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The official member magazine of the **American Academy of Otolaryngology–Head and Neck Surgery**

FEBRUARY 2019

CPG

CLINICAL PRACTICE GUIDELINE

Tonsillectomy in Children Update

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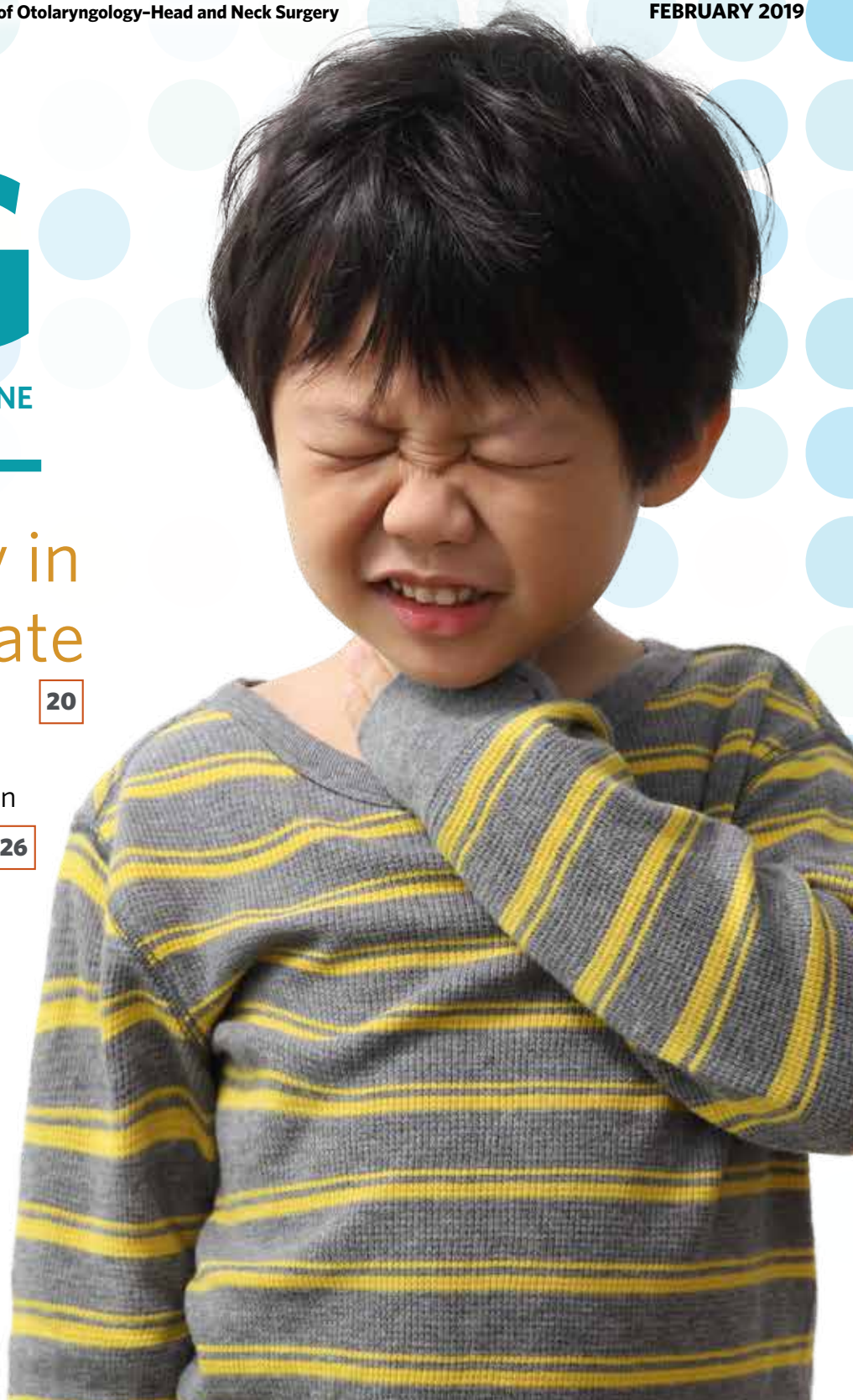
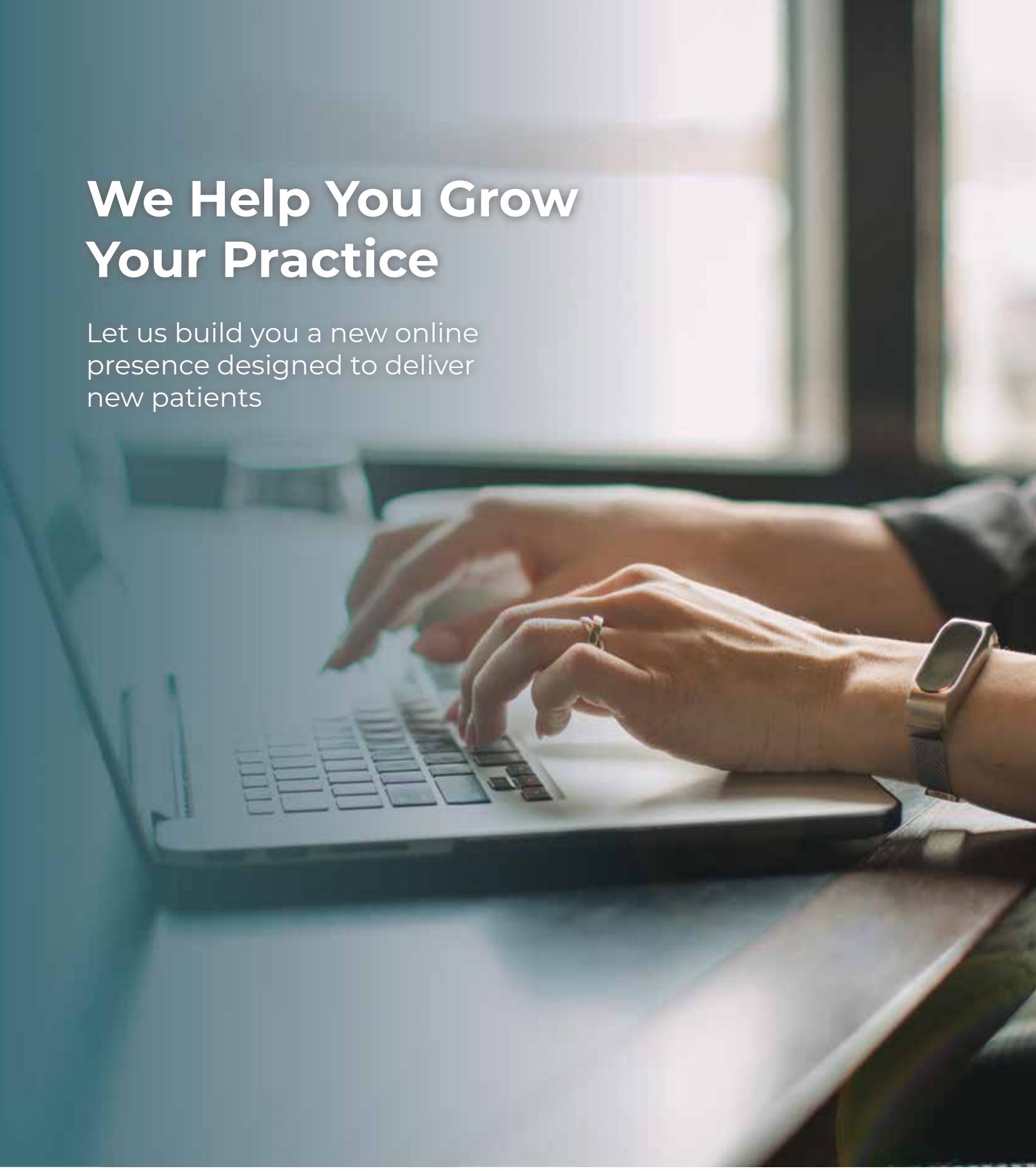
Committee report: The prescription opioid crisis and otolaryngology 26

Kids ENT Health Month: Addressing ankyloglossia 31





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bulletin

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Longer article available:
Humanitarian service in Rwanda

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The best and brightest

Winter brings otolaryngology residency (and fellowship) interview season. You know the drill: letters of recommendation, travel snafus, origin stories, polished (and not so polished) answers to standard questions, and on and on.

Regardless of your career path, practice type, subspecialty, demographics, or geographic region, we all have one thing in common: We all trained in otolaryngology residency. Of course, many of our AAO-HNS members had excellent training in other countries or journeys that didn't include the winter army of dark-suited applicants parading through department conference rooms and hospital hallways. However, the majority of you were that hopeful applicant at some point.

What are our responsibilities in screening and interviewing applicants? I try to find the person in the paperwork—who are they? What compels them to pursue this career? It is crucial to be aware of our own biases during this process. I don't mean the grossest errors of gender bias, but the subtle language differences many of us use when talking to applicants. Review your letters of recommendation. Are there any patterns in tone or vocabulary that strike you?

What about the pool of applicants in general? You might recall that the single liveliest ENTConnect Open Forum (**http://entconnect.entnet.org/home** with member sign-on required) discussion this year was about the 2017 and 2018 otolaryngology match during which the number of applicants dropped and 10 to 15 otolaryngology programs had positions that were initially unmatched.

Spoiler Alert: The applicants are back and strong as ever this year.

My unscientific poll of colleagues from programs around the country reveals that applicant numbers are up 20 to 40 percent this year over last year. The reasons why there was a dip in recent years are important to analyze and understand. Generational changes? The infamous program-specific paragraph? Are we perceived as too competitive?

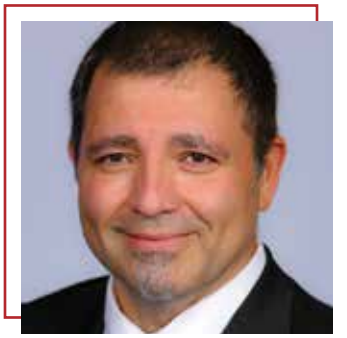
The reasons why this was such a hot topic to otolaryngologists deserve some attention as well. Why does it matter if we get two applicants for every spot? Does this appeal to some sense of elitism or exclusivity in ourselves? I have been guilty of this feeling at times. Have you?

Whether the 2017-2018 match years were an exception, we can't take student interest in otolaryngology for granted. One of our AAO-HNS initiatives for 2019 and beyond touches on this issue, joining energy from every corner of otolaryngology to reaffirm our identity and role in medicine, in medical training, and in our communities. Local leaders, not just among our academic programs, but those stepping up through our Board of Governors and component societies will have the support of the AAO-HNS in local otolaryngology interest forums that will begin to roll out in 2019.

The new AAO-HNS Student Programs feature information about the field and the match process to complement the efforts of our colleagues who are also part of the Society of University Otolaryngologists, a superb organization. The new medical student membership category has blossomed in popularity and is a great place for aspiring otolaryngologists to get involved, get connected, and begin their careers in our amazing specialty.

Whether you are doing community outreach at your local high school, advising a neighbor college student, or greeting a dark-suited otolaryngology applicant, we are all at our best when sharing the joy and commitment we have for our careers. Otolaryngology is changing in healthy ways; we should look like the patients we care for and the communities we serve.

