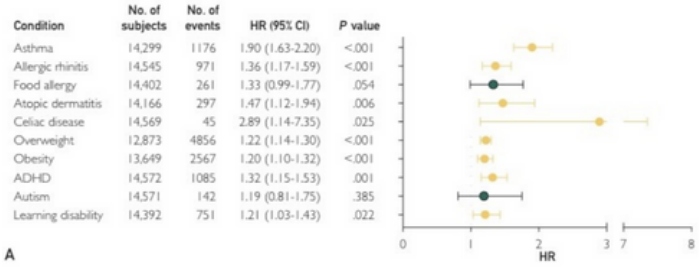
Written by Amber Lowrimore, PharmD Candidate 2026
and Ansley Mole, PharmD Candidate 2026

Antibiotics are commonly prescribed to treat upper respiratory tract and skin infections in the pediatric population. Upper respiratory infections including pharyngitis and acute otitis media are both caused by bacterial and viral pathogens. Additionally, most of these infections have viral origins in which antibiotics are not needed. This overprescribing leads to drug resistance, unnecessary adverse effects, and extra costs.

The drivers of overprescribing antibiotics in the outpatient setting include absenteeism from school or work, parental and societal pressures, and overall lack of education on uncomplicated childhood illnesses. Many schools or daycare centers require students to obtain a doctor's note and meet exclusion criteria for influenza-like-illness prior to the student's return to class. A randomized control trial was conducted to investigate the relationship between antibiotics prescribed for influenza-like-illness and class absenteeism while measuring illness duration. [1] Children ages 2 months to 12 years with flu-like symptoms were evaluated in the emergency department. Rapid molecular respiratory pathogen testing along with viral testing was performed during the visit. Out of the total pediatric patients, about 80% had positive viral testing, and antibiotics were prescribed to 26% of patients with symptoms. The resulting evidence concluded that there was no statistically significant association with prescribing antibiotics and missed class days due to illness. [1] This primary outcome provides evidence supporting how clinicians prescribe antibiotics when it is unnecessary. Providers must navigate parental pressures by educating on the adverse effects and the downfalls of antibiotic misuse.

Pivoting from class absenteeism, a secondary concern arises when antibiotics are given at a high rate in pediatric populations. In one study from the Mayo Clinic, an association of infant antibiotic exposure with childhood health outcomes was studied in 14,572 children. [2] Of the children included, 70% received at least one antibiotic during the first 2 years of life. The children receiving early life antibiotics exposure showed a statistically significant risk of asthma, allergic rhinitis, atopic dermatitis, celiac disease, overweight, obesity and attention deficit hyperactivity disorder as shown in the figure below.

Figure 1. Associations between antibiotic exposure in the first 2 years of life and the risk of several common health conditions with childhood onset. [2]



The association between early antibiotic exposure and negative health outcomes were dependent upon the number, type, and timing of exposure, ultimately showing that the children exposed to multiple antibiotics had a higher association of having a combination of conditions. The most frequent offenders are penicillins, cephalosporins, and macrolides, which specifically were more likely to correlate with asthma and allergic rhinitis in children exposed in the first 2 years of life. [2]

What should be done about this public health concern? Healthcare workers are at the forefront of this issue and can implement changes to combat the desire to seek antibiotics first for uncomplicated sickness. Simply promoting vaccinations, hand washing, and education about the harm of meaningless antibiotic use can have a positive impact on this effort. [3] Although more studies need to be performed in order to find causation with increased antibiotic use and negative outcomes, eliminating unnecessary antibiotic treatment helps patients and clinicians alike. The takeaway from the data should not be to stop giving antibiotics but to understand the cause and educate on the necessity of the medications at play.

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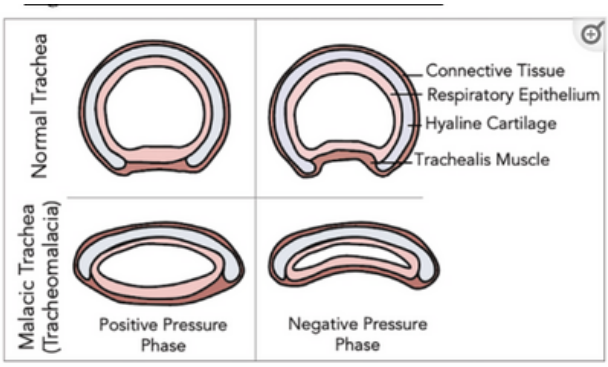
Tracheomalacia in Infants

