

bulletin



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MAY 2021



AAO-HNSF 2021 ANNUAL MEETING & OTO EXPERIENCE

Los Angeles, California
October 3 - 6

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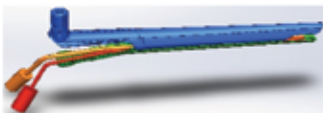
TWO NEW ZEITELS LARYNGOSCOPES

The 1st Novel Laryngeal Surgical Speculum Design Developments in Decades

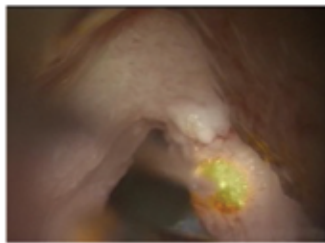
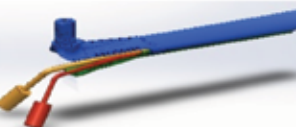
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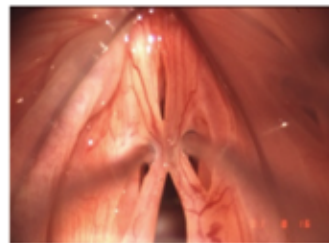
UNIVERSAL MODULAR
SUBGLOTTISCOPE



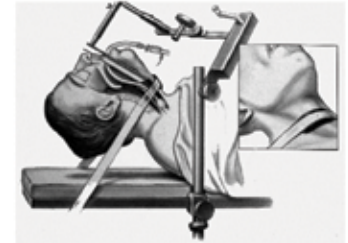
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bulletin features

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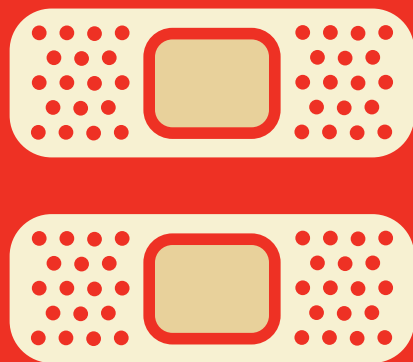
At the forefront

In "World Voice Day April 16, 2021: One World, Many Voices" (Vol. 40, No. 3), the contributors' quotes were incorrectly attributed in the print version. For the correct version, go to <https://bulletin.entnet.org/home/article/21342968/out-of-committee-voice-world-voice-day-april-16-2021-one-world-many-voices>.

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Health Equity and Inclusive Diversity: Why it Matters

“Health cannot be a question of income; it is a fundamental human right.”

– Nelson Mandela

As you know, we recently updated our Core Purpose and Core Guiding Principles. You may have noticed that we added the word “equitable” to our Core Purpose. Our updated Core Purpose is:

- We engage our members and help them achieve excellence and provide high-quality, evidence-informed, and equitable ear, nose, and throat care through professional and public education, research, and health policy advocacy.

We also updated our Core Guiding Principles. One of our updated Core Guiding Principles is:

- Promote inclusive diversity and equity in ENT patient care and throughout our specialty and organization.

So it is evident that the American Academy of Otolaryngology–Head and Neck Surgery and its Foundation are committed to advancing equitable ear, nose, and throat care. This newly articulated purpose then leads to some questions we must begin to try to answer. How do we define equitable ear, nose, and throat care? What does it mean to promote inclusive diversity and equity in ENT patient care? Why does health equity matter?

Let’s begin with a definition of health equity. The Robert Wood Johnson Foundation provides this definition: “Health equity means that everyone has a fair and just opportunity to be as healthy as possible. This requires removing obstacles to health such a poverty, discrimination, and their consequences, including powerlessness and lack of access to good jobs with fair pay, quality education and housing, safe environments, and health care.” As you can appreciate, achieving equitable care is a pretty tall order. How might we, as an Academy, move forward on this journey?

In order to define equitable ear, nose, and throat care, we first need to understand what disparities exist. Our Outcomes Research and Evidence-based Medicine Committee report on page 16 in this issue indicates that disparities in access and outcomes exist in many areas addressed by our specialty, including head and neck cancer, hearing loss, and sleep apnea. The challenge is that these disparities exist due to societal factors, called social determinants of health, rather than the disease itself. In other words, to truly achieve health equity, we need to address social issues such as poverty, access to health insurance, and discrimination. This will require the engagement and investment of everyone.

Second, what does inclusive diversity mean and how might we advance this guiding principle? I believe that inclusive diversity is the approach to foster the inclusion that leads to diversity in the workforce. I also believe that our specialty’s aspirational goal is to mirror or reflect the communities we collectively serve. This is a critical step for us to realize true equity in care.

Finally, and perhaps most importantly, why does health equity matter? The COVID-19 pandemic has shone a bright light on health disparities in our country. Our Black, Latino, and Native American communities have been disproportionately devastated by COVID-19. Pre-existing conditions are more prevalent in communities of color in our country. There is similar inequity in vaccine distribution and acceptance. Structural and societal inequities and social determinants of health are deeply influenced by implicit bias and discrimination.

As we begin to emerge from the COVID-19 pandemic and look forward to a post-vaccine world, we understand that our society, and we as individuals, have changed. We are more aware of inequity and the fragility of life. We are aware that access to high-quality, safe care should be a right and not a privilege. We understand that we must work together and engage with our communities to realize our Core Purpose and Guiding Principles. I look forward to working with all of you on this important journey. ■



Carol R. Bradford, MD, MS
AAO-HNS/F President

“
...to truly achieve health equity, we need to address social issues such as poverty, access to health insurance, and discrimination. This will require the engagement and investment of everyone.”

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Honoring Our Past and Forging Ahead

Celebrating our 125th Annual Meeting & OTO Experience with innovative program enhancements

This year marks the 125th anniversary of our organization that was founded in 1896. For several years, we have been planning a number of celebratory events culminating in our 125th Annual Meeting & OTO Experience, October 3-6, in Los Angeles, California.

We remain optimistic that we will be able to hold the scheduled meeting in Los Angeles in-person as planned. As the world emerges from the COVID-19 pandemic and vaccination becomes more widespread, conditions that would allow that to take place appear to be falling into place. Last year's sudden shift from an in-person meeting in Boston to a virtual meeting following the June pandemic-related cancellation by Boston gave us valuable experience in putting together a virtual meeting. This year, we are planning a hybrid meeting that will include an outstanding in-person component as well as a virtual component that will offer both live streaming and on-demand programming. We have selected an experienced vendor with an outstanding platform that we think will be a significant upgrade from last year's virtual meeting.

The Annual Meeting Program Committee (AMPC), led by Annual Meeting Program Coordinator **Daniel C. Chelius, Jr., MD**, constructed a fabulous scientific program with several additional innovative program enhancements for this year's meeting, including nine "Great Debate" format panels addressing critical issues across the breadth of the specialty, an expanded simulation program including a visit to a local simulation center, the new "ENTrepreneur Face-off," and a great blend of speakers delivering our "named lectures."

Additionally, the AMPC introduces the "Personal and Professional Development Track" that will include topics on finance, leadership, diversity, wellness, and others. Our President, **Carol R. Bradford, MD, MS**, has chosen a nationally known speaker, Neha Sangwan, MD, who will be speaking on leadership and wellness. Her innovative program, the i-Five Experience™, uses

scientifically proven techniques to reduce stress, build resilience, and foster individual and team accountability.

Dr. Bradford will host the Presidents' 125th Anniversary reception Saturday, October 2, which will celebrate current and past presidents of the Academy as well as those of all specialty societies participating in our meeting footprint this year. The Los Angeles Convention Center lobby will be the site of our history of the Academy exhibit featuring historical artifacts and an illustrated timeline dating back to 1896. We also will be giving out the sequel to the *Century of Excellence* book describing our first hundred years, *Legacy of Excellence*, at the meeting with signing opportunities with past and current leaders of the organization.

We are delaying opening the registration for the upcoming meeting until June, hoping for more clarity on what the in-person October meeting will look like in terms of convention center spacing requirements and social opportunities. Los Angeles offers a very attractive portfolio of hotel accommodations that meet the needs for all attendees. We have also recently been able to obtain significant reductions in room rates from many hotels in our block. I hope you will plan on joining us for the landmark 125th Anniversary Annual Meeting & OTO Experience.

Our annual election that will choose the future leaders who will take us forward over the next three to five years is now open through June 3. The Nominating Committee, chaired by Immediate Past President **Duane J. Taylor, MD**, has identified an exceptional group of candidates this year who deserve your consideration. Over the last five years, we have averaged a voting rate of only 11.5%. The current voting process should take less than three minutes, so I challenge us to reach the 20% mark or more in this our 125th anniversary year.

Recently, Dr. Bradford appointed three separate search committees to select our next Editor in Chief-elect of the AAO-HNSF journals, *Otolaryngology-Head and Neck*



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



Surgery and *OTO Open*, Coordinator-elect for Research & Quality, and the Chair-elect of the Ethics Committee. I want to thank and congratulate the chairs of each committee and their respective committee members for the great job they did identifying the three individuals who will fill these positions.

Ken Yanagisawa, MD, chaired the search for the Editor in Chief-elect of the journals that selected **Cecelia E. Schmalbach, MD, MSc**. **Valerie A. Flanary, MD**, chaired the search for the Coordinator-elect for Research & Quality that selected **Vikas Mehta, MD**. **Susan D. McCammon, MD**, chaired the search for the Chair-elect of the Ethics Committee that selected **Andrew G. Shuman, MD**. I would like to congratulate all three and offer my profound thanks for their willingness to serve our organization and specialty in these critical positions. ■



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TOGETHER
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SHAPING OUR FUTURE TOGETHER

125 STRONG

James C. Denny III, MD

AAO-HNS/F Executive Vice President and CEO

The AAO-HNS/F Boards of Directors recently passed the Strategic Plan at the April 18, 2021, meeting, culminating the seven-month process directed by our President, **Carol R. Bradford, MD, MS**. The updated Strategic Plan contains new elements that perfectly align with her areas of focus during her presidential year and the program areas that will be supported by the 125 Strong Campaign as it moves forward under the direction of the campaign Steering Committee and our staff led by Marylou Forgione, MBA, Senior Manager, Development.

The Steering Committee, led by President Bradford and Campaign Co-Chairs **Sujana S. Chandrasekhar, MD**, and **Albert L. Merati, MD**, includes Committee Chairs **Angela M. Powell, MD**; **Richard V. Smith, MD**; **Dana M. Thompson, MD, MS**; and **Kathleen L. Yaremchuk, MD, MSA**, and the recently added Development Consultant, **KJ Lee, MD**. Beginning in the June *Bulletin*, each committee will have a detailed article describing specific recommendations in their respective areas and recommended projects within these areas that will receive funding from the campaign for immediate use.

The recommended projects have been approved by the Executive Committee of the Board of Directors and will build programs that have immediate impact, but also lay the groundwork for future advancement in the areas of **Diversity, Equity, and Inclusion; Education; Leadership Development and Mentorship; and Wellness and Resiliency**. The members of each of the four committees spent considerable time assessing the needs and vetting potential solutions in each area that are designed to make a demonstrable difference in the future direction of our specialty.

Our members and other supporters can help shape the future of not only our organization, but also our specialty as well. I encourage you to carefully look at both the focus areas and the specific projects that each team has developed and consider donating to those areas that speak to you personally and move you to want to make a difference with these programs. If more than one area is important to you, there are opportunities to support as many of the four as you would like. Should the 125 Strong Campaign exceed expectations in any particular area, we have the ability to add projects as recommended by the respective committee based on resources available.

Join your many colleagues and friends and help us *Shape Our Future Together*. ■

"Your gift will help us drive transformation and innovation, expand and magnify our programs, and collectively partner for the health and wellbeing of our members and those we serve."

- **Carol R. Bradford, MD, MS**
AAO-HNS/F President



"Your investment in the **#WeAre125** campaign can bring these dreams to life. We are excited to partner with each and every one of our 12,000 fellow otolaryngologists to shape our future."

- **Sujana S. Chandrasekhar, MD**
Albert L. Merati, MD

■ milestone moments

In the Year 1982 ...



The first Annual Meeting of the newly formed AAO-HNS was held in New Orleans, Louisiana. The picture shows **Bobby R. Alford, MD**, passing the gavel to **Loring W. Pratt, MD**.

The Board of Governors held its first meeting in New Orleans, Louisiana, with **Marvin Singleton, MD**, serving as the first Chair.



The Academy's *Perceiver* and the American Council of Otolaryngology newsletters combined to form the new AAO-HNS *Bulletin*.



AAO-HNS STUDENT MEMBER MENTORSHIP PROGRAM

Serve as a mENTor to a Future Otolaryngologist

The new AAO-HNS program, mENTor, connects medical student members to practicing otolaryngologists across the country who will share their guidance, advice, and personal experiences. Through one-on-one interactions, students will have an opportunity to learn directly from these mentors in a welcoming, confidential environment.

The response from medical students has been overwhelming. Please consider becoming a mentor to an eager medical student who has told us how much they need your expertise and knowledge.

Students and mentors are matched on a first-come, first-served basis. Contact information will be shared between mentor and student, with a mutual responsibility to connect and maintain communication. Participation in the program is completely voluntary.

For more information and to volunteer as a mentor, visit: <https://www.entnet.org/content/mentor-new-aa-hns-student-member-mentorship-program>. ■

Published as a Supplement to
Otolaryngology-Head and Neck Surgery
in April 2021.

Accompanying Resources to the CPG:

- Plain language summary
- Executive summary
- Slide deck
- Podcasts
- Patient handouts (in both English and Spanish)
- Official quick-reference pocket guide and app
- Video on safe storage and disposal of opioids

Access all these resources and more at
www.entnet.org/opioidscpg. ■



May Is Better Hearing and Speech Month

ENThealth.org offers information for your patients

Better Hearing and Speech Month is a time to raise awareness about communication disorders and available treatment options that can improve the quality of life for those who experience problems speaking or hearing.

ENThealth.org is dedicated to helping patients and providing resources for you to share with your patients. Through the work of our expert member contributors and reviewers, ENThealth offers a roadmap for consumers seeking health-related information about the ear, nose, throat, and head and neck.

From conditions and treatments to wellness and prevention tips and strategies, ENThealth aims to provide a community of support to patients seeking expertise on their health-related matters.

Follow ENThealth on Twitter at [@BeENTsmart](https://twitter.com/BeENTsmart) to help us share this important patient information. ■



NOW LIVE: AAO-HNSF Quality Manuscript on Age-Related Hearing Loss Measures

Quality Improvement in Otolaryngology–Head and Neck Surgery: Age-Related Hearing Loss Measures published online in *Otolaryngology–Head and Neck Surgery* on March 23.

In developing these quality measures, a Measure Development Group of experts reached consensus on four de novo measures listed below. These measures were created for the diagnosis and treatment of age-related hearing loss (ARHL) disorders, including bilateral presbycusis and symmetric sensorineural hearing loss, and they are intended to assist providers in enhancing quality of care.