Let's have leadership from all pathways in otolaryngology—show yourselves and your passion for the field. The applicants are superb, the field is full of wonderful and amazing people, and the future is indeed bright. ■



Albert L. Merati, MD
AAO-HNS/F President

> "Otolaryngology is changing in healthy ways; we should look like the patients we care for and the communities we serve."

What do you want written on your tombstone?

My friend and former partner **Daniel E. Bruegger, MD,** would ask the interview candidates, "When it is all said and done, what do you want written on your tombstone?"

While the occasional smart-alec would answer "pepperoni," the moments of consideration and reflection have been remarkable. When I contacted Dan recently to confirm this memory, he reminded me that he himself had borrowed it from Charley Norris, longtime chair of the KU Otolaryngology Department in the 1980s.

Do you have a few favorite interview questions? Send them to me at **bulletin@entnet.org**. Perhaps I will feature a few of these in a future column.

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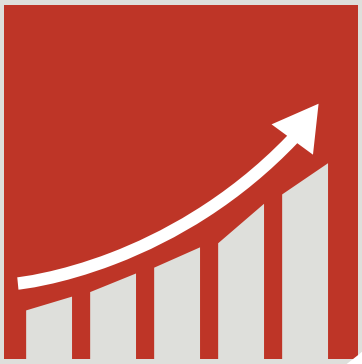

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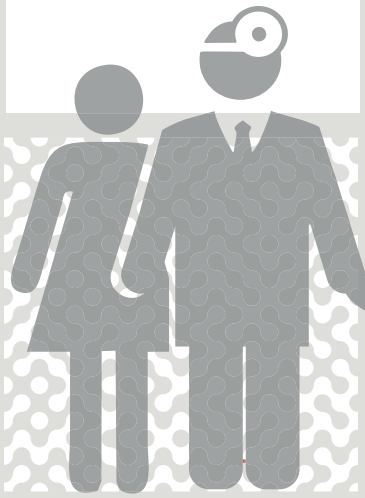

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Celebrate the small victories

As we look forward to the new year, there are several defining events for which we need to prepare.

First, the AMA combined CPT/RUC report on altering the E/M system as proposed by CMS this year will be presented at the February CPT meeting. The results of that report and proposal for CPT coding will be discussed and could possibly create significant changes in the way we document and see office patients.

Second, the commission formed to look at the future of Board Certification and MOC released its report, recommendations, with a comment period that closed January 15. The recommendations and the resultant responses could well affect the future of the ABMS system as well as CME as it relates to licensing and privileging.

Third, we are optimistic that by the end of the first quarter we will have completed our search for a Reg-ent[SM] partner and will have executed agreements that will allow us to expand our network, increase research opportunities, and begin active clinical trials. We will continue to work with the academic community to incorporate their valuable knowledge and patient populations in the registry.

Also, the recently filed American Hospital Association lawsuit against the federal government attempting to reverse "site of service" payment changes made in the FY 2019 final rule will be interesting to watch as will the consolidation in the healthcare industry not only among hospital systems, but also including data organizations, pharmacies, and other venture capital organizations launching commercialized versions of care.

We expect that the audiology sponsored legislation requesting "physician" designation by CMS and multistate licensure will be back on the table. The expected FDA release of proposed regulations for the OTC sale of hearing aids will trigger significant activity resulting from this major policy change affecting the majority of our members.

I was recently in Jackson, MS, where I spoke both to the private community and the academic department at the University of Mississippi. While there, I heard an inspiring talk that encouraged all to recognize and celebrate "difference-making moments" that occur in all facets and stages of our lives. It has become more challenging to do this both in a professional and personal context as schedules become crowded and life's complexities and uncertainties abound.

Necessity seems to dictate adherence to routines that ensure things move forward, but they don't allow you to fully comprehend the significance of many things going on around you. It becomes easy to grouse about happenings or events that interrupt or add to these well-thought-out schedules designed to allow us to survive and overlook concurrent happenings that might bring joy to our lives.

At a time when burnout is high, due to multiple factors including the continuing addition of perceptually unimportant responsibilities, along with the unpredictable direction of the healthcare delivery system evolution, the joy traditionally associated with the practice of medicine has significantly declined for many. Unfortunately, that has also carried over to the private lives of physicians as well.

Despite these challenges, there is still an abundance of "moments" associated with professional activities and personal and family interactions that can bring great joy and satisfaction to our lives. The trick is to recognize them as they are happening and celebrate them.

Moments such as a child hearing after myringotomy tube placement, placement of a hearing aid or cochlear implantation, telling patients that their cancer has been eradicated and they are free of disease, the gratitude of a patient successfully treated for benign paroxysmal positional vertigo, helping older patients regain the ability to swallow their own nutrition, and innumerable other scenarios reflect the true mission of physicians. Watching a student or resident as they learn something new or successfully complete a difficult operation, discovering a new concept or treatment, helping a colleague take care of a particularly difficult patient, convincing an insurer to cover a patient's needed treatment, or defining best care using advanced data analytics. All of these and many more, when recognized, can bring joy and validation to the decision to practice medicine and the years of dedication for mastering the profession.

Equally as important outside of the office: your child's first step or words, attending a ball game or recital, the first day of school, a graduation, a first romance, a family vacation, or even a simple thank you are worth their weight in gold when recognized. Take the time to celebrate even the smallest victories, both personal and professional, with your family and staff. ■

James C. Denneny III, MD
AAO-HNS/F EVP/CEO

UPDATE:

On January 14, the AAO-HNS submitted comments on the ABMS Vision Initiative's Draft Report on Continuing Board Certification. While lifelong learning is essential, the AAO-HNS believes professional self-regulation through continuous learning and assessment must fit within the normal flow of a physician's practice and be available at a reasonable expense. The letter highlights the Academy's concerns with several of the Initiative's recommendations, including the consolidation of ABMS oversight at the expense of individual specialty boards and the expectation that all diplomates participate annually in continuing certification programs. These recommendations would limit the ability for specialty boards such as the American Board of Otolaryngology - Head and Neck Surgery (ABOHNS) to continue with their innovative solutions tailored to our specialty. We look forward to continuing to work with the ABOHNS to achieve the goals stated in the Academy's letter commenting on the 96-page draft recommendation document.

https://www.entnet.org/sites/default/files/aao-hns_response_to_abms_vision_init_jan_2019.pdf

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ENT ADVOCACY NETWORK

Keep an ear to the ground

By joining the ENT Advocacy Network—a free AAO-HNS member benefit—you can take an active role in improving legislation and regulations affecting the practice of otolaryngology. Often, elected officials look to physicians in their districts for expertise when trying to develop or change healthcare policies.

Members of the ENT Advocacy Network have access to:

- *The ENT Advocate*, a monthly e-newsletter providing timely advocacy updates;
- Briefing materials about the Academy's legislative and policy priorities;
- Assistance in organizing and hosting a Member of Congress or state legislator at your practice; and
- Pre-written messages or talking points to use in contacting your lawmakers via AAO-HNS Calls to Action. (See www.entadvocacy.org.)

Successful legislative advocacy starts with you. Join the ENT Advocacy Network today and become an active participant in the political process. To sign up, visit www.entnet.org/advocacy or email govtaffairs@entnet.org. ■

AGENDA

PRACTICE MANAGEMENT PEARLS AND SUCCESSES / WELLNESS

All sessions are open to all attendees unless otherwise noted
(events subject to change)

FRIDAY, APRIL 26, 2019

1:00-7:30 pm

Registration / Folder Pick-Up

2:00-4:50 pm

State OTO Society Round Table (Invitation only)

Sponsored by BOG Governance & Society Engagement Committee

Invited Speaker: TBD

Moderators: Daniel Wohl, MD, BOG GSE Committee Chair, and Boris Chernobilsky, MD, BOG GSE Committee Vice Chair

- Roundtable introductions
- Creating value for your members
- Leveraging effective tools of communication
- Engagement and retention
- Open Forum

5:00-5:50 pm

Executive Directors & Society Administrators Meeting

5:00-5:50 pm

BOG Executive Committee Meeting (Invitation only)

6:00-7:30 pm

Welcome & Networking Reception (All are welcome)

SATURDAY, APRIL 27, 2019

7:30-9:45 am

Registration/Folder Pick Up/Breakfast Available

7:30-8:15 am

BOG Governance & Society Engagement Committee Meeting (Mandatory for BOG Committee members – Guests are welcome)

Daniel Wohl, MD, Chair and Boris Chernobilsky, MD, Vice Chair

8:15-9:00 am

BOG Socioeconomic & Grassroots Committee Meeting (Mandatory for BOG Committee members – Guests are welcome)

Lance Manning, MD, Chair and Daniel Chelius, MD, Vice Chair

9:00-9:45 am

BOG Legislative Affairs Committee Meeting (Mandatory for BOG Committee members – Guests welcome)

David Boisoneau, MD, Chair and Karen Rizzo, MD, Vice Chair

9:45-10:00 am

BREAK – Meet the Exhibitors

10:00-10:30 am

BOG General Assembly

Moderator: Ken Yanagisawa, MD, BOG Chair

*BOG Executive and Committee Reports

10:30-11:15 am

A 21st Century Medical Practice Love Story: The Physician/APP Relationship –

Moderator: Kristi Gidley, PA-C. Panelists: Scott Stringer, MD, Bill Blythe, MD, Wendy Stern, MD

11:15 am-12:00 pm

Engaging Young Physicians and Retaining Senior Ones

Moderator: Dan Chelius, MD. Panelists: Sanjay Parikh, MD, David Edelstein, MD, Wendy Stern, MD, Peter Abramson, MD, Cristina Baldassari, MD, Nikhila Raol, MD, Nathan Lindquist, MD

12:00-12:15 pm

GRAB LUNCH

12:15-1:00 pm

KEYNOTE SPEAKER: Defense Attorney Joyce Lagnese, JD

"A Precious and Invaluable Partnership Between Defense Attorneys and Otolaryngology State Societies"

1:00-1:45 pm

Speed Mentoring with Academy Leadership (Open only to AAO-HNS physician members)

Sponsored by Young Physicians Section

Moderators: Carol Yi Chun Liu, MD, and Davey Cohen, MD

1:00-2:00 pm

SEC Meeting (Invitation only)

1:45-2:00 pm

Regent Update – James Denneny, III, MD

2:00-2:30 pm

What's New in the Academy? – James Denneny, III, MD, Gavin Setzen, MD, Albert Merati, MD

2:30-2:45 pm

BREAK

2:45-3:15 pm

Congressional Guest - Do's and Don'ts (Etiquette) For Effective and Meaningful Legislative Visits, Update on Issues

3:15-3:45 pm

Federal Legislative Hot Topics – Academy Staff / ENT PAC – PAC Chair

3:45-3:55 pm

Wrap Up and Adjourn, Ken Yanagisawa, MD, BOG Chair

REGISTER TODAY!

www.entnet.org/leadershipforum

4:00-5:30 pm

BOD Executive Committee Meeting (Invitation Only)

4:30-5:30 pm

YPS Governing Council Meeting (Invitation only)

5:30-6:00 pm

BOD Executive Committee Executive Session, TBD (Invitation Only)

6:00-8:00 pm

ENT PAC Reception (Open to ENT PAC Investors contributing $365+; Residents $100+)

SUNDAY, APRIL 28, 2019

7:00-9:45 am

Registration/Folder Pick Up/Breakfast Available

7:00-8:15 am

Board of Directors Executive Session, TBD (Invitation Only)

Board of Directors Breakfast

7:00-8:00 am

WIO Governing Council Meeting (Invitation only)

8:00-8:45 am

BOG Regional Representatives Networking Meeting (Invitation only)

Troy Woodard, MD, BOG Member-at-Large

8:15 am-3:00 pm

Board of Directors Meeting

8:50-9:00 am

Welcome and Opening Remarks

Samantha Anne, MD, BOG Secretary, and Troy Woodard, BOG Member-at-Large

9:00-9:45 am

PANEL #1: Microaggressions and Why They Matter

Moderator: Noriko Yoshikawa, MD. Panelists: David Brown, MD, Keith Chadwick, MD, Carrie Francis, MD, Cristina Cabrera-Muffly, MD

Sponsored by the Diversity & Inclusion Committee

9:45-10:15 am

BREAK

10:15-11:00 am

PANEL#2 – Disclosing Complications

Moderator: Zainab Farzal, MD. Panelists: Cherie-Ann Nathan, MD, Angela Powell, MD, Brian Thorp, MD

Sponsored by Section for Residents and Fellows-in-Training

11:00-11:45 am

PANEL #3: Sleep for Us!!

