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JULY 2020

AAO-HNSF 2020 VIRTUAL ANNUAL MEETING & OTO EXPERIENCE

13

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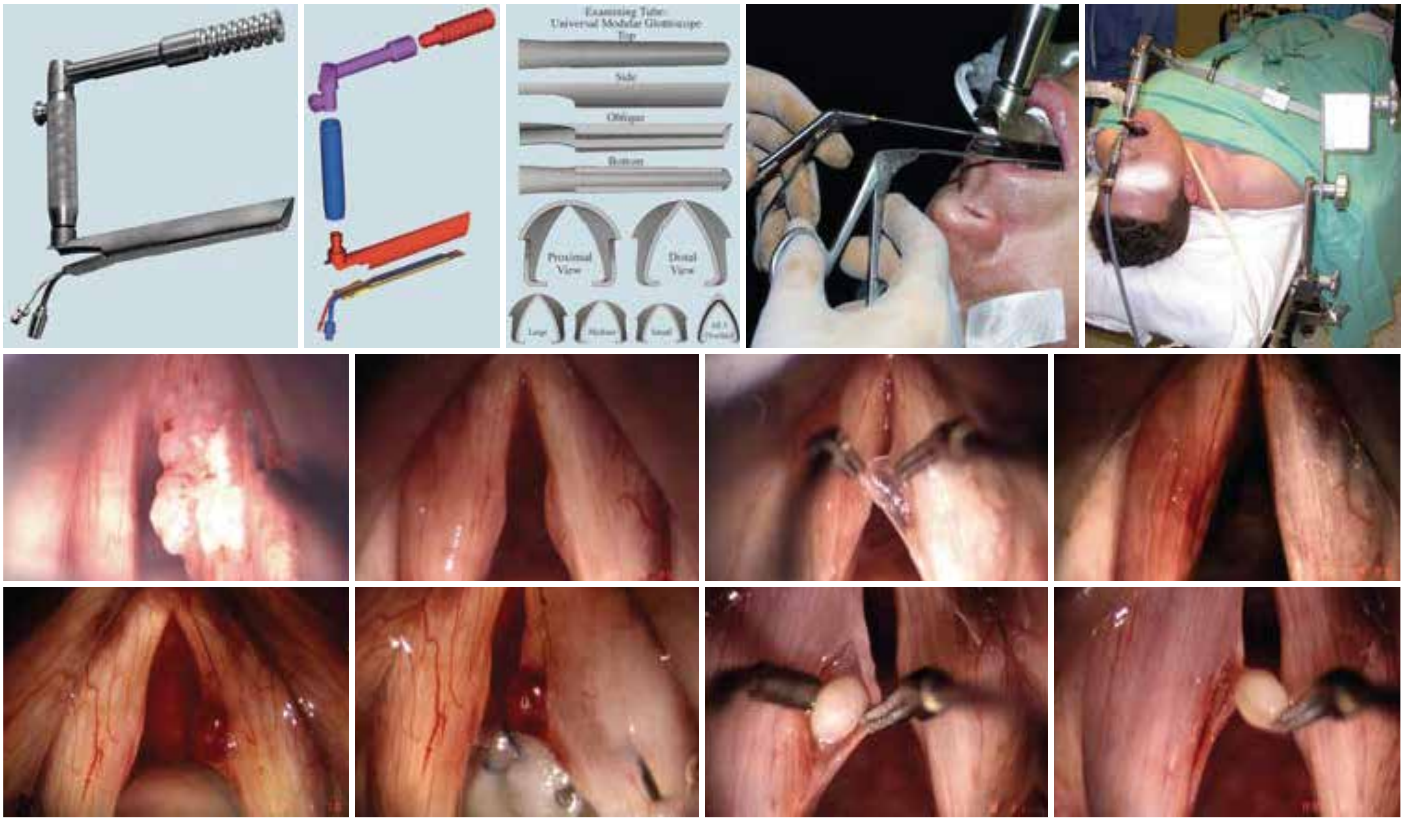

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A Time for Leadership

Editor's note: In an urgent meeting, the Executive Committee of the Boards of Directors approved this statement for immediate release.

Duane J. Taylor, MD
AAO-HNS/F President

The American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS) realizes that our country is currently in the midst of a crisis and potentially at a crossroads. The recent current events have placed a spotlight on the racial injustice in our country and made us all question why we as a nation have tolerated the disregard for a human life solely based on our differences. Our Academy is speaking out to denounce the individuals, elements, and institutions in our society that perpetuate the racism, social injustice, and disparities that exist.

We empathize and support our members who have been and continue to be subjected to this unfortunate divide. We stand together to do our part as leaders in our local, state, and national communities to highlight the need for change, initiate the dialogue, and work toward peaceful change. Even as the COVID-19 pandemic has illuminated the disproportionate impact on our minority communities with limited access and greater mortalities, we are also faced with the more obvious blight on our society—of hatred, discrimination, and bigotry. We as leaders in our community have the potential to demand change. We will continue to support our programs to promote diversity and inclusion, educate our members regarding cultural sensitivity and implicit bias, and seek ways on how we can be a part of the solution to change these destructive narratives threatening to undermine our country.

The AAO-HNS remains committed to providing the best care for all patients regardless of ethnicity, gender, race, religion, sexual orientation, or social status and advocating for equal access and treatment for all people. We are one.

Duane J. Taylor, MD
AAO-HNS President

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Bringing Together the World of Otolaryngology Virtually

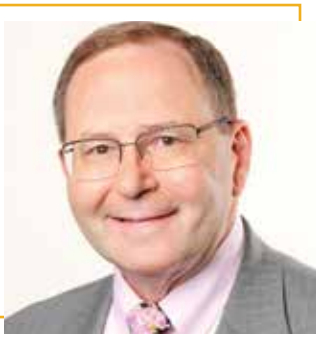
The AAO-HNS Board of Directors, after considerable thought and discussion, moved the in-person AAO-HNSF 2020 Annual Meeting & OTO Experience in Boston to one of a virtual experience due to safety concerns and unavailability of the facilities to hold the meeting. We now enter the "new frontier" of planning and producing the first worldwide virtual meeting in otolaryngology this September. This formidable task has created a great deal of excitement among our staff and throughout the meeting planning team, led by our Annual Meeting Program Coordinator, **Mark K. Wax, MD,** and Coordinator-elect, **Daniel C. Chelius, Jr., MD.** The virtual format will allow us to introduce innovative programming that will expand access to cutting-edge content. We are also pleased to share that we will be able to offer many community and relationship-building networking activities that are tradition to the Annual Meeting via virtual events.