- Screening for Hearing Loss in Older Adults
- Audiometric Evaluation for Older Adults with Hearing Loss
- Advanced Diagnostic Imaging for ARHL—Avoidance of Inappropriate Use
- Shared Decision Making for Treatment Options for ARHL

To read the published article about the ARHL quality measures, visit <https://journals.sagepub.com/doi/full/10.1177/01945998211000442>. ■



Education Opportunities in Allergy

OTO Source covers numerous topics from basic immunology to allergies in the senior population through a standard study guide with teaching tools to assist with board certification, recertification, and lifelong learning. Review conditions and treatment options in the Allergy Unit at www.otosource.org. ■

2021 AAO-HNS Annual Election Now Open

The ballot is open May 3 through June 3. Don't miss the opportunity to share your voice, cast your vote, and select the future leaders of your Academy. Check your email for access to the 2021 AAO-HNS election ballot via an email from YesElections (Help+AAOHNS@yeselections.com). Questions? Contact elections@entnet.org. ■

2021 RRDP and International Community Curriculum Spotlight

"Introduction and Approach to Peer Review for Clinicians" is presented by **Erika Celis-Aguilar, MD**, and **Jennifer J. Shin, MD, SM**, who discuss the peer-review process for *Otolaryngology–Head and Neck Surgery*, the importance of understanding the current literature when crafting a study, and more. View on demand at <https://www.youtube.com/watch?v=yw9HXmHmNKO>. ■

HUMANITARIAN TRAVEL GRANT Medical Mission in Nepal

In March 2018, **Adam Master, MD**, spent two weeks working with Mike Smith, MBBS, LRCP, DLO, and **Nirmal Thapa, MD**, of Ear Aid Nepal, in the western Nepalese city of Pokhara. Pokhara is the second largest city in Nepal and a major urban center in the western half of the country. Nepal is mainly a rural country, and health infrastructure and transport are severely limited.

Chronic ear disease is exceedingly common in Nepal, and access to otologic care is limited. Under the guidance of Dr. Smith, Dr. Master performed and assisted in chronic ear surgery, performing tympanoplasties and mastoidectomies almost daily. Dr. Master and his team also traveled to a rural village to screen the local population. Most of the population in Nepal rarely travels to the cities

from their villages, and it is important to provide healthcare services that are accessible to rural populations. During this visit, they performed free ear and hearing examinations and identified many patients in need of surgical otologic care.

Dr. Master also provided an education seminar to Nepalese otolaryngologists. In a surprisingly well-attended seminar, he gave four hours of lectures on topics ranging from vertigo to lateral graft tympanoplasty.

"I am very thankful to Dr. Smith of Ear Aid Nepal for all his guidance and assistance with organizing my stay. I am also grateful to Dr. Thapa, who I worked very closely with during my time at The Ear Centre," said Dr. Master. ■

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pearls from your **peers:** Treatment of Acoustic Neuromas



INTERVIEWEE

Robert Cullen, MD

Otolaryngologist and Neurotologist, Saint Luke's Hospital, Kansas City, Missouri
Pediatric Neurotologist and Clinical Assistant Professor of Surgery, University of Missouri-Kansas City School of Medicine



INTERVIEWER

Marc L. Bennett, MD

Professor, Otolaryngology and Neurotology and Quality Officer QSRP, Department of Otolaryngology Head and Neck Surgery, Vanderbilt University Medical Center

What are the common symptoms and signs you see in patients with acoustic neuromas?

Most people present with hearing loss. Occasionally people present with disequilibrium or unsteadiness. Lastly, a minority of patients can present with cerebellar signs, blurred vision, or headache.

How often do you work up unilateral sensorineural hearing loss and diagnose an acoustic neuroma?

It's relatively uncommon—maybe once or twice a year I will actually diagnose a vestibular schwannoma primarily; most patients with acoustic neuromas are referred to my practice with a known diagnosis.

What is your diagnostic workup for an acoustic neuroma, outside of an MRI?

MRI remains the gold standard. We do a hearing test on everyone as it can change options for treatment. Vestibular testing is helpful in the decision process for some patients. We often obtain an ABR if hearing preservation surgery is an option for the patient.

What do you offer for patients who have a medical contraindication for an MRI?

For patients with medical contraindications like a spinal cord stimulator or internal defibrillator, we will order a CT scan of the temporal bones with

contrast. It will show us tumors that are larger. In addition, we utilize ABRs, but MRI is still the gold standard.

How do you accommodate patients with claustrophobia?

For mild symptoms, we typically use diazepam to be taken, one to two tablets prior to the MRI. For more severe symptoms, we will use sedation; often in the form of a general anesthetic.

What are your standard treatment options?

We offer observation (serial imaging), surgery, and stereotactic radiation (Gamma Knife). We educate people on the benefits and risks of all treatments and allow them to choose the best option. For observation, we typically image every six months after the initial MRI.

Does age play into the treatment options?

We typically attempt to avoid radiation on younger patients due to concerns about long-term effects from radiation. For elderly patients, we are more likely to offer radiation. For both groups, we let the overall medical condition help dictate the treatment.

Do you see any common complications from radiation?

Complications are uncommon. The most common is hearing loss, which can occur

suddenly but is more commonly progressive over time. We also see disequilibrium, that may be associated with tumor edema. Facial nerve complications are uncommon.

How often do you image patients after treatment?

For radiation, we start with imaging every six months, then yearly. For tumors with total resection, we image at one and five years. For those with subtotal resections, we image at three months, then yearly.

Do you routinely use balance therapy after treatment?

Balance therapy is important for patients with acoustic neuromas. After surgery, we typically give the patient one month or so for central compensation and then offer therapy for those still struggling. For younger and healthier patients, compensation occurs more quickly and they have less of a need for formal vestibular therapy.

Are there any changes you anticipate in treatment of acoustic neuromas in the upcoming years?

I anticipate increasing frequency of radiation treatment. In addition, I see a role for cochlear implantation and hearing restoration in these patients. Many patients struggle with the unilateral hearing loss, and this treatment shows promise in rehabilitating this symptom. ■



Taking Peer Mentorship to the Next Level

Nausheen Jamal, MD, YPS Chair

This year's main goals of the AAO-HNS Young Physicians Section (YPS) are to promote diversity, inclusion, and equity, while embracing the important role of peer mentorship. We were excited, therefore, to debut our initiative for mentoring YPS members with their programming submissions for the upcoming AAO-HNSF 2021 Annual Meeting & OTO Experience.

Previously, the YPS Governing Council (GC) played a more traditional role with respect to Annual Meeting submissions by offering sponsorship of proposals only upon request from the sponsoring members. By sharing our previous experiences, it seemed the initial crafting and planning of the first submission was most intimidating to YPS members. Since many members on the GC had extensive experience with creating and proposing Annual Meeting programming, we chose to take a much more proactive role this year. We distributed calls for topics that are pertinent to early-career otolaryngologists as well as encouraged proposals that showcase section members and their incredible expertise and accomplishments. Additionally, we emphasized the need for presentations that pertained to diversity, equity, and inclusion, and offered active mentorship from GC members to submitting authors.

Our membership enthusiastically answered the call for proposals, and many actively sought mentorship from the GC. Through our new and more intensive pre-submission mentorship and review process, we were able to sponsor several dozen high-quality submissions this year—a dramatic increase from the roughly half dozen that the YPS sponsored annually in years past.

We are proud to have helped increase YPS involvement and engagement with the AAO-HNS via encouragement of Annual Meeting participation and this new mentorship initiative. We hope that this proposal mentorship program leads to a heightened sense of belonging to the YPS and the AAO-HNS, thereby enabling continued engagement and dedication to the worldwide otolaryngology community while highlighting the topics that are important to our YPS constituents and providing them a greater voice in the AAO-HNS.

Although the call for papers is closed for the 2021 Annual Meeting, we plan to continue the active mentorship approach to YPS-sponsored submissions and encourage any YPS members who plan to submit topics pertinent to early-career otolaryngologists or need feedback and support with forming their submissions to contact us. We look forward to interacting on ENT Connect in our YPS community and hope to inspire YPS members to submit in the years to come. ■



Nausheen Jamal, MD
YPS Chair

“This year's main goals ... are to promote diversity, inclusion, and equity, while embracing the important role of peer mentorship.”



AAO-HNSF 2021
ANNUAL MEETING & OTO EXPERIENCE
LOS ANGELES, CALIFORNIA | OCTOBER 3-6
WE ARE ONE TWENTY-FIVE

Global Young Physicians Unite at the AAO-HNSF 2021 Annual Meeting & OTO Experience

Don't miss the International Young Physicians Forum to be held during the Annual Meeting, October 3-6, 2021, in Los Angeles, California. This annual event provides networking opportunities for

young physicians around the world to meet with members of the Academy's leadership.

Look for more details and information on the official [Annual Meeting website](https://www.entnet.org/bulletin).



Business of Medicine—A Critical Component for ALL Providers



Ken Yanagisawa, MD



James C. Denny III, MD

Ken Yanagisawa, MD

AAO-HNS/F President-Elect

James C. Denny III, MD

AAO-HNS/F Executive Vice President and CEO

The 2021 AAO-HNS Strategic Plan was recently approved by our Board of Directors under the guidance of **Dr. Carol Bradford** and **Dr. James Denny**, and facilitated by Mr. Paul Meyer. Multiple stakeholders and constituent groups provided invaluable input and data that steered and shaped our Strategic Plan into a visionary, focused, and measurable document.

An exciting new component of this year's plan is the "Business of Medicine," which has a goal of supporting and improving the efficiency of otolaryngology practices. Even before COVID-19 struck, practices sought guidance and tips for navigating the increasingly complex network of state and federal regulations, ever-changing insurer requirements, and a variety of reimbursement and coding dilemmas.

During the height of the pandemic, the Academy offered incredible clinical practice advice and key means to access the various federal stimulus and loan programs that were offered to assist practices through the darkest COVID-19 times. As we emerge from the pandemic turmoil, ALL practitioners in every practice setting can benefit from practice management guidance. The purpose of the

"Business of Medicine" program is to raise awareness of the many resources that the Academy offers, to share instructive member experiences, to advocate for improvements and stability related to reimbursement issues, and to lessen administrative burdens.

Among the existing resources, the Board of Governors (BOG), chaired by **Dr. Lance Manning**, facilitates information and issues in a bidirectional fashion between the Board of Directors and local, state, regional, and national otolaryngology-head and neck surgery organizations. The BOG Socioeconomic and Grassroots Committee, chaired by **Dr. Andrew Coughlin**, identifies issues of government regulations and third-party actions that impact medical practices. Our 10 dedicated BOG Regional Representatives around the country (modeled after the U.S. Health and Human Services Region Map) as well as our BOG Specialty Regional Representative, collect information and discuss these issues under the guidance of our BOG Member-at-Large, **Dr. David Boiesoneau**. Any relevant items are presented for further review and investigation.

Our Academy's Physician Payment Policy (3P) Workgroup—chaired by **Dr. R. Peter Manes**, the Academy's Coordinator for Advocacy—works continuously on our behalf to aid practices in facilitating reimbursements for procedures by leading our private payer advocacy efforts, optimizing coding and documentation, and advocating for otolaryngological procedures at the Relative Value Scale Update Committee (RUC) and the AMA Current Procedural Terminology (CPT) Editorial Panel meetings. Additionally, it promotes and updates resources such as our Position Statements and Clinical Indicators.

The objectives for the new "Business of Medicine" program include:

- Advocate for appropriate reimbursement and diminished administrative burdens.

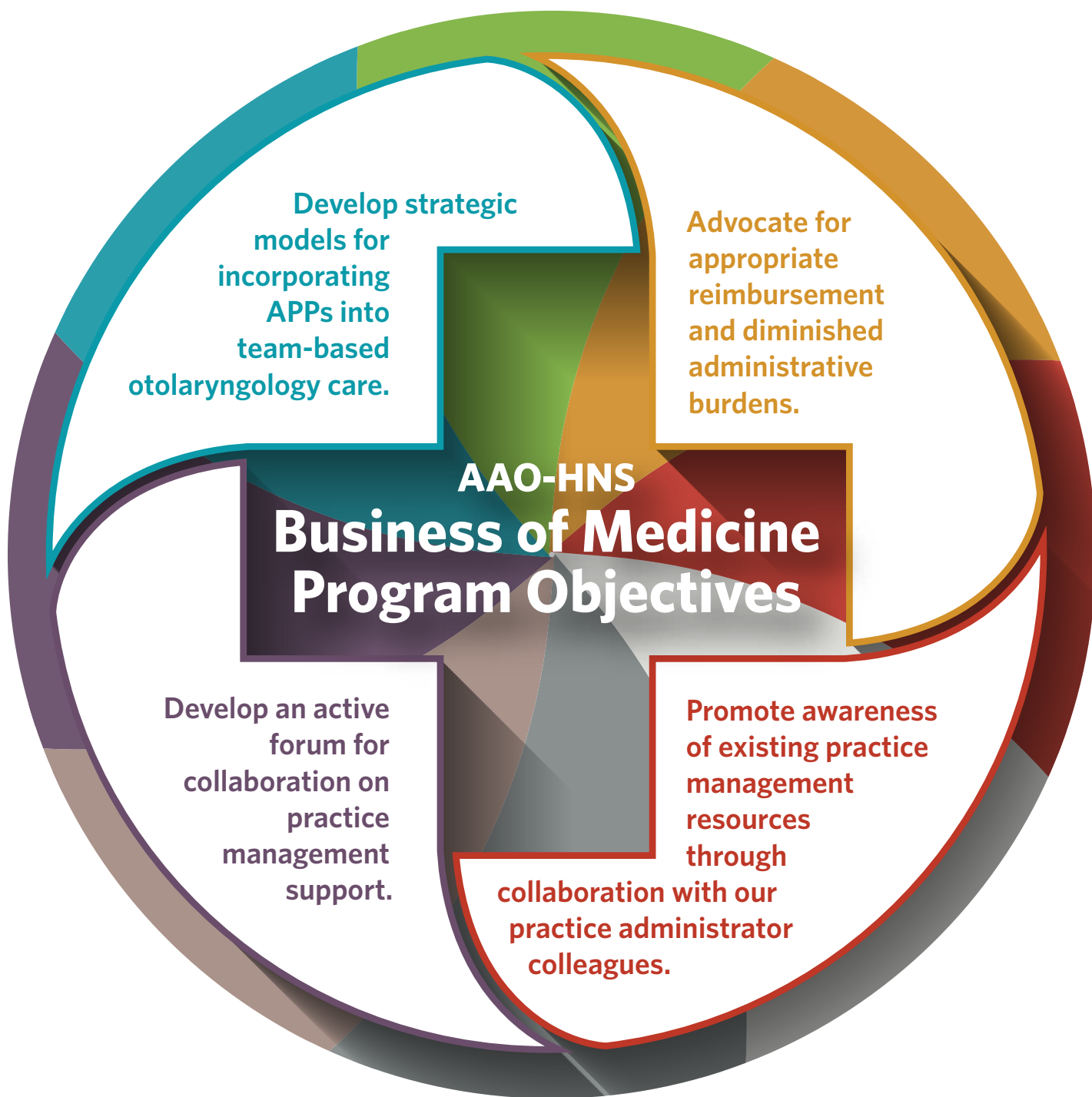
- Promote awareness of existing practice management resources through collaboration with our practice administrator colleagues.
- Develop an active forum for collaboration on practice management support.
- Develop strategic models for incorporating advanced practice providers (APPs) into team-based otolaryngology care.

An assortment of venues and approaches will be utilized to attain these objectives. Some of the planned strategies to deliver these goals include:

- Presenting regular virtual town halls on topics of interest.
- Continuing and improving "Business of Medicine" program offerings at the AAO-HNSF Annual Meeting & OTO Experience.
- Creating a forum for managing physicians and providers to exchange information.
- Working to disseminate core curriculums to APPs.
- Developing a strategy to share practice efficiency tips and pearls.

