VIRGINIA • PEDIATRICS

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Virginia Chapter

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

Sandy Chung, MD, President Virginia Chapter, American Academy of Pediatrics welcoming Governor Ralph Northam to the VMAP Stakeholders meeting.

Governor Ralph Northam presenting the importance of Pediatric Mental Health and the impact on the Commonwealth.

Senator Creigh Deeds and Bela Sood, MD discussing the importance of the Virginia Mental Health Program.

Virginia Mental Health Access Program

On December 13, 2019, the Chapter along with the Virginia Department of Behavioral and Developmental Services and the Virginia Department of Health sponsored a stakeholder meeting for the Virginia Mental Health Access Program (VMAP). This program is a statewide initiative to provide education on pediatric mental health disorder screenings, diagnoses and treatment, a child psychiatry consult line, telepsychiatry and family care navigation services. In 2019 and 2020, educational programs (REACH and Project ECHO) are being held around the state and the child psychiatry consult line is now active. At our meeting, we were honored to have Governor Northam and Secretary of Health Daniel Carey speak about the importance of improving child mental health and access to mental health services in our state. Senator Creigh Deeds, a longtime advocate of improving mental health services in our state, also came to provide support for VMAP. Chapter President Sandy Chung serves as Medical Director and coordinates the efforts of over 55 volunteers including pediatricians, child psychiatrists, nurse practitioners, advocates, parents and families. We appreciate the support of our academic institutions, state agencies, and multiple stakeholder partners who are helping to make VMAP a successful program in our state! This program has been successful in over 27 other states and the Chapter is very pleased to lead the development of a mental health access program to improve care for Virginia's children and adolescents.

For more information,
please visit the Chapter website
virginiapediatrics.org,
or the VMAP website at vmapforkids.org.

Inside this issue ...

Inova Schar's team of 10 renowned radiation oncologists are board-certified to use the latest techniques to ensure the most effective, safe and compassionate care for patients (more: p.16)

President's • MESSAGE

Advocacy season is upon us!


Sandy Chung

The Virginia Chapter of the AAP is working hard this season to advocate for issues important to child health, including increased access to mental health care, preventative care including essential health benefits (like the recommendations in Bright Futures) and immunizations, protecting the healthcare of immigrant children, gun safety and gun violence prevention, and environmental health as it related to child health. We have been active in early child health and education, early hearing detection, improving nutrition, as well as focusing on diversity and inclusion initiatives.

To highlight a few of our activities:

Mental Health – the Virginia Mental Health Access Program (VMAP) is designed to help primary care providers (PCPs) better manage mental health conditions in our offices by providing PCP education, a child psychiatry consult line, telepsychiatry and care navigation for our families. We need to advocate for full funding for VMAP so that we can offer the full program statewide. We are excited that we have recruited faculty across the state (PCPs and child psychiatrists) who will be engaged in teaching PCPs how to screen, diagnose and manage conditions such as depression, anxiety and ADHD in children and adolescents. Our first cohort of faculty attended a REACH train the trainer program November 2019, and should be ready to teach their first sessions spring 2020. To see when the next educational sessions will be, please see our Chapter's website, www.virginiapediatrics.org -> Initiatives -> Virginia Mental Health Access Program. (www.virginiapediatrics.org/vmap/#mental health)

Gun Safety – our Legislative Committee's workgroup on Gun Violence Prevention has been very busy these past several months. We have presented at various town halls and conferences, worked to pass resolutions supporting these efforts at the Medical Society of Virginia, written op-eds for our newspapers. We gave oral and written testimony to the State Crimes Commission who was responsible for addressing the various bills proposed in the July special session. We will be providing ongoing testimony for any gun safety legislation to improve child safety and child health.

Immunizations – the Chapter has been active with the revitalization of our state Immunization Coalition where we will be assisting with issues that arise with vaccines, including our VIIS, legislation and regulations regarding access to immunizations. Stay tuned for additional opportunities to help with this important new initiative for the Chapter.

Immigrant Health – we have been active with efforts to improve transitions of care for children being discharged from ORR (Office of Refugee and Resettlement) sites. These are facilities where children who have arrived unaccompanied or who have been separated from their families are housed until they are reunited with families or adults responsible for their care. These children often do not have access to health care and the Chapter has been working with ORR to improve that in Virginia.

Environmental Health – our Chapter has provided testimony to the EPA, met with U.S. congressional members, and worked with our state government to bring the pediatric perspective to the effects of global warming and climate change, as well as working to decrease pollutants and exposure to toxic substances. As members of the new Virginia Department of Health Climate Change Committee, we work with state leadership, researchers, and public health specialists to ass the evident of climate change and the need for public health intervention.

So, as you can see, the Chapter has been very busy with the help of great pediatricians and pediatric providers. It takes a village, so please help us! Only by working together will our voices be heard and impactful. Please contact Jane Chappell, jchappell@ramdocs.org for more information on how to get involved.

Dates to Remember

Clinical Challenges in Pediatric Primary Care 2016
March 21, 2010
Lewis Ginter Botanical Garden
1800 Lakeside Avenue
Richmond

Contact: Karon Wilson
karol.wilson@vcuhealth.org

McLemore Birdsong Conference
March 27 – 29, 2020
Omni Homestead

For more information and registration go to www.cmevillage.com

2020 Peds at the Beach Conference
July 17 – 19, 2020
Hilton Oceanfront
Virginia Beach

Questions? Contact VCU Health Continuing Medical Education
cmeinfo@vcuhealth.org
804.828.3640

A Delegation to Remember, But It Was Just the Beginning

Rodney"Scott" Keel, MD

A call to action for all medical students and residents!

Exciting times are ahead thanks to this new and unfamiliar political climate in Virginia. The excitement is building around the meaningful resolutions put forth by our Virginia chapter, AAP members such as Barbara Broadman, MD and others including several amazing students and residents from around the great Commonwealth. These resolutions were put forth during the 200th annual delegation of the Medical Society of Virginia. This event is an amazing opportunity for medical students and residents to learn more about our advocacy efforts while cultivating passionate ideas of their own. Students and residents are assisted along the process with excellent tutelage from mentors graciously willing to assist. Through this wonderful opportunity, one can learn how to develop and write a Resolution. Then present to the delegation via an American Parliamentary procedure format. Going forward, the next two years will be favorable to residents and students who wish to propose legislation that can have a favorable and lasting impact on the lives of all children in our state.

