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

OCTOBER 2018



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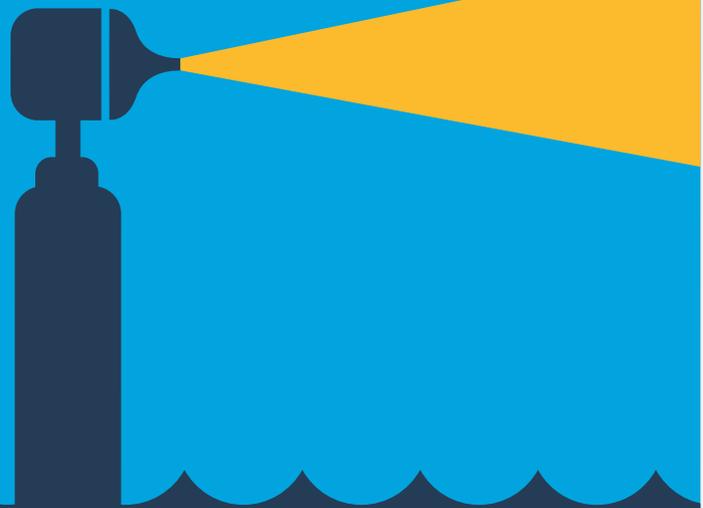
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Nostalgic reflections and hopeful predictions

This presidential year has been remarkable for me on many levels, and I am enormously grateful to have had this unique opportunity. I have worked with so many creative individuals, passionate about medicine and the field of otolaryngology, all demonstrating **commitment and a deeply seated work ethic**.

I would like to thank **James C. Denny III, MD**, for his inspiring leadership and collaboration in working together with me; the remarkably talented and dedicated Academy staff; the Executive Committee of the Board of Directors; and the Boards of Directors of the AAO-HNS/F.

It should be specifically noted, with gratitude and admiration, that the entire **AAO-HNS/F staff** at 1650 Diagonal Road works tirelessly on behalf of our members and the patients we serve. Their work product is nothing short of remarkable. I am continuously struck by their level of commitment and dedication in “**getting the job done**” no matter how vast the project might seem, or how unattainable the goal might appear. They always deliver high-quality results that continue to propel our Academy to greater heights.

Add to this the remarkable sense of dedication, passion, and commitment from well **over 1,000 volunteer members** involved in a multitude of different committee, task force, education, and other Academy and Foundation activities, generating a vast array of data-driven scientific and other education materials and **Reg-entSM**, while delivering on practice management, coding, advocacy-related issues, and so much more.

There are several enduring activities that will continue well into the future, favorably impacting and elevating our specialty. Our new patient website, **ENThealth.org**, positions the AAO-HNS/F as THE trusted source for patient-centered otolaryngology-head and neck surgery information. **OTOSource**, the most current otolaryngology-head and neck surgery curriculum reflecting the changing practice of modern medicine, provides residents, program directors, faculty, and practicing otolaryngologists a standard study guide with teaching tools to assist with board certification, recertification, and lifelong learning. In addition, I convened a task force to review the **Board of Governors and Component Societies** in order to enhance collaboration and optimize resource utilization in furthering the strategic goals of the Academy. This

will also inform the work of the Future of Otolaryngology Task Force, addressing key elements including resident recruitment, workforce issues, changes in education and practice of otolaryngology, advanced practice providers (APPs), and technology, among many other important areas of focus. **Diversity and global otolaryngology** initiatives will continue to strengthen, energized by the palpable enthusiasm and progress experienced at the AAO-HNSF 2018 Annual Meeting & OTO Experience in Atlanta, Georgia.

The list goes on, but my final comment relates to Reg-ent, the Academy’s clinical data registry, that will provide members from all practice settings tools to fully participate in the successor payment and practice models, along with clinical research, allowing us to define and measure quality for our specialty, plus other related benefits.

I have learned many lessons on a daily basis from my teachers, mentors, fellow otolaryngologists, other medical colleagues, administrators, allied health providers, family, friends, Sal, the cafeteria chef in the hospital where I have worked for the past 20 years (tuna melt, par excellence), and especially patients, who have helped me mature, made me pause and reflect to better understand the human condition, while continuously striving to be a better person, friend, husband and father, all the while working to be the best otolaryngologist possible.

The myriad challenges in medicine will no doubt continue to mount, and the Academy no doubt will continue to focus the recently concluded strategic plan on activities and initiatives that will make the practice of otolaryngology less complicated, more fulfilling, and more rewarding to continuously strengthen the joy from our collective ability to provide the best otolaryngology care to our patients.

Thank you to **Gregory W. Randolph, MD**, Immediate Past President, for your leadership, friendship and mentorship. I am thrilled to pass on the gavel to my friend **Albert L. Merati, MD**, who I know will excel in this role...onward and forward, AI!

My final tribute and thank you goes to my incredible wife and soulmate, **Karen**, and my two wonderful sons, Lee and Sean, without whom none of this would have been possible, nor would I be half the person I am today. I love you and am eternally grateful that you are in my life.

The Academy, its leadership, and staff are here to serve you. We have your back. WE ARE ONE! ■



Gavin Setzen, MD
AAO-HNS/F President

“Our new patient website, **ENThealth.org**, positions the AAO-HNS/F as THE trusted source for patient-centered otolaryngology-head and neck surgery information.

”



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What we are doing for you

This year our Annual Meeting & OTO Experience occurs later than usual. This timing has allowed us to incorporate several “breaking news” panel presentations that we feel will be of significant interest to our attendees. In addition to the outstanding program assembled by **Mark K. Wax, MD**, Annual Meeting Program Coordinator, and his dedicated team on the Program Advisory Committee, we have included presentations covering the CMS Medicare payment proposed rule for CY 2019; the FDA Symposium on Sleep Disordered Breathing; the transition to Phase II of our Clinical Data Registry, Reg-entSM; and the preview of our new patient-focused website ENThealth.org and how it integrates with your practice.

At the meeting, specialty leaders will present the proposed changes by CMS to the Medicare Physician Payments and the impact on you and your patients. They will also be available for questions and answers following the presentation. The presentation on our new ENThealth.org website will include a demonstration of the features, content, and navigability as well as how you can use the upgraded “Find an ENT” feature to promote your practice through the patient-centric information contained on the site.

From the outset, a primary goal of Reg-ent was quality reporting. For the 2017 reporting year, 66 percent of those reporting MIPS measures through Reg-ent scored at a level to receive the superior classification. We are now positioned to move to Phase II with expanded opportunities for clinical trials, specific disease study, inclusion of hospital and ASC data, and linkage to private payers. We invite you to attend a special session detailing these opportunities, which will be followed by a “Users Group” conference.

There has been considerable anxiety generated around the CMS proposed rule for 2019 based on significant changes that would dramatically affect current practice by otolaryngologists. The most significant of these includes a 50 percent reduction to the lowest valued CPT code when the 25-modifier is appended to an E/M service. This proposal is designed to mirror the existing 50 percent reduction applied to usage of the 51-modifier signifying multiple procedures. Suffice it to say, no matter whose projections you look at, there would be a significant negative financial impact for almost every otolaryngologist if this proposal is implemented.

There is also a proposal to collapse E/M services from the current five levels for new and established patients to two levels, with an alternative proposal establishing three levels. CMS also proposed to create a G code for specialties, such as otolaryngology, that submit a higher proportion of upper-level codes than the overall fee schedule median. A stated goal of this change is to lessen physician administrative burden, thus improving wellness. CMS has also asked for an in-depth look at the pricing for the balloon sinus kits used for Balloon Sinus Ostial Dilation as well as comments concerning the number of sinuses that can be dilated per balloon. There also are several lesser issues that could affect our specialty. The proposal that has the potential to have the most significant mid- to long-term effect, however, lies in the QPP area of the rule. CMS proposes to remove intellectual property protections from the QCDR measures. This could markedly slow the progress in establishing quality measures that define care.

Your Academy staff has worked for two months preparing cogent and actionable responses to these proposals that we feel have merit. I would like to thank all the specialty societies and practicing otolaryngologists who collaborated with us during our research phase of this process and were instrumental in crafting our response. We also worked with other medical specialty societies outside of otolaryngology on issues affecting the broader house of medicine.

This month we start a new feature in the *Bulletin*. “What We Are Doing for You” will feature activities that the Academy engages in on members’ behalf. The inaugural article describes the journey we had in dealing with The Joint Commission recommendations from the survey sent out in May, to our phone call with The Joint Commission in June, and their subsequent determinations received in August. I encourage all of you to read this good news that should lessen the burden of compliance, both economically and psychologically, in both the office and hospital settings.

As I close this month’s column, I would like to thank **Gavin Setzen, MD**, for the exceptional leadership he has shown during his presidential year, using his considerable knowledge and judgment to identify and promote key projects that will help ensure our success into the future. ■



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

“

From the outset, a primary goal of Reg-ent was quality reporting.

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BOARD OF GOVERNORS

Perseverance, dedication, and stamina: The magic ingredients

■ Ken Yanagisawa, MD
Chair, Board of Governors



Ken Yanagisawa, MD

As I marvel at my fifth child, Kevin, completing yet another 1,650-yard (aka “the mile”) competitive swim on his way to collegiate competition, the keys to success in this grueling 66-lap event are perseverance, dedication, and stamina. Our professional careers as physicians, and our duties to fulfill the multitude of current climate expectations, demand these exact same traits. On a seemingly daily basis, we must face, conquer, and satisfy numerous requirements imposed by a variety of external forces, including our patients, insurers, and regulators.

The routine becomes tiring and trying. In fact, it can become downright overwhelming. Yet we all persevere. And we are fortunate and blessed that we have amazing resources at our fingertips. Our dedicated Academy leadership, staff, and engaged physicians work around the clock on our behalf.

In like fashion, the Board of Governors (BOG) maintains its pivotal role as the voice and the representative of the grassroots providers, embracing participation of ALL practitioners whether in private practice, employed, or hybrid models. Some recent significant accomplishments include numerous advocacy victories, as well as an expanding chest of toolkits to help practitioners and societies grow and succeed.