As we endeavor to bring together the world of otolaryngology in both a geographic as well as specialty sense, we are presenting content over a six-week period from September 13 through October 25. The meeting will kick-off with the Opening Ceremony featuring Joel Selanikio, MD, our outstanding speaker who will be discussing COVID-19 and its relationship to the future of otolaryngology practice. He will then host a Q&A session immediately following his presentation. Succeeding that will be 45 hours of live content over the next three days. Built into the schedule of live events are breaks for networking, wellness activities, exhibitor appointments, and more. Immediately following the Opening Ceremony over 300 scheduled hours of new on-demand content through the meeting platform. The virtual format will allow attendees a much broader selection of visual presentations that they can access at their convenience for several months and then subsequently on our education website.

One of the most exciting aspects of this meeting will be the designation of specialty specific weeks during which topics related to specific specialties are presented for a week, rotating each week through the conclusion of the meeting. We are collaborating with a number of the specialty societies to augment content with reciprocal access during the designated week focusing on their respective areas of expertise. These education sessions will run in the evening during the week as well as selective weekend hours and offer both prerecorded and live sessions with Q&A and chat room functionality. Included in these groupings will be the highlighted submissions from the International Symposium. Additionally, there will be over 300 posters with video presentations and CME credits available throughout the meeting. The education content of the entire meeting will reside on our new platform OTO Logic, formerly AcademyU®, following the conclusion of the meeting. One of the highlights of the meeting will be the be the Women in Otolaryngology (WIO) Section 10th anniversary celebration capped off by the premier showing of a fabulous film documenting the history of the WIO.

The AAO-HNS recognizes the severe disruption that the COVID-19 pandemic has caused to otolaryngologists across the globe, particularly the prolonged interruption preventing return to practice. We are committed to providing exceptional value to our members and specialty. **We are offering free registration to our 2020 Virtual Annual Meeting to all who purchase our new, next generation flagship education product FLEX by August 31.** This opportunity gives participants access to over 600 hours of learning opportunities delivered on multiple devices whenever you choose.

I would like to recognize and thank the many individuals and organizations that have worked diligently for more than a decade to formulate the "Complex Pediatric Otolaryngology" subspecialty certification program described by Dr. Nussenbaum in this issue of the *Bulletin*. The thoughtful process used by the American Board of Otolaryngology - Head and Neck Surgery (ABOHNS) involved all stakeholders in multiple discussions over many years and truly serves the best interests of otolaryngology, our patients, and physicians. The ABOHNS solicited, received, and incorporated input from the pediatric otolaryngology and general otolaryngology communities, and the societies representing them into the final product. The joint statement endorsed by the ABOHNS, ASPO, and the Academy clearly enforces the ability and competence of Board-certified otolaryngologists to evaluate and treat pediatric patients. ***"The evaluation and management of pediatric otolaryngology patients are within the scope of practice of diplomates of the ABOHNS board certified in Otolaryngology-Head and Neck Surgery. In fact, Pediatric Otolaryngology is explicitly stated on the primary certificate."*** The Board of Governors deserve special mention for their role over many years and representing the specialty and helping to craft the final agreement. ■



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

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Financial Wellness

Andrew J. Tompkins, MD, MBA
Member of the AAO-HNS Physician Wellness Task Force

Physician wellness has taken the stage as a national issue, and rightly so. A recent *Medscape* survey revealed a 36% burnout rate among otolaryngologists.[1] In response to similarly alarming numbers across medical disciplines, specialty societies have responded with wellness initiatives, the largest push nationally coming from the National Academy of Medicine (NAM) action collaborative on clinician wellness and resilience.[2] NAM identifies multiple external and internal factors contributing to wellness, or lack thereof. One of the personal factors identified is financial stress, something that contributes to burnout in one-third of otolaryngologists and is cited as the second most common reason for contributing to physician depression.[1,3]

Financial stress comes in various forms and is inseparable from other burnout considerations. Electronic health records and government regulation, aside from detracting from the enjoyment of work, impact efficiency and reimbursement. The fixed costs of running a practice are on the rise. Consequently, reduced efficiency and reimbursement comes on the margin, affecting the physician directly. Compounding this issue is that physicians have been turned into de facto debt collectors, increasingly having to chase their income due to the trend toward high deductible health plans. To make up for this financial squeeze some may work longer hours, pulling them away from home. Otolaryngologists appear to have jumped on this treadmill, with a significant number reporting decreased satisfaction that work leads to adequate time for personal/family time.[4]

Why do we get on this treadmill? Financially speaking, physicians start their careers in a precarious position. In 2019 75% of medical school graduates left with a median education debt of $200,000.[5] While our fellow college graduates enter the workforce immediately, otolaryngologists embark on an educational journey of nine-plus years where meaningful saving is difficult and debts accumulate. In many cases debt continues to grow during training, causing graduates to enter the workforce significantly underwater, sometimes pursuing less-fitting jobs specifically because of attendant loan forgiveness opportunities. And having put off spending for years, we often come into significant incomes and allow lifestyle creep to diminish our after-tax ability to save. Higher marginal tax rates then require significantly more effort to retain that which we previously saved.

Due to the duration, focus, and rigor of study on the path to become a physician, little time is left to develop know-how of personal finance. This lack of information makes that indebted graduate prone to financial advisor predation, poor oversight, and lack of clear direction. Our debt-laden starting positions and medical market financial pressures leave one path out—get on the treadmill. The fee-for-service model leaves us with only a few levers to pull—increase the speed or enhance productivity. For those who have throughput as the only lever, increased volume may come at the detriment of physician quality of life and, perhaps, patient care.

Our national organizations are working to address some of the external pressures that motivate us to get on this treadmill. But what can we do on a personal level to help prevent or alleviate these financial stressors? First, build a solid foundation on which to stand. For any individual that foundation is focused on protecting streams of future cash flows generated from their work and protecting them from immediate, large cash needs. Next, lay out a financial plan that incorporates optimal debt management, investment strategies, and budgeting that allows you to reach specific financial goals within designated time periods.

SARS-CoV-2 has brought one foundational aspect of financial wellness into the light both on a practice and personal level—immediate access to capital with sudden, large, cashflow needs. Those practices with better working capital and access to lines of credit found themselves better able to weather the storm. The personal equivalent is an emergency fund, typically advised to total three to six months of spending and to be placed in a highly liquid and low-risk vehicle.[6] Imagine how different America would have looked during the coronavirus crisis from an economic and policy perspective if Americans employed this practice more broadly.