Another key element in promoting "Business of Medicine" development will be our evolving partnership and collaboration with the Administrator Support Community for ENT (ASCENT), formerly the Association of Otolaryngology Administrators (AOA). Engaging our administrative support teams will expand our resources, services, and collective awareness of current and ongoing practice management concerns.

Providers in every practice model (private practice, employment models, and hybrid models) all share the need to improve efficiency, improve reimbursements, and understand the multitude of mandates expected of physicians and providers and measurement tools utilized to gauge our provision of care. The Academy has a great deal of practice information already



available online at www.entnet.org/content/practice-management.

The mission of this “Business of Medicine” division is to broadcast and raise awareness of the valuable information currently available and to maximize the collaborative efforts of the many stakeholders, programs, and resources at our fingertips. It will also promote discussion and education

through a variety of media—accessible to all Academy members—including lectures, town halls, or online forums, to name just a few. Equally important is for members to identify their most pressing needs and issues to understand the avenues of notifying our Academy of these concerns and to proactively submit the information necessary to intervene on their and their colleagues’

behaves. Armed with this information, the Academy can hone, improve, and tailor the content and the delivery of our “Business of Medicine” content.

It is inspiring to develop this “Business of Medicine” element of the Strategic Plan, and we look forward to hearing from members for thoughts, feedback, and contributions to this vital project. ■



Tele-otolaryngology: Through the Pandemic, and Beyond

Interim findings of the Study of Telehealth in Otolaryngology

AAO-HNS Telemedicine & Telehealth Working Group

The COVID-19 pandemic created a set of conditions that served as an accelerator for telemedicine over the past year. Lockdown restrictions often made virtual visits the only means of patient care, telemedicine platforms embraced improvements to the user experience, and insurance policies adapted to accommodate reimbursements for this new form of care. The AAO-HNS Telemedicine Working Group is actively reflecting on telemedicine experiences among otolaryngologists. What worked and what should be improved? Importantly, what could work but requires support or investigation? What do we carry forward in our practices?

These are questions we seek to answer with the Telehealth in Otolaryngology study. The aims of this study are:

- To understand tele-otolaryngology practice patterns
- To identify barriers to tele-otolaryngology use
- To identify ways that the AAO-HNS can support providers

- To define potential use cases for tele-otolaryngology for future outcomes studies

We performed an interim analysis of data collected to date from 405 respondents. The following are a few key findings:

- **Tele-otolaryngology will see sustained use post-pandemic.** Of 282 (70%) who answered questions about practice volume, 99% reported increased use of telemedicine during the pandemic. Eighty-eight percent reported that they intend to increase use of telemedicine post-pandemic, compared to pre-pandemic. Sixty-five percent had not used telemedicine prior to the pandemic. Among these telemedicine-naïve providers, 85% reported that they intend to continue using telemedicine after the pandemic.
- **Providers, patients, and organizations have developed some degree of comfort with telemedicine.** Ninety percent of providers are comfortable identifying patients appropriate for telemedicine visits, and 76% believe that patients have responded favorably to the use of telemedicine as part of their care. Fifty-four

percent are personally motivated to increase telemedicine use, and 62% believe their organizations are motivated to increase use. Meanwhile, a majority do not believe that telemedicine will contribute to their burnout.

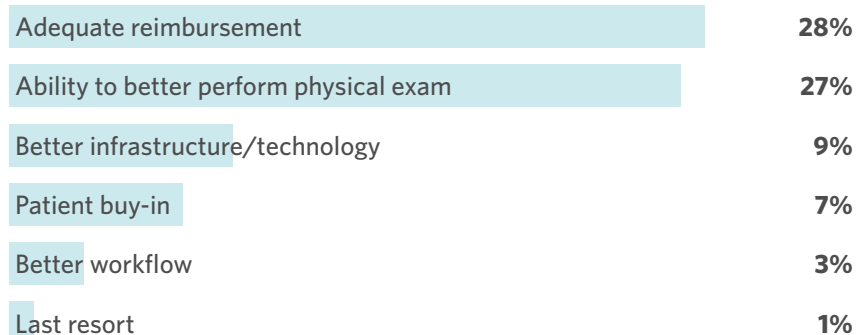
- **Barriers and concerns:** Reimbursement, ability to perform physical exam, and infrastructure and technology are the three top barriers to telemedicine use.

Thank you to those who participated in this pilot phase of the survey. We are grateful to learn from your experiences. The next phase of the survey will expand representation, incorporating input from a broader constituent base while capturing the evolving perspectives shaped by the latest stages of the pandemic. **Please watch for an email invitation to participate.** We appreciate your help in informing how we can help develop practices to safely and effectively care for patients remotely. ■

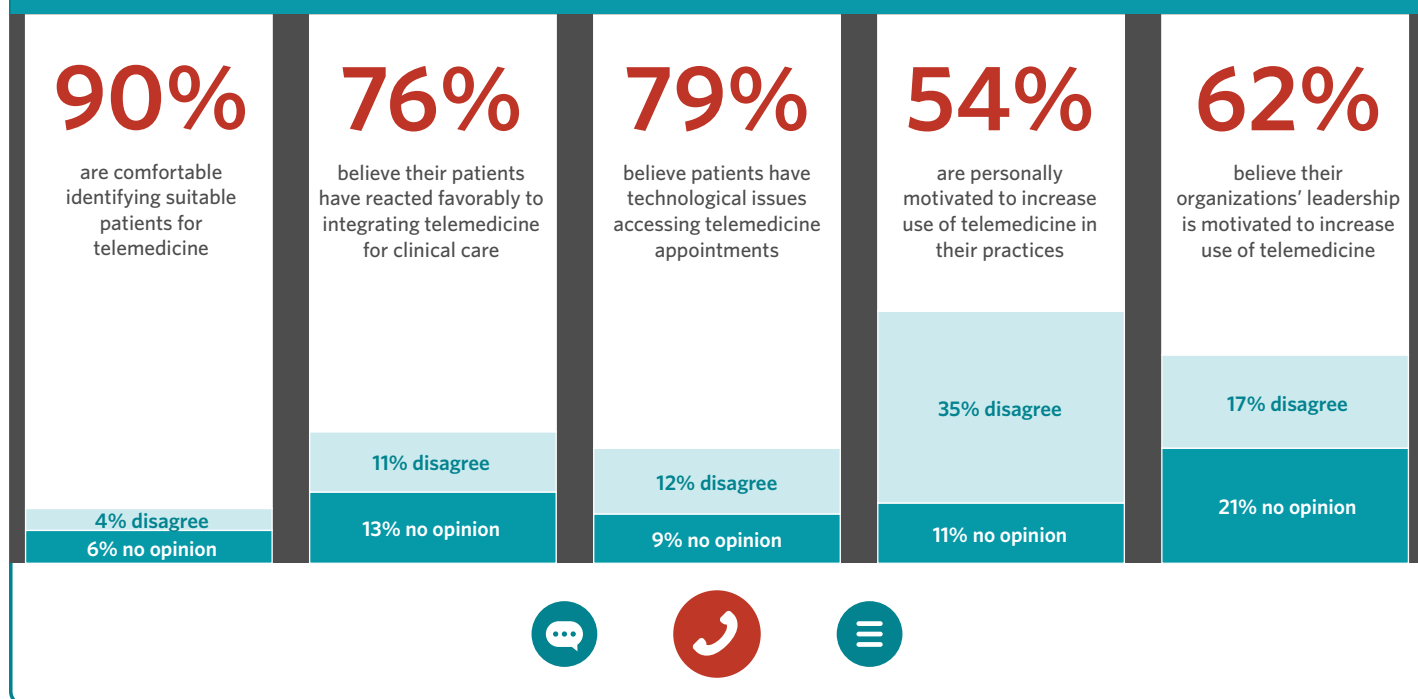
AAO-HNS Telemedicine & Telehealth Working Group

Jessica R. Levi, MD; Victoria X. Yu, MD; Anthony Y. Cheung, MD; Jonathan Overdevest, MD, PhD; and Douglas M. Hildrew, MD

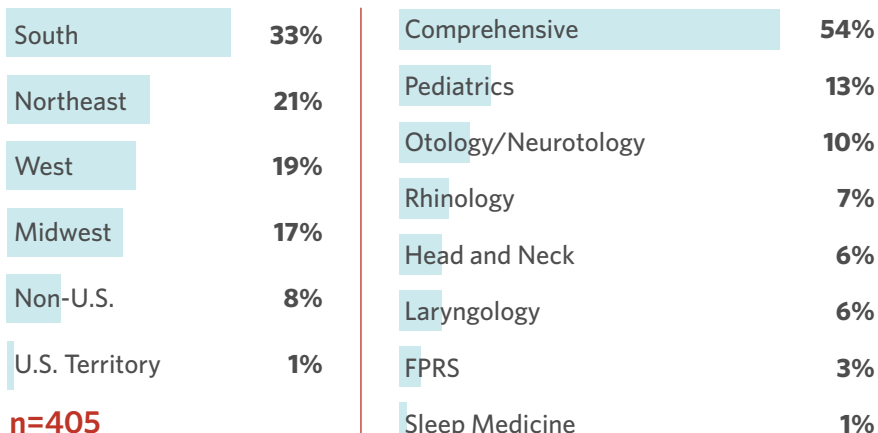
What would convince otolaryngologists to use telemedicine more often?



What do otolaryngologists think about telemedicine?



Respondent Demographics





OUT OF COMMITTEE: OUTCOMES RESEARCH AND EVIDENCE-BASED MEDICINE

Growing the Evidence Base for Healthcare Disparities and Social Determinants of Health Research in Otolaryngology–Head and Neck Surgery

Uchekwukwu Megwalu, MD, MPH; Nikhila P. Raol, MD, MPH; Allison K. Ikeda, MD; Victoria S. Lee, MD; Li Xing Man, MD; Jennifer J. Shin, MD, SM; and Michael J. Brenner, MD

Take two men, Ben and Larry, both diagnosed with oropharyngeal cancer in 2015. Ben is a software engineer for a thriving tech company with employer-based insurance; Larry earns minimum wage at a fast-food restaurant, has limited access to medical care, struggles to pay rent, and cannot miss work. Ben's tumor was detected at an early stage. Ben had timely initiation of therapy, and he is currently alive and disease free—considered cured five years out. Larry was diagnosed with advanced disease, underwent chemoradiation, and suffered recurrence. He underwent salvage surgery but died in 2017. Now suppose that Ben is White and Larry is Black.

A Tale of Two Tumors or of Structural Inequity?

The preceding depiction is disquieting because it lays bare how inequities in access to care translate into starkly different outcomes. Even if one matched Ben and Larry for tumor stage at presentation, medical morbidities, HPV-positive tumor status, and any number of other biological variables, disparate outcomes would still persist at the population level. While outcomes may differ as a function of disease characteristics, social determinants of health and structural inequities underlie health disparities. The National Library of Medicine defines health disparities as variation in rates of disease occurrence and disabilities between socioeconomic and/or geographically defined population groups. Systemic inequity in healthcare access and outcomes across race and wealth has long been evident in the United States healthcare system.

At the 1966 Chicago Convention of the Medical Committee for Human Rights, Martin Luther King, Jr. observed that “Of all the forms of inequality, injustice in health care is the most shocking and inhumane.” Yet, progress on the healthcare front has been slow and arduous in the ensuing half century, and there is significant evidence of disparity in otolaryngology-head and neck surgery. The Institute of Medicine, in its 2001 publication, “Crossing the Quality Chasm,” asserted that healthcare should “[n]ot vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status.” Twenty years later, the COVID-19 pandemic has revealed persistent staggering disparities, with Black, Latinx, and Native Americans suffering far higher rates of hospitalization and mortality from COVID-19 compared with non-Hispanic Whites.

What Is the Evidence Base in Otolaryngology–Head and Neck Surgery?

Disparities in access to care and treatment outcomes have been documented in several areas of our specialty, including head and neck cancer, pediatric sleep apnea, and hearing loss. In addition to clinical risk factors, sociodemographic factors—such as race/ethnicity, gender, socioeconomic status, geography, and insurance status—exert powerful influences on health. Among patients with head and neck cancer, Black patients and patients with Medicaid or no insurance are less likely to receive appropriate treatment. Several studies have also shown that low socioeconomic status is associated with later stage at diagnosis and worse survival in patients with head and neck cancer. Black patients are more likely to be socioeconomically disadvantaged, further increasing the likelihood of presenting with advanced stage disease. Racial disparities also exist in the pediatric otolaryngology population, where Black children with sleep-disordered breathing are less likely to undergo adenotonsillectomy than other racial groups despite higher rates of disease. Studies of children with allergic rhinitis have shown that racial/ethnic minorities and those enrolled in Medicaid have higher sensitization, poorer control, and less access to care.

Significant disparities are also associated with insurance status, a pattern best documented in patients with head and neck cancer. Uninsured and Medicaid patients are more likely to present with advanced disease, are less likely to receive appropriate treatment, and have worse survival, even after adjusting for disease stage and treatment received. Because racial/ethnic minorities are also more likely to be uninsured or underinsured, the



Call for Papers: Health Inequity

Otolaryngology–Head and Neck Surgery is seeking papers relevant to diversity, equity, and inclusion in otolaryngology-head and neck surgery for a themed issue to be published in Summer 2022. The deadline to submit your manuscript is December 20, 2021, 11:59 pm (ET). Learn more at <http://info.sagepub.com/q/15Y1IOQOZIsFCi6Wym/wv>.



IN/EQUALITY

interactions between race/ethnicity, insurance status, and socioeconomic status further drive racial disparities in health outcomes.

Beyond Defining the Problem

Growing the evidence base on disparities is but the first step in health disparities research, which has been described as having three phases: detecting, understanding, and reducing. Most disparities research in otolaryngology has focused on documenting the scope of the problem; however, evidence for what works to resolve these disparities remains disappointingly thin. It is time for us to engage a broad variety of investigators who will purposefully identify, implement, and rigorously test viable solutions.

Identifying these solutions requires an in-depth understanding of the drivers of disparities. These drivers are often complex and multifactorial, requiring a multilevel approach. Variation in quality of care exacerbates disparities in health outcomes. Several studies have shown that racial minorities are more likely to receive treatment in low-quality hospitals. Addressing variation in quality of care should be a priority for clinicians because quality of care is an actionable target within the control of clinicians. Quality improvement projects aimed at achieving better outcomes at low-performing hospitals may help mitigate disparities.

There is a paucity of data on what is reliably effective to address disparities, and otolaryngology-head and neck surgery as a specialty has a responsibility for generating valid knowledge and evidence. Grant mechanisms are needed to support new investigators committed to studying disparities and to delivering equitable outcomes. Our

specialty needs to attract a variety of researchers in all subspecialties and career stages.

Disparities research has inherent appeal to many and need not be confined to a select few. Considering the health-related consequences of social determinants of health, measured in quality and quantity of life, there is an urgent need for such work.

Confronting Bias in Clinical Practice and Growing the Research Pipeline

Every cross-cultural patient-provider encounter is an opportunity to improve understanding and address disparities. Provider attitudes toward patients based on age, disability, ethnicity, gender, gender identity, geographic location, primary language, race, religion, sexual orientation, and socioeconomic status can negatively impact care for disadvantaged patients. Implicit bias includes unconscious thoughts and feelings toward others and has been shown to negatively impact the patient-provider interactions, treatment decisions, treatment adherence, and health outcomes. Clinicians should be mindful of their implicit biases in order to try to reduce them and promote health equity. Otolaryngologists can also aspire to cultural humility, a concept that, in contrast to cultural competency, recognizes an ongoing need for learning without a defined endpoint, as well as efforts to recognize and reduce power differentials.