The 200th annual delegation was one to remember but it was only the beginning! Through the power of the Medical Society of Virginia and the Virginia Chapter, AAP we can come together to promote our Mission to attain optimal physical, mental, and social health and wellbeing of all citizens. The hard work and sweat put in by so many have led to advocacy in action. These resolutions are moving forward and can make a direct impact on a child's ability to reach their full potential. From metal health access for all, to smart gun violence prevention, the call to action is now.

Now is the perfect opportunity for medical students and residents to get more involved in advocacy efforts in their communities. The next big step will be to rally up our peers and colleagues for a big push on Capitol Hill, January 22nd for our annual White Coat day. Mark your calendars now. We hope to see you all there. Let us help get these resolutions to the Governor's desk.

"Advocacy is in the DNA of Pediatric Care" -Abraham Jacobi

What's in your DNA?

Drs. Scott Keel, Barbara Boardman and Aimee Seibert, VA-AAP Lobbyist at MSV Annual meeting.

Scott Keel, MD sharing an experience about the importance of gun safety.

Drs. Arshia Qaadir and Marsha Griffin during meeting with INOVA and DC-AAP.

Dr. Barbara Boardman supporting Virginia Chapter, AAP resolutions.

VA-AAP Chapter members discussing legislative issues.

Accreditation

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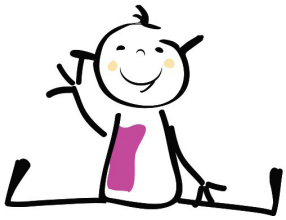

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How to Obtain Credit:

Review the articles on pages 5-12. Complete the attached VA-AAP Newsletter Registration and Evaluation Form and return to the the Children's of The King's Daughters. CME Office 601 Children's Lane | Norfolk, VA 23507, or 757-668-7122.
You may also visit: https://www.surveymonkey.com/s/VAAAPWinter2020 and complete online. Please allow 1-2 weeks to receive certificate.

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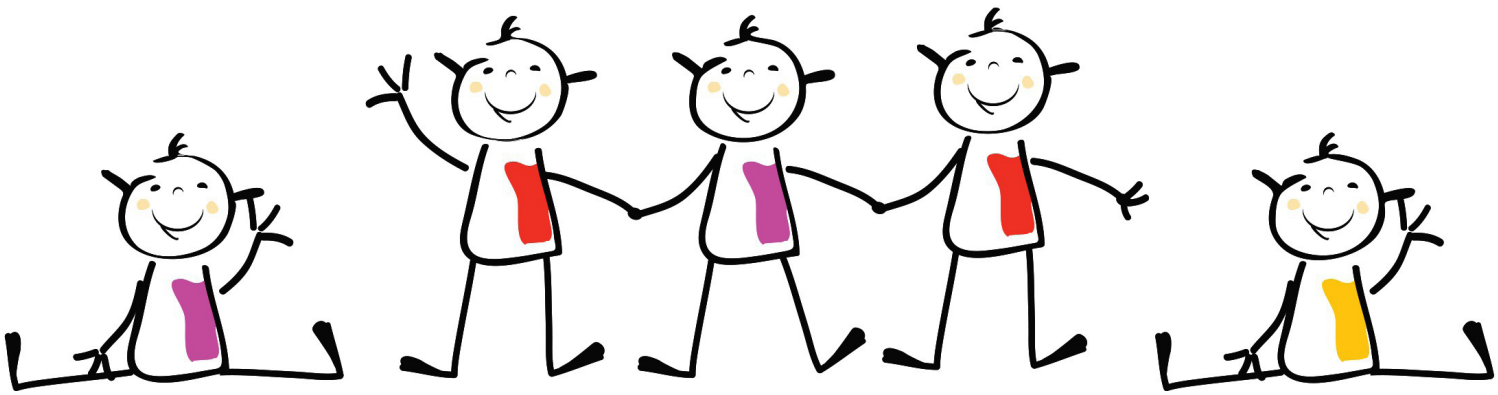

Treating Anxiety in Young Children: Key Points for the Pediatrician to Know

Paige Trojanowski, MA
Graduate Teaching Assistant
George Mason University

Robyn Mehlenbeck, PhD, ABPP
Clinical Full Professor
Department of Psychology
George Mason University

Objective: *Improve clinician knowledge about Cognitive Behavioral Therapy for anxiety, and how to talk with parents about CBT treatment.*
ACGME Competencies: *Patient Care, Practice-based Learning and Improvement.*

Anxiety disorders are the most common mental health conditions diagnosed in children and adolescents. Estimates of lifetime prevalence of anxiety disorders in adolescents range from around 15 to 30% and are significantly more common in females than males (Beesdo et al., 2009; Merkingas et al., 2010). Thankfully, Cognitive-Behavioral Therapy for anxiety disorders (e.g., specific phobias, social anxiety, separation anxiety, and generalized anxiety disorders) consistently shows robust treatment effects for the treatment of anxiety (Hofmann et al., 2012).

If you have a patient who has clinically significant anxiety (i.e., they are experiencing significant distress or impairment due to their anxiety), the best step is to recommend that they seek out Cognitive-Behavioral Therapy (CBT). However, not all therapists are trained in CBT, and even when they say they are, families need to know what CBT truly looks like so that they can feel empowered to find effective, evidence-based services for their child.

So, what can you tell parents?

- CBT helps the parent and child identify and change thoughts, feelings and behaviors, with a high focus on the thoughts and behaviors.
- CBT should begin with a thorough assessment of their presenting problem from parent(s) and child and with establishing goals for therapy.
- CBT is skill-based and time-limited, and parents will be involved in therapy to help their children apply the skills they learn with their therapist in their daily life—effective therapy for children and adolescents always involves their parents.
- CBT for anxiety should involve 3 major components: relaxation training, cognitive restructuring (i.e., changing your self-talk and challenging negative cognitions about situations that make you anxious), and exposures (e.g., building a fear ladder and exposing themselves to the situations that make them anxious in a graded fashion).