To combat the forces that intrude on our practices, we must remain informed and unified as an otolaryngology community. Various strategies to overcome our battle fatigue are being

carefully studied. These may include personal time preservation, allowing us to reflect on our many accomplishments, virtues, and strengths, and could be yoga, exercise, or even old school “sit around the kitchen table” time with our families.

As we celebrate our 122nd Annual Meeting in Atlanta, Georgia, please consider attending the two BOG-sponsored talks on “Infection Control” and “Development of Professional Expertise.” In addition, our BOG General Assembly will be held on Saturday, October 6, at 4:30 pm (ET), NOT on the traditional Monday afternoon. PLEASE mark your calendars.

Our AAO-HNS/F Leadership Forum & BOG Spring Meeting will be held April 26-29, 2019, in Alexandria, VA, and will focus on many timely topics, including APPs, wellness, the opioid crisis, defense attorney support/partnership, insurer challenges, and the future of otolaryngology.

Staying actively involved with our specialty is the best way to stay informed, pertinent, and rejuvenated. Of the many leadership opportunities offered through our Academy, one of the most effective and efficient tracks is through the BOG. We endorse involvement by ALL providers, especially our younger physicians, fellows, and residents. Early involvement garners meaningful participation and promotes progression.

The BOG values all viewpoints. Through our three-pronged Committee structure—Socioeconomic & Grassroots Committee, Legislative Affairs Committee, and Governance and Society Engagement Committee—we tackle head-on the common issues that affect

and impact our lives, our practices, and our patients. I encourage you to dive confidently and enthusiastically into a new arena or committee, test the waters, and help us to make a difference. Take your mark. Get set. Go! ■

Call for 2019 AAO-HNS candidates

The AAO-HNS Nominating Committee is calling for recommendations of individuals to be considered for an elected office. Academy member(s) must be in good standing and it is recommended that they have held membership the last three consecutive years, have proven leadership qualities, be active in the Academy, be familiar with the strategic direction of the Academy, and be able to dedicate the necessary time to serve.

Please complete the application packet of materials and submit to any member of the Nominating Committee requesting he/she support your nomination for elected office. For more information and the application packet, visit www.entnet.org/content/annual-election.

Application deadline is December 3, 2018. (No extensions permitted.) ■

PEARLS FROM PEERS

What do you incorporate into your schedule to achieve work-life balance?

I have a life-long passion for soccer and have been lucky to continually play the sport throughout my medical training and beyond. In 2017 and 2018, I was



Hernan Goldshtein, MD
La Jolla, CA

honored to represent our country by playing for Team USA in the physicians World Cup. I owe a great deal of thanks to my partners and especially to my family who support and encourage my love of the game. ■

This is me leading the charge at Medical Association of Georgia's day at the capital. Healthcare includes advocacy, not only patient care. Both are my passion.



Lisa C. Perry-Gilkes, MD
McDonough, GA

Another outlet is dance. My first-grade report card said, "Lisa likes creative expression through dance." Well, it's not a surprise that we have a line dance class in my office for me and the staff every other Thursday before office hours, taught by one of our patients. ■

Over the last few years I have really gotten into running when I am outside of work. Several days a week as soon as I get home, I change into running gear and I'm



Ryan H. Belcher, MD
Nashville, TN

out the door and have even participated in a couple half-marathons. After spending all day in an operating room or clinic, running outside helps me keep my mind and body fresh. ■

New guideline for creating unbiased educational content

■ **Richard V. Smith, MD**

AAO-HNSF Coordinator for Education

We recently needed to take down a Patient Management Perspectives (Pmp) course, as it had culturally insensitive and biased language. Although this course was created nearly a decade ago, it quickly brought to light an opportunity to improve the way we approach education in our specialty and to develop a guideline to ensure we are creating unbiased education content.

Through input from the Education Steering Committee and reviewed by the Ethics Committee and Diversity/Inclusion Committee, the guideline was developed and approved by the Executive Committee. We are also in the process of developing a new course on

unconscious bias that will include ways we can improve our workplace, patient care, and the future of medicine. This course will be made available under the Faculty Development Series at AcademyU.org in early 2019.



Richard V. Smith, MD

I'd like to especially thank **Cristina Cabrera-Muffly, MD**, Residency Program Director, Department of Otolaryngology, University of Colorado School of Medicine, for her contributions on this initiative.

We are among the first specialties to address this important topic at the Academy level. It is truly a privilege to work with our Academy and membership, all of whom care

“ We are also in the process of developing a new course on unconscious bias that will include ways we can improve our workplace, patient care, and the future of medicine. ”

deeply about how we educate ourselves and care for our patients.

To view the AAO-HNSF Continuing Professional Development Guideline on Creating Unbiased Educational Content, visit www.entnet.org/education. ■



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Humanitarian service: Uganda

In May 2018, **Akina Tamaki, MD**, and **Shawn Li, MD**, traveled to Mbale, Uganda, under the leadership of **Chad A. Zender, MD**, with the Head and Neck Outreach (HNO) team, a partnership between Case Western Reserve University, University Hospitals Cleveland Medical Center, the Uganda Cancer Institute, and Makerere University School of Medicine. There, a team of 10 from the United States worked with local providers to screen and treat patients with a wide range of pathologies, including head and neck cancers, congenital malformations, tracheal stenosis, and thyroid or parotid masses. Bottom left, members of the HNO team from the U.S. and Uganda (from left): Fred Bisso, MD; Dr. Zender; Isaac Mukiibi, MD; Judith Tuhaise, MD; Idress Kabezzi, MD; Jeffrey Otiti, MD; Ian Bwete, MD; Fiona Kabegenyi, MD; Dr. Li; and Dr. Tamaki. Bottom right, Dr. Zender operates with members of the HNO team.

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DONOR SPOTLIGHT

Betty S. Tsai, MD

From resident to Millennium Society Lifetime donor in five years

The AAO-HNS *foundation* is honored to spotlight **Betty S. Tsai, MD**, who became a Millennium Society Lifetime donor through her generous pledge of \$50,000 in 2013 to the *foundation's* Annual Fund. Dr. Tsai's philanthropic support of the *foundation* as a resident and fellow-in-training and her dedication and commitment to the Academy through her volunteerism and leadership is awe-inspiring.

Dr. Tsai, who completed her pledge this past June, joined the Academy in 2006 as a resident at the University of California, San Francisco, Department of Otolaryngology. At that time, Dr. Tsai made full use of the many resources that have helped her succeed at different stages of her still-young career, such as the education offered through AcademyU® and the combination of education and networking opportunities at the Annual Meeting.

The biggest influence on Dr. Tsai's decision to give back to the specialty was becoming a CORE grantee in 2009, receiving funding for her research on "Effect of cochlear capsule bone matrix material properties on hearing." This solidified her passion to support not only the *foundation* but the Annual Fund. When Dr. Tsai made her pledge in 2013 she said, "My reason for giving is to enable the Academy to have the time and money to develop resources to optimize training and learning opportunities. As a resident, I had the opportunity to do research through a CORE grant and I want others to have the same opportunity."

She still feels that way today. "I wanted to give back to the Academy so that it could continue its mission of supporting my colleagues, future colleagues, and our patients. In the past five years, the AAO-HNS



Foundation has offered many products and education programs of high value and quality to all of us, and that has made my donation worth it," said Dr. Tsai.

She continues to give back to the specialty through her involvement in resident education, her participation on several AAO-HNSF Education Committees, her role in developing content for the Academy's new patient health website ENThealth.org, and her work on clinical practice guidelines, just to name a few.

Dr. Tsai encourages others to consider donating to the Annual Fund to continue to build upon the strength and reach of the Foundation's

programs. "Life is short. Make it count. Contributing to the AAO-HNSF Annual Fund impacts all our lives and ultimately all of our patients' lives. Even if it is a small gift, together we can create something great," she said.

Since Dr. Tsai made her pledge in 2013, she has become the mother of two daughters, Paisley, four years old, and Evelyn, one year old. She lives with her "amazing husband," Kim Lee Do, "without whom none of this would be possible. He is the glue that holds our family together so that I can contribute as much as I can to the field of otolaryngology and to all our Academy activities," said Dr. Tsai. ■

COMMENTARY

Consider osteopathic medical students

■ Akshay V. Patel, DO, MA

Connecticut Ear, Nose, and Throat Physicians; Co-Director, Head and Neck Cancer Program, Helen and Harry Gray Cancer Center at Hartford Hospital; Assistant Clinical Professor, University of Connecticut Department of Otolaryngology-Head and Neck Surgery

I have been paying attention to the growing concerns regarding declining application numbers for otolaryngology-head and neck surgery (OHNS) residency and unfilled positions with interest. Undoubtedly, a more rigorous application process¹ and the high level of academic achievement expected of applicants are hurdles among medical students. Diminished exposure to OHNS curriculum likely inhibits growing interest.

I worry that the recent reduction in applications is a prediction for the future, particularly among a generation of millennial trainees. Millennials are more aware of work-life balance, risks of burnout, and potential financial limitations of longer training programs.

Evidently, the ACGME and residency program directors are addressing factors related to work-life balance and resident wellness to combat burnout.² As applicants' awareness increases regarding mitigation of burnout, interest might rebound to some degree. Financial limitations of longer training programs are more complicated, and each institution must address this as appropriate.

One simple adjustment is for program directors to broaden their reach. Osteopathic medical students make up 25 percent of the medical student population³, and each year osteopathic medical students apply for American Osteopathic Association and ACGME-accredited residency programs. Osteopathic otolaryngology-head and neck surgery programs are

“ Few ACGME-accredited otolaryngology-head and neck surgery residency programs have interviewed osteopathic candidates, and fewer have accepted these bright, hardworking, eager, and well-rounded physicians as part of their training programs. ”

competitive and draw well-qualified applicants. Historically, well-qualified osteopathic medical students have been deterred from applying to ACGME-accredited OHNS residencies due to unsubstantiated, unfavorable bias. 2018 NRMP data show that less than six percent of allopathic OHNS programs “often” consider osteopathic medical students for interview and ranking.⁴ Only three osteopathic medical students were accepted to ACGME-accredited OHNS programs in 2018.⁴

Few ACGME-accredited otolaryngology-head and neck surgery residency programs have interviewed osteopathic candidates, and fewer have accepted these bright, hardworking, eager, and well-rounded physicians as part of their training programs. It is less uncommon that osteopathic otolaryngologists are interviewed and accepted for competitive fellowship programs, but still bias exists.