There is also a pressing need to improve the diversity of the otolaryngology workforce. Black and Hispanic physicians are significantly underrepresented in otolaryngology. There is evidence for improved patient-provider interactions when

racial/ethnic minority patients are seen by physicians of similar racial/ethnic or gender backgrounds. For example, receptiveness to recommended therapy increases, barriers to trust may be diminished, and risk of bias is reduced. A diverse workforce can also invigorate research efforts. The small numbers of diverse surgeon scientists will only grow if our specialty commits to purposeful outreach at key transition points and to providing the resources to execute the science. Improving the diversity of the workforce thus can improve ability to meet the needs of diverse communities.

Conclusion

Significant disparities in care and treatment outcomes exist in otolaryngology-head and neck surgery and improving the evidence base in this domain is critical. While there has been significant growth in health disparities research in our specialty, studies thus far have predominantly focused on problem identification. Further progress relies on understanding the drivers of disparities, and then identifying and testing interventions. The future of disparities research will increasingly incorporate implementation science, using a transdisciplinary lens that brings together epidemiology, population health, and healthcare delivery. Through partnership across disciplines, we can improve early detection and treatment as well as preserve quality of life. Success of such efforts is predicated on attracting and supporting new investigators committed to careers in studying disparities. ■

See the online version of this article for a complete list of references used.

OUT OF COMMITTEE: HEARING

Cochlear Implantation for Unilateral Hearing Loss in Adults and Children

Kevin D. Brown, MD, PhD; Daniel M. Zeitler, MD;
and Matthew L. Carlson, MD

Unilateral severe-to-profound sensorineural hearing loss, hereafter unilateral hearing loss (UHL), has been estimated to affect between 12 and 27 per 100,000 adults in the United States and 0.4 to 3.4 per 1,000 live births. In children the incidence rises throughout childhood to a prevalence of 2 to 5 per 1,000 school-aged children. There are known problems with auditory function and speech perception, including difficulty understanding speech in noise, the inability to localize sound on the horizontal plane, and tinnitus.

Intervention for UHL was initially focused on listening devices that reroute sound from the deafened ear to the normal or near-normal hearing ear, such as contralateral routing of signal (CROS) aid or bone-anchored hearing implant (BAHI). These technologies provide access to sound from the poorer hearing side, but do not restore binaural hearing. Speech perception in noise is therefore only improved in selective situations, and conversely the signal from BAHI or CROS can actually interfere with speech perception. Localization of sound is not improved with either BAHI or CROS and neither is tinnitus.

Considerations in the Adult Population

Tinnitus is an important indication for considering cochlear implantation in case of UHL. Electrical stimulation of the peripheral auditory system has been shown to reduce or abolish tinnitus percepts in many adults. Thus, cochlear implantation is particularly appealing for patients with advanced UHL, where conventional hearing aids and masking strategies are generally not effective. Indeed a recent metanalysis reports that over 90%

of adults with single-sided deafness received significant benefit from this approach.

Adults with UHL also suffer from reduced speech perception in quiet and noise as well as difficulty with localizing sound. Two prospective clinical trials, with 20 subjects each (total 40 subjects), were performed as part of a recent Food and Drug Administration (FDA) trial in the U.S. A separate 34-subject prospective trial was performed by a group comprising patients from Australia and Belgium (Tavora-Vieira, Rajan et al. 2019). Another prospective National Institute of Health trial was also performed with an additional 47 subjects for a total of 121 subjects (Firszt, Reeder et al. 2018). Buss et al. demonstrated a mean increase in speech perception in quiet for CNC words from an average of 4% to a mean of 55% with the cochlear implant alone at 12 months after implantation (Buss, Dillon et al. 2018). An improvement in sentence perception was also demonstrated in quiet with multiple talkers (TIMITQ) from 55% correct to 75% when both the acoustic hearing ear and the cochlear implant ear were used together (Firszt, Reeder et al. 2018). As much of human existence occurs in work and social settings in which noise is a constant attendant, speech perception in noise is a more critical metric to determine how subjects are performing. Buss et al. demonstrated an improvement in sentence perception in noise by an average of 36 percentage points (Buss, Dillon et al. 2018). A marked improvement in speech perception in noise was also seen using adaptive tests (Firszt, Reeder et al. 2018, Tavora-Vieira, Rajan et al. 2019). Collectively these data demonstrate improvements in speech perception in quiet and noise with the cochlear implant in comparison to without the implant.

Localization is also markedly improved with the addition of a cochlear implant. An

improvement in localization from an average of 64 degrees RMS error to 25 degrees was demonstrated in the FDA trial, this persisted out to one year (Dillon, Buss et al. 2017, Buss, Dillon et al. 2018). Data from the multicenter trial demonstrated a similar improvement from 60 degrees RMS error to 22 degrees (Tavora-Vieira, Rajan et al. 2019) using the same system. Firszt et al. also showed consistent, significant improvement with an average RMS error improving from 50% to 30% RMS error. These studies demonstrate that patients are able to better determine the direction that sound is coming from after cochlear implantation for unilateral hearing loss.

It is of substantial interest to also determine how the subject perceives the benefits as it relates to their quality of hearing/quality of life. The multicenter trial evaluated subjects before and after implantation using the short form of the Speech, Spatial and Qualities (SSQ12) form. This demonstrated a marked improvement in the SSQ12 score from an average score of 4 to 6 after 5 years of use (Tavora-Vieira, Rajan et al. 2019). Firszt et al. used the full SSQ questionnaire and demonstrated marked, statistically significant improvements in all three domains of the SSQ, including speech, spatial hearing, and qualities of hearing (Firszt, Reeder et al. 2018). They also utilized the Glasgow benefit inventory to determine overall benefit and determined a benefit of a cochlear implant of 37.9 (score of zero would indicate no benefit). The FDA trial data also demonstrated significant benefit of a cochlear implant in the Abbreviated Profile of Hearing Aid Benefit (APHAB) test, most notably showing benefit in situations of background and reverberant noise (Dillon, Buss et al. 2017). Similar marked and significant benefits were seen with speech, spatial, and qualities of hearing in this study as well.



Considerations in the Pediatric Population

Due to the exciting benefits seen in the adult population for cochlear implantation in cases of UHL, it is not surprising that substantial interest has occurred in implanting children with UHL. There are, however, a number of considerations that exist in children that are different than in adults. Due to different etiologies in children with UHL, it becomes critically important to distinguish anatomic contraindications to implantation, including cochlear nerve deficiency and cochlear malformations more severe than Mondini. This is a crucial distinction, as poor outcomes due to distorted cochlear implant signals through a severely malformed cochlea or hypoplastic nerve will likely lead to non-use in the presence of normal hearing in the contralateral ear.

The effects of UHL on children can be similar to adults with some notable considerations. Children with UHL have greater difficulty than their normal hearing peers in both quiet and dynamic listening environments. They also have more difficulty with localizing the source of sound. The key difference is that children, especially younger children, are still developing and learning language. The impacts of UHL on speech and language development as well as psychosocial development in an education setting could be substantial. Children are unable to spatially orient themselves favorably to variable locations of sound source and noise with one hearing ear in a classroom setting.

Accumulated auditory effort from straining to hear could lead to substantial fatigue with further negative impact on learning. Not surprisingly, children with UHL have demonstrated poorer language scores than their hearing peers and are more likely to be held back a grade (Lieu 2018).

With these known substantial impacts, it became critical to perform well-designed studies to address the benefit of cochlear implantation in children with UHL. Retrospective studies and case series have evaluated outcomes in children receiving cochlear implants off-label. These have variably demonstrated improved speech in quiet, improved speech in noise, and better localization of sound. An improvement in subjective measures of speech, spatial, and qualities of hearing also has been seen. Results from a prospective clinical trial (ClinicalTrials.gov identifier NCT02963974) are forthcoming. This study evaluated outcomes in 20 children with UHL following cochlear implantation. This trial demonstrated rapid and consistent increases in speech perception outcomes in quiet and noise, and substantial improvement in sound localization. Subjective quality of hearing was likewise markedly improved especially in subdomains associated with binaural hearing, suggesting that children are now able to appreciate the benefits of binaural hearing. Together these data suggest that children with UHL who undergo CI are now able to access binaural cues that are unable to be provided by any alternative technology.

Restoration of binaural hearing is the standard of care in patients with bilateral hearing loss. Patients with UHL should be no different. Given the consistent and significant improvements in speech perception in quiet and noise, sound localization, suppression of disabling tinnitus, and hearing-related quality of life, CI for UHL was approved by the FDA in 2019 for adults and children ages five years and older. It should be strongly considered as a therapeutic option for interested and motivated adult and pediatric patients with UHL. ■

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Spotlight: Humanitarian Efforts

Robert J. Sinard, MD



Where do you currently practice and what is your specialty area?

Vanderbilt University Medical Center,
Otolaryngology Head and Neck Surgery

What humanitarian efforts are you involved with?

We work with the local and missionary surgeons at Kijabe Hospital in Kijabe, Kenya, teaching them large tumor resections and free flap reconstruction.

What got you started in committing your time and practice to humanitarian efforts?

God called us and provided the opportunity.

How does your work impact the communities you serve and how does it impact you as a person?

The local surgeons are now doing these cases on their own, making Kijabe the only hospital in East Africa with this capability.

This strengthens our faith and the faith of those we serve.

What would you say to encourage others to support humanitarian efforts around the world?

If you are called to go, then go. You will not be disappointed. ■



AAO-HNSF 2021
ANNUAL MEETING & OTO EXPERIENCE
LOS ANGELES, CALIFORNIA | OCTOBER 3-6
WE ARE ONE TWENTY-FIVE

Attend the 2021 Humanitarian Efforts Forum at the AAO-HNSF 2021 Annual Meeting & OTO Experience

October 3-6, 2021, Los Angeles, California

Highlighting the global connection of the otolaryngology-head and neck surgery community, the Humanitarian Efforts Forum features the breadth and depth of work carried out by Academy members. The agenda includes a keynote speaker, presentations by Academy members engaged in volunteer surgical work in low-resource settings, as well as a panel discussion on topics that are relevant to the international otolaryngology community.

This forum is provided as a resource for any Annual Meeting attendee to

learn about volunteer opportunities within otolaryngology-head and neck surgery abroad. It offers engagement and collaboration with international colleagues in volunteer clinical, educational, and research efforts. Whether you are still in training or nearing retirement, the Humanitarian Efforts Forum represents a unique occasion to network with colleagues regarding best practices in humanitarian outreach.

Look for more details and information on the official [Annual Meeting website](#). ■



Brief Summary of Prescribing Information

1 INDICATIONS AND USAGE

1.3 Chronic Rhinosinusitis with Nasal Polyposis

DUPIXENT is indicated as an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP).

4 CONTRAINDICATIONS

DUPIXENT is contraindicated in patients who have known hypersensitivity to dupilumab or any of its excipients [see *Warnings and Precautions* (5.1)].

5 WARNINGS AND PRECAUTIONS

5.1 Hypersensitivity

Hypersensitivity reactions, including generalized urticaria, rash, erythema nodosum and serum sickness or serum sickness-like reactions, were reported in less than 1% of subjects who received DUXIPENT in clinical trials. If a clinically significant hypersensitivity reaction occurs, institute appropriate therapy and discontinue DUXIPENT [see *Adverse Reactions* (6.1, 6.2)].

5.2 Conjunctivitis and Keratitis

In subjects with CRSwNP, the frequency of conjunctivitis was 2% in the DUXIPENT group compared to 1% in the placebo group in the 24-week safety pool; these subjects recovered. There were no cases of keratitis reported in the CRSwNP development program [see *Adverse Reactions* (6.1)].

Advise patients to report new onset or worsening eye symptoms to their healthcare provider.

5.3 Eosinophilic Conditions

Patients being treated for asthma may present with serious systemic eosinophilia sometimes presenting with clinical features of eosinophilic pneumonia or vasculitis consistent with eosinophilic granulomatosis with polyangiitis, conditions which are often treated with systemic corticosteroid therapy. These events may be associated with the reduction of oral corticosteroid therapy. Physicians should be alert to vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy presenting in their patients with eosinophilia. Cases of eosinophilic pneumonia were reported in adult patients who participated in the asthma development program and cases of vasculitis consistent with eosinophilic granulomatosis with polyangiitis have been reported with DUXIPENT in adult patients who participated in the asthma development program as well as in adult patients with co-morbid asthma in the CRSwNP development program. A causal association between DUXIPENT and these conditions has not been established.

5.5 Reduction of Corticosteroid Dosage

Do not discontinue systemic, topical, or inhaled corticosteroids abruptly upon initiation of therapy with DUXIPENT. Reductions in corticosteroid dose, if appropriate, should be gradual and performed under the direct supervision of a physician. Reduction in corticosteroid dose may be associated with systemic withdrawal symptoms and/or unmask conditions previously suppressed by systemic corticosteroid therapy.

5.6 Patients with Comorbid Asthma

Advise patients with CRSwNP who have co-morbid asthma not to adjust or stop their asthma treatments without consultation with their physicians.

5.7 Parasitic (Helminth) Infections

Patients with known helminth infections were excluded from participation in clinical studies. It is unknown if DUXIPENT will influence the immune response against helminth infections.

Treat patients with pre-existing helminth infections before initiating therapy with DUXIPENT. If patients become infected while receiving treatment with DUXIPENT and do not respond to antihelminth treatment, discontinue treatment with DUXIPENT until the infection resolves.

6 ADVERSE REACTIONS

The following adverse reactions are discussed in greater detail elsewhere in the labeling:

- Hypersensitivity [see *Warnings and Precautions* (5.1)]
- Conjunctivitis and Keratitis [see *Warnings and Precautions* (5.2)]

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.

Chronic Rhinosinusitis with Nasal Polyposis

A total of 722 adult subjects with chronic rhinosinusitis with nasal polyposis (CRSwNP) were evaluated in 2 randomized, placebo-controlled, multicenter trials of 24 to 52 weeks duration (CSNP Trials 1 and 2). The safety pool consisted of data from the first 24 weeks of treatment from both studies.

In the safety pool, the proportion of subjects who discontinued treatment due to adverse events was 5% of the placebo group and 2% of the DUXIPENT 300 mg Q2W group.

Table 4 summarizes the adverse reactions that occurred at a rate of at least 1% in subjects treated with DUXIPENT and at a higher rate than in their respective comparator group in CSNP Trials 1 and 2.

Table 4: Adverse Reactions Occurring in ≥1% of the DUXIPENT Group in CRSwNP Trials 1 and 2 and Greater than Placebo (24 Week Safety Pool)

Adverse Reaction	CSNP Trial 1 and Trial 2	
	DUPIXENT 300 mg Q2W N=440 n (%)	Placebo N=282 n (%)
Injection site reactions ^a	28 (6%)	12 (4%)
Conjunctivitis ^b	7 (2%)	2 (1%)
Arthralgia	14 (3%)	5 (2%)
Gastritis	7 (2%)	2 (1%)
Insomnia	6 (1%)	0 (<1%)
Eosinophilia	5 (1%)	1 (<1%)
Toothache	5 (1%)	1 (<1%)

^a Injection site reactions cluster includes injection site reaction, pain, bruising and swelling.