Finding a CBT therapist can take time, so what can you do in the meantime?

- Identify and label anxiety as real for parents and normalize that many children deal with significant anxiety
- Encourage parents to validate their child's emotion and help them to label their anxiety/nervousness/fear
- Encourage parents to never punish or dismiss the fears (e.g., "You're fine—just get over it")
- Parents should remain calm themselves when their children are becoming anxious or nervous—parental modeling of emotion regulation is critical.
- Parents should also avoid reinforcing the anxiety (i.e., allowing child to get out of doing what is making them anxious, such as going to school) because repeated avoidance just helps the anxiety build and worsen over time. It is important to remain encouraging and help the child learn that the anxiety will not last forever and that they can live through the anxiety. This last point, though, is much easier said than done and often the most difficult point for parents. This is often a key focus of CBT.

Additionally, most children and adolescents respond to CBT, and therefore do not need medication for the anxiety. If medication is prescribed, we strongly recommend concurrent CBT treatment. CBT for anxiety and phobias has a large base of empirical support, and parents should be highly encouraged to seek help for their children. Pediatricians serve a critical role in normalizing therapy and can dispel any beliefs that it will last forever or that it is only for extreme cases. If a child is experiencing distress or impairment, therapy can help to prevent a larger problem down the line by giving children a set of tools to cope with their "Anxiety Monster" whenever it rears its ugly head!

<u>A couple great references:</u>

- *Book for Pediatricians: MATCH ADTC: Modular Approach to Therapy for Children with Anxiety, Depression, Trauma or Conduct Problems by Bruce Chorpita and John Weisz*
- *Book for Families: What to Do When You Worry Too Much: A Kid's Guide to Overcoming Anxiety by Dawn Huebner*

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The Opioid Epidemic: Taking Action Locally

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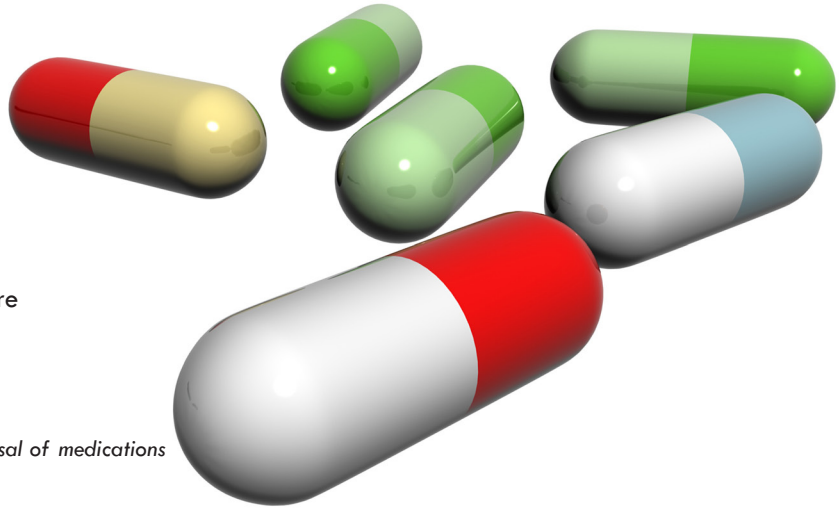

Objective: *Educate and promote awareness for proper disposal of medications*
ACGME Competencies: *Systems-based Practice*

The growing opioid epidemic plaguing our country continues to claim lives regardless of age, race, or gender. The CDC states that nearly two million Americans were dependent on or abused prescription opioids in 2014. As of October 31, 2019, US poison control centers have managed over 48,000 opioid substance exposure cases. As an epidemic centered-around prescription medications, healthcare practitioners are uniquely positioned to provide guidance and solutions to this issue.

In an effort to reduce both unwanted side effects and exposure of opiates, practitioners should consider multimodal pain management. Incorporating medications with varying mechanisms of action into the treatment regimen provides an opportunity for treatment synergism as well as the potential to reduce the amount of opiates necessary for pain control. In addition, educating patients on proper storage of medications (out of reach from children and controlled substances should be securely locked) is crucial to reducing unintended exposures.

Educating patients on proper disposal of medications is an additional talking point providers can provide. Additionally, providers should raise awareness about drug take back programs within the local communities. The Federal Drug Enforcement Agency revealed that over 882,000 pounds of unused, expired, and potentially lethal medications were turned in during the last National Prescription Drug Take Back Day[ii]. These programs are established to aid in the safe removal of unused and potentially lethal medications from family households.

There are two main ways that medications may be properly disposed of[iii]:

1. Drug Take Back Programs

National Prescription Drug Take Back Day, sponsored by the US Drug Enforcement Administration (DEA), usually occurs in late October and is offered in communities nationwide. The next National Prescription Drug Take Back Day will be April 25, 2020. National Take Back Day is a safe, convenient, and responsible way to dispose of unused or expired prescription drugs. More information can be found on the FDA website.

Inova Fairfax Medical Campus offers two take back boxes located in their retail pharmacies all year round.

2. **Disposal at home**

- Patients should remove medications from the original container and mix with something undesirable including cat litter, coffee grounds, or dirt in a sealed container and place into their garbage can.
- The local health department offers free drug disposal bags.
- It is important to note that unused medications should not be flushed down the toilet as this could lead to contamination of our water supply.

Opioid (narcotic) pain medications. American Association of Poison Control Centers. Accessed 12/2/2019: https://aapcc.org/track/opioids
ii Opioid use in children. J Pediatr Pharmacol Ther. Acces
ii 18th national drug take back day. Drug Enforcement Administration Diversion Control Division. Accessed 11/24/2019: https://takebackday.gov/sites/default/files/NTBI%2018%20Totals.pdf
iii Why and how to dispose medications. Virginia Department of Behavioral Health & Developmental Services. Accessed 12/2/2019: http://www.dbhds.virginia.gov/assets/doc/OIH/drug-disposal-alert-detailed.pdf

Macrolides: Managing Myths

Andrew Nuibe, MD, MSCI
Pediatric Specialists of Virginia
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Objective: *Increase knowledge of macrolides toxicities and non- antimicrobial properties.*
ACGME Competencies: *Patient Care, Practice-based Learning and Improvement, Medical Knowledge.*

In the vast landscape of antimicrobial options, macrolides stand out as unique snowflakes. Indeed, macrolides are sometimes ascribed near mythic qualities for healing beyond their known antimicrobial properties while at the same time carrying the potential for serious patient harm. Thus, we need to re-examine these popular protein synthesis inhibitors and disentangle fact from fiction to ensure the best use of macrolides.