Written by Melina Kelley, PharmD Candidate 2027

Airway malacia is an abnormality in the formation of the respiratory system. These defects are not common, but the most widespread type of airway malacia is congenital tracheomalacia, affecting 1 in 2100 children. [1] This condition features the collapse of the trachea while exhaling because of weak tracheal cartilage and muscle. The trachea walls should be rigid, but in the presence of tracheomalacia, the cartilage is soft and flexible. Infants can be born with this anomaly, and treatment depends on the severity. [1] During the first year of birth, the infant can have difficulty or noisy breathing. It may sound like wheezing or a rattling sound. A stridor or high pitched cough can also be present. [2] Figure 1 shows an illustration of a normal trachea and a malacic trachea during the cycle of respirations. The malacic trachea is more narrow, leading to a collapse in the airway. [3]

Figure 1. Normal vs Malacic Trachea



Tracheomalacia can be diagnosed through X-rays, CT scans, and airway fluoroscopies. These tests can show images of the trachea and larynx, movement during respirations, and narrowing of the airways. [2]

A positive diagnosis can be seen with a crescent or U shaped trachea while exhaling. According to an article published in the International Journal of Surgery, during laughing or coughing, the tracheal walls narrow and the presence of tracheomalacia can cause a lack of secretion clearance, leading to infections. There might also be insufficient ventilation causing an intolerance to exercise and occasional hypoxia spells. [1]

Tracheomalacia is managed depending on the severity or other underlying issues. Commonly, the newborn will grow out of tracheomalacia within 18-24 months. Doctors recommend nonpharmacologic therapies for mild cases, such as the use of a humidifier to add moisture to the air and mitigate irritation and dryness of the respiratory tract. Caution is recommended when feeding the infants. [2] Monitor for symptoms, like coughing or wheezing, while they are sleeping. Different sleeping positions can better or worsen the breathing, so it is important to assess what works best for the baby. [4] In addition, antibiotics may be required to prevent infections. At other times, anticholinergic nebulizations, such as ipratropium bromide, are prescribed to reduce secretion production. [2]

Severe cases of tracheomalacia may require surgery. Operations including tracheal resections, pexy procedure, and stent implantations are considered for this abnormality. These stents are a temporary fix while the tracheal cartilage tries to reform. The purpose of pexy procedures is to relieve the pressure through static suspension

sutures so the area of the airway can be increased. These surgical procedures are time consuming and come with the risk of infections and the possibility of suture breakdown. The rigidness of the sutures can also inhibit the normal neck movements of the baby. [3]

Some recent studies have been experimenting with hydrogels, biocompatible systems that are similar to tissues and provide an environment suitable for cell growth. These would be ideal in replacing extraluminal stents and would reduce tissue damage. [3] An article published in iScience discusses the formation of these hydrogels. They are soft and flexible, mimicking the natural movement of the trachea which would contribute to pain reduction compared to other methods. This study used hydroxyethyl acrylamide and polyethylene glycol methacrylate for the main polymer network to supply adhesiveness and inhibit tracheal collapse. Figure 2 shows a normal trachea, a malacic trachea, and a malacic trachea with a hydrogel. [2] The study tried a few different models and concluded that utilizing an adhesive hydrogel patch in tracheomalacia is beneficial by preventing airway collapse and is a “promising solution”. [3]

Overall, tracheomalacia is an uncommon abnormality that newborns usually outgrow. The tracheal cartilage of the infant is weak and closes in during exhalation. Along with nonpharmacologic treatments, a newborn’s tracheomalacia goes away on its own once the tracheal cartilage and muscle has time to fully develop. Although surgery is very rare, there are severe cases that require invasive surgeries and stents. However, recent studies have been looking at adhesive hydrogels as a potential, less invasive solution.

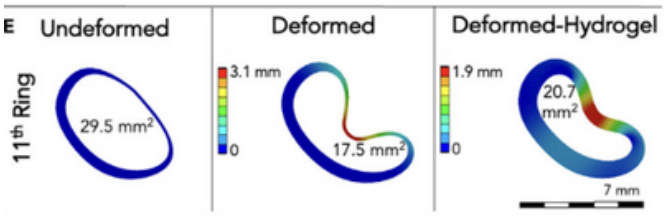


Figure 2. Cross sections of Trachea at the 11th Ring

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