Just as businesses look to business interruption insurance to protect against loss of future cash flows, so should individuals through disability and life insurance policies. These policies vary markedly, and physicians need to be very cautious about being sold policies that do not fit their needs. I have personally found trustworthy and vetted brokers on The White Coat Investor.[7] Auto, home, and umbrella insurance policies help to round out a solid foundation to protect against sporadic cash shocks. Once this foundation is laid, construct a sound financial plan.

Your financial plan should incorporate debt management, financial goals, and involve constructing a budget to ensure adequate saving to meet these goals and protect against lifestyle inflation. This plan should be highly specific to your situation, risk comfort, and have focus on specific and realistic financial goals. Our knowledge deficit can lead to decision paralysis and reliance on financial planners who take percentages of assets under management (AUM) as their fees. To make matters worse, these planners often invest your money in more costly, actively-managed mutual funds, which have been proven to provide lower

returns than diversified index funds over time.[8] By the time we enter the workforce, we have already sacrificed nearly 10 years of opportunity cost with our educational investment and typically start off with a profoundly negative net worth. We do not have time to waste without a plan and should not be spending our hard-earned money on unnecessary fees that compromise our financial well-being.

If you do not have comfort with creating a financial plan, which many of us do not, draft a plan with a fee-based financial planner who will charge a fixed fee for developing a plan with you and can charge fixed fees on an as-needed basis.

The importance of low-cost, diversified, index fund investing and moving away from AUM and active management charges can't be overstated. The difference between actively managed funds with AUM fees versus index funds and fee-based planning advice can easily be measured in hundreds of thousands in current dollars. More importantly, the difference can be measured in years of waiting to attain your financial goals and in the pressure one might feel to get on and stay on the throughput treadmill.

Financial wellness plays a significant role in overall wellness and is inextricably linked to many wellness factors identified by NAM. While we can't disentangle finances from these factors, those other factors are more complicated and difficult to address. Luckily, we can make relatively simple moves in the financial arena to put us on relative autopilot in order to protect our financial and overall well-being. ■

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at the forefront

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Cancer Immunotherapy: What the Otolaryngologist Needs to Know

Many otolaryngologists are unaware of the indications for cancer immunotherapy and may not refer patients for consideration of this treatment. This new eCourse reviews the benefits of treatment for head and neck cancer patients with recurrent or metastatic disease who have failed standard therapy and how to identify clinical cases where referral for immunotherapy is appropriate. This new course was authored by **Nicole C. Schmitt, MD,** and **Larissa Sweeny, MD,** of the AAO-HNSF Head and Neck Surgery Education Committee. http://academyu.entnet.org/diweb/catalog/item/id/5234592 ■

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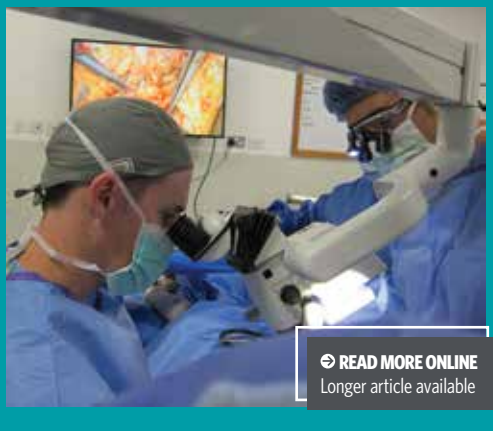
Kijabe, Kenya Humanitarian Surgical Trip

Brian Cervenka, MD, spent a week in May 2019 on a surgical mission trip in Kijabe, Kenya, to focus on both the reconstruction of bony facial defects, primarily caused by ameloblastoma, and the education surrounding the procedures. The group, which included **Robert J. Sinard, MD,** David Nolen, MD, and Michael W. Sim, MD, performed one ameloblastoma resection and fibular free flap reconstruction per day for five days.

"The primary goals of these operations were two-fold. One was direct patient care, and the other was education for the local surgeons who performed the operations with us and learned the microvascular and free flap harvest portions," Dr. Cervenka said. "Dedication to a single site with stable local surgeon presence is key if education is an important goal to the team." ■



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SRF SECTION FOR RESIDENTS AND FELLOWS-IN-TRAINING

Resident Spotlight: Arvind K. Badhey, MD, PGY5, Icahn School of Medicine at Mt. Sinai in New York City

I started my chief rotation at Elmhurst Hospital Center in Queens, NY, with three coresidents. Soon after, news vans, agency nurses, and patients swarmed to the aptly labeled "epicenter of the epicenter," COVID-19's new New York City home. In contrast to our ER colleagues, we had a choice of whether to wait for ENT to be called upon or to volunteer. We volunteered as a team of 12 residents to staff an overflow ICU that would come to be known as the "ENT COVID ICU."

As surgical trainees, we're used to learning on the job and embodying the mantra "you don't know what you don't know." While we were prepared for uncertainty to be the new normal, one thing we were not prepared for was how much fear would become an integral part of our lives. We never expected to be saving lives while fearing for our own. Every day I was scared, not only of this deadly virus, but also that I would never recover from the trauma I was seeing.

COVID-19 is a deadly disease. One of the most painful things about working in the ICU is that, regardless of what we did, patients' outcomes and prognoses were poor. While we have all cared for sick patients during residency, I've witnessed more death in the past month than in all of residency combined.

Our team channeled our fears, anxiety, and feelings of helplessness into becoming a bridge between our patients and their families. We made sure that the families knew that in those final moments, their mother, father, brother, or sister was not alone. If, in the future, subspecialists are debating whether or not to volunteer, I hope they think of my patients. While many of them didn't survive, had it not been for our team, they would have died in an overwhelmed system—alone.

If all we did was help families say goodbye, it was worth it. ■

Left to right: Peter Filip, PGY3; Arvind Badhey, PGY5; Usmaan Basharat, PGY1; Benjamin Laitman, PGY2; Caleb Fan, PGY2

Left to right: Kevin Wong, PGY2; Christine Barron, PGY2; Doug Worrall, PGY5; Jaclyn Klimczak, PGY4; Eli Kinberg, PGY3; Noel Phan, PGY2

EPISODE 14 **Band of Residents**

Hear more from this group of ENT Residents who volunteered to provide care as a COVID-19 surge ICU team at Elmhurst Hospital Center in New York City. Their selflessness and willingness to volunteer beyond the call of duty when needed exemplifies what "We Are One" means to all of us, even beyond the specialty. The Academy salutes them and all our colleagues helping to do their part during this challenging time.