Despite molecular similarities, erythromycin, clarithromycin, and azithromycin are very different. In fact, their differences make them more akin to second cousins than siblings. In terms of toxicities, erythromycin leads the trio. Of the three, erythromycin is the most likely to cause gastrointestinal symptoms, in as many as 30% who take it; in contrast, gastrointestinal symptoms are seen in about 12% of patients who take clarithromycin or azithromycin.[1]

Classically, these gastrointestinal symptoms are attributed to the motilin stimulatory properties of the macrolides, and it is thought that in some cases this leads to the curious phenomenon of macrolide-associated infantile hypertrophic pyloric stenosis (IHPS). Indeed, a modern cohort study showed that systemic erythromycin does increase the risk for IHPS, especially when given to infants within the first two weeks of life.[2] Similarly, systemic azithromycin also increases the risk for IHPS, yet clarithromycin does not.[2,3] Beyond the first two weeks of life, systemic erythromycin and azithromycin still increase the risk for IHPS, albeit to a reduced degree.[2,3] That said, it should be recalled that IHPS is a relatively rare outcome with an estimated incidence of 2 out of 1000 live births in the U.S.[4] Therefore, the decision to use either systemic erythromycin or azithromycin in infants should be balanced against the risk of precipitating this relatively rare disease state.

Another unexpected macrolide adverse effect is QT prolongation, a proarrhythmic outcome which can lead to sudden cardiac death. Most of the evidence of macrolide associated QT prolongation stemmed from case reports involving erythromycin and clarithromycin with the thought that these agents affected the delicate timing of ventricular depolarization and repolarization.[5,6] In a 2012 cohort study, azithromycin was also found to increase the risk for sudden cardiac death by nearly three-fold compared to peers who did not receive any antibiotics.[7] The authors ascribed these mortalities to azithromycin's proarrhythmic properties, and this study's findings were so compelling that the Food and Drug Administration subsequently issued a black box warning on azithromycin's risk for QT prolongation. Yet, closer scrutiny of this study makes extrapolation to pediatric patients difficult: the mean age of the azithromycin cohort was ~50 years old. Furthermore, a majority of the study population was female and other concurrent medications, which could have also prolonged the QT interval, were not obviously clear.

A subsequent study sought to better elucidate the risk of azithromycin associated QT prolongation specifically in pediatric patients. The authors compared the frequency of cardiopulmonary resuscitation and all-cause mortality in children hospitalized with pneumonia who received either azithromycin or a beta-lactam, i.e. a penicillin-derivative or a cephalosporin. Using regression analysis the authors did not observe a difference between the antimicrobial cohorts and concluded that in otherwise healthy children without underlying long QT syndrome azithromycin did not increase the risk for cardiac events.[8]

In terms of other properties beyond antimicrobial activity, macrolides are often hailed for their anti-inflammatory effect. This originates from observations in the management of a chronic idiopathic pulmonary inflammatory condition known as diffuse panbronchiolitis. Despite a phenotype similar to cystic fibrosis, physicians struggled to effectively treat diffuse panbronchiolitis with steroids, bronchodilators, or even antimicrobials. That is until the 1980s when researchers discovered that long term erythromycin improved the lifespan of those with diffuse panbronchiolitis.[9] Subsequent investigation revealed that it was not erythromycin's antimicrobial activity which improved the lifespans, rather erythromycin blunted the body's response to cytokines as well as impaired the buildup of neutrophils within the airways; it was thought that these anti-inflammatory effects led to decreased airway inflammation and improved survivorship with diffuse panbronchiolitis.

This remarkable observation led to widespread application of clarithromycin and azithromycin as novel anti-inflammatory medications in other chronic inflammatory conditions with mixed results outside of diffuse panbronchiolitis. Regarding the question of whether macrolides reduce airway inflammation in pediatric asthma, there is an absence of robust data. One meta-analysis showed that macrolides did result in less oral steroid use with improvement in the FEV1 in children. However, this analysis only included 69 children and the benefit was only seen with troleandomycin, a macrolide agent not widely available.[10] While another recent study did see faster resolution of asthma-like symptoms in children treated with azithromycin versus placebo, the study population did not extend beyond 3 years of age and did not review the impact on long term asthma control.[11] Therefore, questions remain regarding the true benefit that macrolides have on reducing pediatric asthma-associated airway inflammation.

Despite the above outcomes, macrolide prescribing remains high. A recent U.S. survey using contemporary outpatient prescribing data calculated that pediatric macrolide prescribing is so high that an

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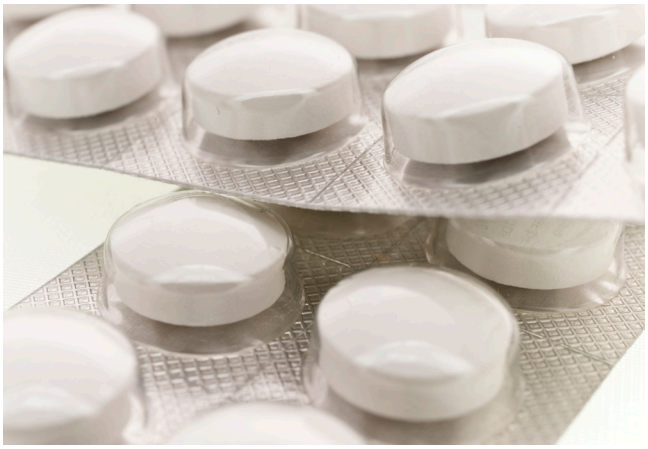

average of one out of every two children receive a macrolide annually.[12] This is a frightening statistic with the inevitable outcome of selecting for resistant pathogens. U.S. surveillance data undeniably confirms this: as sales of azithromycin skyrocketed following its introduction in the 1990s, the number of Streptococcus pneumoniae resistant to macrolides also dramatically increased.[13] While macrolides can do a lot, they are not a harmless panacea, and I challenge providers to carefully consider their antimicrobial prescribing.