Moderator: Kathy Yaremchuk, MD, MSA. Panelists: Christine Heubi, MD, Ofer Jacobowitz, MD, Pell Waldrop, MD

Sponsored by Women in Otolaryngology

11:45am-12:00 pm

GRAB LUNCH

12:00-12:45 pm

PANEL #4: Mentorship for Millennials

Moderator: Tjoson Tjoa, MD. Panelists: Stacey Gray, MD, Marita Teng, MD, Giancarlo Zulliani, MD

Sponsored by Young Physicians Section

12:45-1:15 pm

Opioid Crisis Panel

Moderator: David Boisoneau, MD. Panelists: Todd Falcone, MD, Ryan Li, MD, Scott Powell, MD

1:15-1:30 pm

BREAK

1:30-2:15 pm

Insurer Challenges -- Socioeconomic and Practice Management Hot Topics – Two Views – Peter Manes, MD, and Richard Waguespack, MD

2:15-3:00 pm

Future Practice of Otolaryngology – David Eibling, MD, Stella Lee, MD, And KJ Lee, MD

3:00-3:05 pm

Closing Remarks and Adjournment

Ken Yanagisawa, MD, BOG Chair and Spencer Payne, MD, BOG Chair-Elect

3:15-4:45 pm

BOG Executive Committee Wrap Up and Strategic Planning (Invitation only)

3:30-4:30 pm

SRF Governing Council (Invitation only)

MONDAY, APRIL 29, 2019

8:00 am-3:00 pm

AAO-HNS Leadership Meetings on Capitol Hill (Invitation only)

BOARD OF GOVERNORS

Your 2019 resolution

Spencer C. Payne, MD
Chair-Elect, Board of Governors

By the middle of February, nearly 80 percent of individuals have already stumbled in maintaining their New Year's resolutions. Plus, internet-derived commentary suggests that the reasons for these failures are summed up nicely with the acronym CLIFF, which stands for:

C – **C**an't find the time.
L – **L**acking a game plan to keep you going.
I – **I**gnoring your commitment and falling into old patterns.
F – **F**rustrated with lack of early results.
F – **F**orgetting why you started.

What does this have to do with otolaryngologists and the Board of Governors (BOG)? Forgive me for being presumptive, but now that you might have extra time from your failed New Year's resolution dreams, I would like to ask you to resolve to get more involved in the Academy's BOG.

As an organization, we have been working on solutions to the CLIFF and are excited to share them with you at the upcoming AAO-HNS/F 2019 Leadership Forum & Spring BOG Meeting.

The meeting will be held April 26-28, in Alexandria, VA. Panels of experts will discuss optimization of advanced practice provider relationships (freeing up your time), mentorship (enlisting help with creating game plans), engagement of younger and senior physicians (mutual commitment assurances), what's new in the Academy (information regarding the results of current efforts), and networking and social events to remind you all why we got involved in the first place, to help each other provide the best ear, nose, and throat care for our patients. We will also discuss myriad other topics covering sleep hygiene, the effects of microaggressions, legislative updates, and the opioid crisis.

For the third year running, a State Oto Society Roundtable will kick things off. It will begin the afternoon of Friday, April 26. Complementing our prior format of open discussion, we will also feature an expert in direct marketing and membership engagement to help frame the conversations around strengthening our state and local societies.

Oh, and for those of you who have kept that exercise routine going strong, the gym at the Westin Alexandria hotel is quite nice.

See you in April. ■

“As an organization, we have been working on solutions to the CLIFF and are excited to share them with you at the upcoming AAO-HNS/F 2019 Leadership Forum & Spring BOG Meeting.”

Call for nominees

2019 Nikhil J. Bhatt, MD International Public Service and Humanitarian Awards

In an effort to foster a global otolaryngology community, the AAO-HNS Foundation supports otolaryngologists around the world who demonstrate a unique commitment to the specialty. The AAO-HNSF Nikhil J. Bhatt, MD International Public Service and Humanitarian Awards recognize the achievements of non-U.S. otolaryngologist-head and neck surgeons.

The recipients will be recognized during the AAO-HNSF 2019 Annual Meeting & OTO Experience, September 15-18, in New Orleans, LA.

Visit **www.entnet.org/content/nikhil-j-bhatt-md-international-awards** for more information and **www.entnet.org/content/nikhil-j-bhatt-md-international-awards** to learn about past recipients of these prestigious awards.

Deadline for submitting the nominee form is April 15.

2019 Jerome C. Goldstein, MD Public Service Award

The Jerome C. Goldstein, MD Public Service Award recognizes members for commitment and achievement in service, either to the public or to other organizations within the United States, when such service promises to improve patient welfare. Funded anonymously by an Academy member, any member of the Academy is eligible to receive, and nominate other members, for this award. The awardee is honored during the Annual Meeting & OTO Experience with a commemorative certificate and $1,000 honorarium.

Visit **https://www.entnet.org/content/jerome-c-goldstein-md-public-service-award** for more information. Deadline submitting the nominee is March 1.

2019 Arnold P. Gold Foundation Humanism in Medicine Award

In 2009, the Arnold P. Gold Foundation selected the American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNSF) as one of three medical specialty societies to confer the Gold Foundation's new Humanism in Medicine Award, with the goal of advocating for the compassion, empathy, and sensitivity displayed by practicing physicians caring for their patients. These goals align with the AAO-HNS/F vision to be "The global leader in optimizing quality ear, nose, and throat patient care."

Visit **https://www.entnet.org/content/arnold-p-gold-foundation-humanism-medicine-award** for more information. Deadline for submitting the nominee for is April 15.

2018 Award Recipients

TANIA M. SIH, MD
2018 NIKHIL J. BHATT, MD INTERNATIONAL PUBLIC SERVICE AWARD RECIPIENT

PROFESSOR MOHAN KAMESWARAN
2018 NIKHIL J. BHATT, MD INTERNATIONAL HUMANITARIAN AWARD RECIPIENT

NORMAN D. HOGIKYAN, MD
2018 JEROME C. GOLDSTEIN, MD PUBLIC SERVICE AWARD RECIPIENT

MARK G. SHRIME, MD, MPH, PHD
2018 ARNOLD P. GOLD FOUNDATION HUMANISM IN MEDICINE AWARD RECIPIENT

ADVOCACY IN ACTION

Revised physician compounding requirements improved

The AAO-HNS recently submitted comments to the United States Pharmacopeia (USP) supporting its proposed revisions to Chapter 797 regarding in-office sterile compounding by physicians. The revised chapter, which is markedly different from the first USP draft released in 2016, re-establishes an exception for allergen extracts mixed with aseptic technique, but without the environmental and other controls required for more dangerous compounded drugs.

Given the critical role that the management of allergic disorders plays in our specialty, the AAO-HNS, the American Academy of Otolaryngic Allergy (AAOA), and other affected organizations have been working collaboratively over the past three years to influence this latest iteration of the USP Chapter 797 draft.

Physicians have been preparing allergenic extracts in their offices for more than 100 years under general aseptic conditions, but outside of an ISO-classified environment, with no evidence of sterility problems or patient harm. In the Academy's comments, we thanked the USP Expert Committee for its decision to protect patient safety while maintaining patient access to allergen immunotherapy through physician in-office compounding of allergenic extracts.

The final version of the chapter is expected to be posted on June 1, 2019, and will take effect in December 2019.

To view the AAO-HNS letter to USP, visit **www.entnet.org/advocacy** or contact **healthpolicy@entnet.org**. ■

Professor Eugene N. Myers – Honorary President of the Balkan Society of Otolaryngology – HNS, his wife Barbara, and members of the Balkan Society.

XI Balkan Congress of Otorhinolaryngology

Golden Sands, Bulgaria

While the waves lapped the sand and rock music blared from the loudspeakers of the many bars lining the beach, inside the Congress Center of the International Hotel in Golden Sands, Bulgaria, the XI Balkan Congress of Otorhinolaryngology took place.

Rumen Benchev, PhD, MSc, Chairman of the Bulgarian National Society of Otorhinolaryngology – Head and Neck Surgery was the President of the Balkan Society of Otorhinolaryngology, and special thanks was offered to Mario Milkov, MD, PhD, of nearby Varna, who made the local arrangements and organized the scientific and social programs, and special events, including a spirited football game.

The official opening of the Congress took place on May 31, 2018. Following greetings from local officials and University faculty, Prof. Pavel Dimov, MD, of Stara Zagora presented a detailed lecture entitled, "First five years before IV Balkan Congress of Otorhinolaryngology – Head and Neck Surgery: Our activities and Prof. Dr. Todor Karchev." A reception followed, featuring Bulgarian local specialties. Two singers from the Bulgaria State Opera entertained the guests with arias from many popular operas.

The Congress was attended by more than 400 ENT specialists from 12 countries. The Scientific Program was held in three conference halls where the participants had a choice among 25 keynote lectures, 14 round tables, instructional courses, video cases, and nine satellite symposia. Many individual speakers, whose lectures covered every aspect of contemporary otolaryngology, and a "Young Scientists" session were included. Guest lecturers of the Congress included world-renowned names such as **Eugene N. Myers, MD, FRCS; Dan Fliss, MD**; Andrew Schmelzer, **Karl Hoermann**, **MD**, **Piotr**

Skarzynski, MD, PhD, MSc; J. Haijiianou, Hesham Negm, MD, MSc; and Ninai Kuman. The high quality of the Congress indicated the remarkable progress the Balkan Society has made in the 17 years since its reorganization.

Professor Myers, Honorary President of the Balkan Society and Regional Advisor to the Balkan Countries from the American Academy of Otolaryngology – Head and Neck Surgery, gave a lecture entitled "Neck Dissection: An Operation in Evolution." A very touching in memoriam for our beloved colleague Merko Tos, MD, was included.

The Board of the Balkan Society chaired by Prof. Dr. Cem Uzun met and, amongst other business, elected to become an International Corresponding Society of the AAO-HNSF. Prof. Dr. Karl Hoermann of Mannheim and Prof. Dr. Hesham Negm of Cairo were elected to Honorary Membership. The next meeting will be held in Lake Ohrid, Macedonia in 2020. ■

Professor Mario Milkov lecturing.