^b Conjunctivitis cluster includes conjunctivitis, allergic conjunctivitis, bacterial conjunctivitis, viral conjunctivitis, giant papillary conjunctivitis, eye irritation, and eye inflammation.

The safety profile of DUXIPENT through Week 52 was generally consistent with the safety profile observed at Week 24.

Specific Adverse Reactions

Conjunctivitis

In the 52-week CRSwNP study (CSNP Trial 2), the frequency of conjunctivitis was 3% in the DUXIPENT subjects and 1% in the placebo subjects; all of these subjects recovered [see *Warnings and Precautions* (5.2)].

Eczema Herpeticum and Herpes Zoster

Among CRSwNP subjects there were no reported cases of herpes zoster or eczema herpeticum.

Hypersensitivity Reactions

Hypersensitivity reactions were reported in <1% of DUXIPENT-treated subjects. These included serum sickness reaction, serum sickness-like reaction, generalized urticaria, rash, erythema nodosum, and anaphylaxis [see *Contraindications* (4), *Warnings and Precautions* (5.1), and *Adverse Reactions* (6.2)].

Eosinophils

DUXIPENT-treated subjects had a greater initial increase from baseline in blood eosinophil count compared to subjects treated with placebo. In subjects with CRSwNP, the mean and median increases in blood eosinophils from baseline to Week 16 were 150 and 50 cells/mL, respectively.

Across all indications, the incidence of treatment-emergent eosinophilia (≥500 cells/mL) was similar in DUXIPENT and placebo groups. Treatment-emergent eosinophilia (≥5,000 cells/mL) was reported in <2% of DUXIPENT-treated patients and <0.5% in placebo-treated patients. Blood eosinophil counts declined to near baseline levels during study treatment [see *Warnings and Precautions* (5.3)].

Cardiovascular (CV)

In the 24-week placebo controlled trial in subjects with CRSwNP (CSNP Trial 1), CV thromboembolic events (CV deaths, non-fatal myocardial infarctions, and non-fatal strokes) were reported in 1 (0.7%) of the DUXIPENT group and 0 (0.0%) of the placebo group. In the 1-year placebo controlled trial in subjects with CRSwNP (CSNP Trial 2), there were no cases of CV thromboembolic events (CV deaths, non-fatal myocardial infarctions, and non-fatal strokes) reported in any treatment arm.

6.2 Immunogenicity

As with all therapeutic proteins, there is a potential for immunogenicity. The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors, including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to dupilumab in the studies described below with the incidence of antibodies in other studies or to other products may be misleading.

Approximately 5% of subjects with atopic dermatitis, asthma, or CRSwNP who received DUXIPENT 300 mg Q2W for 52 weeks developed antibodies to dupilumab; ~2% exhibited persistent ADA responses, and ~2% had neutralizing antibodies.

Regardless of age or population, ~2% to 4% of subjects in placebo groups were positive for antibodies to DUXIPENT; ~2% exhibited persistent ADA responses, and ~1% had neutralizing antibodies.

The antibody titers detected in both DUXIPENT and placebo subjects were mostly low. In subjects who received DUXIPENT, development of high titer antibodies to dupilumab was associated with lower serum dupilumab concentrations [see *Clinical Pharmacology* (12.3) in the full *Prescribing Information*].

Two adult subjects who experienced high titer antibody responses developed serum sickness or serum sickness-like reactions during DUXIPENT therapy [see *Warnings and Precautions* (5.1)].

6.3 Postmarketing Experience

The following adverse reactions have been identified during postapproval use of DUPIXENT. 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.

Skin and subcutaneous tissue disorders: Facial Rash

7 DRUG INTERACTIONS

7.1 Live Vaccines

Avoid use of live vaccines in patients treated with DUPIXENT.

7.2 Non-Live Vaccines

Immune responses to vaccination were assessed in a study in which subjects with atopic dermatitis were treated once weekly for 16 weeks with 300 mg of dupilumab (twice the recommended dosing frequency). After 12 weeks of DUPIXENT administration, subjects were vaccinated with a Tdap vaccine (Adacel®) and a meningococcal polysaccharide vaccine (Menomune®). Antibody responses to tetanus toxoid and serogroup C meningococcal polysaccharide were assessed 4 weeks later. Antibody responses to both tetanus vaccine and meningococcal polysaccharide vaccine were similar in dupilumab-treated and placebo-treated subjects. Immune responses to the other active components of the Adacel and Menomune vaccines were not assessed.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Exposure Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to DUPIXENT during pregnancy.

Please contact 1-877-311-8972 or go to <https://mothertobaby.org/ongoing-study/dupixent/> to enroll in or to obtain information about the registry.

Risk Summary

Available data from case reports and case series with DUPIXENT use in pregnant women have not identified a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. Human IgG antibodies are known to cross the placental barrier; therefore, DUPIXENT may be transmitted from the mother to the developing fetus. In an enhanced pre- and post-natal developmental study, no adverse developmental effects were observed in offspring born to pregnant monkeys after subcutaneous administration of a homologous antibody against interleukin-4-receptor alpha (IL-4Rα) during organogenesis through parturition at doses up to 10-times the maximum recommended human dose (MRHD) (*see Data*). The estimated background risk of major birth defects and miscarriage for the indicated populations are unknown. All pregnancies have a background risk of birth defect, loss or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Data

Animal Data

In an enhanced pre- and post-natal development toxicity study, pregnant cynomolgus monkeys were administered weekly subcutaneous doses of homologous antibody against IL-4Rα up to 10-times the MRHD (on a mg/kg basis of 100 mg/kg/week) from the beginning of organogenesis to parturition. No treatment-related adverse effects on embryofetal toxicity or malformations, or on morphological, functional, or immunological development were observed in the infants from birth through 6 months of age.

8.2 Lactation

Risk Summary

There are no data on the presence of dupilumab in human milk, the effects on the breastfed infant, or the effects on milk production. Maternal IgG is known to be present in human milk. The effects of local gastrointestinal and limited systemic exposure to dupilumab on the breastfed infant are unknown. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for DUPIXENT and any potential adverse effects on the breastfed child from DUPIXENT or from the underlying maternal condition.

8.4 Pediatric Use

CRSwNP

CRSwNP does not normally occur in children. Safety and efficacy in pediatric patients (<18 years of age) with CRSwNP have not been established.

8.5 Geriatric Use

Of the 440 subjects with CRSwNP exposed to DUPIXENT, a total of 79 subjects were 65 years or older. Efficacy and safety in this age group were similar to the overall study population.

10 OVERDOSE

There is no specific treatment for DUPIXENT overdose. In the event of overdosage, monitor the patient for any signs or symptoms of adverse reactions and institute appropriate symptomatic treatment immediately.

17 PATIENT COUNSELING INFORMATION

Advise the patients and/or caregivers to read the FDA-approved patient labeling (Patient Information and Instructions for Use).

Pregnancy Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to DUPIXENT during pregnancy. Encourage participation in the registry [*see Use in Specific Populations (8.1)*].

Administration Instructions

Provide proper training to patients and/or caregivers on proper subcutaneous injection technique, including aseptic technique, and the preparation and administration of DUPIXENT prior to use. Advise patients to follow sharps disposal recommendations [*see Instructions for Use*].

Hypersensitivity

Advise patients to discontinue DUPIXENT and to seek immediate medical attention if they experience any symptoms of systemic hypersensitivity reactions [*see Warnings and Precautions (5.1)*].

Conjunctivitis and Keratitis

Advise patients to consult their healthcare provider if new onset or worsening eye symptoms develop [*see Warnings and Precautions (5.2)*].

Eosinophilic Conditions

Advise patients to notify their healthcare provider if they present with clinical features of eosinophilic pneumonia or vasculitis consistent with eosinophilic granulomatosis with polyangiitis [*see Warnings and Precautions (5.3)*].

Reduction in Corticosteroid Dosage

Inform patients to not discontinue systemic or inhaled corticosteroids except under the direct supervision of a physician. Inform patients that reduction in corticosteroid dose may be associated with systemic withdrawal symptoms and/or unmask conditions previously suppressed by systemic corticosteroid therapy [*see Warnings and Precautions (5.5)*].

Patients with Comorbid Asthma

Advise patients with atopic dermatitis or CRSwNP who have comorbid asthma not to adjust or stop their asthma treatment without talking to their physicians [*see Warnings and Precautions (5.6)*].

AAO-HNSF 2021 ANNUAL MEETING & OTO EXPERIENCE



**Registration
Opens in June**





New Innovative Program Offerings for 2021

Daniel C. Chelius, Jr., MD

Annual Meeting Program Coordinator

As I sit here writing, I've just finished watching a thought-provoking discussion on the state of pediatric otolaryngology from the American Society of Pediatric Otolaryngology (ASPO) annual meeting. Like many of our members, I attended the Combined Otolaryngology Spring Meetings (COSM) virtually April 7-11, tuning in for live-streamed education offerings from ASPO and the American Head and Neck Society (AHNS). As we've all experienced so often during the pandemic, the formal meetings were on my computer screen while text messages, emails, and other real-time electronic communications from friends, colleagues, and collaborators streamed through my phone. Sometimes these notes were the digital equivalent of leaning over to whisper an observation about a scientific presentation or an idea for a new study. Other times they were a chance to congratulate my friends on a new position or a great talk, albeit delivered from across the country or the world. Of course, we had to catch up on families and careers, substituting laughter in the hall outside a meeting room for smiling emojis. Uniformly the conversations ended with the same sentiments—I can't wait to see you again and to do this together.

Our 125th AAO-HNSF Annual Meeting & OTO Experience will be an important time

of reconnection, education, and inspiration. The necessity of meeting remotely during the pandemic has cast sharp focus on how precious our time together is. As **Blake C. Papsin, MD**, implored the ASPO and Triologic Society audience that weekend in April, it is critical for us to come together outside our narrow subspecialty silos to participate in the greater otolaryngology community and the greater house of medicine because that is where we can begin to solve our society's biggest problems. Our Annual Meeting Program Committee (AMPC) and our Academy staff have been working diligently to organize a meeting under the uncertainty inherent in the pandemic that will still provide the background structure on which we can move both our individual practices and our entire field forward.

With over 1,400 submissions, the response to our Annual Meeting Call for Science was incredible, despite the restrictions of the pandemic. Presenter notifications will be sent in May. While we will enjoy many of the presentation formats and themes that have been solidified over the meetings of the past decades, we will continue to incorporate new platforms and focuses, both to meet our attendees' education needs and to restructure the discussion around important topics.

One highlight of the meeting will be our new **Otolaryngology–Head and Neck Surgery Great Debates** series. I'm grateful to **Cecelia Damask, DO**, and **Richard K.**

Gurgel, MD, who led our AMPC Education Innovation Strategic Team in crafting the platform. The AMPC education track leaders have collaborated with the AAO-HNSF Education Committees and associated subspecialty societies to identify contentious issues deserving of our collective focus and deliberation as well as prominent thought leaders who can push these discussions forward via structured debate. While speaker confirmations and scheduling are ongoing, the topics are set and reflect timely and critical issues in our community (see the sidebar).

This year's Annual Meeting also will launch our new **Personal and Professional Development (PPD)** education track with the aim to improve our individual ability to most effectively provide the care that we work so hard to discover—to optimize and to revolutionize in the clinical subspecialty tracks. The PPD subgroup, led by **Minka L. Schofield, MD**, received exceptional proposals on a wide range of topics including wellness, communication, leadership, mentorship, community engagement, and equity in healthcare and in the house of medicine.

In most of the side conversations during COSM, friends also asked me if we'll really be meeting live in Los Angeles, California, this fall. The most honest answer is that we are planning for it, and I truly hope so. We will have to see how the California health and safety guidelines change this summer and what our travel capabilities are. In all our planning for the live meeting, we are building virtual contingencies and creating a flexible plan to meet October's circumstances, whatever they may be.

As I finish writing this article, I had the opportunity to also attend the AAO-HNSF 2021 Leadership Forum & BOG Spring Meeting, held on April 17. **Lance A. Manning, MD**, Board of Governors Chair, put together an exciting and relevant program that also allowed time set aside to see so many dear friends and to honor their work over this past year. But now with that meeting over, I'm looking forward to being together in LA. ■

AAO-HNSF 2021 Annual Meeting & OTO Experience Great Debates Series

Does Volume Matter in Otolaryngology—Head and Neck Surgery?

Deintensification for HPV-associated Tumors: Are We There Yet?

Take It or Leave It: Intracapsular Versus Extracapsular Tonsillectomy for OSA

Biologics for Nasal Polyps: Is This the End of Sinus Surgery?

Meniere's Disease: Medical Versus Surgical Management

The Future of the Practice of Otolaryngology: Private Practice, Academics, and Contemporary Models

Is Hypoglossal Nerve Stimulation the Future of Sleep Surgery?

PPIs: Angels or Demons?

Facial Plastic & Reconstructive Surgery Great Debate Topic TBD

Special 125th Anniversary Presidents' Reception: A Celebration of the Specialty as One

The otolaryngology-head and neck surgery community has risen to the occasion time and again over the course of the Academy's 125-year history to strive for the highest quality patient care.

*It is time to celebrate **THAT**.*

What has been experienced by our community and our patients over the past year and a half in the face of the COVID-19 pandemic specifically is unprecedented.

*It is time to celebrate **US**.*

While we have returned to practice and persevered through this pandemic and communicated via many preferred online meeting and gathering platforms (i.e., Zoom, Teams, Google, Facetime, etc.), we have so missed the in-person camaraderie, networking, and learning that happens face to face.

*It is time to celebrate **TOGETHER**.*

There has been much thought and attention devoted to the planning of the Presidents' Reception, which is scheduled for Saturday evening to kick off the 125th anniversary celebratory events taking place throughout the Annual Meeting. It will be an unforgettable occasion marking the Academy's long history of specialty unity with current and past presidents of the Academy as well as those of all specialty

societies participating in our meeting programming this year.

Make plans to arrive early in LA to attend this can't-miss Presidents' Reception. Held just steps from the STAPLES Center and Microsoft Theater, home to The Emmys, ESPYs, and American Music Awards red carpets, Xbox Plaza provides the perfect backdrop for affording attendees ample time and space to connect with colleagues

from coast to coast and around the globe—something that has been sorely missed in our interactions throughout the pandemic.

This high-profile networking event creates the much-anticipated opportunity to reunite with the specialty and celebrate the Academy's monumental 125th anniversary. Kick off your #OTOMTG125 experience by meeting new friends and reconnecting with old friends in the heart of LA. ■



JOIN US

AAO-HNSF 2021 Annual Meeting & OTO Experience Presidents' Reception

NEW DATE! Saturday, October 2

6:30-8:30 pm (PT)

Xbox Plaza

Los Angeles, California

Presidents' Reception Memories



Presidents' Reception at the AAO-HNSF 2016 Annual Meeting & OTO Experience in San Diego, California, on the balcony of the convention center.