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[10] *Mikailov A et al. J Asthma and Aller 2013*
[11] *Stockholm J et al. Lancet Resp Med 2016*
[12] *King LM et al. Clin Infect Dis 2019*
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Cell Phones, Lap Tops, Tablets and Autism

Lowry Shropshire, MD, FAAP
Developmental Pediatrician
Pediatric Associates of Alexandria

Objective: *Provide advice for parents*
ACGME Competencies: *Patient Care.*

Most every day in the developmental office, I see two or three children with autism. The majority come in with a screen of some sort in their hand, are visually locked on that screen, refuse to surrender it, become emotionally distraught and sullen without it, and become calm and composed once it is back in their hands. Patients with other developmental diagnoses come in looking at screens, but there is a qualitative difference in those with autism.

We encourage and prescribe a language-rich home environment for children with autism, but most of the content on screens brought into my office is visually based with little language and no capability for reciprocal communication between the device and the child. Nor is the child's parent usually involved in talking with the child about the content on the screen. Some digital programs are available that provide the opportunity for verbal reciprocity between the child and a device, but I rarely see a child using such a program while in the office. The screen occupies and placates, and one can understand parents' need for something to provide quiet and composure in the often emotionally hectic daily lives of families living with autism. Much recent research has been conducted on typically developing children to study the impact of screen time on physical health, brain connectivity, educational achievement, cognition, and social connectedness, but relatively little research has looked specifically at the impact on children with autism. Slobodin et al in the March 2019 issue of the Journal of Developmental and Behavioral Pediatrics conducted a meta-analysis on the subject of screen time and autism with the findings that 1) children with autism are exposed to much more screen time than typically developing children and 2) that exposure starts at a much younger age. The authors speculate (as do many of us) about the short and long-term consequences of such early screen exposure on the neurologic and physical health of the child with autism. A link between excessive screen time and obesity, diabetes, and sleep disorders (conditions all too common in children with autism) seems plausible and provides impetus for further study. Might excessive screen use impede the development of a child with autism? Some reason for concern.

Lane and Radesky in the same journal in April 2019 also note the paucity of research into use of screens by children with autism. They recommend research into: how the personalities of children with autism make them vulnerable to aspects of media use; how such media use might prove beneficial in promoting prosocial abilities; which aspects of media use interfere with sleep, exercise, homework, or play; and how screen time might be used to positive effect in reducing sensory overload.

Lacking good evidence, we are left to our experience and opinion. My experience and opinion support the recommendation that children with autism should have minimal screen time and maximal playtime with peers and attentive adult caregivers. However, more research is needed.

Delabel Penicillin Allergic Patients When Appropriate

Darlene Mansoor, MD
Medical Director of Allergy and Immunology
Pediatric Specialists of Virginia

Objective: *Update on DRUS challenges for MULD reactions.*
ACGME Competencies: *Patient Care.*

Many children are labelled with a penicillin allergy from an early age, due to the appearance of a rash while taking the antibiotic. However, the rash could be due to the illness and/or combination of factors and not the antibiotic.

Around 10% of the population is labeled as being allergic to penicillin. Even if a patient had a true IgE mediated reaction to penicillin, 90% of patients outgrow the allergy within a 10-year period. Penicillins have important roles in treating bacterial infections. Being labelled allergic to penicillin increases medical costs and contributes negatively to the patient's overall treatment of further infections. Alternative antibiotics, which are often less effective, are used and this places the patient at risk for further complications. There is a great need to delabel these patients and to find out if they are truly allergic.

Obtaining a through history of the reaction is a critical step. Recent studies have showed that if a child developed a mild rash several hours after a dose and had no other systemic symptoms, they can proceed to an office drug challenge without skin testing. Most drug challenges are done by administering a 10% test dose of amoxicillin followed by a 30-minute observation period. If patient is doing well a 90% dose is given next and the patient is observed for another 30-60 minutes. The challenge rules out an Ig-E mediated drug allergy.

Drug challenges are not done for patients with histories that suggest an immediate reaction to the antibiotic (hives, angioedema, respiratory symptoms within one hour of dose). Drug challenges are also not done when the history suggested severe cutaneous reactions; serum sickness reaction, Stevens-Johnson, DRESS (drug reaction with eosinophilia and with systemic Symptoms) and AGEP (acute generalized exanthematous pustulosis).

Drug challenges are a safe and necessary practice in pediatrics and can be done in the office setting as long as the provider is capable of treating an acute allergic reaction.

Modulator Therapy for Cystic Fibrosis

Sunil Kapoor, MD
Medical Director Pediatric Lung and Allergy Center
Section Chief, Division of Pediatric Pulmonology
Inova Fairfax Hospital for Children

Objective: *Provide an overview of the current modulator therapies available for clinical use.*
ACGME Competencies: *Patient Care, Medical Knowledge.*

Cystic Fibrosis (CF) is a lethal, inherited, progressive multisystem disease stemming from abnormal transport of Cl- and HCO3-. This abnormal transport is secondary to mutations in the gene coding for cystic fibrosis transmembrane regulator (CFTR). CF affects approximately 80,000 individuals with a current average life expectancy of approximately 40 years.

Historically, therapies for cystic fibrosis have focused on the downstream consequences of the cellular defect. Over the last several years however, therapies directed at modulating the basic cellular defect have been introduced. The goal of this update is to provide an overview of the current modulator therapies available for clinical use.

Mutations in CFTR can lead to different mechanisms of abnormal CFTR function. This can involve little to no CFTR production, abnormal CFTR transport or processing or decreased functioning of CFTR. The most common mutation in CF (Phe508del) leads to a processing defect. Current modulator therapies can be grouped into two categories: Potentiators and Correctors. Potentiators work to increase the function of existing CFTR, while correctors fix folding errors in the protein allowing for increased amounts of functional CFTR.