Humanitarian service in Rwanda

Rwanda Goiter Mission is a collaboration between Medical Missions for Children (MMFC) and the Anesthesia Department at the University of Nebraska Medical Center (UNMC). The 20-member team included three surgical attendings and two residents. MMFC has fostered a strong relationship with the community and staff at Gitwe Hospital. The U.S. team was assisted and complemented by the local team of physicians, nurses, hospital administration, and interpreters.

READ MORE ONLINE
Longer article available

REG-ENT PERSPECTIVE

Q&A

Reg-ent
ENT CLINICAL DATA REGISTRY

Epic-approved solution for data sharing in pilot-testing with the Reg-ent Registry

Interview with Tim Parr, Vice President of Technology at FIGmd

Epic is one of the most highly used electronic health records and is used by many Academic Medical centers, hospitals, and health systems. FIGmd has been working with Epic to develop an Epic-approved solution for use across all the FIGmd registries, including Reg-ent.

Tim Parr

Tim Parr, FIGmd's Vice President of Technology, sat down with the *Bulletin* to discuss a new solution that will allow practices with Epic to share data with the Reg-ent registry once the pilot concludes in early Spring 2019.

Q What is the new solution that will allow practices with Epic to share data with Reg-ent?

A The new solution is the Epic FIGmd Registry Practice Connector (RPC) app, which is available in the Epic App Orchard. The app works by connecting directly to the Caboodle data warehouse within Epic. It does require that a site have version 15 or higher of Epic Caboodle because those versions have a component called Kit, which is a gateway. So, you need both Kit and Caboodle to be able to interface successfully with the Epic Caboodle enterprise data warehouse. Once the FIGmd RPC is connected to Caboodle, FIGmd is able to query a standard data model that has been provided by Epic to allow for extraction of data for the Reg-ent registry.

With the Epic FIGmd Registry Practice Connector utilizing the Epic Caboodle data warehouse, we have access to more and better data than would typically be available through a data-push scenario, where files are prepared and then data is pushed to the Reg-ent registry.

Q How will this benefit the Reg-ent registry?

A Since this app is an Epic-approved solution, it streamlines the compliance, security, and privacy approval processes for institutions that want to contribute data to Reg-ent. The end result is a more straightforward path to participation in Reg-ent.

Q When will Reg-ent Epic practices be able to use this new solution?

A Epic practices will be able to use the new solution once the pilot is complete, which is anticipated to be spring 2019. At that point, it will be opened to the general Reg-ent membership, and we look forward to onboarding all Epic practices that want to participate in Reg-ent.

Q Why should AAO-HNS members participate in Reg-ent?

A Contributing your otolaryngology-specific clinical data to the Reg-ent data set allows you to receive access to your data and, through the Reg-ent dashboard, access to comparison benchmark data of your peers participating in Reg-ent. In addition, you will be contributing to the larger, de-identified data set that can be used for advocacy, research, FDA product surveillance, and future measures development. ■

AMA HOUSE OF DELEGATES REPORT

Issues impacting otolaryngology

Douglas R. Myers, MD
Chair of the AAO-HNS Delegation to the AMA House of Delegates

The American Medical Association (AMA) held its 2018 Interim House of Delegates (HOD) Meeting November 9-13, at National Harbor, MD. The American Academy of Otolaryngology–Head and Neck Surgery was represented by Delegation Chair **Douglas R. Myers, MD**; Delegate **Robert Puchalski, MD;** Delegate **Craig S. Derkay, MD**; Alternate Delegate **Susan D. McCammon, MD**; and Alternate Delegate **James C. Denneny III, MD**, AAO-HNS EVP/CEO.

Below is a summary of the debated reports and resolutions most relevant to our specialty.

Opposition to mandatory licensing requirements for qualified clinical data registries

The AAO-HNS co-sponsored this resolution with 21 other specialty societies in response to a proposal by the Centers for Medicare & Medicaid Services (CMS) that, as a condition of a QDCR measure's approval for purposes of MIPS quality reporting, QDCR owners would be required to enter into a license agreement with CMS to provide the measure free of charge to other QCDRs. That proposal was made contrary to CMS' policy to protect the intellectual property rights of QCDR measure owners. Amendments made during the meeting did not detract from the resolution's intent.

Site of service payment differential

This report from the Council on Medical Services supported Medicare payment policies that are site-neutral without lowering total Medicare payments. It further called for payments (which for private practices and ambulatory surgery facilities have not kept up with medical cost inflation) to be based on the actual costs of the service. The report was approved.

Ban on tobacco flavoring agents

This resolution from the American Thoracic Society, Society of Critical Care Medicine, and the American College of Chest Physicians originally called for preventing flavorings from being added to electronic cigarette solutions or other tobacco products unless they are proven to not be toxic. Because of their role in luring a new generation of youth into the use of nicotine, the HOD passed an amended version that called for a ban of all tobacco product flavorings. There was strong sentiment to prohibit access to tobacco products by anyone under 21 years of age, which is current AMA policy.

Addressing surgery performed by optometrists

The states of Louisiana, Kentucky, and Oklahoma have allowed optometrists to perform anterior chamber ophthalmic laser surgery as well as several scalpel surgeries. Graduates of optometric schools from other states who have had no surgical experience may obtain licensure to perform surgery in the three states noted above by completing a 16-hour course. The resolution submitted by the American Academy of Ophthalmology calling for state and federal laws prohibiting optometrists from performing surgery received wide support in the HOD and was passed without amendment.

The next meeting of the AMA HOD will be June 8-12, in Chicago, IL. If you have questions regarding this report and other AMA HOD activities, contact govtaffairs@entnet.org. ■

CME that counts for MOCME

■ **Richard V. Smith, MD**
AAO-HNSF Coordinator for Education


Richard V. Smith, MD

This summer, the Accreditation Council for Continuing Medical Education (ACCME®) and the American Board of Otolaryngology - Head and Neck Surgery (ABOHNS) announced a new collaboration to expand opportunities for ABOHNS Board-Certified Physicians to receive Maintenance of Certification (MOC) credits, or continuing certification, by participating in accredited continuing medical education (CME).

AcademyU.org has over 50 activities registered in www.CMEfinder.org that are now deemed for CME and MOC credit with plans to grow the opportunities available in the coming year. I encourage you to take advantage of **Member+** when you renew your 2019 AAO-HNS dues. For an additional $50, you gain access to over 200 courses for the price of one—many of which count for MOC.

The AAO-HNSF 2019 Annual Meeting & OTO Experience will offer CME that counts for MOC for the first time. Full conference registrants will receive access to additional enduring CME activities, where MOC credit can be earned after the conference is over by completing the course, posttest, and evaluation. As a CME provider, AAO-HNSF is responsible for submitting diplomate MOC completion information to ACCME, which will then report this to ABOHNS. This saves members the step of having to track this in AcademyU.

I would like to recognize and thank Brian Nussenbaum, MD, MHCM, for his leadership in guiding the ABOHNS and his willingness to work with the Academy on this important benefit for our mutual members. None of this would be possible without the tremendous dedication of the Foundation's Education Committees that develop these activities; and to Tirza Lofgreen, CHES; Bryan H.D. May; and the Education team for their work to make them accessible in AcademyU.

To learn more, visit www.AcademyU.org. ■

Passport to Get Involved

Make your impact on the specialty by engaging with the Academy. From publishing and advocacy opportunities to getting involved with sections and committees, there are several pathways that are designed to fit different levels of participation based on your availability.

Engage Online

Ready to start engaging with the Academy right now? There are several ways to get started from the comfort of your home or office or on the go using your mobile device.

Advance Clinical Otolaryngology

Share your expertise with a global audience by submitting an article for publication consideration to *Otolaryngology–Head and Neck Surgery*, the Foundation's flagship journal, or *OTO Open*, the Foundation's open access journal. Also, apply to be a peer reviewer for the journals. The peer review process is essential to the development of research and is a great way to get involved with the Academy.

Participate on a Committee

The Academy flourishes and succeeds from the contributions of its members. Serving on a committee provides the chance to collaborate, build your professional network, stay on the cutting edge of research and issues affecting the body of medicine, and earn honor points. The annual committee application cycle runs from November-January.

Get Involved with Your Section

Strengthen your network through the Academy's three sections: Section for Residents and Fellows-in-Training (SRF), Women in Otolaryngology (WIO), and the Young Physicians Section (YPS).

Represent Your State/National Society on the BOG

The Board of Governors (BOG) is made up of local, state, regional, and national otolaryngology-head and neck surgery societies from around the U.S. and Canada and serves as an important avenue of communication with the Board of Directors.

Be an Advocate

In today's regulatory and legislative climate, it's vital for U.S. otolaryngologists to use their clinical expertise to advocate on behalf of the specialty. The AAO-HNS provides numerous opportunities for members to influence federal and state healthcare policies, communicate with elected officials, and advocate for your patients.

Passport Submission is as Easy as 1-2-3!

1. Check off the activities below that you've accomplished

2. Take a photo

3. Email to **memberservices@entnet.org** with the subject line "My Academy Passport"

Those with three or more activities checked will receive a special gift and will also be entered into a monthly drawing for an Academy branded fleece jacket.*

Visit **entnet.org/getinvolved** to see what other opportunities spark your interest!

GET INVOLVED

ENGAGE

PUBLISH

Check off the activities that you've accomplished for a special gift and to be entered into a monthly grand prize drawing.

NAME: _____ AAO-HNS ID: _____

ENGAGE ONLINE

☐ Post or reply to a post on ENTConnect

☐ Follow **@AAO-HNS** on Facebook, Twitter, and Instagram

☐ Update your ENThealth.org 'Find an ENT' Profile

ADVANCE CLINICAL OTOLARYNGOLOGY

☐ Submit an article to *Otolaryngology–Head and Neck Surgery*

☐ Submit an article to *OTO Open*

☐ Become a journal reviewer

PARTICIPATE ON A COMMITTEE

☐ Apply for a committee (2018 and/or 2019 cycle)

☐ Attend a committee meeting as a guest at the Annual Meeting

GET INVOLVED WITH YOUR SECTION

☐ Post or reply to a post on your section's ENTConnect community

☐ Attend a section General Assembly at the Annual Meeting

☐ Apply for a grant

REPRESENT YOUR STATE/NATIONAL SOCIETY ON THE BOG

☐ Check the BOG Region Map to find your local/state society

☐ Attend the Leadership Forum & BOG Spring Meeting

☐ Attend the BOG General Assembly at the Annual Meeting

BE AN ADVOCATE
(U.S. MEMBERS ONLY)

☐ Join Project 535

☐ Become a State Tracker

☐ Join the ENT Advocacy Network

APPOINT LEADERS

☐ Vote in the AAO-HNS Annual Election (May 2019)

☐ Submit an award nomination form

PARTICIPATE

entnet.org/passport

**While supplies last. Grand prize winners will be selected at random each month. Submit early for multiple chances to win. Submission must be sent by an AAO-HNS member in good standing. Final grand prize drawing will take place on December 31, 2019.*

CLINICAL PRACTICE GUIDELINE

Tonsillectomy in children update

Adapted from the February 2019 Supplement to *Otolaryngology–Head and Neck Surgery*. Read the guideline at **www.otojournal.org.**

"Tonsillectomy with or without adenoidectomy is one of the most common surgical procedures performed on children in the United States. The principal indications are obstructive sleep disordered breathing (oSDB) and recurrent sore throats. Since the guideline's publication in 2011, there has been a large number of new studies published on tonsillectomy, including randomized-controlled trials and several meta-analyses. This makes an update important and timely," said **Ron B. Mitchell, MD**, who chaired the 2019 guideline update, with **Sanford M. Archer, MD**, serving as assistant chair, **Stacey L. Ishman, MD, MPH**, as the methodologist, and **Richard M. Rosenfeld, MD, MPH, MBA,** as consultant.