As the single GME accreditation system draws closer, some osteopathic OHNS residencies aim to remain individually active, but will accept allopathic medical student applications. Other osteopathic OHNS programs are merging with ACGME-accredited allopathic OHNS programs, and one would hope that these combined programs will foster an equitable

environment absent of bias against osteopathic medical students. Well-qualified osteopathic medical students interested in otolaryngology are available to help fill in the match gap. I urge allopathic OHNS program directors to reach out and consider osteopathic medical students more often. ■

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2019-2020 committee application cycle opens November 1

Apply to become an AAO-HNS/F committee member and let your voice be heard! The 2019-2020 application cycle will open on November 1, 2018, and close on January 1, 2019. All committee applicants shall be in good standing with the Academy and must be a voting fellow, member, resident member, scientific fellow, international fellow, or international member of the Academy to be eligible to serve as a committee member.

If you have any questions about the committee process, please email committees@entnet.org.

Get Involved! ■



Wyoming Otolaryngology with Cope Norcross, MD

Data is a critical component in today's ever-changing healthcare environment. Participants using the Reg-ent registry are harnessing the power of data to guide the best ENT care for their patients.

Wyoming Otolaryngology became a Reg-ent participant to do just that. Cope Norcross, MD, learned about the otolaryngology-specific clinical data registry during his attendance at the AAO-HNSF 2015 Annual Meeting & OTO Experience in Dallas, TX. Since joining Reg-ent in 2016, they have reported PQRS 2016 and MIPS 2017 through Reg-ent.

"In addition to meeting reporting requirements through Reg-ent, one of the other invaluable benefits for us is that if we use it properly, we will be able to show that what we think we are accomplishing in patient care and quality is actually what we are accomplishing," said Dr. Norcross.

Reg-ent is the only otolaryngology-specific Qualified Clinical Data Registry (QCDR) focused on quality improvement and patient outcomes. As a QCDR, Reg-ent

accommodates all required reporting for MIPS 2018 performance categories including Quality, Promoting Interoperability (PI) (previously called Advancing Care Information [ACI]), and Improvement Activities (IA).

Improving quality of life for his patients is at the core foundation for why Dr. Norcross chose otolaryngology. "It matched what I really wanted to do—to have expertise in a specific body area. I get to treat all ages and all stages of life. I build relationships with patients and their caregivers over time. I can perform short, less intricate surgeries or more complex surgeries. Otolaryngology offers the full spectrum of patient care."

Wyoming Otolaryngology was founded in 1967 and is one of the oldest medical practices in the state of Wyoming. With three practicing otolaryngologists, two audiologists, and a nurse practitioner, they are a busy practice seeing patients who travel within two to three hours of their Casper, WY, office, with symptoms covering the spectrum of general otolaryngology conditions and diseases.

Dr. Norcross joined the practice in 2006, and since then has seen the complexity and increased demands on physicians. "The business of medicine impacts patient care because we have to change what we do to fit the ever-changing reporting regulations. This, of course, takes away from the patient/doctor experience," he said.

The practice implemented an EMR five to six years ago. Dr. Norcross noted that it did manage to help keep the computer out of the patient/doctor relationship; however, with more complex meaningful use reporting requirements, "we were finding it difficult to adequately report what we needed to report despite having an EMR. Not only did Reg-ent help with reporting requirements working with our EMR, but it demonstrated our outcomes to show that we are an excellent practice."



Cope Norcross, MD

Data Mapping

The AAO-HNSF partnered in the development of Reg-ent with FIGmd, Inc., a company that specializes in extracting clinical data from EHRs into clinical data registries. FIGmd provides support to Reg-ent participants for the process of data mapping, where the data that is relevant to the registry is extracted automatically from the EHR and is then transmitted on a scheduled basis directly to the Reg-ent registry and validated for accuracy.

“We had outstanding support from FIGmd in addressing any obstacles and overcoming any initial challenges with the setup of our data mapping. The best advice I can give is that if you put in the time upfront to the setup, then the rest is fairly seamless. We have accomplished more with Reg-ent than we could have done on our own,” said Dr. Norcross.

Dashboard

Reg-ent offers a customizable dashboard that creates a visual representation of each participant’s data, allowing them to view and select all categories of MIPS including Quality, PI, and IA, monitor performance in all three categories, and track performance against Reg-ent registry benchmarks and CMS quality measure deciles.

While indicating that the practice intends to make greater use of the dashboard moving forward, Dr. Norcross noted its value: “Using the dashboard is an easy way for us to tell what is going on with diagnosis codes, meeting all of the standards, and just overall telling us if we are doing a good job.”

The future of reporting with Reg-ent

“The reporting benefit of Reg-ent is a big one. Not only does it capture what we want

but it will help us in the future. No doubt that insurance companies will join CMS in quality reporting. They will want to make sure we are good at what we are doing and that we have quality and good outcomes,” said Dr. Norcross.

The data contributed to the registry helps to grow the data repository within Reg-ent that will serve countless purposes beyond quality reporting—to not only define quality patient care and outcomes, but also to demonstrate the value of the care provided.

Wyoming Otolaryngology plans to continue as a participant of Reg-ent for years to come, Dr. Norcross said. “It is cost-effective and offers more and more of what we are required to do in the business of medicine that also translates into improving quality of life and the enhanced care we provide to our patients daily.” ■

Neurotology quality measures coming to Reg-entSM in 2019

The AAO-HNSF and the American Association of Neurology (AAN) partnered to develop quality measures from the updated AAO-HNSF Clinical Practice Guideline: “Benign Paroxysmal Positional Vertigo (BPPV).” Five new measures have been created for patients experiencing neurotology conditions that cause dizziness and balance problems. These measures address numerous conditions with a focus on vertigo NOS, BPPV, Meniere’s disease, vestibular migraine, and unilateral hypofunction (UVH).

As with all quality measures, these are intended to assist clinicians in improving the quality of care they provide to their patients. Four of the measures are process measures

(what a clinician does to improve or maintain health), and one is a patient reported outcome measure (PROM), measuring how a patient feels they are doing using a validated tool.

It is important to note that the Quality of Life (QoL) measure is the first QoL measure specific to those with neurotology conditions. PROMs allow clinicians to determine how they are addressing what is important to the patient. The following measures will be available in Reg-ent in 2019:

- QoL for patients with neurotology disorders
- Vestibular rehabilitation for unilateral or bilateral vestibular hypofunction
- Dix-Hallpike Maneuver performed for patients with BPPV



- Canalith Repositioning Procedure performed for patients with Posterior Canal BPPV
- Standard BPPV management

The measures were published in the October issue of *Otolaryngology–Head and Neck Surgery* and appeared online in *Neurology* on September 1.

For questions regarding these new measures, or measure development, email measures@entnet.org. ■

■ at the forefront

Alphabet soup:

Acronyms you need to know

Ever read an article, had a conversation, or watched a news program that included myriad acronyms that cause a “what does that mean” moment? Cross a couple of those questions off your list by reviewing this compilation of acronyms you need to know to be an effective advocate for the specialty! Questions about these terms or how to get involved? Contact the AAO-HNS Advocacy Team at GovernmentAffairs@entnet.org.

3P – Physician Payment Policy Workgroup.

3P is an advisory body to Academy leadership and staff on issues related to socioeconomic advocacy, regulatory activity, coding and reimbursement, and practice management. 3P oversees the review and content for the Clinical Indicators and the Position Statements, and produces resources to members such as template appeal letters and CPT for ENT coding guidance articles.

APM – Alternative Payment Model.

APMs are a type of payment methodology that incorporates quality and total cost of care into reimbursement. Eligible clinicians that successfully participate in a CMS-defined Advanced APM may be exempted from MIPS reporting (see below) and receive an incentive payment.

CBO – Congressional Budget Office.

CBO produces independent analyses of budgetary and economic issues to support the congressional budget process. CBO “scores” proposed bills to help lawmakers understand the cost or savings associated with a legislative package.

CHHC – Congressional Hearing Health

Caucus. CHHC is a bipartisan caucus of members from the U.S. House of Representatives

and Senate committed to supporting the needs of people with hearing loss and other auditory disorders. The AAO-HNS is a member of the Friends of the CHHC.

CMS – Centers for Medicare & Medicaid

Services. CMS is a federal agency within the U.S. Department of Health and Human Services. It is responsible for administering the Medicare program and working with states on the administration of their Medicaid programs.

HIT – Health Information Technology.

Software and computer systems make medical records electronic, reducing paperwork errors and redundant forms. Federal and state governments are implementing numerous proposals to encourage the adoption of HIT while promoting quality initiatives and protecting patient privacy.

I-GO – In-district Grassroots

Outreach. The Academy’s I-GO program connects AAO-HNS members with their elected federal officials at home in their legislative districts. These in-district opportunities provide a more personal and relaxed setting for legislators and AAO-HNS members to interact and discuss the Academy’s legislative priorities and their impact on patient care.

MACRA – Medicare Access and CHIP

Reauthorization Act. MACRA repealed the Sustainable Growth Rate (SGR) formula that Medicare previously used to determine physician reimbursement and established the QPP and MIPS (see below).

MIPS – Merit-based Incentive

Payment System. MACRA created the MIPS to replace the previous CMS Quality Initiative Programs and the SGR formula. MIPS

incorporates aspects of several legacy CMS quality programs to develop a component score to determine physician payment. Eligible clinicians report on four categories that add up to a composite performance score (CPS).