In this podcast, **David M. Cognetti, MD,** Associate Professor and Co-Director, Thomas Jefferson University Center for Head and Neck Surgery in Philadelphia, PA, is joined by **Arvind K. Badhey, MD**, a PGY5 ENT Resident at the Icahn School of Medicine at Mt. Sinai in New York City and one of his colleagues, **Usmaan Basharat, MD,** an ENT intern in the same program to discuss their unique and challenging experiences on the frontlines as part of a group of ENT residents volunteering at Elmhurst Hospital Center in Queens, NY, on COVID-19 surge ICU team in one of the "epicenters of the epicenter" in the United States.

The podcast is also offered in a video version. Find both at **https://www.entnet.org/content/covid-19-podcast-series.**

American Head & Neck Society

Christine G. Gourin, MD, MPH, and Richard J. Wong, MD, AHNS Scientific Program/Resident Courses Service members
Cherie-Ann O. Nathan, MD, AHNS President

The American Head & Neck Society (AHNS) is a vibrant society committed to being patient centric, collaborative, innovative, ethical, value based, and global. To maximize member engagement, AHNS restructured to have sufficient organizational capacity in achieving their mission (as displayed in the graphic). So what are the challenges and opportunities in practice and patient care?

The "face" of head and neck cancer in 2020 has changed, with fewer tobacco-related cancers and an increasing number of HPV-related oropharyngeal, thyroid, and skin cancers. The HPV-related oropharyngeal cancer epidemic is associated with a growing cohort of long-term survivors. Deintensification of radiation and/or chemotherapy can be accomplished with transoral surgery in patients without evidence of extranodal extension and clear margins, all being studied in globally initiated multidisciplinary clinical trials. Surgeon-initiated trials include elective versus therapeutic neck dissection in node negative oral cavity cancer and the E3311 transoral surgery study, with a postoperative radiation deintensification arm.

Immunotherapy and targeted therapy show promise for advanced skin and head and neck mucosal cancers, with a better tolerated side effect profile. Melanoma mortality rates have started to decline for the first time in decades. The U.S. Food and Drug Administration approved cemiplimab for advanced cutaneous squamous cell cancer and hedgehog inhibitor for advanced basal cell carcinoma. In recurrent mucosal head and neck cancer, response rates with immunotherapy are 10%-20%. Neoadjuvant immunotherapy trials are underway to determine the role of immunotherapy in primary treatment for mucosal disease.

Active surveillance is increasingly recognized as a safe option for patients with low-risk thyroid cancers that are favorably located and without metastases. Molecular analysis of FNA samples can determine the relative risk of malignancy. Targeted therapy now exists for medullary and anaplastic thyroid cancer based on molecular profiling. RET-mutated medullary thyroid cancers have response rates of 60%-70% range to the new RET inhibitors LOXO-292 and BLU-667. Anaplastic thyroid cancers with BRAF mutations have a response rate of 69% to combination BRAF and MEK inhibition. This is a dramatic improvement over prior ineffective therapies for a disease viewed as fatal.

As patients with head and neck cancer live longer, survivorship issues are increasingly important. Multidisciplinary care is required to address lymphedema, dysphagia, dental issues, surveillance, new primaries, and radiation-induced malignancy. Speech-language pathology-directed swallowing exercises during and after treatment reduce the incidence of late dysphagia. Salvage surgery is associated with increased morbidity and mortality and often requires reconstruction and complex decision making. The opioid epidemic has led to unintended consequences of pain management for patients who suffer protracted pain from treatment. The management of head and neck cancer continues to evolve with the changing disease landscape, the emergence of new technologies and therapies, and a stronger emphasis on optimizing quality of life.

The COVID-19 pandemic presents an entirely new set of challenges. How do we prioritize care during this pandemic? How do we protect our staff during procedures that may aerosolize virus, particularly in mucosal sites that carry high viral loads? How can telemedicine allow us to best connect remotely with our patients? The AHNS website's COVID-19 Bulletin Board is an outstanding resource that addresses many of these issues. ■

Transition to In-office Treatments: Head and Neck

Submitted on behalf of the American Head & Neck Society: **M. Boyd Gillespie, MD, MSc, Andrew J. McWhorter, MD, and Cherie-Ann O. Nathan, MD**

Advances in technology have propelled the field of in-office diagnostics and minimally invasive surgery and allowed for transition to in-office treatment in head and neck surgery (Figure 1). This decreases lost time from work and costs for patients and allows for more speedy diagnosis and recovery from procedures. The advanced imaging associated with distal chip scopes and minimization of scope caliber while maintaining a working channel has created the opportunity for laryngeal biopsy and treatment of premalignant vocal fold disease with in-office laser treatment with both KTP and CO2 wavelength fiber-based lasers. These procedures previously done in the operating room can safely and cost-effectively be performed while avoiding general anesthesia.

In patients who require a secondary puncture for a trachea-esophageal voice prosthesis, the use of transnasal esophagoscopy combined with multiple described puncture techniques from Seldinger to open are now being utilized in the office. The upright awake patient is sometimes easier to puncture with better visualization. The positioning of the prosthesis as well as having the patient clearing secretions with swallowing and opening the esophagus with swallowing facilitate placement.

Office-based ultrasonography is becoming an increasingly important tool within head and neck surgery practices. Ultrasonography allows real-time, on-site imaging of a variety of lesions in the thyroid, salivary glands, and lateral neck. Advantages of the technique include efficiency, ability to perform image-guided fine-needle aspiration (FNA) (Figure 2), ability to follow lesions over time without concern for excess radiation exposure, lack of need for contrast enhancement, and relative low cost. It provides additional revenue potential for offices that integrate the findings of U.S. examination within their electronic medical records (EMRs). More recently, several academic head and neck practices have combined office-based ultrasonography with radiofrequency ablation of symptomatic, compressive thyroid nodules not suspicious for cancer following adequate fine-needle aspiration. By applying a radiofrequency probe via percutaneous technique under ultrasound guidance, surgeons are able to achieve up to 50%-80% volume reduction without surgery in select symptomatic nodules. The slower adoption of office-based ultrasonography in the U.S. compared to Europe is likely due to lack of exposure to the technique during residency training, therefore appropriate coursework and ongoing medical education are required for its successful application.

Sialendoscopy (salivary endoscopy) is transitioning from the operating room to the office in practices that have gained experience with the technique. Office-based sialendoscopy allows both diagnosis and management of various obstructive (stones, scar) and inflammatory (chronic sialadenitis, Sjogren's) conditions of the salivary gland in cooperative adult patients. The technique is most applicable to smaller stones (< 4mm), ductal scars that can be dilated with the tip of the scope or guidewire/bougie system, or hydrostatic dilation and lavage of symptomatic, chronically inflamed glands. Due to the fragility and expense of the scopes, office staff require focused training on scope care and sterilization.