The purpose of this multidisciplinary guideline is to identify quality improvement opportunities in managing children under consideration for tonsillectomy and to create explicit and actionable recommendations to implement these opportunities in clinical practice. Specifically, the goals are to educate clinicians, patients, and/or caregivers regarding the indications for tonsillectomy and the natural history of recurrent throat infections.

"This update seeks to optimize the perioperative management of children undergoing

ENThealth.org: a reliable source for newly released and updated CPG patient information

ENThealth.org provides a reliable resource for patients wanting to understand guideline recommendations. Its "Conditions and Treatments" pages are developed and updated with the CPG participants in coordination with these important findings.

New updates for this guideline include changes to these topics: Tonsils, Tonsils and Adenoids, and Pediatric Sleep-Disordered Breathing and are available for patients currently.

In the "Be ENT SMART" section of the website, patients who want to know more can connect to the new guideline itself and its associated patient-focused fact sheets and tables. In this way, patients can find the right information in one place to manage existing health issues and make more informed choices.

Direct your patients with confidence to: **https://www.enthealth.org/be-ent-smart/latest-research-guidelines/**.

tonsillectomy, emphasizing the findings of new published studies, improving counseling and education of families of children who are considering tonsillectomy for their child, highlighting the management options for patients with modifying factors, and reducing inappropriate or unnecessary variations in care," said Dr. Mitchell.

Methods

A draft of the original Tonsillectomy in Children Clinical Practice Guideline was sent to a panel of expert reviewers from the fields of nursing, infectious disease, consumers, family medicine, anesthesiology, sleep medicine, pediatrics, and otolaryngology-head and neck surgery. The reviewers concluded that the original guideline action statements remained valid but should be updated with major modifications, including the development of new key action statements.

Changes from the prior guideline include two consumer advocates added to the update group; evidence from one new clinical practice guideline, 26 new systematic reviews, and 13 new randomized controlled trials; enhanced emphasis on patient education and shared decision-making; the addition of an algorithm to clarify action statement relationships; changes to five of the key action statements (KASs) from the original guideline; incorporation of new evidence profiles to include the role of patient preferences, confidence in the evidence, differences of opinion, quality improvement opportunities, and any exclusion to which the action statement does not apply; and the addition of seven new KASs.

GUIDELINE KEY ACTION STATEMENTS (KAS)

KAS1: Watchful waiting for recurrent throat infection (strong recommendation)
Clinicians should recommend watchful waiting for recurrent throat infection if there have been fewer than seven episodes in the past year, fewer than five episodes per year in the past two years, or fewer than three episodes per year in the past three years.

KAS2: Recurrent throat infection with documentation (option)
Clinicians may recommend tonsillectomy for recurrent throat infection with a frequency of at least seven episodes in the past year, at least five episodes per year for two years, or at least three episodes per year for three years with documentation in the medical record for each episode of sore throat and one or more of the following: Temperature greater than 38.3C or 101.F, cervical adenopathy, tonsillar exudate, or positive test for group A beta-hemolytic streptococcus.

KAS3: Tonsillectomy for recurrent infection with modifying factors (recommendation)
Clinicians should assess the child with recurrent throat infection who does not meet criteria in KAS2 for modifying factors that may nonetheless favor tonsillectomy, which may include but are not limited to: multiple antibiotic allergies/intolerance, PFAPA (periodic fever, aphthous stomatitis, pharyngitis, and adenitis), or history of more than one peritonsillar abscess.

KAS4: Tonsillectomy for obstructive sleep-disordered breathing (recommendation)
Clinicians should ask caregivers of children with obstructive sleep-disordered breathing (oSDB) and tonsillar hypertrophy about comorbid conditions that may improve after tonsillectomy, including growth retardation, poor school performance, enuresis, asthma, and behavioral problems.

KAS5: Indications for polysomnography (recommendation)
Before performing tonsillectomy, the clinician should refer children with oSDB for polysomnography (PSG) if they are under two years of age or if they exhibit any of the following: obesity, Down syndrome, craniofacial abnormalities, neuromuscular disorders, sickle cell disease, or mucopolysaccharidoses.

KAS6: Additional recommendations for PSG (recommendation)
The clinician should advocate for PSG prior to tonsillectomy for oSDB in children without any of the comorbidities listed in KAS5 for whom the need for tonsillectomy is uncertain or when there is discordance between the physician examination and the reported severity of oSDB.

KAS7: Tonsillectomy for obstructive sleep apnea (recommendation)
Clinicians should recommend tonsillectomy for children with obstructive sleep apnea (OSA) documented by overnight PSG.

KAS8: Education regarding persistent or recurrent oSDB (recommendation)
Clinicians should counsel patients and caregivers and explain that oSDB may persist or recur after tonsillectomy and may require further management.

KAS9: Perioperative pain counseling (recommendation)
The clinician should counsel patients and caregivers regarding the importance of managing posttonsillectomy pain as part of the perioperative education process and should reinforce this counseling at the time of surgery with reminders about the need to anticipate, reassess, and adequately treat pain after surgery.

KAS10: Perioperative antibiotics (strong recommendation against)
Clinicians should not administer or prescribe perioperative antibiotics to children undergoing tonsillectomy.

KAS11: Intraoperative steroids (strong recommendation)
Clinicals should administer a single, intraoperative dose of intravenous dexamethasone to children undergoing tonsillectomy.

KAS12: Inpatient monitoring for children after tonsillectomy (recommendation)
Clinicians should arrange for overnight, inpatient monitoring of children after tonsillectomy if they are under the age of three years old or have severe obstructive sleep apnea (OSA); apnea-hypopnea index [AHI] of 10 or more obstructive events/hour, oxygen saturation nadir less than 80 percent, or both).

KAS13: Postoperative ibuprofen and acetaminophen (strong recommendation)
Clinicians should recommend ibuprofen, acetaminophen, or both for pain control after tonsillectomy.

KAS14: Postoperative codeine (strong recommendation against)
Clinicians must not administer or prescribe codeine, or any medication containing codeine, after tonsillectomy in children younger than 12 years.

KAS15A: Outcome assessment for bleeding (recommendation)
Clinicians should follow up with patients and/or caregivers after tonsillectomy and document in the medical record the presence or absence of bleeding within 24 hours of surgery (primary bleeding) and bleeding occurring later than 24 hours after surgery (secondary bleeding).

KAS15B: Post-tonsillectomy bleeding rate (recommendation)
Clinicians should determine their rate of primary and secondary posttonsillectomy bleeding at least annually.

The target patient population for the guideline is any child 1 to 18 years of age who may be a candidate for tonsillectomy. The guideline does not apply to populations of children excluded from most tonsillectomy research studies, including those with neuromuscular disease, diabetes mellitus, chronic cardiopulmonary disease, congenital anomalies of the head and neck region, coagulopathies, or immunodeficiency. This guideline is intended for all clinicians in any setting who interact with children who may be candidates for tonsillectomy.

The methods outlined in the AAO-HNSF Clinical Practice Guideline Development Manual, Third Edition, were followed in developing this update. (**http://oto.sagepub.com/content/148/1_suppl/S1.long**)

The full guideline, as well as other resources, are available at **https://www.entnet.org/tonsillectomyCPG** and in *Otolaryngology–Head and Neck Surgery* as published at **www.otojournal.org**.

ENThealth.org includes patient-focused information on the topic of tonsillectomy in children that incorporates the key action statements of the update to this guideline. ■

Guideline authors

Ron B. Mitchell, MD (chair); Sanford M. Archer, MD (assistant chair); Stacey L. Ishman, MD, MPH (methodologist); Richard M. Rosenfeld, MD, MPH (consultant); Sarah Coles, MD; Sandra A. Finestone, PsyD; Norman R. Friedman, MD, DABSM; Terri Giordano, DNP, CRNP, CORLN; Douglas M. Hildrew, MD; Tae W. Kim, MD; Robin M. Lloyd, MD; Sanjay R. Parikh, MD; Stanford T. Shulman, MD; David L. Walner, MD; Sandra A. Walsh, BS; and Lorraine C. Nnacheta, MPH

Endorsements

The guideline is endorsed to date by American Academy of Family Physicians (AAFP), American Academy of Sleep Medicine (AASM), The American Society of Pediatric Otolaryngology (ASPO), Infectious Diseases Society of America (IDSA), Society of Anesthesia and Sleep Medicine (SASM), The Society of Otorhinolaryngology and Head-Neck Nurses (SOHN), The Society for Pediatric Anesthesia (SPA), and The Triological Society.

The American Society of Anesthesiologists' (ASA) Administrative Council has approved endorsement. Since the document has neither been presented to nor approved by either the ASA Board of Directors or House of Delegates, it is not an official or approved statement or policy of the Society.

Disclaimer

This clinical practice guideline is not intended as an exhaustive source of guidance for managing tonsillectomy in children. Rather, it is designed to assist clinicians by providing an evidence-based framework for decision-making strategies.

The guideline is not intended to replace clinical judgment or establish a protocol for all individuals with this condition and may not provide the only appropriate approach to diagnosing and managing this program of care. As medical knowledge expands and technology advances, clinical indicators and guidelines are promoted as conditional and provisional proposals of what is recommended under specific conditions, but are not absolute.

Guidelines are not mandates. These do not and should not purport to be a legal standard of care. The responsible physician, in light of all circumstances presented by the individual patient, must determine the appropriate treatment. Adherence to these guidelines will not ensure successful patient outcomes in every situation. The AAO-HNSF emphasizes that these clinical guidelines should not be deemed to include all proper treatment decisions or methods of care, or to exclude other treatment decisions or methods of care reasonably directed to obtaining the same results.