NIDCD – The National Institute on Deafness and Other Communication

Disorders. NIDCD is one of 27 Centers and Institutes that make up the National Institutes of Health (NIH) and conducts biomedical and behavioral research in the fields of hearing, taste, smell, voice, balance, language, and speech, thereby supporting disease prevention and health promotion.

PAC – Political Action Committee.

PACs allow individuals with shared interests the opportunity to pool their voluntary donations to make contributions to federal candidates on behalf of the entire group. PACs represent a legal way to participate in the election process. ENT PAC (www.entpac.org) is the political action committee of the AAO-HNS.

TIA – Truth in Advertising.

The AAO-HNS and others in the physician community support state and federal efforts to implement TIA legislation requiring ALL healthcare providers to inform patients of their credentials and/or level of training in patient communications and marketing materials. TIA is an important component of providing patients with the best possible care.

QPP – Quality Payment Program.

QPP provides Medicare payment incentives for physicians and other eligible clinicians, rewarding value and outcomes in one of two ways (based on practice size, specialty, location, or patient population); through either MIPS or Advanced APMs. ■

AMA House of Delegates report:

Issues impacting otolaryngology

■ Robert Puchalski, MD

Chair, AAO-HNS Delegation to the AMA House of Delegates

The American Medical Association (AMA) held its 2018 Annual House of Delegates (HOD) Meeting in Chicago, IL, June 9-13. Your Academy was represented by **Robert Puchalski, MD**, Delegation Chair; **Douglas Myers, MD**, Delegate and Otolaryngology Section Council Chair; **Craig S. Derkay, MD**, Delegate; and **James C. Denny III, MD**, AAO-HNS EVP/CEO, as Alternate Delegate.

The 2018 AMA Annual Meeting was full of discussion on the big topics facing the medical community and the nation. U.S. Surgeon General Jerome Adams, MD, MPH, a special guest at the meeting, gave a speech encouraging physicians to lead the nation in a civil discussion on the pressing issues of our day, such as gun violence, substance-use disorders, and health equity.

Dr. Adams, an AMA Delegate, encouraged physicians to look “upstream for root causes and preventative solutions” to substance-use disorders and other health issues. Noting that he joined the AMA 20 years ago, he said the experience “lit a fire,” helping him to develop into a physician leader.

Below is a summary of the meeting, highlighting a few of the many debated reports and resolutions most relevant to our specialty.

Retrospective ER coverage denials

Retrospective denials are becoming an increasing trend among national payers. The AMA voted to work to strengthen the enforcement of federal and state laws which require payers to cover ER care when a patient reasonably believes they are in need of immediate medical attention, including

the imposition of meaningful financial penalties on insurers who do not comply with the law.

Grill brush warning

The AMA voted to secure placement of a warning label on all wire-bristle grill brushes informing consumers about the possibility of wire bristles breaking off and being accidentally ingested.

Portable listening devices and noise-induced hearing loss

The AMA voted to advocate for labeling on earbuds that do not have amplitude limiters to warn of the risk of hearing loss with extended use at high volume levels for extended periods.

Compensation for pre-authorization requests

In an effort to reduce unnecessary administrative and related financial burdens, the AMA voted to petition CMS that CPT code 99080 be reimbursed by Medicare.

Physicians at the meeting also:

- Sought to boost affordability and competition in ACA marketplaces
- Adopted policy that puts organizational muster behind achieving health equity in the U.S. health system
- Agreed upon common-sense gun safety measures
- Committed to integrating precision medicine into alternative payment models
- Declared that drug shortages are a matter of national security.

The next meeting of the AMA HOD is scheduled for November 10-13, 2018, at National Harbor, MD. With questions regarding this report and other AMA HOD activities, please contact govtaffairs@entnet.org. ■

Otolaryngologists: Masters of hearing health

■ **Robert T. Sataloff, MD, DMA, FACS**

Professor and Chairman, Department of Otolaryngology – Head and Neck Surgery; Senior Associate Dean for Clinical Academic Specialties; Drexel University College of Medicine, Philadelphia, Pennsylvania

With the concurrence of the Council of the American Society of Geriatric Otolaryngology

In June 2018, Beck et al. published an article proposing that audiologists perform dementia screening.¹ They highlighted their view of “hearing care professionals as gatekeepers,” and stressed that audiologists should be knowledgeable about dementia screening and prepared to be active in the conversation regarding memory issues. Admirably, they advocated referral to clinicians with expertise in dementia. However, this suggested expansion of the scope of audiologic practice should be viewed in the context of other attempts at scope-of-practice expansion (in several states) that have proposed giving audiologists the authority to make diagnoses and to eliminate the requirement or recommendation for medical consultation. We would be remiss if we responded to these initiatives merely with resistance, concern for our own practice scope, or even concerns about patient safety. The scope-of-practice debate also should encourage us to re-examine our own skills and training to ensure that all otolaryngologists have and promulgate the knowledge necessary to provide optimal, comprehensive care of patients with hearing and related disorders.

The proposals mentioned above represent one small part of an extremely important issue that we are not addressing as a field as well as we might. **George A. Gates, MD**, has proposed the establishment of “Auditory Medicine” as one of our disciplines. Both Gates and I have been involved actively in central auditory testing in adults since the 1980s, long before the recent discovery of the correlation between peripheral hearing loss and cognitive function. Central hearing impairment and related issues always have been within the scope of practice of otolaryngologists. In addition, as physicians, we all have had courses in neurological sciences and psychiatry, areas not covered as comprehensively and expertly during standard audiology training. Physicians also have unique training in the otologic consequences of systemic diseases and their treatments; the effects of medications on hearing, balance, and cognition; and the evaluation of polypharmacy in older patients with apparent otologic and/or cognitive impairments. These important topics are not included in audiology training. Dementia, other cognitive impairments, and processing disorders are medical diagnoses. The diagnosis of at least selected central impairments is within our scope of practice, and outside the scope of practice of audiologists, who do not have the requisite breadth and depth of training. Collaboration with audiologists is invaluable and is routine in most otologic and neurologic practices; audiologists should function as members of a medical team whether they are testing hearing, balance, or central function. Abrogating our responsibility to interpret tests

to establish medical diagnoses and to determine underlying etiologies would not be in the best interest of the public.

The concern that I mentioned above about otolaryngology’s approach to this problem relates to our residency training curriculum and requirements, and might warrant more intense discussion with the AAO-HNSF and American Board of Otolaryngology–Head and Neck Surgery (ABO-HNS). As an example of the kind of issues we face, audiologists tried recently to introduce legislation in Pennsylvania that would effectively have defined hearing tests as being solely within the scope of audiologists’ practice. Most of us in otology agree that physicians should be permitted to perform a hearing test if they choose to do so, and that testing hearing is and should be within our scope of licensure. The proposed law would have challenged that. We also should be able to perform and especially interpret central auditory testing and other cognitive screening that we deem to be within our purview; and physicians should retain the exclusive responsibility for assigning any medical diagnosis, and certainly diagnoses as important as hearing loss, central auditory disorders, and dementia. If otolaryngologists are to continue to have a credible basis on which to assert that performance and interpretation of auditory and related testing is within our scope of practice (even if we choose to delegate performance of tests to audiologists or other professionals much of the time), then we should document consistently that our physicians have been trained during residency to perform and interpret such testing. It is incumbent upon each

of our training programs and the ABO-HNS to review the training in each of our residencies to be certain that every otolaryngologist is well-versed in how to perform an audiogram, VNG, ABR, and other otologic tests, and that every residency graduate has performed supervised tests and interpreted them accurately. Moreover, those competencies should be documented as meticulously as we document surgical cases; and auditory medicine knowledge should be represented well on Board examinations, documenting further that these activities are part of otolaryngology. If audiologists succeed in having the privilege to perform tests for hearing, balance, and perhaps some aspects of cognition designated exclusively to them, then that is going to make it much easier for them to assert that they should be interpreting the tests and rendering diagnoses.

We need to document well how we address the diagnosis and treatment of disorders of the ear and related structures within our specialty, and within our training programs. If we allow

training deficiencies, or insufficient documentation of competency, in performance and interpretation of tests of the ear and related structures (including the brain), those shortcomings are likely to become the root cause of our loss of control of patient care. Since no one but a physician has our depth of knowledge and understanding, this shift in scope of practice toward non-physicians would not be in the best interest of the public. It is time to review and enhance (where necessary) our residency training requirements for performance and interpretation of tests of hearing and balance, and ideally of facial nerve, auditory processing, cognition, and other neurotologic functions, as well. We need not only to **think** of ourselves as masters of comprehensive hearing health, but also to be sure that we really **are** masters. ■

References

1. Beck DL, Weinstein BE, Harvey MA. Dementia Screening: A Role for Audiologists. *Hearing Review* 2018;25(7):36-39.



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ENThealth.org:

Primed for preview: The new patient health website

ENThealth.org, debuting at the 2018 Annual Meeting & OTO Experience in Atlanta, Georgia, this month, is the Foundation's new dynamic patient health website—a consumer-facing online resource that will position the AAO-HNS/F as THE trusted source for patient-centered otolaryngology-head and neck surgery information.

The goal is to offer approachable, patient-oriented health information that reliably informs the public about ENT topics in interactive and engaging formats. To accomplish that, the site includes:

- conditions and treatments from A-Z
- a symptom checker to navigate possible causes of what they and/or their loved ones are experiencing
- videos showcasing AAO-HNS physicians speaking about a variety of conditions and diseases
- a unique visual module called “It’s All Connected,” where visitors can explore the holistic view of the interrelationships between many ENT conditions
- Find an ENT, a best-in-class physician directory connecting patients with AAO-HNS members
- quizzes and polls to test knowledge and to engage visitors with the site



- easy-to-share pages with icons on each page, making it a simple click to share content through social media, such as Facebook, Twitter, or Instagram, or print at home
- and more!

ENThealth.org provides peer-reviewed, copyrighted information on otolaryngology-head and neck surgery conditions, symptoms, and treatments, the website also offers materials that focus on wellness and prevention in a section called “Be ENT Smart.”