With the COVID-19 pandemic, salivary endoscopy and in particular TEPs and laryngeal in-office laser procedures are high risk aerosolizing procedures and protocols are rapidly evolving. COVID-19 testing prior to the procedure, negative pressure office-based rooms, turn over time between patients in order to allow time for disinfection, use of PPEs, and a number of other measures need to be considered prior to proceeding. ■

Figure 1: Photo of Dr. Gillespie's faculty, Dr. Sandra Stinnett, using office-based laser to treat vocal cord dysplasia.

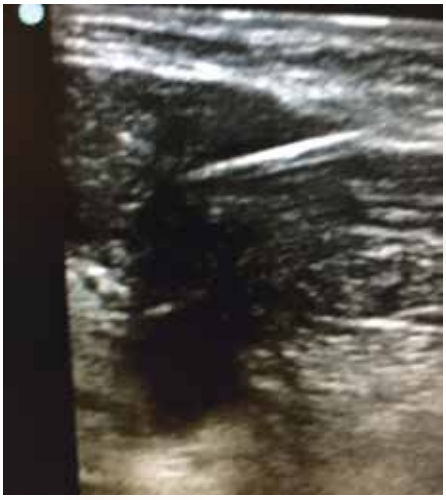


Figure 2: Photo of an ultrasound needle aspiration of a plunging ranula.

Complex Pediatric Otolaryngology Update from the American Board of Otolaryngology - Head and Neck Surgery

Brian Nussenbaum, MD, MHCM
Executive Director, ABOHNS

The American Board of Otolaryngology - Head and Neck Surgery (ABOHNS) wants to provide an update about the progress toward subcertification in Complex Pediatric Otolaryngology (CPO). This effort started in 1992 with approval of subcertification by the American Board of Medical Specialties (ABMS), followed by accreditation of fellowship training programs in pediatric otolaryngology by the Accreditation Council for Graduate Medical Education (ACGME). The number of accredited fellowship programs increased from four in 2001 to 30 in 2019, with more than 40 fellowship positions now available each year.

In January 2018, the ABOHNS formed the CPO Steering Committee composed of directors from the ABOHNS and leaders from the American Society of Pediatric Otolaryngology (ASPO). The ABOHNS directors include **Kathleen C. Y. Sie, MD, Ronald B. Kuppersmith, MD, MBA, Jeffrey M. Bumpous, MD,** and **Marlan R. Hansen, MD.** ASPO leaders include **Kenny H. Chan, MD, Stacey L. Ishman, MD, MPH,** and **Diego A. Preciado, MD, PhD.** The Steering Committee is advisory to the ABOHNS Board of Directors.

The Steering Committee has been working diligently during the past two years. One of the early activities was to endorse a formal definition of the subspecialty recognizing that CPO subcertification is not intended to include the evaluation and management of all children with otolaryngologic disease. The majority of pediatric patients can be treated by ABOHNS diplomates within the scope of the primary certification in Otolaryngology-Head and Neck Surgery. **The ABOHNS, AAO-HNS, and ASPO co-authored and endorsed a position statement on CPO subcertification that will provide a formal and consistent message about this fact to credentialers, insurers, peer physicians, patients, and others moving forward.**

Complex Pediatric Otolaryngology is defined as the compendium of medical knowledge and care for children with complex otolaryngologic disorders and/or common otolaryngologic disorders in otherwise complex children. A key tenet of CPO is that these children are, on many occasions, better suited for medical or surgical care in tertiary pediatric facilities within interdisciplinary teams.

The CPO subcertification process will include a Written Qualifying Examination (WQE) and an Oral Certifying Examination (OCE). For the first seven years, there will be two open pathways to obtain subcertification: 1) the training pathway that requires completion of an ACGME accredited fellowship within the previous five years, and 2) the practice pathway that does not specify a training requirement. Eligibility criteria to validate a CPO clinical practice will include practice setting, case types, and participation in multidisciplinary activities. Further information about eligibility criteria and qualifying cases can be found on the ABOHNS website.

Exam development for the WQE began with defining the scope of knowledge for CPO subcertification, which was based on the core curriculum for pediatric otolaryngology fellowships. Public comments were solicited from pediatric otolaryngology program directors and representatives from ABOHNS-sponsoring societies, including the AAO-HNS, to help delineate knowledge that is beyond expectations of the primary certification in Otolaryngology-Head and Neck Surgery.

After feedback was obtained, the CPO WQE blueprint was created. The blueprint was finalized and approved by the ABOHNS Board of Directors after receiving input from pediatric otolaryngology fellowship program directors, chiefs of pediatric otolaryngology divisions, chairs of the pediatric and pediatric education committees of the AAO-HNS, and the ASPO president, along with four ASPO designees. The WQE blueprint is available on the ABOHNS website.

The CPO Steering Committee created a diverse Item Writing Working Group composed of 25 members. These item writers are now in the second year of authoring items for the WQE. The first CPO WQE date is scheduled for July 29, 2021. Exam registration is expected to begin in October 2020.

The CPO Oral Certifying Exam Working Group was also formed by the Steering Committee. The charge of this Working Group is to discuss the structural and process details of the OCE and to write oral exam protocols. The OCE will focus on the application of knowledge necessary for safe and effective practice in a tertiary care pediatric facility. Eligibility for this exam will occur after passing the CPO WQE and fulfilling all eligibility requirements in either the training or practice pathway.

The ABOHNS encourages those that are interested in applying for CPO subcertification to attend one of the informational virtual town hall meetings that will take place during the summer of 2020. Prospective candidates can find these dates along with additional information at **www.abohns.org/Complex_Pediatric_Otolaryngology.html.** ■