CLINICAL PRACTICE GUIDELINES

PATIENT INFORMATION

POST-TONSILLECTOMY PAIN MANAGEMENT FOR CHILDREN: EDUCATION FOR CAREGIVERS

HOW LONG IS THE RECOVERY AFTER SURGERY?	Pain lasts about 7-10 days and can last as long as two weeks. Your child may complain of throat pain, ear pain and neck pain. The pain may be worse in the morning; this is normal. You should ask your child if they are having any pain every four hours remembering that they may not say they are in pain.
WILL MY CHILD BE TAKING PAIN MEDICATION?	Yes, your child will be prescribed pain medications such as ibuprofen or acetaminophen. Ibuprofen can be used safely after surgery. Pain medication should be given on a regular schedule. You may be asked to give pain medication around the clock for the first few days after surgery, waking your child up when he or she is sleeping at night. Alternating medication such as ibuprofen and acetaminophen may be recommended. Rectal acetaminophen may be given if your child refuses to take pain medication by mouth. Ask your child if their pain has improved after giving pain medication.
DOES MY CHILD NEED TO RESTRICT THEIR DIET AFTER SURGERY?	No, your child can eat as they normally would as long as it does not bother them. Make sure your child drinks plenty of fluids like water or juice. Offer frequent small amounts of fluids by bottle, sippy cup or glass. Fluids can help with their pain. Encourage your child to chew and eat food including fruit snacks, popsicles, pudding, yogurt or ice cream.
WILL OTHER THINGS BESIDES PAIN MEDICATION HELP MY CHILD'S PAIN?	Yes, there are things other than medication that can also be utilized. You can distract your child by playing with them, having their favorite toys or video games available, applying a cold or hot pack to their neck and/or ears, blowing bubbles, doing an art project, coloring, watching television or reading a book.
WHAT SHOULD I DO IF I CANNOT MANAGE MY CHILD'S PAIN?	Call your healthcare provider.

SOURCE: Mitchell, RB, Archer, SA, Ishman, SL, et al. Clinical practice guideline: tonsillectomy in children (update). Otolaryngol Head Neck Surg. 2019;160 (Suppl 1):S1-S42.

AMERICAN ACADEMY OF OTOLARYNGOLOGY–HEAD AND NECK SURGERY FOUNDATION

www.entnet.org

ABOUT THE AAO-HNS/F

The American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS) represents approximately 12,000 specialists worldwide who treat the ear, nose, throat, and related structures of the head and neck. The AAO-HNS Foundation works to advance the art, science, and ethical practice of otolaryngology–head and neck surgery through education, research, and lifelong learning.

CLINICAL PRACTICE GUIDELINES

PATIENT INFORMATION

TONSILLECTOMY AND AIRWAY OBSTRUCTION DURING SLEEP CAREGIVER COUNSELING

WHAT IS OBSTRUCTIVE SLEEP-DISORDERED BREATHING?	oSDB is when air is blocked during sleep. It can be caused by large tonsils and adenoids. Children that are overweight may also have oSDB. Children with oSDB may be sleepy during the day, act out, struggle in school, have nighttime bedwetting and be small for their age.
HOW IS OSDB DIAGNOSED?	A sleep study or polysomnography (pol-ee-som-nog-ruh-fee) or "PSG" may be needed to see if your child has oSDB. The test is done in a sleep lab. A medical technician will put small discs or pads on your child's head and body. Your child's heart rate, body movements, oxygen levels, and breathing through their mouth and nose will be measured.
WILL MY CHILD'S OSDB GO AWAY AFTER TONSILLECTOMY?	Tonsillectomy helps almost all normal-weight children with oSDB and it improves sleep in most children in this group. Tonsillectomy also helps overweight children with oSDB but sleep is not always improved. Your child's oSDB may not go away or it may return even after tonsillectomy.
WHAT IF I HAVE MORE QUESTIONS?	Contact your healthcare provider if you have any further questions.

SOURCE: Mitchell, RB, Archer, SA, Ishman, SL, et al. Clinical practice guideline: tonsillectomy in children (update). Otolaryngol Head Neck Surg. 2019;160 (Suppl 1):S1-S42.

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COMMITTEE REPORT

The prescription opioid crisis and otolaryngology

■ **John D. Cramer, MD**
Department of Otolaryngology – Head and Neck Surgery; Wayne State University School of Medicine. Detroit, MI

From the: AAO-HNSF Patient Safety and Quality Improvement Committee (PSQI)

The U.S. is facing an opioid epidemic, the scale of which is difficult to overstate. Surgeons are important contributors to this public health crisis. Opioids form the backbone of postoperative pain control in the United States, however, concerns about the potential risks of abuse from short-term postoperative opioids are relatively new.

Despite the frequency with which otolaryngologists prescribe opioids, the risks of developing opioid use disorder as a result of postoperative prescriptions is underappreciated.

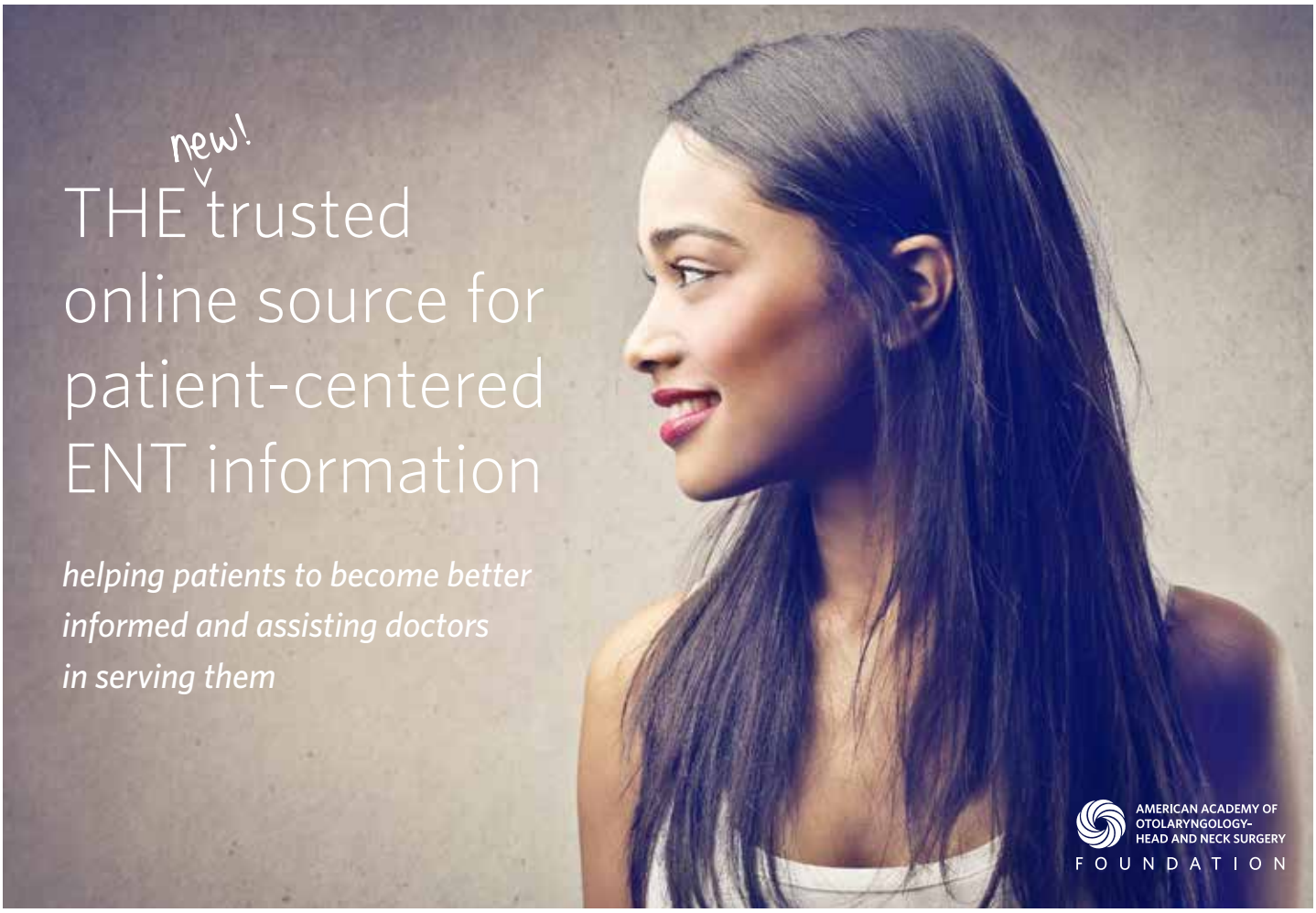
New research suggests that six percent of opioid-naïve otolaryngology patients prescribed opioids postoperatively will continue to take them one year after surgery.[1] After the initial opioid prescription, additional opioid scripts frequently come from other specialists and therefore may not be appreciated by the surgeon. After developing opioid dependency, many patients escalate to drugs of abuse over time. However, opioid prescribing practices vary widely, and otolaryngologists have previously received little formal education focused on pain.

After common procedures, some otolaryngologists reported prescribing no opioids while others reported prescribing over 60 opioid tablets.[2] This calls on all otolaryngologists to judiciously assess their opioid-prescribing practices and review the latest data on strategies to minimize abuse.

To address this educational gap, the American Pain Society[3] and American Society of Anesthesiologists[4] created guidelines to help all surgeons manage acute postoperative pain. These guidelines are essential reading but require adaption to the unique constraints of the head and neck where strategies like epidural analgesia are not practically feasible. The approach described here is largely consistent with these guidelines and has been described in greater detail elsewhere.[5]

Comprehensive perioperative pain control

Pain control touches on all phases of surgical care. Optimal pain control starts preoperatively. During the preoperative discussion, it is vital to set expectations. Zero pain postoperatively is an unrealistic expectation. Using shared decision-making, patients can develop a pain management plan that addresses their history and values. Preoperatively, patients should be assessed for the risk of developing opioid abuse. Prior history of anxiety, depression, or tobacco or alcohol abuse are each associated with an increased risk of developing chronic opioid use disorder.



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> New research suggests that six percent of opioid-naïve otolaryngology patients prescribed opioids postoperatively will continue to take them one year after surgery.

On the day of surgery, evidence suggests that multimodal non-opioid analgesia is one of the best strategies to control pain and minimize opioids after surgery.[5] Multimodal analgesia approaches stress preventive analgesia in which pain medications are administered prior to a painful stimulus to prevent the development of hyperalgesia and minimize opioid requirements.

Traditionally, local anesthesia offered a limited duration of benefit. Newer approved agents, such as liposomal bupivacaine that lasts 96 hours, are changing this paradigm and can be employed after different procedures in the head and neck. While epidural analgesia is not feasible for head and neck surgery, regional nerve blocks using long-acting local anesthetics can be performed.

Postoperatively, multiple non-opioid agents can be used synergistically with other non-opioid agents. Acetaminophen should be combined with NSAIDs whenever feasible. In patients who are at risk for significant bleeding, celecoxib, a highly selective COX-2 inhibitor, provides enhanced pain control without any theoretical risk of bleeding. Importantly, COX-2 inhibitors, like all NSAIDs, need to be prescribed with caution in patients with cardiovascular disease. Adjunctive strategies, including gabapentin, provide another option when postoperative acetaminophen and NSAIDS are inadequate.

Safe opioid prescribing when necessary

When multimodal non-opioid analgesia provides inadequate pain control, then opioids may be required. Opioid prescribing requires careful selection of the type of opioid, strength, frequency, and number of pills. Patients who require opioid therapy postoperatively should be warned about the side effects, risks of abuse, and alternatives to therapy.

The patient should be aware that the expected duration of opioid therapy is short, and all opioids carry the potential for abuse. Tramadol offers an attractive opioid option for analgesia for many otolaryngologic surgeries. Tramadol targets both opioid receptors but also inhibits reuptake of serotonin and norepinephrine. Compared with other opioids, some data indicates that tramadol has a lower potential for misuse, abuse, and dependency.[6]

Codeine, on the other hand should be avoided. Codeine was previously commonly prescribed after adenotonsillectomy, but due to variable metabolism was issued a black box warning for use in children by the U.S. Food and Drug Administration.