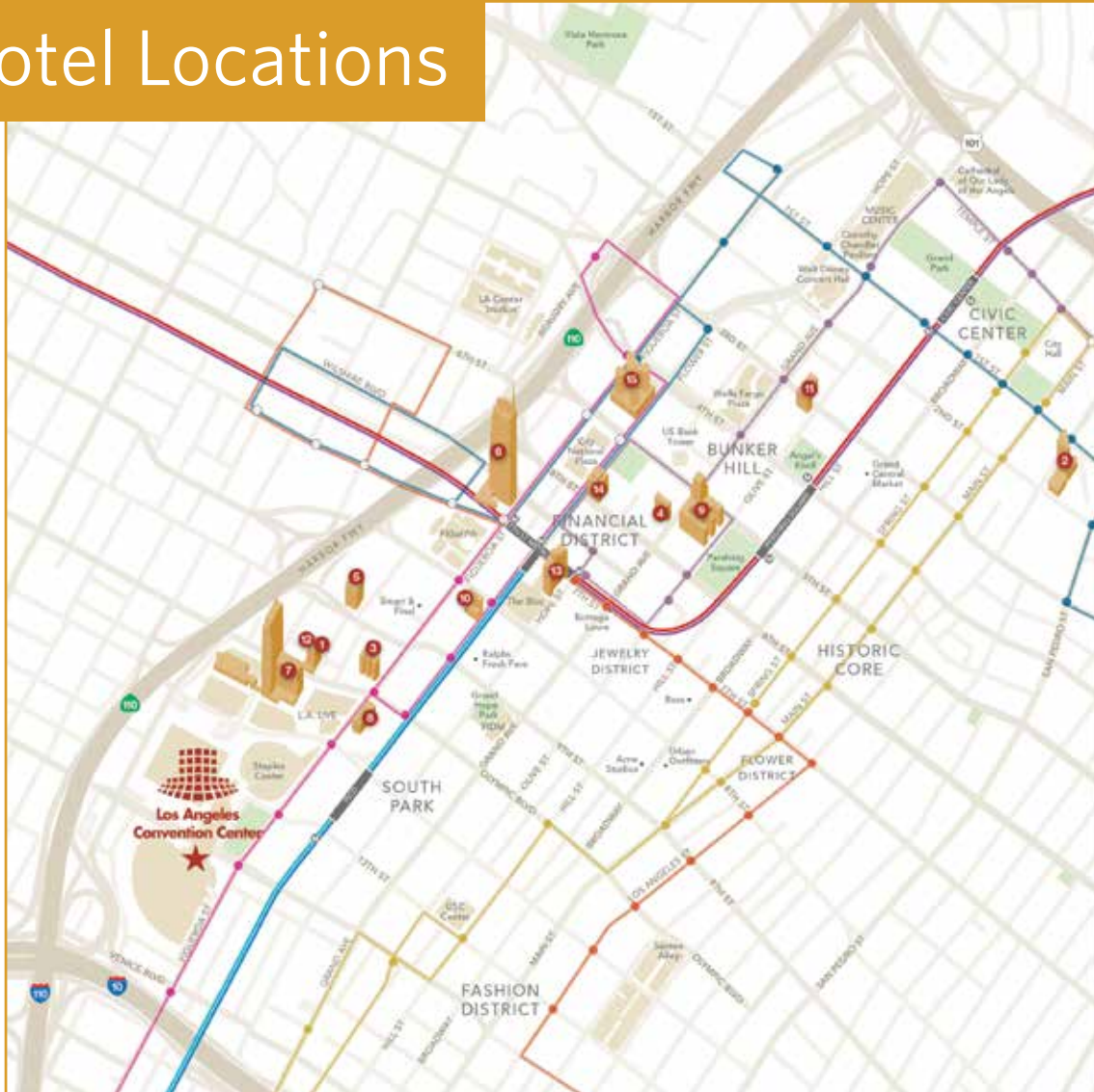


Presidents' Reception at the AAO-HNSF 2018 Annual Meeting & OTO Experience in Atlanta, Georgia, at the Georgia Aquarium.



Presidents' Reception at the AAO-HNSF 2019 Annual Meeting & OTO Experience in New Orleans, Louisiana, at Mardi Gras World.

Hotel Locations



- ★ Los Angeles Convention Center**
1201 S. Figueroa St.
- 1 Courtyard by Marriott L.A. Live**
901 W. Olympic Blvd.
- 2 DoubleTree by Hilton Hotel**
120 S. Los Angeles St.
- 3 Hotel Figueroa**
939 S. Figueroa St.
- 4 Hilton Checkers Los Angeles**
535 S. Grand Ave.
- 5 Hotel Indigo LA Downtown**
899 Francisco St.
- 6 InterContinental LA Downtown**
900 Wilshire Blvd.
- 7 JW Marriott Los Angeles L.A. Live***
900 W. Olympic Blvd.
- 8 E-Central Hotel**
1020 S. Figueroa St.
- 9 Millennium Biltmore Hotel Los Angeles**
506 S. Grand Ave. A
- 10 O HOTEL**
819 Flower St.
- 11 Omni Los Angeles Hotel**
251 S. Olive St.
- 12 Residence Inn Downtown L.A. Live**
901 W. Olympic Blvd.
- 13 Sheraton Grand**
711 S. Hope St.
- 14 The Standard Downtown L.A.**
550 Flower St.
- 15 The Westin Bonaventure Hotel & Suites**
404 S. Figueroa St.

* HEADQUARTER HOTEL

BACK BY POPULAR DEMAND:

Worst-Case Scenarios Managing OTO Emergencies in Practice Workshop

Monday, October 4

Hosted at Cedars-Sinai Medical Center in Los Angeles, California, this is a 4.5-hour course geared toward practicing otolaryngologists to prepare them for low frequency, high stakes emergency situations that they may not encounter often in their daily routines. Attendees participate in a rotation of six simulated otolaryngology emergencies with a cohort of six peer attendees. Each simulated emergency is done as a duo with a partner from the group. Following each simulation, a debriefing is held with the group and a facilitator and includes discussion of best practices for these situations based on published guidelines and available literature. ■

Pictured right from the AAO-HNSF 2019 Annual Meeting & OTO Experience, Worst-Case Scenarios Managing OTO Emergencies in Practice Workshop held at Tulane Center for Advanced Medical Simulation Center



AAO-HNSF 2021
ANNUAL MEETING & OTO EXPERIENCE
LOS ANGELES, CALIFORNIA | OCTOBER 3 – 6
WE ARE ONE TWENTY-FIVE

CALL FOR SCIENCE LATE-BREAKING ABSTRACTS

The AAO-HNSF will be accepting applications for Annual Meeting late-breaking abstracts in May. Check the Annual Meeting website for details.

www.entannualmeeting.org



Get to Know the #OTOMTG21

Australian Society of Otolaryngology Head and Neck Surgery

The Australian Society of Otolaryngology Head and Neck Surgery (ASOHNS), established in 1950, is the representative organization for otolaryngology head and neck surgeons in Australia.

ASOHNS has 497 member surgeons and administers training for over 75 trainees across Australia.

Otolaryngology-head and neck surgery is highly advanced in Australia, and members are closely connected with colleagues internationally. On completion of training, a large portion of young fellows travel overseas to complete further advanced training. Australia also welcomes visiting fellowships for overseas-trained surgeons. Australian surgeons are passionate learners, keen researchers, and strong advocates for their patients.

ASOHNS works in collaboration with the Royal Australasian College of Surgeons (RACS) to train the next generation of OHNS surgeons, one of nine surgical specialties supported by RACS. The training program is competency-based and takes approximately five years to complete. Flexible training allows for interruption or part-time training to pursue personal life choices, including research, parental leave, and overseas aid work.

Continuing professional development for members is supported through an annual scientific meeting with international keynote speakers. ASOHNS members also have access to online education resources on the AAO-HNS education platform.

The ASOHNS' top strategic priorities include audit registries, addressing hearing health of first nations people, and workforce maldistribution given the geographical size of Australia.

We have been fortunate in Australia with advance warnings internationally on the SARS-CoV-2 pandemic and we were able to implement precautions to protect the population. While international travel for Australia is on hold at the writing of this, we hope to connect with colleagues virtually at the Annual Meeting, October 3-6, in Los Angeles, California. ■



Brazilian Association of Otorhinolaryngology and Cervical-Facial Surgery

The Brazilian Association of Otorhinolaryngology and Cervical-Facial

Surgery (ABORL-CCF) is a civil society of a scientific, nonprofit nature and legitimate representative of the professional class of otorhinolaryngology.

ABORL-CCF aims to promote the development of the specialty and the scientific, technical, cultural, and social exchange between its professionals. It is linked to the Brazilian Medical Association. There are more than 70 years between federation, society, and association acting in the defense and development of the specialty in Brazil, representing more than 8,000 otorhinolaryngologists.

ABORL-CCF promotes teaching and research in otorhinolaryngology in its most diverse sectors, such as otology, otoneurology, pediatric otorhinolaryngology, occupational otorhinolaryngology, snoring and sleep apnea, rhinology, bucco-pharyngo-laryngology, traumatological, aesthetic orthodontic surgeries and recuperators of the face, head and neck, and skull base surgery, otoneurosurgery, microsurgery, allergy, phoniatics diagnosis, endoscopy, and other sectors. In addition, the ABORL-CCF promotes education campaigns, makes themselves heard in the organization of ENT services and campaigns, promotes and provides training courses, meetings, congresses, internships in the country and abroad, grants scholarships for research and continuing education, institutes stimulus awards for those who stand out, and participates in the elaboration of the specialty teaching programs in undergraduate and graduate lato-sense courses.

The association maintains the journal of the specialty as an official organ of ABORL-CCF and an information bulletin. It also cultivates the memory of the Brazilian and worldwide ENT and honors its outstanding members. ■



ABORL-CCF Executive Board



International Guests of Honor

Brazilian Society of Head and Neck Surgery



Antonio A. T. Bertelli, MD, MS
Board of Directors, Brazilian
Society of Head and Neck Surgery



Antonio J. Gonçalves, MD, PhD
President, Brazilian Society of Head
and Neck Surgery

The Brazilian Society of Head and Neck Surgery (BSHNS) was founded in 1967 in São Paulo during the first meeting of head and neck surgeons. The leading surgeon at that time was Jorge Faribanks Barbosa, a worldwide, well-known Brazilian head and neck surgeon who published more than 100 publications, including the book *Surgical Treatment of Head and Neck Tumors* published in 1974. Barbosa standardized extended maxillary resections, introduced a new technique of base of tongue cancer surgery preserving function, described pull-through access for oral and oropharynx tumors, and other remarkable contributions for head and neck surgery (HNS). He was the first president of BSHNS.

Since that time, BSHNS became the largest society of HNS in Latin America, with more than 800 members. Since 1974, it has had its own publication, currently called *Archives of Head and Neck Surgery* (ISSN 2595-2544) and is one of the founding societies of the Latin American Federation of Head and Neck Surgeries Societies. There are 38 residency training centers accredited by BSHNS all over Brazil.

In Brazil, otolaryngology and HNS societies are different societies. The Brazilian Association of Otolaryngology has more than 8,000 members. Usually, the otolaryngologist takes care of benign disease and the head and neck surgeon focus on cancer and thyroid surgeries. Most head and neck surgeons come from general surgery, although it is possible to do HNS residency after otolaryngology. ■



First Brazilian Meeting of HNS, when BSHNS was founded: left to right: Ataliba Belizzi, Jorge de Marsillac, Jorge Fairbanks Barbosa, Romulo Falcão, Antonio Bertelli, unknown gentleman.

Otorhinolaryngology Society of Ghana

Prior to 2003 when the Ghana College of Physicians and Surgeons was formed, there were only a few ENT surgeons available in Ghana, with postgraduate training only being done by the West African College of Physicians and Surgeons. Since then, the number has grown multiple fold with the accessibility to training and retention of manpower in the country.

The Otorhinolaryngology Society of Ghana (OSoG) was founded to achieve quite a few objectives, such as to promote fellowship among otolaryngologists, address specific ENT problems in Ghana and contribute to the solutions, and collaborate with other international, regional, and local societies on areas of common interest.

There is an increasing need for training for subspecialties in ENT, which was initially only available in South Africa (clinical fellowship in advanced head and neck surgery and FESS) and other limited resource countries outside Africa. Two fellows completed training in head and neck surgery and one in FESS.

The Komfo Anokye Teaching Hospital in Ghana has introduced a Newborn Screening Program as a new service to screen all newborn babies for hearing loss. To improve access to hearing screening and treatment for hearing loss, the hospital has purchased otoacoustic emissions and auditory brainstem response test to run the screening for newborns.

In the past year with the COVID-19 pandemic affecting the world, guidelines were developed and tailored for safe practice to address the challenges we faced in low-resource settings and with limited PPE available. Through COVAX, in March 2021, the AstraZeneca vaccine was introduced to Ghana, the first African country to receive and distribute free vaccines. ■



Anna Konney, MD



Additional Resources:

www.sbccc.org.br
www.flscyc.org/
www.aborlccf.org.br



AAO-HNSF 2021 ANNUAL MEETING & OTO EXPERIENCE

New Zealand Society of Otolaryngology, Head and Neck Surgery



Jacqui Allen, MD, FRACS ORL HNS,
NZ AAO Representative



Kevin Smith, FRACS ORL HNS,
Secretary NZSOHNS



Zahoor Ahmad, FRACS ORL HNS,
President NZSOHNS

Originally founded in 1947, with just five members, the New Zealand Society of Otolaryngology Head and Neck Surgery (NZSOHNS) now has 153 members with 123 active surgeons. The Society's purpose remains the same as that proffered in 1947: "a Society of Ear Nose and Throat Specialists to safeguard the interests of the Specialty and of patients..." and act for the benefit of members but also as an advocacy group to promote the best care for otolaryngology patients in New Zealand.

Training occurs nationally, with two-to-three trainees selected per year and rotated across jurisdictions for their training term of five years. In the last 12 years, a surgeon-scientist training pathway has been in place allowing trainees to undertake dedicated research, including a PhD as part of the training journey. This has been welcomed and has expanded the research output of otolaryngology in New Zealand.

NZSOHNS continues to pursue equitable funding and access to hearing aids and now cochlear implants for our population. The Society supports programs to address health disparities in New Zealand, particularly for indigenous groups and migrants. We now face the challenge of SARS-CoV-2, whose rampant disease course has extended across the globe. The Society was swift to advocate for the safety of our patients and members during the current pandemic, backing the provision of PPE, campaigning for vaccination of high-risk workers, and more.

New Zealand is a unique place. NZSOHNS strives to do the best for our members and patients under our care and to be true to our Kiwi roots.

Stay safe, kia kaha. ■



Society of Polish Otorhinolaryngologists, Audiologists and Phoniatriests

(Towarzystwo Otorynolaryngologów, Foniatriów i Audiologów Polskich)



Prof. Piotr H. Skarzynski, MD, PhD, MSc, Board Secretary

Otolaryngology-head and neck surgery is an essential and significant medical specialty in Poland. The main otolaryngological and head and neck procedures in Poland are sinus surgeries, cancer surgeries of the head, neck, and larynx, laryngectomies, surgeries for benign and malignant tumors, cysts, and abscesses. Otolological procedures include adenotomy, tonsillectomy, stapedotomy, hearing implantations with cochlear implants, bone conduction implants, middle ear implants, and reconstructive surgery.

The Society of Polish Otorhinolaryngologists, Phoniatriests and Audiologists (Towarzystwo Otorynolaryngologów, Audiologów i Foniatriów Polskich) cooperates with central and regional public administration bodies, professional self governments, and associations to provide the adequate standards of clinical management and treatment in otolaryngology (including paediatric otolaryngology), audiology, phoniatics, head and neck surgery, speech therapy, surdopedagogy, rehabilitation, telemedicine, and the related fields. The Society organizes and supports research and scientific works dedicated to otolaryngology-head and neck surgery fields and cooperates with other institutions and associations in these areas.