Ivacaftor, the first modulator therapy for CF, is a potentiator with specific efficacy for gating mutations and was approved in 2012. Initial studies demonstrated an approximate 10% improvement in FEV_1, but only 4-5% of individuals with CF have a mutation, which can benefit from this therapy. A recent observational 5-year study demonstrated improved nutritional measures, incidence of cystic fibrosis diabetes, rate of pulmonary exacerbations and hospitalization rate suggesting a disease-modifying role of this therapy.[1] This is a crucial potential long-term benefit as Ivacaftor is now approved in children as young as 6 months of age with appropriate CFTR mutations.

Two therapies have been approved for individuals homozygous for Phe508del. This population represents slightly less than half of affected individuals with CF. Both agents are a combination of a potentiator (Ivacaftor) with a corrector (Lumacaftor or Tezacaftor). While both therapies were initially approved for ages 12 and older,

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currently Orkambi (Lumacaftor/Ivacaftor) is approved for age[2] and above while Symdeko (Tezacaftor/Ivacaftor) is approved for age 6 and above. Both therapies have demonstrated relatively modest effects on FEV_1 (3-4% improvement), but there has been demonstrated improved symptom scores and quality of life measures.

In October 2019 triple combination therapy (Trikafta) was approved for use in individuals ≥ 12 heterozygous for Phe508del. This increases genetic eligibility for modulator therapy to 90% of all individuals with CF. Trikafta is a combination of 2 correctors (tezacaftor, elexacaftor) with Ivacaftor. Preliminary studies demonstrated a robust pulmonary function response (14% improvement in FEV1), with associated improvements in nutritional status and sweat chloride levels.[2] Given the degree of pulmonary function change and the large percentage of patients who stand to benefit, this therapy is a potential game-changer in CF care. All the approved modulator therapies have potential liver and ocular side effects and come at an extreme cost ($311,000 annual cost for Trikafta). This raises a significant question: Should they be initiated to maintain normal lung function and prevent pulmonary function decline, or should they be utilized only when a certain threshold of clinical severity is met? There are currently limited formal guidelines to assist in answering this question, but clearly, the face of CF therapy is evolving at a rapid pace.

References:
[1] N. Volkova, K. Moy, J. Evans, et al., Disease progression in patients with cystic fibrosis treated with ivacaftor: Data from national US a…, Journal of Cystic Fibrosis, https://doi.org/10.1016/j.jcf.2019,05.015
[2] P.G. Middleton, M.A. Mall, P. Drevinek, et al., Elexacaftor-Tezacaftor-Ivacaftor for Cystic Fibrosis with a Single Phe508del Allele. N. Engl J Med 2019; 381; 1809-19

Correction of Congenital Ear Anomalies Using Infant Ear Molding

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Objective: *Bullet overview of craniosynostosis.*
ACGME Competencies: *Patient Care, Medical Knowledge.*

Congenital ear anomalies occur in 33% of the population, and less than one third of these anomalies self-correct without treatment (Chan S et al. Plast Reconstruct Surg. 2019 144:4 pp648e-658e). If a deformed ear does self- correct, it usually occurs within the first week of life. Therefore, it is recommended that infants beyond a week of age be referred for molding therapy within the first three weeks of life. If left uncorrected, ear anomalies may lead to teasing and social difficulties in school.

Traditionally, ear molding has been difficult to employ well unless one was facile in dental materials and could see the patient within the first few weeks of life. Patients who were not treated early had to wait until they were surgical candidates (7-8 years of age), and this delay frequently resulted in patient and/or parental anxiety. Additionally, surgery can be challenging, and the best surgical results may fall short of patient expectations. Advances in ear molding now make it possible to treat patients nonsurgically and painlessly. Improvements in the design of prefabricated systems allow plastic surgeons to improve or correct many infant ear anomalies, including protruding ears, helical rim anomalies, Stahl's ear, lop ear and even cryptotia. This early nonsurgical intervention frequently eliminates the need for surgical correction, which may not be covered by insurance. Several commercial ear-molding systems are available facilitating application of ear molding and increasing the number of providers facile in this technique. Ideally, infants should be referred for molding within the first 2-3 weeks of life to achieve the best results, but good results can be obtained starting as late as eight weeks after birth.

Ear molding can permanently reshape the ear during the narrow window when circulating maternal estrogen remains at a high level in the child (Matsuo K, Hirose T. Ann Acad Med Singapore. 1988;17:358-365; Matsuo K, et al. Plast Reconstr Surg. 1989;83:25-31; Matsuo K, Hirose T. Br J Plast Surg. 1991;44:5-11). It is believed that the high level of estrogen at birth correlates with increased hyaluronic acid, which inhibits the linking of the cartilage intercellular matrix. If the cartilage is molded while maternal estrogen circulates within the newborn, it tends to retain its new shape as the maternal estrogen is metabolized.

In most cases, nonsurgical molding treatment eliminates the need for surgery. Even if a child needs surgery when he or she is older, the surgery likely will be less complicated than if molding had not been initiated. Additionally, the ear will look better until surgical correction is an option at 7-8 years of age, reducing psychosocial problems. It is important that parents have realistic expectations to avoid post-