When opioids are required after procedures with high levels of pain, institutional standards for opioid prescribing offer an opportunity to minimize excess opioids in the community. These standard prescribing recommendations enable data driven approaches based on published usage instead of anecdote.

Finally, prescription drug monitoring programs exist in 49 states and allow otolaryngologists another opportunity to screen for prior opioid use prior to prescribing and coordinate with other prescribers.

Safe disposal of opioids

When opioid medications are no longer needed, patients and physicians should be aware of safe disposal options. Consumers and caregivers should remove unneeded medicines to help reduce the chance of accidental ingestion or intentional misuse. The best option is to return medications to approved collection sites that can securely collect and dispose controlled substances.

Another option includes mixing medications with an unpalatable substance such as dirt, cat litter, or used coffee grounds then throwing them into the trash. Flushing opioids is a possibility if no other take-back options are readily available.

Opioid avoidance: proof of concept

While multimodal non-opioid analgesia strategies have been discussed for over 20 years, their adoption has lagged until now. There has been a surge in interest investigating multimodal non-opioid analgesia strategies in otolaryngology. One institution that implemented a multimodal non-opioid analgesia pathway was able to decrease the percentage of patients requiring a postoperative opioid after thyroid and parathyroid surgery to less than two percent.[7] These strategies may also minimize complications and decrease length of stay by decreasing sedation and improving patient's function after surgery.

Otolaryngologists need to acknowledge the potential harm caused by opioids. If an opioid-naïve patient develops opioid use disorder as a result of surgery, this is a surgical complication.

As surgeons, otolaryngologists have a duty critically evaluate opioid prescribing practices to minimize the potential for abuse from the medications that we prescribe. ■

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Ankyloglossia

- **Robert H. Chun, MD, Chair,** Pediatric Otolaryngology Committee
- **Ryan H. Belcher, MD, Member,** Pediatric Otolaryngology Committee
- **Rose J. Eapen, MD, Member,** Pediatric Otolaryngology and Media and PR Committees

Ankyloglossia, also known as "tongue-tie," is an anomaly in which there is restricted tongue movement due to a short or thickened lingual frenulum or a highly attached genioglossus muscle. Despite the lack of consensus on diagnostic criteria, there has been a steady increase over the last 20 years in the diagnosis of ankyloglossia, as well as in lingual frenotomy procedures. This trend has been observed in both the Medicaid and in the private insurance populations. The steady increase has been attributed to a national and international effort to promote breastfeeding as well as knowledge of the role ankyloglossia is thought to play in hindering successful breastfeeding.[1]

There is a reported incidence of 25-80 percent of breastfeeding difficulty in infants with ankyloglossia.[2] Due to the tongue's restriction of mobility, infants are unable to extend their tongues over the gum line to form a proper seal and instead use their jaws to keep the breast in the mouth. This results in ineffective latch, maternal breast pain, poor milk supply, refusal of the breast, and failure to thrive.[3]

Ankyloglossia has also been implicated as a contributor to other feeding difficulties such as bottle-feeding, deglutition, and licking foods. It has also been purported to be responsible for difficulty playing wind instruments, oral hygiene, kissing, and drooling. It can reduce self-esteem or be a contributor in psychological issues for older patients.[4]

Although ankyloglossia can contribute to difficulties with feeding, children often can have other comorbidities such as hypotonia, oral motor

discoordination, or laryngomalacia that can cause or contribute to their dysphagia.

Managing the goals and expectations of the family in these instances is often a delicate conversation as conservative measures and/or a frenotomy alone most likely will not resolve the feeding difficulty.

Surgical intervention/treatment

Indications for surgical intervention for ankyloglossia remain controversial. There is variation among clinicians in the role ankyloglossia plays in breastfeeding difficulty. One study showed 10 percent of pediatricians, 30 percent of otolaryngologists, and 69 percent of lactation consultants said that ankyloglossia frequently caused breastfeeding problems.[5] These attitudes and beliefs can affect the referral patterns to the otolaryngologist for surgical intervention. A recent systematic review of the literature concerning treatment of ankyloglossia and breastfeeding outcomes did show evidence that suggests frenotomy may be associated with improved breastfeeding as reported by mothers.[3] It should be noted that research is lacking on nonsurgical interventions for ankyloglossia and on the mid- to long-term breastfeeding outcomes among infants that had a frenotomy.[3]

Traditionally, local anesthesia offered a limited duration of benefit. Newer approved agents, such as liposomal bupivacaine that lasts 96 hours, are changing this paradigm and can be employed after different procedures in the head and neck. While epidural analgesia is not feasible for head and neck surgery, regional nerve blocks using long-acting local anesthetics can be performed.

Postoperatively, multiple non-Frenotomy is the most common surgery to treat ankyloglossia if conservative measures are not sufficient. This is performed by "clipping" the lingual frenulum and can often be performed without local anesthesia in the office setting with minimal bleeding. Some of the potential adverse effects include bleeding, pain, scar formation, and damage to the surrounding structures if not performed carefully.

"A recent systematic review of the literature concerning treatment of ankyloglossia and breastfeeding outcomes did show evidence that suggests frenotomy may be associated with improved breastfeeding as reported by mothers."

The infant may feed immediately after the procedure. A frenotomy may need to be repeated if scarring occurs tethering the tongue. Alternatively, frenuloplasty may be performed. This procedure requires general anesthesia and involves one or multiple Z-plasties to release the frenum closed with sutures. If a revision surgery be considered, especially one requiring general anesthesia, you should ensure that there are no unidentified causes for the feeding difficulty or dysphagia.

Future directions

The majority of literature surrounding surgical management of ankyloglossia is concentrated on breastfeeding difficulty and outcomes. Strong scientific evidence and data concerning outcomes for frenotomy for issues outside of breastfeeding difficulty is limited. A systematic review looked at studies that evaluated all of the available literature on the treatment outcomes for ankyloglossia for medium- to long-term speech concerns, feeding processes other than breastfeeding, and social impact. This study found a deficiency of comparative data, against a backdrop of inadequate natural history data related to ankyloglossia.[4]

There are a multitude of other aspects of ankyloglossia that are yet to be studied thoroughly or to have strong evidence in either direction. Some of those aspects include

- How do comorbidities affect frenotomy outcomes?
- Does the type of tongue tie matter for outcomes?
- Do surgical revisions help?
- And other helpful questions that could assist feeding teams and physicians in management of these patients.

This emphasizes the need for quality prospective research to be performed in the future.

The American Academy of Otolaryngology–Head and Neck Surgery Foundation is convening a clinical consensus statement workgroup for ankyloglossia in 2019. Although it will not provide specific recommendations, a clinical consensus statement will reflect the opinions and practice from experts for the management or treatment of patients. ■

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Department of Otolaryngology –
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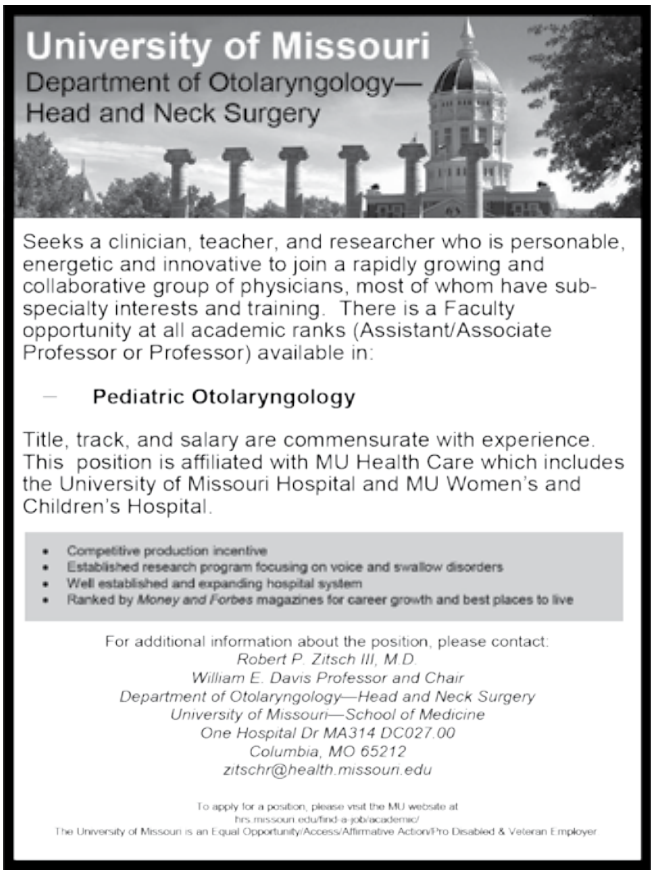

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Please address cover letter to: Joseph Paydarfar, MD; Section of Otolaryngology

Dartmouth-Hitchcock Clinic is an equal opportunity employer and all qualified applicants will receive consideration for employment without regard to race, color, religion, sex, national origin, disability status, veteran status, or any other characteristic protected by law.

AOC
HEAD & NECK SURGEONS

Private Practice Opportunity - General Otolaryngologist

Arizona Otolaryngology Consultants is one of the largest single specialty, physician-owned practices in the Valley, providing high quality medical care since 1997. Our group consists of multiple subspecialties, emphasizing all aspects of Otolaryngology/ Head & Neck Surgery, including head & neck oncology, pediatric otolaryngology, laryngology, neurotology and hearing aid sales. We offer patients ease of access at any of our 4 office locations and many surgery options as a result of over a dozen surgical affiliations.

Due to continued growth, we are looking to add a BC/BE General Otolaryngologist to our team of providers who offer a unique and collaborative approach to patient care.

Employment opportunities with AOC include:

- Excellent salary with partnership track
- Competitive health benefits
- Paid time off
- Malpractice insurance
- CME reimbursement

Interested candidates please submit your current CV and letter of interest to:

Alison Scott, Practice Administrator – Alisons@aocphysicians.com

For more information about our practice, please visit www.AOCPhysicians.com

Central Florida
100% Pediatric Otolaryngology
$600,000+ Potential

- Join **Orlando's premier Pediatric Otolaryngology** practice with **partnership opportunity**
- Guaranteed Salary plus bonuses and robust benefits
- **Surgery Center - Partnership Potential**
- State-of-the-art facilities with a **full support staff** and ancillary services including **audiology and allergy**

No State Income Tax!

- Live in a **"Top 5 Suburbs to live in Florida"**
- **"A" rated public and private schools**
- Enjoy international airports and **Florida's best theme parks year-round**
- **East and west coast beaches are 1-hour away!**
- **World-class golfing,** high-end shopping, and **sophisticated dining** in this affordable, family-friendly city.

Contact **Emily Glaccum** at: 678-331-5208 and send a copy of CV to emily.glaccum@themedicusfirm.com
Please reference: **PDO 7580**

Wake ENT
Ear, Nose and Throat Specialists

Are you tired of the cold and shoveling snow? Fed up with the administrative hassles of running your own office? If you have ever wanted to have your cake and eat it too, then we have the position for you! Wake Ear, Nose and Throat Specialists are looking for a highly motivated nonsurgical Physician to join our cutting edge Otolaryngology practice in Cary, NC, right in the center of the state with quick access to both the mountains and the coast. The Raleigh/Durham/Chapel Hill (Research Triangle) area has repeatedly been named as one of the best places to live and is currently ranked by Money Magazine as Number 5 in the country with venues for the arts, sports, and outdoor activities. The area also boasts several exceptional universities and charter schools as well as the largest public school system in the state.