In addition, through content focused on “What’s an ENT?” the website aims to promote public understanding of the otolaryngology-head and neck surgery specialty, increasing awareness of the breadth and diversity of the types of conditions and diseases treated by the specialty.

The transition of the Academy’s patient health information to its own dedicated website will also include a new licensing

and printed program in January 2019. More information will be forthcoming about the new subscription program that will offer both co-branded, downloadable PDF patient hand-outs as well as content licensing with real-time, automatically updated access to ENThealth.org content.

The website content is being developed by your peers through a governance structure that includes teams of clinician experts in their area of specialty, referred to as Consumer Health Development Groups (CHDGs). An ENThealth.org Executive Committee, composed of clinical experts, provides guidance and overview.

Look for more in the November *Bulletin* about all that ENThealth.org offers as well as more about the members of the ENThealth.org Executive Committee and the CHDGs. Until then, please check it out at ENThealth.org. ■

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- **Welcome Ceremony** - Sunday, October 7, 5:00 pm, GWCC, Building B, Ballroom 2-3
 - **Panel Presentation: "How Our Upcoming ENThealth.org Website Will Benefit You and Your Patients"** - Tuesday, October 9, 7:30 am, GWCC, Building A, Room 307
 - **ENThealth Booth** in Academy Central - Saturday, October 6 - Wednesday, October 10, GWCC, International Boulevard Entrance, Registration Hall
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What are we



doing for you?

Irritating rules burdening day-to-day practice

■ James C. Denny III, AAO-HNS/F EVP/CEO

The direct relationship between policies and rules that are perceived as burdensome, inappropriate, and unnecessary and the overall wellness of the physician community has been established multiple times over the last five to 10 years. Otolaryngologists are not immune from this phenomenon and may be near the front of the line when it comes to the “danger level” caused by an increasing series of both in-office and facility-based requirements

related to instrument cleaning, packaging, and storage. This topic generates a great deal of discussion on ENTConnect and elsewhere.

To identify and clarify the specific issues and concerns affecting our members and their patients, we sent out a short survey of six questions through multiple media avenues. The questions covered type of practice setting; what policies, recommendations, rules, or standards negatively affect your practice and how; the most onerous requirements as they apply to your practice, including specific examples; and estimates of the additional cost to your practice

for compliance with these rules. We received 158 detailed responses in the first 10 days.

After collating the answers to the survey, we were able to obtain an audience with The Joint Commission, led by its Director, David Baker, MD, with the aid of **Russell W. H. Kridel, MD** (AMA, Trustee), Helen Burstyn, MD (CMSS, EVP) and Jay Randolph, MD (General Surgeon member of the Joint Commission). We had previously provided them the results of our survey via teleconference on June 18, 2018. We discussed the results of the survey and major areas of concern by our members. The Joint

Table 1: What Type of Practice Setting Best Describes Your Current Situation?

Practice Type	Number
Academic	53 (33.5%)
Employed-Hospital system	29 (18.4%)
Military	14 (8.9%)
Private (single/multi specialty)	62 (39.2%)

Table 3: What JC Policies, Rules or Standards Negatively Affect your Practice and Wellness?

Policy Type	Number
Hospital/OR standards	122
ASC standards	66
Office-based OR standards	67
Policies specific to VA system	107
Private (single/multi specialty)	20
All policies reasonable with no negative effect	1

Table 2: In What Areas Do Policies You Consider Inappropriate Negatively Affect Your Practice?

Area Affected	Number
Patient Safety	95
Cost of Practice	135
Time	141
Quality	86
Staff and Physician frustration	148
No negative affect	2

Table 4: Please List in Order the Most Onerous JC Requirements as They Apply to Your Practice?

Most Onerous Requirements	Number
Peel packing instruments for office exams	122
Flexible non-channeled scope cleaning policies	66
Sterilization procedures in hospital	67
Storage of OR instruments (airway carts)	107
Changing suction cannisters/tubing	20
Surgical attire	13
Medications in OP clinic rooms	12

Commission addressed each of these issues individually through thoughtful discussion.

The survey represented all major practice types in our specialty (Table 1). The responders described how policies affected the different areas of their practice, as noted in Table 2. They also looked at the major consequences of these policies in Table 3. Finally, Table 4 ranks the most onerous requirements to their practice.

The Joint Commission response was very encouraging, both in the willingness to listen and discuss the matter with us and with the results of the discussions. They suggested that they produce a perspective article for their September bulletin, which would include clarifications related to the issues we discussed. They also agreed to do an online FAQ clarification of their policies and discuss them with their surveyors. Additionally, they suggested setting up a hotline for physicians to directly report areas of concern that they feel are not achieving the stated goal of the policy. Subsequently, we received a letter detailing The Joint Commission responses to the areas of concern raised in the survey in August (Points from it follow).

The specific areas in which they offered comments addressing the situations identified in our survey include **the peel packing of instruments in the office setting; the methodology for cleaning non-channeled endoscopes; the storage of OR equipment in airway carts; and OR attire**, which represent the most commonly cited concerns.

We appreciate the work that **C. W. David Chang, MD**, representing the PSQI committee (recently selected as a “Committee of Excellence” award winner for 2018) put into this project. This is an example of how groups working together addressing a problem from multiple perspectives can facilitate change and improvement in existing policy.

On August 16, 2018, an official letter was received from The Joint Commission.

It outlined the nine areas we spoke about of concern to members. The following excerpts key points from the document:

1. Peel packing instruments for office exams

The Joint Commission does not have a requirement that instruments that will touch mucous membranes be individually peel-pouched.

The minimum standard for instruments that will touch mucous membranes but will not penetrate the mucosa is high level disinfection. However, so as not to have to meet all of the requirements for high level disinfection of instruments and to be able to wash and process in batches, many facilities have decided that it is easier to sterilize these instruments and place them in peel pouches to ensure that they are kept clean during distribution to clinical sites.

The minimum storage requirement for items that will touch mucous membranes is storage in a manner that will prevent contamination. Therefore, if sterilized instruments are distributed in peel-pouches, they can be opened and distributed to multiple clean drawers.

2. Decontamination procedures for channeled scopes are applied to flexible nonchanneled endoscopes

The Joint Commission does not have such a requirement. The FDA, CDC, Association for Medical Instrumentation (AAMI), The Joint Commission and multiple other organizations have all emphasized the importance of carefully following manufacturer instructions for use when reprocessing any endoscope in order to protect patients. In order to ensure the safest possible equipment is used on patients, it is the expectation of The Joint Commission that facilities will follow manufacturer instructions for cleaning all endoscopes regardless of the presence of lumens. This includes the manufacturer’s instructions for the endoscope (pre-cleaning at point of use, leak testing, cleaning, high level disinfection, rinsing, and drying) and associated cleaning products and equipment.

3. Requiring facilities to define a maximum allowable time before endoscope reprocessing is needed.

Thank you for bringing this issue up. We have reviewed the current practice of requiring facilities to define a maximum allowable time between endoscope reprocessing. We have found no increased risk related to storage time as long as manufacturer instructions were followed. ***Therefore, we are instructing the Joint Commission Surveyors to not score if the facility has not reprocessed an endoscope that has been stored, unless the endoscope is visibly soiled or dusty or the manufacturer specifies a maximum “hang time.” We are in the process of educating surveyors on this change.***

4. Not allowing flash sterilization

The Joint Commission recognizes that flash sterilization is often necessary when an instrument is contaminated during a procedure. However, we will cite facilities if they are using Immediate Use Steam Sterilization routinely (e.g., in non-emergent cases).

5. Storage of OR instruments (airway carts)

As stated above, instruments must be stored in accordance with their intended use. Items that will come in contact with mucous membranes but will not enter sterile areas or tissue must be stored in a way that maintains cleanliness after disinfection. **It is acceptable to store these types of instruments that have been high level disinfected or sterilized (for convenience) in a cart or cabinet for emergency airway access.**

8. Surgical attire

The Joint Commission does not have a requirement for bouffant hair covering.

We have reviewed studies sponsored by the American College of Surgeons showing that these do not offer greater protection than the traditional surgeon's skull cap, and they may actually be worse.

Surgical attire is often governed by State Department of Health (e.g., licensing) rules and regulations. Facilities should ensure that they are compliant with any state regulations. In the absence of state regulations, facilities should ensure that they follow CMS requirements that surgical attire (e.g., scrubs) be worn and all head and facial hair be covered by personnel entering semi-restricted or restricted areas.

9. Medications in outpatient clinic rooms

The Joint Commission evaluates medication vial storage based on guidance established by CDC guidelines related to safe injection practices and in accordance with key stakeholders requirements (CMS).

CDC recommendations state:¹

Multi-dose vials should be dedicated to a single patient whenever possible. If multi-dose vials must be used for more than one patient, they should only be kept and accessed in a dedicated medication preparation area (e.g., nurses station), away from immediate patient treatment areas. This is to prevent inadvertent contamination of the vial through direct or indirect contact with potentially contaminated surfaces or equipment that could then lead to infections in subsequent patients. If a multi-dose vial enters an immediate patient treatment area, it should be dedicated for single-patient use only.

¹ Available at: https://www.cdc.gov/injectionsafety/providers/provider_faqs_multivials.html

However, based on your questions, we revisited the CDC guidelines and have identified some practical limitations and barriers to healthcare providers complying with the CDC recommendations. We have attempted to contact CDC to discuss this issue, but we have not yet been able to do so. We will continue to work to get our questions answered, and we will update you when we do and notify you of any changes in our survey policy.

As you can see, these comments clarify policy and recommendations in areas that are clearly “pain points” for our members and supporting staffs, both in the private and academic sectors. The results of these interpretations—particularly as related to “peel packing” of instruments both in the office and hospital setting, sterilization requirements for non-channeled endoscopes, and storage of operating room instruments (airway carts)—would seem to offer significant relief in financial terms, physician and staff frustration, time management, and patient safety.