The main goal of the Society is to provide high-quality healthcare to patients from Poland and abroad by pursuing and supporting various forms of training and education-related activities for the benefit of representatives of medical or medicine-related professions as well as to broaden their knowledge and practical skills in the fields mentioned above. The activities include granting of patronages, spreading knowledge about the scientific advancements across these fields, and raising public awareness of them, especially within the community of medical students, doctors, and medical personnel.

The Society organizes scientific meetings to share knowledge and experience with other colleagues. These scientific conferences and congresses play the leading role in promoting and increasing healthy lifestyle and focusing attention on preventing and treating ENT diseases. ■





FROM THE EDUCATION COMMITTEES

Sublingual Immunotherapy: Is One Pill All I Need?

Christopher D. Brook, MD

Allergic rhinitis is a highly prevalent disease in the United States population affecting between 10% and 30% of the general population, and the prevalence of the disease seems to be increasing over time. The prevalence of sensitization in many population level studies now approaches 50%.¹ Roughly 60% of sensitized individuals have sensitization to perennial allergens, such as common indoor allergens like dust mites, pests, or pets. The remainder are sensitized only to seasonal allergens, such as trees, grasses, or weeds.² Treatment of allergic disease is typically presented with three arms: (a) medical therapy, (b) avoidance, and (c) immunotherapy. Immunotherapy is thought of as the only one of these arms to modulate the immune system and create lasting tolerance for antigen exposure. In the U.S., it has traditionally been delivered via subcutaneous immunotherapy (allergy shots); however, there is an increasing trend toward oral sublingual delivery.

Sublingual immunotherapy (SLIT) is available in two forms: sublingual drops, which are made from allergen extracts traditionally used for subcutaneous immunotherapy; and sublingual tablets, produced specifically for intraoral use. Allergen extracts are not FDA approved for oral usage and are considered an off-label use of the extracts. SLIT tablets are FDA approved for sublingual usage and not considered off-label.

There are currently four sublingual allergen extract tablets that are FDA approved and on the market. Grasstek (ALK-Abello) and Oralair

(Stallergenes) are both indicated for seasonal grass allergies. Grasstek contains Timothy grass extract, while Oralair is a combination of several different prevalent grass allergens. Both tablets can be used pre-seasonally and continued through the allergy season for relief from seasonal grass allergy. Ragwitek (ALK-Abello) is a ragweed extract tablet indicated for seasonal ragweed allergies and can similarly be used pre-seasonally and continued through the allergy season. The final FDA-approved SLIT tablet is Odactra (ALK-Abello), which is intended for year-round usage and is a combination of house dust mite extracts for *Dermatophagoides pteronyssinus* and *farinae*, the two most prevalent dust mite species in the U.S. Contraindications for all tablets include severe/uncontrolled asthma, systemic hypersensitivity reactions, or a history of eosinophilic esophagitis. All manufacturers recommend a prescription and teaching of an epinephrine autoinjector to patients being prescribed sublingual tablets.³

SLIT drops are made by compounding allergen extracts into a patient-specific formulation based on specific allergy testing. Numerous extracts are available for purchase to use in testing and vial compounding. SLIT drops, although not FDA approved, have a strong track record of safety and are generally considered significantly less likely to generate a systemic reaction than subcutaneous immunotherapy because of the low rate or systemic reactions and the fact no fatalities have been reported with use.⁴

When comparing SLIT tablets and SLIT drops there are several pros and cons for each treatment method. SLIT tablets are standardized, generally covered by payors

because of FDA approval, and convenient because they do not require compounding. There are two major downsides to tablets—they are limited to single antigens (or classes of antigens in the case of Oralair) and there are a very limited number of antigens available for treatment. SLIT drops have several downsides including that they can use standardized or non-standardized extracts and consequently can contain variable amounts of antigenic material. Compounding SLIT also requires a USP 797 compliant area to perform extract compounding, requires on-hand supply of allergen extras—which can be very costly—and expertise in prescribing and compounding of extracts. SLIT drops do have some significant advantages in that they provide a much wider range of antigens with which to provide desensitization and can be combined in a single vial to provide desensitization to numerous antigens at the same time. Regardless of the method chosen, however, SLIT has been shown to be an effective treatment for allergic rhinitis and broadens the treatment options available to the otolaryngic allergist.

The debate on the optimal number of antigens to be used in immunotherapy is a subject for another article. ■

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Adding Allergy to your Otolaryngology Practice

Cecelia Damask, DO, and Matthew W. Ryan, MD

Allergic rhinitis (AR) is a chronic upper airway inflammatory disease affecting 60 million children and adults and is the sixth most common chronic medical condition in the United States. AR may present with a wide spectrum of symptoms, including sneezing, runny nose, nasal congestion, cough, sore throat, and watery, itchy eyes. AR is a comorbidity with many other diseases and conditions treated by otolaryngologists and shares significant symptom overlap with a variety of

diseases relevant to our practices. Currently there is a growing need for specialists to treat allergic conditions, and otolaryngologists are uniquely positioned to assess for the presence of allergic disease in patients with upper aerodigestive tract symptoms. Incorporating allergy testing and immunotherapy into your practice allows you to provide comprehensive care to patients and, as an ancillary service, can help build your practice.

Allergy diagnostic testing is one of the first services you can offer your patients. While a presumptive diagnosis of allergic disease may be made from the patient's history, allergy testing has several important

roles. These include confirmation of the clinical diagnosis, identification of the patient's relevant allergen sensitivities, and selecting a safe starting dose for the provision of immunotherapy. Several different testing modalities are available. Allergen-specific IgE in the serum can be used as a marker of sensitization. An in vitro specific IgE test may be accomplished with a simple blood draw and send out to a reference laboratory. Some busy practices obtain Clinical Laboratory Improvement Amendments (CLIA) certification to perform their own in vitro specific IgE analysis from patient serum samples. However, the most commonly

employed allergy testing technique is skin testing. A simple prick test performed with an allergen extract and a plastic disposable device can identify preformed allergen-specific IgE via cutaneous mast cell degranulation and the classic 'wheal and flare' reaction of the skin. Another technique is to use a small needle to inject diluted allergen into the dermis, looking for a similar reaction (intradermal test). Some practices may choose to incorporate a blended technique of both prick and intradermal tests, commonly known as 'modified quantitative testing.' Allergy diagnostic testing provides the clinician with important information to aid in clinical decision making and is a cornerstone in the management of allergic disease. Most otolaryngology practices should be able to add some form of allergy diagnostic testing with minimal investment.

Most patients with AR are treated with allergen avoidance and pharmacotherapy. However, allergen-specific immunotherapy is the only treatment that addresses the underlying immunologic derangement in allergic disease. Successful immunotherapy decreases symptoms and improves disease-specific quality of life.¹ Immunotherapy achieves these benefits via a variety of mechanisms. It reduces mast cell and basophil degranulation, induces the production of IgG4 'blocking antibody,' upregulates tolerogenic regulatory T cell populations, and reduces allergen-specific IgE over the long term. Comprehensive allergy care thus includes allergen-specific immunotherapy.

A variety of immunotherapy options are utilized in practice. The simplest method for allergen-specific immunotherapy is sublingual immunotherapy (SLIT) using FDA-approved sublingual tablets. These are currently available for the treatment of grass, ragweed, and dust mite allergy. Another option is SLIT utilizing a customized formulation of aqueous allergen extracts that is based upon clinical determination of a patient's relevant allergen sensitivities. The advantage of this approach is that allergens other than grass, ragweed, and dust mite can be treated.

While SLIT has many advantages, the mainstay of immunotherapy in the U.S. is subcutaneous injection immunotherapy (SCIT). SCIT has the longest track record

of clinical use and has been demonstrated to be effective in multiple randomized placebo-controlled trials.¹ SCIT is FDA approved and covered by most health insurance plans. While SLIT is utilized by many practices in one form or other, most allergy practices utilize SCIT for these reasons.

Otolaryngologists have a variety of reasons for incorporating comprehensive allergy care into their practices. Before initiating these services, a practice should consider its goals as well as the requirements for success. Is there a need for allergy services in the area? Will allergy care increase convenience for your patients? Do partners agree about the importance of allergy? Will allergy care make the practice more profitable or build overall patient numbers? Will allergy care disrupt current referral patterns in your community? These and other questions need to be considered before embarking.

Incorporating into Business Plan

Like any other decision involving the services offered by your practice, incorporating allergy care should be undertaken with a business plan in mind. The business plan should include tangible metrics of success: monitoring of referral trends, financials, retention rates of patients, and analyzing patient outcomes. The primary financial investment when starting an allergy practice is the cost of supplies. These include allergen extracts, syringes, testing devices, and emergency supplies (for anaphylaxis treatment). Usually, the existing personnel in a medical office are able to take on the new roles required for allergy care. These roles include performance of allergy skin tests, preparation of testing and immunotherapy vials, and administration of immunotherapy. Medical office assistants or nurses are able to perform these duties depending upon individual state regulations. Ultimately, successful allergy practices will have personnel who are completely dedicated to providing these services.

Office space for the allergy practice must also be considered. A location for preparation of allergen extracts needs to be defined as well as space for testing and administration of immunotherapy injections. Because SCIT carries with it a risk for anaphylaxis,

a monitored location within the office will need to be designated for patient observation after injections are administered. When beginning an allergy practice, existing office space can be utilized. However, as the practice grows, so will requirements for space. An ideal office environment includes a dedicated check-in desk for allergy patients, a separate waiting room for observation, and an allergenic extract compounding area as well as space for testing multiple patients simultaneously and to give injections.

While office staff perform most of the day-to-day tasks, the physician (or advanced practice provider) is the leader of the team and should be the content expert for every aspect of the allergy practice, including the nuances of testing and immunotherapy, management of allergy emergencies, regulatory and compliance issues, proper billing and coding, and documentation. This responsibility entails considerable investment of time and energy on the part of the physician. Becoming an expert in these topics can be accomplished in a variety of ways. Trusted colleagues are a potential source of information and advice. Allergy-specific CME offerings at the AAO-HNSF Annual Meeting and from other sources should be used. Read a variety of texts and monographs on allergy directed toward otolaryngologists. Talk to allergen supply vendors. And finally, enroll in a course that reviews proper billing and compliance information.

There is never an ideal time to get started on the journey of building an allergy practice. Fortunately, allergy services can be gradually added to what you are already offering your patients. It's OK to start slowly. Allergy testing is a simple starting point. In vitro testing and skin prick testing are easy to introduce into your practice flow. Sublingual immunotherapy tablets are a safe and effective way to begin offering immunotherapy to your patients. As you and your staff learn more about allergy and are more comfortable with your knowledge and skills, you can expand to offer a full spectrum of allergy services. ■

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AAOA Publishes "Targeted Molecular Therapies in Allergy and Rhinology" (Damask C. et al) to Help Otolaryngologists

Haidy A. Marzouk, MD

The past decade has seen a rapid expansion in the use of biologic drugs for the treatment of numerous chronic inflammatory diseases. Biologic drugs are monoclonal antibodies targeting specific Type II inflammation molecular pathways for a variety of disease entities in the head and neck. With advances in research and clinical application rapidly expanding, the American Academy of Otolaryngic Allergy (AAOA) recently convened a multidisciplinary expert panel for a biologics roundtable discussion to offer insights into evidence-based practicalities regarding their use in the airway and to identify gaps where more research is needed. A summary of their findings, "Targeted Molecular Therapies in Allergy and Rhinology," was published by Damask et al in *Otolaryngology–Head and Neck Surgery* this year.¹

Chronic allergic and eosinophilic diseases in the head and neck are characterized by Type II inflammation, and thus amenable to targeted molecular therapy with biologics which block this pathway. Endotypes of chronic sinusitis, including chronic sinusitis with nasal polyposis (CRSwNP), aspirin-exacerbated respiratory disease (AERD), and eosinophilic granulomatosis with polyangiitis (EGPA) display Type II inflammation and can be treated with biologic drugs. Other atopic disorders displaying mechanisms of Type II inflammation

include asthma, atopic dermatitis (AD), and chronic spontaneous urticaria (CSU), which have all been treated with biologic therapies in recent years.

Allergic Type II inflammation is driven by Th2 lymphocytes leading to an allergen-specific IgE response via mediators with a variety of cytokines, including IL-4, IL-5, and IL-13. IL-5 is central to eosinophilopoiesis, and to the maturation, activation, and survival of eosinophils. There is a parallel pathway involving non-allergic Type II inflammation where Type II differentiated innate lymphoid cells (ILC2s) cause similar eosinophilic inflammation. As a result of these pathways, tissue damage and cycles of chronic inflammation ensue. Biologics, having the ability of antibodies to target a specific molecule, have allowed successful targeting of Type II inflammatory pathway mediators.

Omalizumab is a monoclonal anti-IgE antibody that inhibits IgE binding to CD23 receptors and consequent cross-linking of IgE on mast cells and basophils. When IgE levels decrease, high-affinity receptors are down regulated as well. Mepolizumab and reslizumab are monoclonal antibodies binding to IL-5 preventing it from binding to its receptor. This results in reduction in production and survival of eosinophils. Benralizumab targets the IL-5 α receptor on eosinophils and basophils. This prevents IL-5 binding and induces a cell-mediated cytotoxicity of eosinophils resulting in apoptosis. Lastly, IL-4 and IL-13

fuel inflammatory responses and affect more cell types beyond eosinophils. Dupilumab is a monoclonal antibody that binds to the IL-4 α subunit, inhibiting IL-13 and IL-4 signaling and decreases IgE production by about 40%.

Biologics in CRSwNP

In the United States, CRSwNP is predominately characterized by Type II inflammation. The mainstay of treatment has been corticosteroids (oral and topical), sinus surgery, and sometimes antibiotics. However, some patients suffer with a severe, refractory form of CRSwNP that does not respond well to corticosteroids and sinus surgery. For these patients who continue to suffer despite appropriate medical and surgical therapy, biologics offer a promising option. Dupilumab was the first FDA-approved biologic for treatment in CRSwNP. In Phase 2 and 3 clinical trials, dupilumab improved nasal polyp score, olfaction, SNOT-22, and LMK CT score in CRSwNP patients with and without asthma, and reduced the need for systemic corticosteroid use in comparison to placebo controls. Dosing of 300 mg SC every two weeks can be performed at home by the patient (first dose in office) and is well tolerated with infrequent adverse effects. However, studies have shown that after cessation of treatment, symptoms tended to recur back to the pre-treatment levels, thus necessitating continuous treatment for an extended period of time.

Omalizumab was the second biologic agent that was FDA approved as an add-on

treatment of nasal polyps. Several randomized, placebo-controlled trials have shown efficacy for omalizumab in patients with CRSwNP, demonstrating improvement in nasal polyp score, QOL, olfaction, and symptoms, compared to placebo-controlled groups.