Wake Ear, Nose and Throat Specialists and Wake Sinus Center offer full service ENT with in-house CT, Allergy and Audiology Departments for "one stop" patient care.

The successful candidate would practice all aspects of ENT within the main clinic and our alternate location.

The clinic has a schedule of Monday through Friday with rotation of call. The successful candidate will be a graduate of an accredited medical school and ENT residency program and have a minimum of five (5) years practice experience. Salary will be commensurate with experience.

This is an excellent full time opportunity with generous benefits for the right person.

Please email C-V to dwalker@wakeent.com or contact Dena Walker, COPM at 919-650-6775 for consideration.

Ochsner Health System | LSU Health SHREVEPORT

Otologist/Neurotologist

Ochsner LSU Health Shreveport
Department of Otolaryngology-Head and Neck Surgery

Position for an Otologist/Neurotologist at the Assistant/Associate/Full Professor Level

Candidates must be fellowship trained and BC/BE by the American Board of Otolaryngology

This is a unique opportunity to further cultivate and develop a robust practice in chronic ear, skull base, cochlea implants and implantation devices in a tertiary care center that draws patients from the entire Arkla-Tex area. Responsibilities include building a clinical practice, resident teaching, temporal bone laboratory and research. Excellent skull base referral source already established with Neurosurgery. The neurosciences center allows for an excellent opportunity to also build a research program.

Direct Contact Information:

Please send curriculum vitae, a statement of current interests, and names of three references to:

Cherie-Ann Nathan, MD, FACS
Professor and Vice-Chairman,
Director of Head and Neck Surgical Oncology
1501 Kings Highway, 9-203
Shreveport, LA 71103-33932
Telephone: 318-675-6262
Fax: 318-675-6260

E-mail: cnatha@lsuhsc.edu

Ochsner LSU Health – Shreveport is an equal opportunity employer and all qualified applicants will receive consideration for employment without regard to race, color, religion, sex, national origin, disability status, protected veteran status, or any other characteristic protected by law.

OTOVEL® (ciprofloxacin and fluocinolone acetonide) otic solution

Brief Summary of Prescribing Information

1 INDICATIONS AND USAGE

OTOVEL is indicated for the treatment of acute otitis media with tympanostomy tubes (AOMT) in pediatric patients (aged 6 months and older) due to *Staphylococcus aureus, Streptococcus pneumoniae, Haemophilus influenzae, Moraxella catarrhalis,* and *Pseudomonas aeruginosa*.

2 DOSAGE AND ADMINISTRATION

- OTOVEL is for otic use only. It is not for ophthalmic use, or for injection.

The recommended dosage regimen is as follows:

- Instill the contents of one single-dose vial 0.25 mL into the affected ear canal twice daily (approximately every 12 hours) for 7 days. Use this dosing for patients aged 6 months of age and older.
- Warm the solution by holding the vial in the hand for 1 to 2 minutes. This is to avoid dizziness, which may result from the instillation of a cold solution into the ear canal.
- The patient should lie with the affected ear upward, and then instill the medication.
- Pump the tragus 4 times by pushing inward to facilitate penetration of the medication into the middle ear.
- Maintain this position for 1 minute. Repeat, if necessary, for the opposite ear *[see Instructions for Use]*.

3 DOSAGE FORMS AND STRENGTHS

Otic Solution: Each single-dose vial of OTOVEL (ciprofloxacin 0.3 % and fluocinolone acetonide 0.025 %) delivers 0.25 mL of solution equivalent to ciprofloxacin 0.75 mg and fluocinolone acetonide 0.0625 mg.

4 CONTRAINDICATIONS

OTOVEL is contraindicated in:

- Patients with known hypersensitivity to fluocinolone acetonide or other corticosteroids, ciprofloxacin or other quinolones, or to any other components of OTOVEL.
- Viral infections of the external ear canal, including varicella and herpes simplex infections and fungal otic infections.

5 WARNINGS AND PRECAUTIONS

5.1 Hypersensitivity Reactions

OTOVEL should be discontinued at the first appearance of a skin rash or any other sign of hypersensitivity. Serious and occasionally fatal hypersensitivity (anaphylactic) reactions, some following the first dose, have been reported in patients receiving systemic quinolones. Some reactions were accompanied by cardiovascular collapse, loss of consciousness, angioedema (including laryngeal, pharyngeal or facial edema), airway obstruction, dyspnea, urticaria and itching. Serious acute hypersensitivity reactions may require immediate emergency treatment.

5.2 Potential for Microbial Overgrowth with Prolonged Use

Prolonged use of OTOVEL may result in overgrowth of non-susceptible bacteria and fungi. If the infection is not improved after one week of treatment, cultures should be obtained to guide further treatment. If such infections occur, discontinue use and institute alternative therapy.

5.3 Continued or Recurrent Otorrhea

If otorrhea persists after a full course of therapy, or if two or more episodes of otorrhea occur within 6 months, further evaluation is recommended to exclude an underlying condition such as cholesteatoma, foreign body, or a tumor.

6 ADVERSE REACTIONS

The following serious adverse reactions are described elsewhere in the labeling: Hypersensitivity Reactions [*see Warnings and Precautions (5.1)*]

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

In clinical trials, 224 patients with AOMT were treated with OTOVEL for a median duration of 7 days. All the patients received at least one dose of OTOVEL. There were 220 patients who received at least one dose of ciprofloxacin (CIPRO) and 213 patients received at least one dose of fluocinolone acetonide (FLUO). The most common adverse reactions that occurred in 1 or more patients are as follows:

Table 1: Selected Adverse Reactions that Occurred in 1 or more Patients in the OTOVEL Group

	Number (%) of Patients		
Adverse Reactions[1]	**OTOVEL N=224**	**CIPRO N=220**	**FLUO N=213**
Otorrhea	12 (5.4%)	9 (4.1%)	12 (5.6%)
Excessive granulation tissue	3 (1.3%)	0 (0.0%)	2 (0.9%)
Ear infection	2 (0.9%)	3 (1.4%)	1 (0.5%)
Ear pruritus	2 (0.9%)	1 (0.5%)	1 (0.5%)
Tympanic membrane disorder	2 (0.9%)	0 (0.0%)	0 (0.0%)
Auricular swelling	1 (0.4%)	1 (0.5%)	0 (0.0%)
Balance disorder	1 (0.4%)	0 (0.0%)	0 (0.0%)

[1]Selected adverse reactions that occurred in ≥ 1 patient in the OTOVEL group derived from all reported adverse events that could be related to the study drug or the drug class.

6.2 Postmarketing Experience

The following adverse reactions have been identified during postapproval use of ciprofloxacin and fluocinolone acetonide otic solution, 0.3% / 0.025% outside the US. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

- Immune system disorders: allergic reaction.
- Infections and infestations: candidiasis.
- Nervous system disorders: dysgeusia, paresthesia (tingling in ears), dizziness, headache.
- Ear and labyrinth disorders: ear discomfort, hypoacusis, tinnitus, ear congestion.
- Vascular disorders: flushing.
- Skin and subcutaneous tissue disorders: skin exfoliation.
- Injury, poisoning and procedural complications: device occlusion (tympanostomy tube obstruction).

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

OTOVEL is negligibly absorbed following otic administration and maternal use is not expected to result in fetal exposure to ciprofloxacin and fluocinolone acetonide (12.3)].

8.2 Lactation

Risk Summary

OTOVEL is negligibly absorbed by the mother following otic administration and breastfeeding is not expected to result in exposure of the infant to ciprofloxacin and fluocinolone acetonide.

8.4 Pediatric Use

OTOVEL has been studied in patients as young as 6 months in adequate and well-controlled clinical trials. No major differences in safety and effectiveness have been observed between adult and pediatric patients.

8.5 Geriatric Use

Clinical studies of OTOVEL did not include sufficient numbers of subjects aged 65 years and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients.

10 OVERDOSAGE

Due to the characteristics of this preparation, no toxic effects are to be expected with an otic overdose of OTOVEL.

Distributed by:
Arbor Pharmaceuticals, LLC
Atlanta, GA 30328

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

For more detailed information, see the full prescribing information for Otovel at www.otovel.com or contact Arbor Pharmaceuticals, LLC at 1-866-516-4950.

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SALVAT

For the treatment of AOMT in pediatric patients due to S. aureus, S. pneumoniae, H. influenzae, M. catarrhalis, and P. aeruginosa.

The difference is in the **delivery.**

OTOVEL®
ciprofloxacin 0.3% and
fluocinolone acetonide 0.025%

The first and only antibiotic/steroid combination ear drop in single-dose vials[1]

- Manufactured using blow-fill-seal technology—each vial is formed, filled, and sealed in a continuous, automated, sterile operation[2,3]
- Technology minimizes human intervention in the fill/finish process[3]
- Single-use vials contain 1 premeasured dose each—dose BID/7 days[4]
- No drop counting. No mixing or shaking required[4]
- Demonstrated efficacy and safety in 2 clinical trials[1,5]

Order Starter Packs today at otovel.com/hcp/resources

AOMT=acute otitis media with tympanostomy tubes; BID=twice daily.

INDICATIONS

OTOVEL® (ciprofloxacin and fluocinolone acetonide) is indicated for the treatment of acute otitis media with tympanostomy tubes (AOMT) in pediatric patients (aged 6 months and older) due to S. aureus, S. pneumoniae, H. influenzae, M. catarrhalis, and P. aeruginosa.

IMPORTANT SAFETY INFORMATION

Contraindications

OTOVEL is contraindicated in:

- Patients with known hypersensitivity to fluocinolone acetonide or other corticosteroids, ciprofloxacin or other quinolones, or to any other component of OTOVEL.
- Viral infections of the external ear canal, including varicella and herpes simplex infections and fungal otic infections.

The following Warnings and Precautions have been associated with OTOVEL: hypersensitivity reactions, potential for microbial overgrowth with prolonged use, and continued or recurrent otorrhea.

The most common adverse reactions are otorrhea, excessive granulation tissue, ear infection, ear pruritis, tympanic membrane disorder, auricular swelling, and balance disorder.

For additional Important Safety Information, please see Brief Summary of Prescribing Information on adjacent page, and full Prescribing Information available at www.otovel.com.

References: 1. US Food and Drug Administration. Orange Book: Approved drug products with therapeutic equivalence evaluations. https://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Accessed July 15, 2016. **2.** Data on file. Arbor Pharmaceuticals, LLC. **3.** Food and Drug Administration. Guidance for industry: sterile drug products produced by aseptic processing—current good manufacturing practice. https://www.fda.gov/downloads/Drugs/Guidances/ucm070342.pdf. Accessed March 15, 2018. **4.** Otovel [package insert]. Atlanta, GA: Arbor Pharmaceuticals, LLC; 2016. **5.** Spektor Z, Pumarola P, Ismail K, et al. Efficacy and safety of ciprofloxacin plus fluocinolone in otitis media with tympanostomy tubes in pediatric patients: a randomized clinical trial. *JAMA Otolaryngol Head Neck Surg*. 2017;143(4):341-349.

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SALVAT