One of the questions on the survey asks each participant to estimate the cost to comply with their current situation as dictated by policies and rules they are subject to. I realize that this is a small sample size and that monetary costs were presented as estimates and not audited amounts. But I feel it is still possible to present a reasonable estimate as to a per-physician benefit that the above-mentioned policy changes represent. Those respondents in private practice and those whose office-based policies are controlled by a hospital system could reasonably expect savings of **\$5,000 - \$15,000** per physician per year, based on the “peel pack” and sterilization changes alone. The time savings and reduced physician and staff frustration is likely **incalculable**. Finally, one saved life in an emergent airway situation is **priceless**.

I want to personally thank everyone who participated in the survey that allowed us to make a difference in your day-to-day practice. We will continue to do our best to help overcome or eliminate barriers you encounter that limit your ability to deliver the highest quality medicine to your patients. ■

Competency: It is everyone's responsibility

■ David H. Chi, MD

Associate Professor, Department of Otolaryngology
Clinical Director, Division of Pediatric Otolaryngology,
Children's Hospital of Pittsburgh of UPMC

Surgical competency is characterized by three S's: solid knowledge base, sound judgement, and surgical skills. While medical knowledge may be assessed with examinations and recertification, surgical abilities and judgment are more challenging to determine and characterize. With further emphasis on quality and safety, surgical competency has become an important aspect of residency training. This concept also extends to otolaryngologists throughout their practice, from early career up to the point of retirement. We highlight the issues of surgical competency that are encountered as a resident, practicing physician, and aging physician.

Residency training

Traditional surgical training has been based on the apprentice model. The concept of "observing, doing, and teaching" a surgical procedure had been the major method of training for the majority of today's practicing surgeons. Surgeons have successfully trained with their mentors and have incorporated lessons learned from unstructured observations into successful practice. Education, however, continues to become more standardized. For surgical specialties, such as otolaryngology-head and neck surgery, case log reporting attempts to ensure that residents meet minimum expected standards for graduation. Yet increasing experience does not guarantee competence.

Therefore, efforts to measure and assess progressive improvement in residency training has led to the establishment of six core competencies. The Accreditation Council for Graduate Medical Education (ACGME) adopted that periodic review be completed of every trainee that encompasses these competencies:

1. Patient care
2. Medical knowledge
3. Practice-based learning and improvement
4. Interpersonal and communication skills
5. Professionalism
6. System-based practice

Routine evaluation of these outcomes provides a measurement of improvement during residency training. The majority of residents are expected to demonstrate successful progression throughout the course of training. Those that do not meet expected standards are identified early, and remediation plans may be initiated. In addition to experiential learning, current residency training has also benefited from advances in technology. Innovative educational models such as hand motion analysis, simulation (animal, cadaveric, 3D-printed models, and virtual reality), and eye tracking continue to provide additional opportunities to monitor surgical competency.

Practicing otolaryngologist

Patient safety and quality is of the utmost importance during the practicing physician's career, and surgical abilities are inherently related to procedural outcomes. The importance of competency becomes emphasized when surgeons are evaluated for credentialing and hospital privileges. Historically, surgeons are

granted hospital privileges after a subjective evaluation, often based on overall impressions of the medical provider, and this review is repeated every two years.

In 2007, The Joint Commission introduced its Ongoing Professional Practice Evaluation (OPPE) and Focused Professional Practice Evaluation (FPPE) processes.¹ These tools help to transition from subjective provider evaluations to objective evidence-based measures.

OPPE is a screening tool to evaluate all practitioners (surgeons and advanced practice providers) who have been granted privileges and to identify those clinicians who might be delivering an unacceptable quality of care. These evaluations are especially applicable to new surgeons, low-volume practitioners, and those introducing new procedures to the institution. OPPE is dependent on the institution and may include reviews of operative and clinical procedures and their outcomes, patterns of pharmaceutical usage, lengths of stay, and morbidity and mortality data. This information may be obtained through periodic chart review, direct observation, monitoring of diagnostic and treatment techniques, and discussion with other individuals involved in patient care.

The information gathered during this process contributes to the decision to maintain, revise, or revoke existing privileges prior to or at the end of the two-year review of the privilege renewal cycle. Typical OPPE is required of all active providers on a regular basis, such as every three or six months. A peer group or committee headed by department or division leaders and quality and safety champion individuals must review the data.



FPPE is the follow-up process to determine the validity of any findings found through OPPE. FPPE may also be initiated because of an egregious event or pattern of preventable unsafe behaviors. FPPE also serves to identify providers with poor technical skills, disabilities, poor judgment, or other impairments that affect patient safety.

The aging surgeon

Like all individuals, surgeons encounter physical changes with age. Visual and hearing capabilities decline. Cognition, visual-spatial ability, and memory capacity may be reduced compared to earlier in one's career.

Mandatory retirement is approved in some professions, such as commercial airline pilots (65 years), National Park Rangers (57 years), and FBI agents (57 years). Mandatory retirement of surgeons does not exist. As more surgeons become employees of hospital systems, they are guarded under the Age Discrimination in Employment Act and cannot have a mandatory retirement age.

The current recommendation from the American College of Surgeons is that, starting at age 65 to 70 years, voluntary and confidential baseline physical examination and visual testing occur.² In addition, surgeons should voluntarily assess their neurocognitive function with online tools. Only a few medical centers have bylaws requiring age-based evaluations.³ Those that have established policies have encountered scrutiny from the medical staff and raised questions of unfair ageism.

Controversial questions remain: Should age ever factor in the surgeon's competency evaluation? Should a senior surgeon have a periodic review of practice? Should evaluations be voluntary or mandatory?

Summary

The importance of quality and safety in patient care is increasingly a priority with high expectations from medical professionals, societies, and the public. This emphasis has resulted in changes that impact an otolaryngologist from their training years and span the entire career.

The evolution of medical education has created higher standards for our current residency graduates. The Joint Commission has also created an expectation for departments to have an ongoing objective process of evaluating healthcare providers that addresses issues with safety and quality of outliers, low-volume providers, and credentialing for new procedures. Lastly, surgeons in the latter aspect of their careers may now have expectations to demonstrate competency to provide the high standards of patient care and quality expected from our specialty and the public. ■

References:

- 1 Joint Commission Standards Frequently Asked Questions. Joint Commission Web site. http://www.jointcommission.org/standards_information/jcfaq.aspx?ProgramId=40.
- 2 American College of Surgeons Board of Governors Physician Competency and Health Workgroup. Statement on the aging surgeon. *Bull Am Coll Surg*. 2016;101(1):42-43.
- 3 Dellinger EP, Pellegrini CA, Gallagher TH. The Aging Physician and the Medical Profession: A Review. *JAMA Surg*. 2017 Oct 1;152(10):967-971.



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A position is available in the Department of Otolaryngology Head and Neck Surgery at the University of Oklahoma College of Medicine for a full-time fellowship trained Pediatric Otolaryngologist at the Assistant or Associate Professor level.

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Letters of interest with accompanying CV should be directed to: Jack C. Borders, MD, Professor and Vice Chair, Otolaryngology Pediatric Service Chief, c/o Nancy Geiger, Department of Otolaryngology Head and Neck Surgery, 800 Stanton L. Young Blvd, Room AAT 1400, Oklahoma City, OK 73104 or via e-mail nancy-geiger@ouhsc.edu.

The University of Oklahoma is an Affirmative Action and Equal Opportunity Employer. Individuals with disabilities and protected veterans are encouraged to apply.



Louisiana State University Health, Shreveport
Department of Otolaryngology-Head and Neck Surgery
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CONTACT:

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

Cherie-Ann Nathan, MD, FACS
Professor and Chairman, Department of Otolaryngology
Director of Head and Neck Surgical Oncology
1501 Kings Highway, 9-203
Shreveport, LA 71103-33932
Telephone: 318-675-6262
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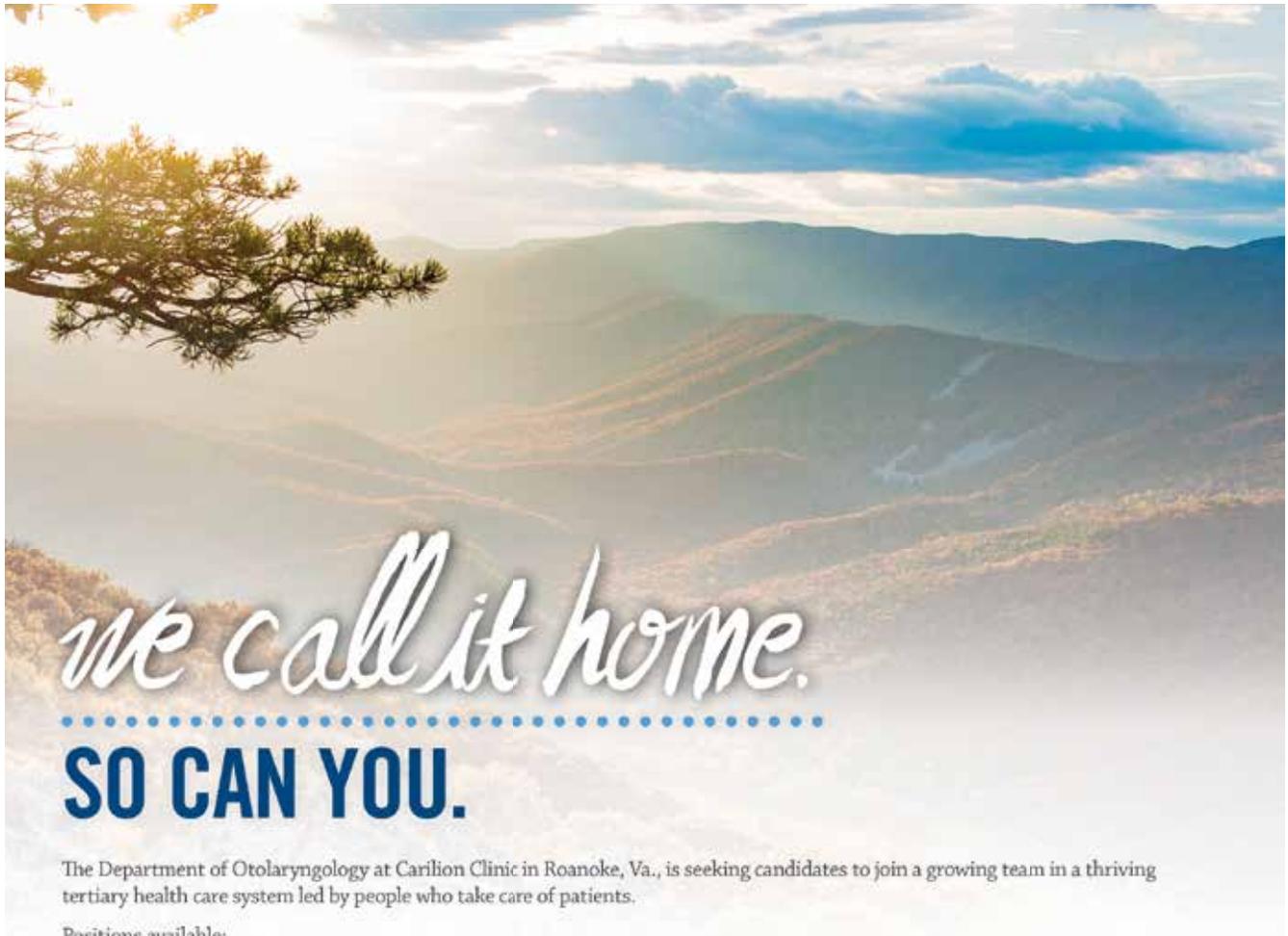
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Stil Kountakis, MD, PhD
Professor and Chairman
Department of Otolaryngology-Head & Neck Surgery
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To Apply, please go to explore.jobs.ufl.edu, search using "Otolaryngology, Gainesville". After applying, please send your CV and cover letter to the appropriate person below:

Pediatric Otolaryngology

Attn: William Collins, MD
email: william.collins@ent.ufl.edu

Otology/Neurotology

Attn: Neil Chheda, MD
email: neil.chheda@ent.ufl.edu

Head & Neck Oncologist

Attn: Peter Dziegielewski, MD
email: peter.dziegielewski@ent.ufl.edu

General Otolaryngology

Attn: Brian Lobo, MD
email: brian.lobo@ent.ufl.edu

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Christopher M. Pezzi, MD, FACS
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Email: bmdacc.md@bmcjax.com



Laryngologist

Birmingham, Alabama

The Department of Otolaryngology - Head and Neck Surgery at The University of Alabama at Birmingham (UAB) School of Medicine is actively recruiting a fellowship-trained Laryngologist to join its nationally ranked department.

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Interested applicants should send letters of inquiry and CV to:

William R. Carroll, MD
 Professor and John S. Odess Endowed Chair
 UAB Department of Otolaryngology - Head and Neck Surgery
 Phone: 205-934-9766
 Email: wcarroll@uabmc.edu

Visit us at www.uab.edu/medicine/otolaryngology

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The Indiana University School of Medicine Department of Otolaryngology-Head & Neck Surgery is seeking a full time faculty physician to join its growing Pediatric Otolaryngology practice at Riley Hospital for Children at Indiana University Health. Rank will be commensurate with experience and training. The primary practice location will be at Riley Hospital for Children, a 400 bed tertiary care children's hospital located in downtown Indianapolis. Our practice is currently staffed by two fellowship trained Pediatric Otolaryngologists and covers the spectrum of Pediatric Otolaryngology including an aerodigestive program/complex airway, sleep surgery, head and neck masses/congenital malformations, otology, a well-established cochlear implant program, rhinology, craniofacial center, laryngology, speech, and a vascular anomalies program.

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For more information, please contact:
Marion Everett Couch, MD PhD MBA FACS
 Richard T. Miyamoto Professor and Chair
 Department of Otolaryngology – Head & Neck Surgery
 Indiana University School of Medicine
 1130 W. Michigan Street, Suite 400
 Indianapolis, IN 46202
 Email address: smaxwell@iupui.edu

**Otologist/Neurotologist
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CONTACT INFORMATION:

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Mike Vaughn, mvaughn@myentdocs.com, 931-520-5831



The University of Utah Otolaryngology seeks BC/BE Neurotologist at Assistant Professor level for full-time faculty position. Fellowship training is required.

Applicants should send updated CV and a list of three references to:

Clough Shelton, MD, FACS, Professor and Chief

University of Utah School of Medicine
50 North Medical Drive 3C120
Salt Lake City, Utah 84132
(801) 585-3186
susan.harrison@hsc.utah.edu

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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 phonemicsurgery (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:
Steven M. Zeitels, MD, FACS
Eugene B. Casey Professor of Laryngeal Surgery, Harvard Medical School
Director: Center for Laryngeal Surgery & Voice Rehabilitation
Massachusetts General Hospital
One Bowdoin Square, 11th Floor
Boston, MA 02114
Telephone: (617) 726-0210 Fax: (617) 726-0222
zeitels.steven@mgh.harvard.edu




UNIVERSITY OF WISCONSIN - MADISON
ASSISTANT/ASSOCIATE PROFESSOR (CHS)
PEDIATRIC OTOLARYNGOLOGIST

The Department of Surgery at the UW School of Medicine and Public Health is seeking an exceptional board certified/board eligible otolaryngology-head and neck surgeon with fellowship training in pediatric otolaryngology. You will join a thriving clinical practice and participate in the education of medical students, residents and advanced practice providers.

Don't miss this wonderful opportunity to join UW Otolaryngology at our state of the art American Family Children's Hospital. American Family Children's Hospital is a Top 50 Children's Hospital per US News and World Report, with four existing pediatric otolaryngology faculty in a comprehensive tertiary/quaternary care outpatient and inpatient practice. This is an excellent opportunity for a pediatric otolaryngologist who seeks a comfortable standard of living combined with an academic practice that affords a wide range of research, teaching, and clinical opportunities.

Rank and faculty track will depend on candidate's interests and academic background. Candidates must be eligible for licensure in Wisconsin.

Interested candidates should go to https://jobs.wisc.edu/PVL_#95155

UW-Madison is an equal opportunity/affirmative action employer. Women and minorities are encouraged to apply. Unless confidentiality is requested in writing, information regarding applicants must be released upon request. Finalists cannot be guaranteed confidentiality. Wisconsin open records and caregiver laws apply. A background check will be conducted prior to offer of employment.

WE WANT YOU!

UNCPN is seeking an Otolaryngologist to join an established group in Rocky Mount, NC

Summary & Responsibilities

- Board certified or board eligible candidate
- Practice includes PA support and medical assistants with scribe capability
- New office with full service audiology, in-office allergy and CO² laser
- Procedure room equipped for minor surgery and sinuplasty

Benefits

- Competitive MGMA salary
- Signing bonus, paid CME days & fund reimbursement and paid annual leave
- Matching 401(k) and malpractice insurance



Please contact Amber Williams at amber.williams1@unchealth.unc.edu to learn more.



UNC PHYSICIANS NETWORK
UNC HEALTH CARE



EXCITING OPPORTUNITY

Atlanta Center for ENT has an opportunity for a full time Board Certified Otolaryngologist in the Buckhead area of Atlanta, Georgia.

Atlanta Center for ENT has a unique opportunity for a talented Board Certified ENT surgeon who is a self starter and a practice builder in the Buckhead area of Atlanta, Georgia.

The practice includes a strong support staff and an Certified Ambulatory Surgical Center on site which yields a superior compensation opportunity via participation in ASC facilities reimbursement, with a potential opportunity for ownership. All aspects of ENT are practiced with a special interest in endoscopic sinus surgery

Contact information:

Donald Dennis, MD, FACS
3193 Howell Mill Rd.
Suite 215
Atlanta, GA. 30327
404-35-1312

<http://www.sinusitiswellness.com/>



Otolaryngology

Call This "Top 10" Community Home

McFarland Clinic is seeking a BE/BC Otolaryngologist to join our extraordinary team and provide exceptional care within Iowa's largest multidisciplinary clinic.

Consistently ranked in the top 10 "Best Places to Live" by Money Magazine and CNNMoney.com, this thriving town has been ranked in the top 3 cities in the country for job growth.

- daVinci Robot and the Olympus Video System
- In-office laryngeal biopsies
- New state-of-the-art minor procedure room
- Epic EMR System
- Weekly cancer case conference
- Established, collegial team and support staff
- Physician owned and governed
- Large, established referral network
- One of the least litigious states in the country
- "#1 Best State to Practice Medicine" - *WalletHub*



Ames, Iowa is a family friendly town that offers top-quality education with the best school district in the state. This Big 12 city has been voted the "Best College Town" by *Livability.com*. Our proud community boasts the cultural, recreational and entertainment amenities of a big city while maintaining the charm that you would expect from small-town living. Welcome to Ames, a place that will quickly become your hometown.

EEO/AA Employer/Protected Vet/Disabled

Contact Doug Kenner

866.670.0334 or dkenner@mountainmed.net



McFarland Clinic

Extraordinary Care, Every Day



INTEGRATED
EAR, NOSE & THROAT
ENT Opportunity
Lone Tree, Colorado

Integrated Ear, Nose, & Throat, P.C. a single specialty group practice in Lone Tree, Colorado, is seeking an Otolaryngologist to replace a retiring partner in August 2019.

Integrated ENT is a general ENT practice that serves the South Denver Metro area. The practice has 4 general otolaryngologists, 3 audiologists, 2 physician assistants, full allergy services, and a facial plastics coordinator. We have a centrally located office near Sky Ridge Medical Center. We offer competitive salary and potential for a productivity bonus, partnership track, 401K/profit sharing plan, vacation time, CME reimbursement, and malpractice/health/dental insurance.