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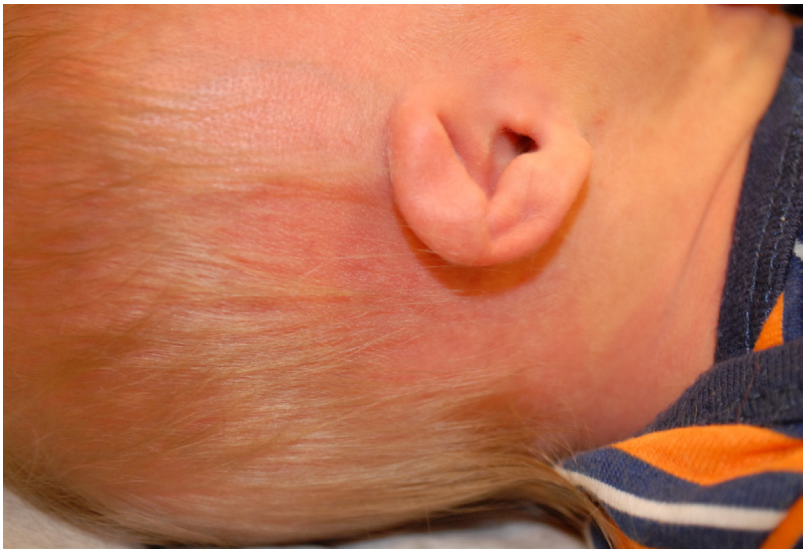
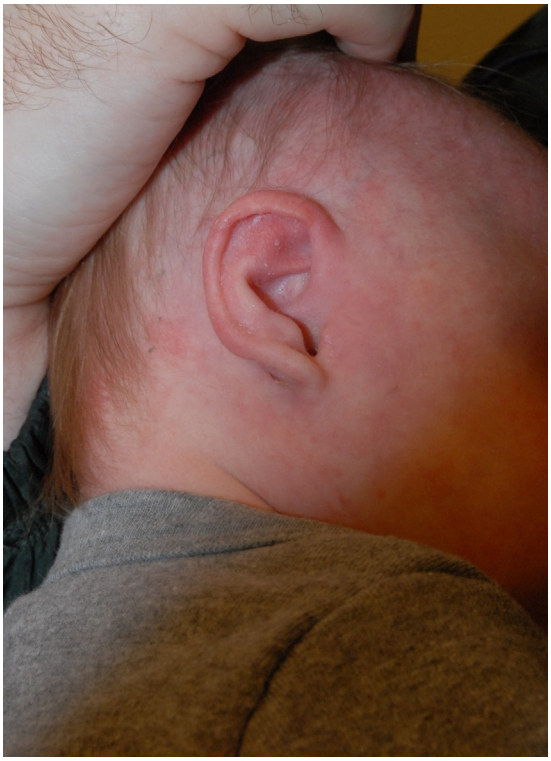
treatment disappointment. They are informed that molding will not result in a perfect ear but likely will improve the shape and form to approximate a more normal ear shape.

Risks and complications of ear molding include skin breakdown under a positioning retractor, skin irritation from the adhesive or failure to meet the parents' aesthetic goals. Skin sensitivity is rare, and any skin breakdown that may occur under a retractor heals well by repositioning the retractor to a healthy area of skin. Patients are seen one week after application to identify and treat any skin breakdown or irritation. After the initial week of molding, pressure points under retractors usually subside.

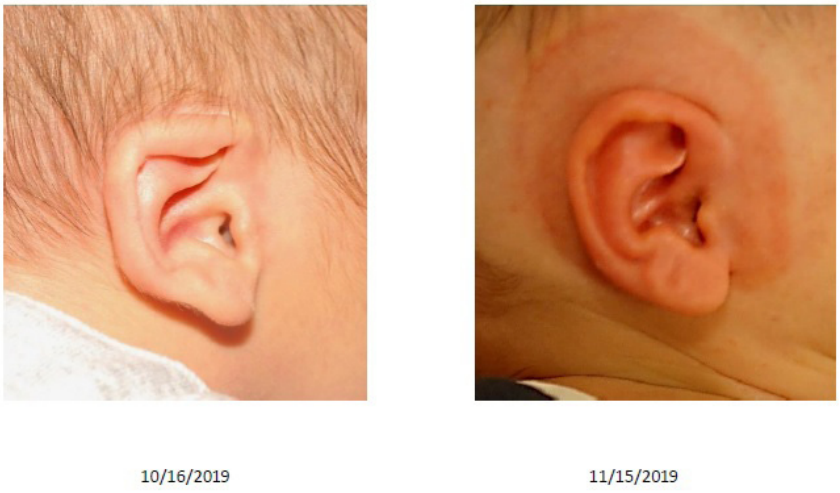
Nonsurgical molding has been demonstrated to correct or improve many ear anomalies that previously would have been corrected surgically with few associated complications. Most insurance plans cover the procedure, reducing out-of-pocket expenses for parents.



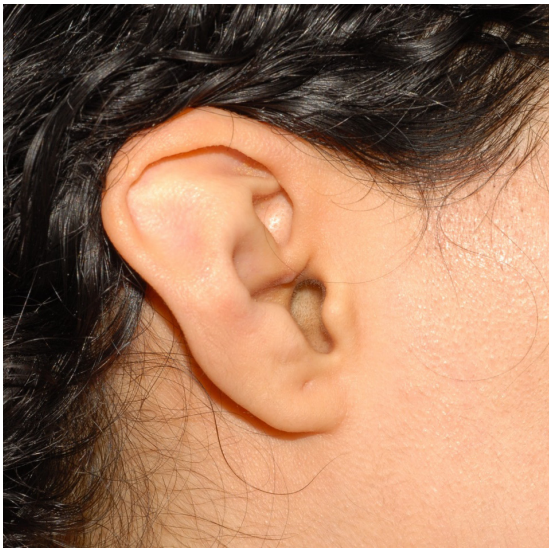
Before Correction of Congenital Ear Anomalies Using Infant Ear Molding



Before Correction of Congenital Ear Anomalies Using Infant Ear Molding



Plastic surgeons can improve many ear anomalies in infants by molding. Images at left show before ear molding; at right, after molding. Photos courtesy of Dr. Stephen Baker, MD, DDS, FACS, FAAP



This adult presurgical patient shows an ear deformity that could have been corrected with infant ear molding

Restoring a child's microbiome to improve future health – updates on research at Inova Children's Hospital

Suchitra Hourigan, MD
Director of Pediatric Research
Inova Children's Hospital

Objective: *Microbiome Research Update*
ACGME Competencies: *Practice-based Learning and Improvement, Medical Knowledge*

The intestinal microbiome is made up of trillions of bacteria and thousands of species that have a critical function for our health. During the first few years of a child's life, there is rapid, dynamic development of the intestinal microbiome that shapes the adult microbiome and therefore future health. Conversely, disruptions to the microbiome during this early critical development, such as from antibiotics, diet or Cesarean section delivery, can lead to an imbalance in the microbiome. This can contribute to the development of diseases including obesity, asthma and allergies.