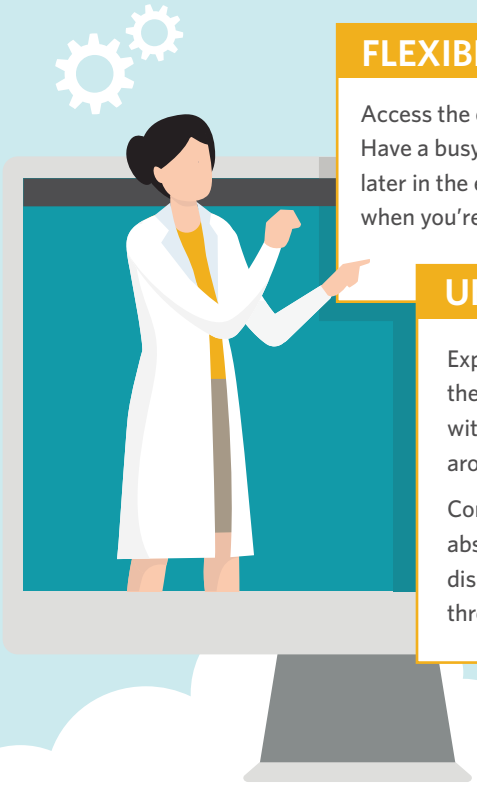
AAO-HNSF 2020 VIRTUAL ANNUAL MEETING & OTO EXPERIENCE

We are excited to host the AAO-HNSF 2020 Virtual Annual Meeting & OTO Experience, where everyone from the global otolaryngology community will have a front row seat for all activities and sessions. This year's meeting will extend over a six-week time frame, starting September 13, allowing access to over 300+ scheduled hours of CME at your convenience. There will be live programming along with new on-demand education sessions, including electronic posters, the International Symposium, unique opportunities for virtual and social networking, interactions with cutting-edge exhibitors, and more. We look forward to bringing the world of otolaryngology together, as one, like never before. Stay connected with the most up-to-date information about #OTOMTG20 by visiting **www.entannualmeeting.org**.

BUILT FOR YOUR CONVENIENCE

EXCEPTIONAL VIRTUAL EDUCATION, CREATIVE NETWORKING, AND EXHIBITS

TOP REASONS YOU DON'T WANT TO MISS #OTOMTG20



FLEXIBLE

Access the education on your time: Have a busy day? No problem, watch later in the evening, the next day, or when you're on the go!

UNITED

Experience a true representation of the global otolaryngology community with speakers and presenters from around the world.

Connect with your peers, faculty and abstract presenters, and exhibitors to discuss the science and ask questions through live Q&A and chat functions.

FOCUSED

Attend dynamic sessions featuring 11 tracks including each specialty area plus additional topics and the International Symposium, with several sessions presented in Spanish.

Participate in specialty-focused weeks that will follow the opening three days and allow exclusive access to in-depth coverage of subspecialty topics.

- Includes a mix of live and new on-demand content as well as set of tools for interacting with speakers for Q&A, even for some on-demand content.
- All scheduled broadcast sessions will be available on demand through the end of October.
- The recorded content will be available after this date via OTOLogic, the AAO-HNSF forthcoming Otolaryngology Education Platform, for three years to all registered attendees.

LIVE EVENT
September 13-15

SEPTEMBER 12:
AAO-HNS/F BOD MEETING
BOG GENERAL ASSEMBLY

Sunday, September 13
12 Hours Representing Each Specialty

Monday, September 14 and Tuesday, September 15
16 Hours Representing Each Specialty

- Includes 'Hot Topics' and Global Otolaryngology 2020
- Immediate Access to over 300+ scheduled hours of On-Demand Content
- Networking Activities as well as Industry Engagement and Education Opportunities

For the latest information and updated scheduling, visit www.entannualmeeting.org

THREE-DAY LIVE KICK-OFF EVENT

Eastern Daylight Time

SUNDAY, SEPTEMBER 13

10:00 - 11:00 am	Opening Ceremony and Keynote Address
11:00 - 11:30 am	Keynote Q&A/Networking/ Wellness Activity/Exhibitors
11:30 - 12:30 pm	Live Education Sessions (choose from 4 options)
12:30 - 1:00 pm	Networking/Wellness Activity/Exhibitors
1:00 - 2:00 pm	Conley Lecture/Networking/Virtual Exhibit Hall
2:00 - 3:00 pm	Live Education Sessions (choose from 4 options)
3:00 - 4:00 pm	Live Education Sessions (choose from 4 options)
4:00 - 5:00 pm	Networking/Wellness Activity/Exhibitors
5:00 - 6:30 pm	SRF General Assembly

MONDAY, SEPTEMBER 14

9:00 - 10:00 am	Wellness Activity
10:00 - 11:00 am	Live Education Sessions (choose from 4 options)
11:00 - 11:30 am	Networking/Wellness Activity/Exhibitors
11:30 - 12:30 pm	Live Education Sessions (choose from 4 options)
12:30 - 1:00 pm	Networking/Wellness Activity/Exhibitors
1:00 - 2:00 pm	Exhibitor Appointments
2:00 - 3:00 pm	Live Education Sessions (choose from 4 options)
3:00 - 4:00 pm	Live Education Sessions (choose from 4 options)
4:00 - 5:00 pm	Networking and Alumni Receptions

TUESDAY, SEPTEMBER 15

9:00 - 10:00 am	Wellness Activity
10:00 - 11:00 am	Live Education Sessions (choose from 4 options)
11:00 - 11:30 am	Networking/Wellness Activity/Exhibitors
11:30 - 12:30 pm	Live Education Sessions (choose from 4 options)
12:30 - 1:00 pm	Networking/Wellness Activity/Exhibitors
1:00 - 2:00 pm	Neel Lecture/Exhibitor Appointments
2:00 - 3:00 pm	Live Education Sessions (choose from 4 options)
3:00 - 4:00 pm	Live Education Sessions (choose from 4 options)
4:00 - 5:00 pm	Networking/Wellness Activity/Exhibitors

SIX SPECIALTY TRACK FOCUSED WEEKS

- Up to 8 hours of Live Education featuring 20-Minute Summaries and 40-Minutes of Q&A
- Presenters will hold 'Office Hours' for Chat Discussions during their Specialty Week
- Links to Specialty Society Meetings

Virtual Exhibit Booths will also be available all six weeks with new specialty focused content available!

WEEK 1: September 16 – 20

- ○ AAO-HNS Career Fair
- ○ Business of Medicine
- ○ COVID-19
- ○ Patient Safety & Quality Improvement
- ○ SIM Tank

WEEK 2: September 21 – 27

- ○ Allergy/Rhinology

WEEK 3: September 28 – October 4

- ○ Head and Neck Surgery and Endocrine
- ○ International Symposium
- ○ IAB General Assembly
- ○ Myers Lecture
- ○ Spanish Webcast
- ○ WIO General Assembly and Documentary Premier

WEEK 4: October 5 – 11

- ○ Laryngology/Broncho-Esophagology
- ○ Pediatric Otolaryngology

WEEK 5: October 12 – 18

- ○ Otology/Neurotology
- ○ Sleep Medicine
- ○ Academic Bowl

WEEK 6: October 19 – 25

- ○ Comprehensive Otolaryngology
- ○ Facial Plastics and Reconstructive Surgery

Receive FREE Annual Meeting registration with purchase of FLEX by August 31 at www.entnet.org/flex

DOMESTIC PHYSICIANS, NONPHYSICIANS, MILITARY, AND ADVANCED PRACTICE PROVIDERS

Members	$395
Nonmembers	$595

INTERNATIONAL PHYSICIANS, NONPHYSICIANS, MILITARY, AND ADVANCED PRACTICE PROVIDERS

Members	$320
Nonmembers	$520

INTERNATIONAL MIDDLE INCOME COUNTRIES

Member	$160
Nonmember	$260

INTERNATIONAL LOWER INCOME COUNTRIES

Member	$80
Nonmembers	$130

RESIDENTS/MEDICAL STUDENTS

Members	$158
Nonmembers	$357

Presidential Citations 2020

The Presidential Citations are given to individuals who have had a profound influence on the AAO-HNS/F President's life and otolaryngology. President **Duane J. Taylor, MD,** has selected these individuals for their outstanding contributions.