Requirements:

- MD Degree
- Completion of accredited residency program in otolaryngology
- Board certification or board eligible
- Eligibility for Colorado Licensure

The South Denver Metro area is one of the fastest growing populations and economies in the country. It offers quick access to the Rocky Mountains, many national parks, and world class skiing/snowboarding. The region offers easy access to fine arts, dining, all major sports teams, and all the amenities of a large metropolitan area but with easy access to nature. Lone Tree was ranked #7 in Money Magazine best places to live in 2017.

Please email your letter of interest and CV to dsorensen@integratedent.com

SOUTH FLORIDA ENT ASSOCIATES



South Florida ENT Associates, a fifty-five physician group practice operating in Miami-Dade, Broward and Palm Beach Counties, has immediate openings for full-time ENT Physicians. South Florida ENT Associates is the second largest ENT group in the country and the largest in the state of Florida. We provide full service ENT including Audiology, Hearing Aid Sales, Allergy, Facial Plastics, Robotics and CT services.

We offer an excellent salary/bonus with partnership track, health insurance, paid vacation time, malpractice insurance and CME reimbursement, plus other benefits.

Candidate must have strong clinical knowledge, excellent communication skills, be highly motivated and hardworking.

This position will include both office and hospital settings.

Requirements:

- Board Certified or Eligible preferred
- MD/DO from approved medical/osteopathy school and graduation from accredited residency program in ENT
- Current Florida license
- Bilingual (English/Spanish) preferred
- Excellent communication and interpersonal skills
- F/T - M-F plus call

For more information about us, please visit www.sfenta.com.

Contact Information:

Contact name: Stacey Citrin, CEO
Phone: (305) 558-3724 • Cellular: (954) 803-9511
E-mail: scitrin@southfloridaent.com

University of Missouri
 Department of Otolaryngology—
 Head and Neck Surgery



Seeks clinicians, teachers, and researchers who are personable, energetic and innovative to join a rapidly growing and collaborative group of physicians, most of whom have subspecialty interests and training. There are three Faculty opportunities at all academic ranks (Assistant/Associate Professor or Professor) available:

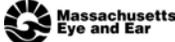
- **Pediatric Otolaryngologist**
- **General Otolaryngologist**
- **Head and Neck Microvascular Surgeon**

Title, track, and salary are commensurate with experience. These positions are affiliated with MU Health Care which include the University of Missouri Hospital and the MU Women and Children's Hospital.

- Competitive production incentive
- Established research program focusing on voice and swallow disorders
- Well established and expanding hospital system
- Ranked by Money and Forbes magazines for career growth and best places to live.

For additional information about the positions, please contact:
Robert P. Zitsch III, M.D.
 William E. Davis Professor and Chair
 Department of Otolaryngology—Head and Neck Surgery
 University of Missouri—School of Medicine
 One Hospital Dr MA314 DC027.00
 Columbia, MO 65212
 zitschr@health.missouri.edu

To apply for a position, please visit the MU web site at <http://hr.missouri.edu/find-a-job/academics/>
 The University of Missouri is an Equal Opportunity/Affirmative Action/Pro Disabled & Veteran Employer.


Harvard Department of Otolaryngology/Massachusetts Eye and Ear
Regional and Specialty Growth Opportunities over the next 1-3 Years

- General Otolaryngology
- Laryngology
- Neurotology
- Pediatric Otolaryngologist

We are expanding to New Hampshire, northern Massachusetts, and Rhode Island and have immediate and longer term openings. Positions are available on our main campus at 243 Charles Street in Boston and our many Boston suburban locations.

The Department of Otolaryngology at Massachusetts Eye and Ear seeks qualified candidates for full-time general otolaryngology positions, as well as two pediatric otolaryngologists, an academic laryngologist with an interest in dysphagia, and a neurotologist with a focus on vestibular disorders. We have available full-time clinician opportunities as well as academic and leadership positions, including regional network director positions.

As a full-time member of the Mass. Eye and Ear staff, there are opportunities to participate in basic and clinical research and/or teaching within Mass. Eye and Ear and Harvard Medical School with academic rank commensurate with experience. The successful candidate must be Board certified or Board eligible in Otolaryngology.

We are an equal opportunity employer and all qualified applicants will receive consideration for employment without regard to race, color, religion, sex, sexual orientation, gender identity, national origin, disability status, protected veteran status, or any other characteristic protected by law.

Please send a letter of interest and curriculum vitae to:
D. Bradley Welling, MD, PhD, FACS
 Professor and Chair, Department of Otolaryngology
brad_welling@meei.harvard.edu



UNIVERSITY OF ILLINOIS
 Hospital & Health Sciences System
 Otolaryngology

The Department of Otolaryngology-Head & Neck Surgery of the University of Illinois at Chicago and the University of Illinois Hospital and Health Sciences System is seeking applicants specializing in Sinus, Rhinology and Skull Base Surgery:

OTOLARYNGOLOGIST-SKULLBASE-RHINOLOGY SURGEON

This is a full-time faculty position with Assistant or Associate Professor rank and tenure to be determined commensurate with experience and interest. We are seeking faculty to join our dynamic and growing clinical academic practice as part of a team-centered approach to patient care. As part of the largest medical school in the US, those interested in pursuing clinical or translational research will find a supportive infrastructure and diverse patient population.

Duties and interest to include providing direct patient care, supervising residents and medical students, and pursuing clinical or translational research. Applicants consideration, application must be received by Oct. 15, 2018. Applications will be reviewed on a rolling basis. Interested applicants should send their curriculum vitae to:

Barry Wenig, MD, MPH, FACS
 Francis L. Lederer Professor and Head
 Department of Otolaryngology-Head & Neck Surgery (M/C 648)
 University of Illinois at Chicago
 1855 West Taylor Street, Room 2.42
 Chicago, IL 60612
 Phone: (312) 996-6582, Fax: (312) 996-1282
 Email: ENTHR@uic.edu
www.otol.uic.edu

The University of Illinois at Chicago is a major clinical and research university offering the cultural, business and entertainment opportunities you can only find in a world-class city. For more information, please visit www.uic.edu or <http://research.uic.edu>

The University of Illinois at Chicago is an affirmative action, equal opportunity employer. All qualified applicants will receive consideration for employment without regard to race, color, religion, sex, national origin, protected veteran status or status as an individual with a disability.

The University of Illinois conducts background checks on all job candidates upon acceptance of contingent offer of employment. Background checks will be performed in compliance with the Fair Credit Reporting Act.



Private Practice Opportunity - General Otolaryngologist

Arizona Otolaryngology Consultants is one of the largest single specialty, physician-owned practices in the Valley, providing high quality medical care since 1997. Our group consists of multiple subspecialties, emphasizing all aspects of Otolaryngology/Head & Neck Surgery, including head & neck oncology, pediatric otolaryngology, laryngology, neurotology, hearing aid sales and CAT scanning. We offer patients ease of access at any of our 5 office locations and many surgery options as a result of over a dozen surgical affiliations.

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

Employment opportunities with AOC include:

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

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

Alison Scott, Practice Administrator – Alisons@aocphysicians.com

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

OTOVEL[®] (ciprofloxacin and fluocinolone acetonide) otic solution

Brief Summary of Prescribing Information

1 INDICATIONS AND USAGE

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

2 DOSAGE AND ADMINISTRATION

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

The recommended dosage regimen is as follows:

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

3 DOSAGE FORMS AND STRENGTHS

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

4 CONTRAINDICATIONS

OTOVEL is contraindicated in:

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

5 WARNINGS AND PRECAUTIONS

5.1 Hypersensitivity Reactions

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

5.2 Potential for Microbial Overgrowth with Prolonged Use

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

5.3 Continued or Recurrent Otorrhea

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

6 ADVERSE REACTIONS

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

6.1 Clinical Trials Experience

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

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

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

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

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

6.2 Postmarketing Experience

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

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

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

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

8.2 Lactation

Risk Summary

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

8.4 Pediatric Use

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

8.5 Geriatric Use

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

10 OVERDOSAGE

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

Distributed by:
Arbor Pharmaceuticals, LLC
Atlanta, GA 30328

Under license of Laboratorios SALVAT, S.A.

OTOVEL is a registered trademark of Laboratorios SALVAT, S.A.

U.S. Patent No: 8,932,610

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

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

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

The difference is in the **delivery.**



OTOVEL[®]
ciprofloxacin 0.3% and
fluocinolone acetonide 0.025%



OTOVEL[®] (ciprofloxacin and fluocinolone acetonide) is a sterile solution—not a suspension¹

- Blow-fill-seal (BFS) technology provides sterile manufacturing and packaging²
- Containers are formed, filled, and sealed in a continuous, automated operation³
- BFS technology reduces human intervention in the fill/finish process³
- Every dose is sterile, precise, and preservative free¹

**Delivered in simple,
single-dose vials¹**

- The first and only antibiotic/steroid combination ear drop in single-dose vials⁴
- Single-use vials contain 1 premeasured dose each—dose BID/7 days¹
- No drop counting. No mixing or shaking required¹
- Demonstrated efficacy and safety in 2 clinical trials^{1,5}

We'd like to deliver Starter Packs to your practice.

Order yours at otovel.com/hcp/resources



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

INDICATIONS

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

IMPORTANT SAFETY INFORMATION

Contraindications

OTOVEL is contraindicated in:

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

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

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

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

References: 1. Otovel [package insert]. Atlanta, GA: Arbor Pharmaceuticals, LLC. 2016. 2. Data on file. Arbor Pharmaceuticals, LLC. 3. Guidance for industry: sterile drug products produced by aseptic processing—current good manufacturing practice. Food and Drug Administration. <https://www.fda.gov/downloads/Drugs/Guidances/ucm070342.pdf>. Published September 2004. Accessed March 15, 2018. 4. Orange Book: Approved drug products with therapeutic equivalence evaluations. US Food and Drug Administration. <https://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>. Updated May 17, 2013. Accessed July 15, 2016. 5. Spektor Z, Pumarola P, Ismail K, et al. Efficacy and safety of ciprofloxacin plus fluocinolone in otitis media with tympanostomy tubes in pediatric patients: a randomized clinical trial. *JAMA Otolaryngol Head Neck Surg*. 2017;143(4):341-349.


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