Here at the Inova Children's Hospital, we are actively conducting research into strategies to restore a child's microbiome to improve future health with exciting findings. Current trials addressing this include the areas of:

1) **Fecal Microbiota Transplantation (FMT)**
At Inova Children's Hospital, we have an active pediatric FMT program for children with recurrent Clostridium difficile infection. The prevalence of Clostridium difficile infection is increasing in children and in the community. Antibiotics can treat the infection, but often there is a recurrence; it is here there is a role for FMT to restore the microbiome and reduce the risk of recurrence. Evidence was lacking in children, but we have shown in the largest study to date that there is over an 80% cure rate in children with recurrent Clostridium difficile infection receiving FMT [1]. Moreover, we showed that FMT in children can decrease the burden of antimicrobial resistance [2], a priority topic for the World Health Organization (WHO).

2) **Vaginal Seeding**

Swabbing of the first newborn involved in vaginal seeding trial at Inova Children's Hospital. Photo: Inova.

While Caesarean section (CS) delivery can be lifesaving for both mothers and their babies, children born by CS have an approximately 50 percent-increased risk of childhood obesity, along with asthma and allergies. There is a marked difference between the microbiomes of babies born vaginally and by CS. The increased risks of diseases associated with CS delivery may due to the lack of mother-to-newborn transfer of beneficial vaginal microbes at birth. At Inova Children's Hospital a novel trial "Vaginal Microbiome Seeding and Health Outcomes in Caesarean-Delivered Neonates: A Randomized Controlled Trial" seeks to assess whether the risks of diseases associated with CS delivery can be reduced during a process known as vaginal seeding, where a sample of the mother's vaginal microbiome is swabbed onto her baby's face and body shortly after delivery. There is critical need for such trials given that vaginal seeding is being increasing requested by Mothers but it is unknown whether it is efficacious or safe [3].This groundbreaking trial was featured on NPR Morning Edition [4].

For more information on microbiome research at Inova Children's Hospital, please contact microbiome@inova.org.

1. *Efficacy of Fecal Microbiota Transplantation for Clostridium difficile Infection in Children. Clin Gastroenterol Hepatol. 2019 Apr 19.*
2. *Fecal Transplant in Children With Clostridioides difficile Gives Sustained Reduction in Antimicrobial Resistance and Potential Pathogen Burden.Open Forum Infect Dis. 2019 Aug 26;6(10):ofz379.*
3. *'Vaginal seeding' after a caesarean section provides benefits to newborn children: FOR: Does exposing caesarean-delivered newborns to the vaginal microbiome affect their chronic disease risk? The critical need for trials of 'vaginal seeding' during caesarean section. BJOG. 2019 Nov 6.*
4. *https://www.npr.org/sections/health-shots/2018/10/30/658254175/doctors-test-bacterial-smear-after-cesarean-sections-to-bolster-babies-microbiom*

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Inova Mather Proton Therapy Center Set to Open Spring 2020

Since the first radiation therapy facility for cancer treatment was founded, radiation oncologists have had to strike a delicate balance: provide high enough radiation doses to kill cancerous cells but leave surrounding healthy tissue unharmed. And while there have been remarkable technical advances in radiation therapy, the implementation and utilization of proton therapy have given physicians a new hope for their patients.

Inova is excited to announce proton therapy will be available to its patients starting in spring 2020 at Inova Schar Cancer Institute in Fairfax, Virginia – the first and only cancer center in Northern Virginia to offer proton therapy.

The Inova Mather Proton Therapy Center led by Gopal K. Bajaj, MD, MBA, will treat patients – including children – with all types of cancers and benign conditions. "The addition of proton therapy at Inova Schar exemplifies our commitment to providing the most advanced therapies to the patients we serve," says Dr. Bajaj. "This forward-thinking approach to the future of cancer care is embodied throughout all aspects of Inova Schar."

Proton therapy is a type of external-beam radiation that uses protons, which are positively charged particles, to destroy cancer cells. Unlike traditional forms of radiation therapy, proton therapy offers unparalleled precision in targeting tumors and sparing adjacent healthy tissue due to the unique ability of protons to deposit most of their energy directly into tumor tissue. This ability to precisely target tumors makes proton therapy an excellent option for treating many types of childhood cancers.

Benefits of Proton Therapy for Pediatric Patients

- Proton therapy delivers up to 60 percent less radiation to surrounding healthy tissues when compared to traditional radiation, resulting in fewer secondary effects from radiation to developing tissues and reducing the risk to develop a secondary cancer later in life.

As the most advanced form of radiation, proton therapy offers painless precision targeting of cancer cells. Children are more likely to maintain normal activities during treatment with fewer side effects.

Patients have the advantage of being treated with a higher dose of radiation safely and accurately.

Proton therapy treatments are non-invasive and typically take 15-45 minutes per treatment.

Inova Schar's team of 10 renowned radiation oncologists are board-certified and use the latest techniques to ensure the most effective, safe and compassionate care for patients. They are one part of the cancer care team made up of medical oncology experts at Pediatric Specialists of Virginia, surgeons, nurses, genetic counselors and dietitians who work together to provide the best treatment plan for each patient.

Inova Schar also provides extraordinary holistic services from programs such as Life with Cancer® and Inova Child Life. Life with Cancer, a leading cancer education and emotional support program providing patients, survivors, and their family members help in coping with cancer and the Inova Child Life specialists dedicate themselves to easing the anxiety and stress affecting children during a hospital stay or outpatient procedure.

The Inova Mather Proton Therapy Center provides a terrific opportunity for patients in the region and the Commonwealth as part of their treatment programs. "This is cutting-edge technology," Dr. Bajaj explains. "There are a limited number of proton centers around the country. We will soon be able to care for children with the most advanced treatment options close to home, which is exactly where they should be."

The Inova Mather Proton Therapy Center includes two treatment rooms to minimize wait time and maximize efficiency (Proton1). With a 360°rotating gantry that moves around the patient, the proton beam is positioned to deliver treatment with the highest precision and accuracy (Proton 6).

To learn more about the Inova Mather Proton Therapy Center call 571-472-0606 to speak to one of our pediatric radiation oncology specialists or visit inova.org/proton.

Get in touch!

We welcome your opinions and ideas. Please contact **Virginia Pediatrics**:

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