Mirion P. Bowers, MD

Dr. Bowers is currently retired but served as a clinical professor at the University of Southern California, assistant professor at the University of California, Los Angeles, chair of otolaryngology at the Martin Luther King, Jr. Residency Program, and president and CEO of PIH Health Good Samaritan Hospital in Los Angeles. I had the pleasure of first meeting him the week before I was to start my residency at a casual gathering through mutual friends and was excited to tell him about the start of my training and specialty at this hospital in South Central Los Angeles, CA. I think by the end of that initial conversation I gleaned from this kind, humble pillar of the community that he was excited and supportive of the fact that I was not only training in the same specialty that he had been practicing for many years, but the program I would enter was one that he started and chaired prior to Gus Gill, MD, who was my chair during residency.

Over the years I crossed paths with Dr. Bowers many times and looked to him as a mentor in my involvement in the Academy. He was responsible for the Harry Barnes Society, having a seat on our Academy's Board of Governors and serving as its first representative, a position that I would hold for many years to follow. He encouraged and supported my participation in the Academy, which led to my many levels of engagement in the years that followed.

Dr. Bowers, a well-respected clinician in the Los Angeles area, is always someone whose leadership, accomplishments, and commitment to the diversity of our specialty, the community, and his family I always admire. He will always be considered a role model. Thank you, Dr. Bowers. ■

Lorenzo S. Brown, MD

Dr. Brown attended medical school at the University of Michigan, received training in general surgery at King Drew Medical Center and the California Hospital Center, and did his otolaryngology residency at Northwestern University. He has been in private practice in Los Angeles for over 35 years and trained countless residents and medical students as an assistant professor of surgery at Charles R. Drew University of Medicine and the University of California, Los Angeles. Dr. Brown served as one of the most influential teachers during my training and his medical knowledge, skill as a surgeon, and the compassionate way he interacted with his patients left an indelible impression, which I strive to replicate.

Over the years he has helped to serve an underserved community at King Drew Medical Center and has given back in so many ways to the community; the depth and breadth of his impact is immeasurable. Finally, his love for teaching young residents and medical students, whether it was on rounds, in a didactic lecture, or in the operating room, were contributions that certainly were a critical part of my foundation and certainly appreciated. Certainly Dr. Brown was another positive role model, who I could only hope to emulate. Thank you, Dr. Brown. ■

Registration is now open!

For more information about registration and the most up-to-date details about the 2020 Virtual Annual Meeting offerings, visit **www.entannualmeeting.org.**

Howard W. Francis, MD, MBA

I first met **Dr. Francis** at an Academy meeting when he was doing a poster presentation while a medical student at Harvard University. At that initial meeting I knew he had a propensity for making a difference in the area of academic medicine within our specialty, which proved to be true. Dr. Francis went on to do his surgery internship, residency, and neurotology training at Johns Hopkins University School of Medicine, followed later by obtaining an MBA. Following his training, Dr. Francis stayed on at Johns Hopkins as faculty, becoming a full professor. During that time he had numerous publications, book chapters, and international presentations and was the recipient of numerous awards. Dr. Francis moved to Duke University in 2017 as chief and professor of the Division of Head and Neck Surgery, which subsequently, under his leadership, became a department. He is now the Richard Hall Chaney, Sr. Distinguished Professor of Otolaryngology and chair of the Department of Head and Neck Surgery & Communication Sciences.

In addition to the many academic accomplishments and teaching of numerous residents, I have admired the poise and professionalism with which Dr. Francis has approached his activities in organized medicine (including our Academy and his service as president of the Society of University Otolaryngologists Head & Neck Surgeons). Dr. Francis has also played an active role in attempting to improve the diversity of our specialty, especially in the academic arena. Dr. Francis, you have been a supportive colleague, and all that you have done through your leadership, the many patients you have cared for (especially ones that I referred), the students you have trained, and the research you have done set you apart to be deserving of this citation. Thank you, Dr. Francis. ■

Ronald B. Kuppersmith, MD, MBA

Dr. Kuppersmith is in practice in Bryan-College Station and Huntsville, TX, and holds an academic appointment as professor of surgery at the Texas A&M Health Science Center College of Medicine. Dr. Kuppersmith is also Past President of the American Academy of Otolaryngology–Head and Neck Surgery and the Texas Association of Otolaryngology-Head and Neck Surgery. He currently serves on the board of directors of the American Board of Otolaryngology – Head and Neck Surgery and as the deputy editor of *ENTtoday*.

When I first met Dr. Kuppersmith, I knew he was a visionary and trailblazer setting the stage to become the youngest president of our Academy. He was attentive and listened to concerns I brought up to him after a meeting with the sister societies related to the lack of diversity in our Academy membership and its leadership. He followed this up with not only supporting the cascade of progress in this area, which would follow, but actively participated in the first-ever mini-seminars on cultural competence, health disparities, and health literacy. Dr. Kuppersmith's tenacity to "walk the walk" for what he believes in has contributed to our Academy in countless ways. He wrote the original draft of the Academy U® vision statement just barely out of training, received the Helen F. Krause Trailblazer award in 2011, and gave the John Conley, MD Lecture on Medical Ethics on Surgical Innovation in 2018. Dr. Kuppersmith is another person whose concern and commitment to our Academy, his patients, and his family I have admired. The discussions we have had and his advice and friendship have all been an integral part of my development and are all sincerely appreciated. Thank you, Dr. Kuppersmith. ■

As an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP)

TAKE A DIFFERENT PATH TO **CRSwNP CONTROL**

DUPIXENT IS THE FIRST BIOLOGIC APPROVED IN CRSwNP that targets the inflammation underlying the disease—so your patients can achieve and maintain control

INDICATION

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

IMPORTANT SAFETY INFORMATION

CONTRAINDICATION: DUPIXENT is contraindicated in patients with known hypersensitivity to dupilumab or any of its excipients.