Biologics in the Unified Airway

Otolaryngologists are in a unique position to appreciate the connection between upper and lower airway diseases. Biologic drugs have been in use for asthma for years prior to the approved indication for CRSwNP. Asthma patients who are oral corticosteroid dependent or who have poor symptom control despite appropriate therapies are candidates for biologic therapy as an add-on treatment if increased eosinophils or fractional exhaled nitric oxide (FeNO) are noted. Omalizumab, anti-IL-5 agents, and dupilumab are all approved as add-on treatments for asthma. As a group, these agents consistently show reduction in asthma exacerbations and improvement in pulmonary function. Selection of specific biologic therapy includes consideration of the potential for treatment responsiveness, patient preferences, age, weight, convenience of setting for injection, and cost. Omalizumab and mepolizumab have an indication down to six years of age. Omalizumab requires administration in a medical care setting whereas mepolizumab, benralizumab, and dupilumab can be administered at home or by a healthcare provider. For uncontrolled asthma in patients with perennial allergies, omalizumab is an option which can target both diseases. Anti-IL-5 agent use may be limited by a low peripheral eosinophil count. Studies on dupilumab suggest a better therapeutic response with elevated FeNO levels.

Patients with AERD have shown improvement in symptoms with biologic therapies. AERD (formerly Sampter's Triad) is an endotype of chronic sinusitis where asthma is triggered by nonsteroidal anti-inflammatories and is contingent on cyclooxygenase 1 inhibition. Appropriate treatments include the use of corticosteroids (oral and topical), leukotriene modifiers, aspirin desensitization, and sinus surgery. However, patients with AERD often have a more severe and recalcitrant form of CRS and can benefit from treatment with biologic drugs. Prospective

studies of omalizumab in patients with AERD demonstrated improvement in upper and lower respiratory tract symptoms with decreased levels of LTE4 and PGD2 metabolites. A retrospective study of mepolizumab showed that after three doses, eosinophil counts, SNOT-22 scores, and FEV1 improved in patients with AERD. A sub-study of a Phase 2 trial of dupilumab for AERD showed improvement of olfaction, SNOT-22, and nasal polyp score.

EGPA is characterized by eosinophil rich, necrotizing granulomatous inflammation, and vasculitis that involves the respiratory tract and other organ systems. These patients often have severe asthma and tissue eosinophilia. The diagnosis is primarily based on clinical parameters. These patients often are steroid-dependent, which are effective in 90% of patients, but they may require additional immunosuppressive therapy. Mepolizumab is FDA approved for the treatment of adults with EGPA with dosing of 300 mg once every four weeks. A randomized placebo-controlled trial showed that treatment with mepolizumab resulted in more weeks of accrued remission, a higher remission rate, improved asthma scores, and a longer time course to the first major relapse of disease compared to placebo controls.

Dermatologic Disease and Biologics

CSU and AD are allergy-related disorders that can manifest in the head and neck and have immunologic pathophysiologies which are amenable to treatment with biologic agents. CSU is characterized by hives for more than six weeks with no apparent trigger. H1 antihistamines are the mainstay of treatment, although some patients continue to suffer despite treatment. Potential add-on therapies include leukotriene antagonists, oral corticosteroids, cyclosporine, dapsone, and methotrexate. Omalizumab is FDA approved for the treatment of CSU in adults and adolescents who remain symptomatic despite use of antihistamines. Dosages are 150 or 300 mg subcutaneously every four weeks. AD diagnosis is primarily clinical and characterized by pruritus, eczema, a chronic relapsing history, and typical morphology and age-specific distribution patterns. Treatment involves nonpharmacologic interventions as well as topical corticosteroids, calcineurin inhibitors, and crisaborole ointment.

Dupilumab is FDA approved for treatment of patients who are over six years old with moderate-to-severe AD who do not respond to other treatments. Typically, adult patients will receive a 600 mg subcutaneous loading dose followed by 300 mg subcutaneously every two weeks.

Biologics drugs offer exciting treatment options for patients with severe and refractory chronic inflammatory diseases of the head and neck. The decision to choose biologic agents focuses around the failure of standard appropriate medical therapies, patient-centered decision-making, dosing schedules, treatment setting, and cost. Insurance coverage and cost-utility remain a concern as these agents require significant financial expenditures with long-term treatment needed. While the short-term safety has been established, there may be long-term consequences of blockade of inflammatory pathways, which is yet unknown.

The AAOA plans to stay at the forefront by providing education on the latest treatment strategies for allergic and inflammatory immune disorders that affect the head and neck. This round-table discussion and subsequent publication provide a thorough summary of the use of biologics in otolaryngology. It is an exciting time in medicine as we are able to provide new options to help those patients with the most severe airway diseases. ■

About AAOA

Celebrating 80 years of service, the American Academy of Otolaryngic Allergy (AAOA) represents over 2,700 Board-certified otolaryngologists and healthcare providers who devote part of their practice to the diagnosis and treatment of allergic disease. The AAOA actively supports its membership through education, research, and advocacy in the care of allergic patients, focusing on its mission to "Advance the comprehensive management of allergy and inflammatory disease in Otolaryngology-Head and Neck Surgery through training, education, and advocacy." Renowned for its innovative educational courses and practice resources, the AAOA strives to help its members stay at the forefront of patient care. For more on the AAOA and its programs, visit www.aaoallergy.org.

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Tech Talk

Growing Role of Big Data

Mike Robey, MS, AAO-HNS/F Senior Director,
Information Technology

Harvesting business intelligence from data is nothing new. Decision support systems and executive information systems have been around since the 1980s. What makes Big Data different are the three Vs: **volume**, **velocity**, and **variety**. Today's datasets are huge. Volumes in the terabyte (2 to the 40th power, 2^{40}) and petabyte (2 to the power of 50, 2^{50}) range are common. Multiple datasets, from internal and external sources, are needed for complex analysis. Combined with the velocity of which new data is getting created, a traditional organization-specific computing environment cannot keep up with demand. To further complicate things, today's data is not just transactional. Meta data, monitoring systems, documents, online postings, and other unstructured data add to the variety of data produced today. Big Data is the field that includes the repositories to support the analysis from these huge disparate sources. This article introduces the major components to give you a better understanding.

Where Is Big Data Stored?

Two terms you may have heard are data warehouses and data lakes (see sidebar for definitions). Both have one thing in common: They are separate repositories than the source systems. Having separate databases for business intelligence and reporting is not new. The rationale is to not hinder the ability of the source system to record transactions.

Relational databases, consisting of rows and columns, are excellent structures to support transactions. They are not the most efficient for multidimensional reporting, such as time series. Multidimensional analytical data structures were developed to support complex business intelligence reporting. These were fed from disparate source systems so as not to hinder the integrity nor ability of the source systems to do their intended job.

As the figure illustrates, loading these central repositories is a three-step process: Extract, Transform, and Load (ETL). The extract phase identifies the source systems where data will be pulled. The source systems may be internal, such as accounting, human resources, and customer relations. External systems, such as census, other government data, or resource data, may also be included. Pertinent data is then harvested from the source systems and transformed in the second phase. Once transformed, data is then loaded into the repository.

ETL is managed by an overall data governance policy, which defines the lifecycle of the data and various implemented controls governing availability, usability, consistency, data integrity, and data security. Included in data governance are other documents such as Master Data Management, which provides a common definition for the reference data found across the different source systems. The Data Dictionary defines the data elements to be extracted and their transformed layout for loading into the data warehouse. Data privacy ensures that personally identifiable information (PII) is properly protected.

With the data layer covered, let us discuss the data scientist who will be doing the analytics. Harkening back to an undergraduate class is econometrics, any analysis begins with a question or hypothesis to be tested. The iterative methodology is defined with the following steps:

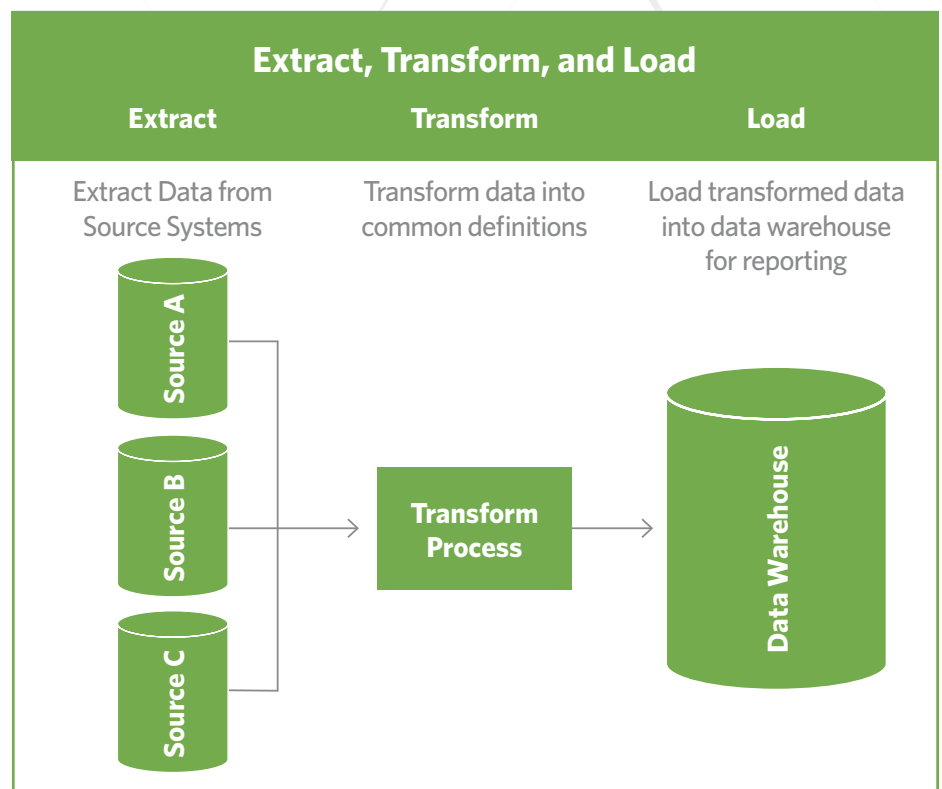
1. Develop a hypothesis
2. Refine the hypothesis into a mathematical model
3. Align data elements to the model's variables
4. Check the model's adequacy; run statistical analysis to ensure variables are independent
5. Test the hypothesis against the derived model
6. Use the model for prediction and forecasting

To be effective, a data scientist needs these skills:

- **Computer science:** Knows how to write code, understands databases, and Big Data architectures
- **Advanced math skills:** Trigonometry and geometry skills (many of the algorithms used to identify proximity of like items are nonlinear)
- **Quantitative analyst:** Statistics background, visual analytics, experience with unstructured data
- **Scientist:** Evidence-based decision making; an understanding of the scientific method
- **Strong communications skills:** Ability to frame the topic for understanding

Now with the data layer identified and the data scientist introduced, let us talk about outcomes. Big Data analytical activities can be organized into two broad categories: an inward focus and an outward focus. Inward focus on topical areas, such as cost reduction, decision improvement, and improvements in products and services, is nothing new. However, the three Vs of Big Data can help improve products and services. For example, with the onset of the Internet-of-Things, appliances and automobiles report service issues back to manufacturers that then use this data to improve products and services. An outward focus on opportunities, changes, and threats is also supported by Big Data.

You can think of Big Data as the third wave of the Industrial Revolution, with each wave defined by the main source of energy: steam → electricity → data. Labor becomes more specialized with each new wave. Similarly, you can think of the last 50 years of the Computer Age defined by computing → networking → Big Data. The computing phase started with the mainframe computer and evolved to include personal computers and now smartphones. The networking phase began with local area networks in the 1980s and the internet in the 1990s. The computing and networking phases provided the technology to support parallel processing and huge distributed datasets. Equally important, organizations are now enabled to think more broadly than simply recording transactions.



Definitions

Data lake: A repository where data is stored in its raw format

Data warehouse: A repository for integrated data from multiple source systems

Data swamp: Unmanaged data that no longer provides value

Finding skilled data scientists is key to the effective use of Big Data for focused analytical activities. But so, too, is finding the right balance between applying the scientific

method (hypothesis → experimentation → customer reaction observation → adjustment) for growth opportunities and maintaining daily operations. ■

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Pediatric Otolaryngologist Hershey, Pennsylvania



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The Department of Otolaryngology – Head & Neck Surgery at Penn State Health Milton S. Hershey Medical Center, Penn State Children's Hospital and Penn State College of Medicine is seeking an additional full-time Pediatric Otolaryngologist. This is a great opportunity to join a growing team of collaborative clinical providers with the resources of one of the leading academic medical centers in the nation. The selected candidate will have the opportunity to build an airway practice should they desire.



Appointment will be at the assistant/associate/professor level. Qualified candidates must have completed an approved Otolaryngology – Head & Neck Surgery residency program, be board certified or board eligible and be fellowship trained to provide clinical and hospital-based Pediatric Otolaryngological care for our patients.

The children's hospital sits on the campus of the Hershey Medical Center, a 548-bed Level I regional trauma center. As central Pennsylvania's only academic medical center and home to the college of medicine, we are sought out as a resource for the most complex adult and pediatric cases. Penn State Children's Hospital ranked among the best in the nation for the tenth consecutive year by *U.S. News & World Report*. Additionally, it is one of only eight hospitals in the nation to be named a Level 1 Children's Surgery Center by the American College of Surgeons Children's Surgery Verification Program.

FOR MORE INFORMATION, PLEASE CONTACT:

David Goldenberg, MD, FACS, Chair, Department of Otolaryngology – Head and Neck Surgery c/o Ashley Nippert, Physician Recruiter
anippert@pennstatehealth.psu.edu or to apply online <https://tinyurl.com/ycapn7jw>



Penn State Health is fundamentally committed to the diversity of our faculty and staff. We believe diversity is unapologetically expressing itself through every person's perspectives and lived experiences. We are an equal opportunity and affirmative action employer. All qualified applicants will receive consideration for employment without regard to age, color, disability, gender identity or expression, marital status, national or ethnic origin, political affiliation, race, religion, sex (including pregnancy), sexual orientation, veteran status, and family medical or genetic information.

**CLINICAL FELLOWSHIP IN
LARYNGEAL SURGERY AND VOICE DISORDERS
Massachusetts General Hospital**

The Division of Laryngeal Surgery is seeking applicants for clinical fellowship positions. The fellowship training covers all aspects of laryngeal surgery, voice disorders, and management of the professional voice. The curriculum will provide a wide range of experiences, including phonosurgery (cold instruments and lasers), laryngeal framework surgery, novel operating-room and office-based laser (Pulsed-KTP, Thulium) treatment, complex laryngeal stenosis with aortic homograft transplantation, and the use of botulinum toxin injections for spasmodic dysphonia. The fellow will participate in the management of voice disorders and clinical research as a member of a multidisciplinary team (voice scientists and speech pathologists) that has access to state-of-the-art voice clinic and surgical engineering laboratory facilities. The research fellowship provides numerous opportunities to focus on grant-funded (NIH and private foundations) clinical and basic science research projects in collaboration with interdisciplinary teams of scientists and clinicians at the Massachusetts Institute of Technology and the Wellman Laboratories of Photomedicine at the Massachusetts General Hospital. The option to collaborate with local music conservatories is also available. Qualified minority and female candidates are encouraged to apply. Send curriculum vitae and three letters of recommendation. The Massachusetts General Hospital is a teaching affiliate of Harvard Medical School.

Direct inquiries to:
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Otolaryngologist


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York is a fast growing community with excellent schools and a very comfortable cost of living. It is convenient to Baltimore, Washington and Philadelphia.

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We are looking for a dynamic, motivated individual for partnership track. Income potential in the 90th percentile.



Contact: Renee Gohn
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