WARNINGS AND PRECAUTIONS

Hypersensitivity: Hypersensitivity reactions, including generalized urticaria, rash, erythema nodosum, anaphylaxis and serum sickness or serum sickness-like reactions, were reported in <1% of subjects who received DUPIXENT in clinical trials. If a clinically significant hypersensitivity reaction occurs, institute appropriate therapy and discontinue DUPIXENT.

Conjunctivitis and Keratitis: Conjunctivitis occurred more frequently in subjects with chronic rhinosinusitis with nasal polyposis who received DUPIXENT. There were no cases of keratitis reported in the CRSwNP development program. Advise patients to report new onset or worsening eye symptoms to their healthcare provider.

Eosinophilic Conditions: Patients being treated for asthma may present with serious systemic eosinophilia sometimes presenting with clinical features of eosinophilic pneumonia or vasculitis consistent with eosinophilic granulomatosis with polyangiitis (EGPA), conditions which are often treated with systemic corticosteroid therapy. These events may be associated with the reduction of oral corticosteroid therapy. Physicians should be alert to vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy presenting in their patients with eosinophilia.

Visit *DUPIXENTHCP.COM/CRSWNP*

DUPIXENT PROVIDED RAPID AND SUSTAINED IMPROVEMENT IN SENSE OF SMELL[1]

AT WEEK 52

71% IMPROVEMENT IN UPSIT SCORE

with DUPIXENT 300 mg Q2W + INCS (n=150) (**9.53** from a baseline score of **13.46**) vs **6% worsening** with placebo + INCS (n=153) (**-0.77** from a baseline score of **13.78**) (LSM difference: 10.30 [95% CI: 8.50, 12.10]) in Trial 2 (secondary endpoint)[1]

67% OF THE TOTAL IMPROVEMENT IN SENSE OF SMELL WAS SEEN AFTER THE FIRST DOSE, AS MEASURED AT WEEK 2[1,a]

[a] **Change in UPSIT score at Week 2 (LSM difference vs placebo: 5.36 [95% CI: 3.62, 7.10]).[1]**

AT WEEK 24

63% REDUCTION IN THE NUMBER OF PATIENTS WITH ANOSMIA[1,2,b]

[b] 79% (n=228/287, pooled DUPIXENT arms) of patients taking DUPIXENT 300 mg Q2W + INCS had anosmia at baseline, which was reduced to 30% (n=84/280, pooled DUPIXENT arms) at Week 24 in Trial 2. There was almost no change with placebo: 76.7% (n=115/150 total patients) of patients taking placebo + INCS had anosmia at baseline, which was reduced to 76.6% (n=111/145 total patients) at Week 24 in Trial 2.[1,2]

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Eosinophilic Conditions (cont'd): Cases of eosinophilic pneumonia were reported in adult patients who participated in the asthma development program and cases of vasculitis consistent with EGPA have been reported with DUPIXENT in adult patients who participated in the asthma development program as well as in adult patients with co-morbid asthma in the CRSwNP development program. A causal association between DUPIXENT and these conditions has not been established.

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

Patients with Co-Morbid Asthma: Advise patients with co-morbid asthma not to adjust or stop their asthma treatments without consultation with their physician.

Parasitic (Helminth) Infections: It is unknown if DUPIXENT will influence the immune response against helminth infections. Treat patients with pre-existing helminth infections before initiating therapy with DUPIXENT. If patients become infected while receiving treatment with DUPIXENT and do not respond to anti-helminth treatment, discontinue treatment with DUPIXENT until the infection resolves.

University of Pennsylvania Smell Identification Test (UPSIT) score (range 0 to 40): higher score indicates improvement.

INCS, intranasal corticosteroids; LSM, least squares mean; Q2W, once every 2 weeks.

Please see additional Important Safety Information throughout and brief summary of full Prescribing Information on the following pages.

DUPIXENT® (dupilumab) Injection 300mg

DUPIXENT OFFERS A NONSTEROIDAL OPTION TO REDUCE NASAL CONGESTION AND OBSTRUCTION

Significantly improved NC score at Weeks 24 (coprimary endpoint) and 52 (secondary endpoint) in patients who were uncontrolled on standard of care[1,3,a]

AT WEEK 52

54% IMPROVEMENT IN NC SCORE

with DUPIXENT 300 mg Q2W + INCS (n=150) (**-1.35** from a baseline score of **2.48**) vs **16% improvement** with placebo + INCS (n=153) (**-0.37** from a baseline score of **2.38**) (LSM difference: -0.98 [95% CI: -1.17, -0.79]) in Trial 2

- **51% IMPROVEMENT AT WEEK 24** with DUPIXENT Q2W + INCS (n=295, pooled DUPIXENT arms) (**-1.25** from a baseline score of **2.46**) vs **16% improvement** with placebo + INCS (n=153) (**-0.38** from a baseline score of **2.38**) (LSM difference: -0.87 [95% CI: -1.03, -0.71]) in Trial 2

[a] All patients in the placebo and DUPIXENT arms were on a background therapy of INCS, mometasone furoate nasal spray.

Trial 1[3,4]: 24-week study–276 adults (≥18 years) were randomized to receive either DUPIXENT 300 mg Q2W + INCS for 24 weeks (n=143), or placebo + INCS for 24 weeks (n=133). Subjects enrolled in Trial 1 were required to be on background INCS[a] and to have CRSwNP despite prior sino-nasal surgery or prior treatment with, or who were ineligible to receive or were intolerant to, systemic corticosteroids in the past 2 years. Patients with chronic rhinosinusitis without nasal polyposis were not included in these trials. Rescue with systemic corticosteroids or surgery was allowed at investigators' discretion. The total population of patients in Trial 1 was unrestricted by minimum baseline blood eosinophil count. **Coprimary endpoints:** Change from baseline at Week 24 in NC score averaged over 28 days and bilateral endoscopic nasal polyps score (NPS). **Key secondary endpoints:** Change from baseline at Week 24 in daily loss of smell score, LMK-CT score, SNOT-22 score, and UPSIT score. **Prespecified pooled analysis:** Change from baseline at Week 52 in proportion of patients requiring systemic corticosteroids or sino-nasal surgery. **Patient demographics:** Mean age: 50 years; male: 57%; mean CRSwNP duration: 11 years; patients with ≥1 prior surgery: 72%; patients with SCS use in previous 2 years: 65%; mean bilateral endoscopic NPS,[b] range 0-8: 5.8; mean NC score,[b] range 0-3: 2.4; mean LMK sinus CT total score,[b] range 0-24: 19; mean loss of smell score[b] (AM), range 0-3: 2.7; mean SNOT-22 total score,[b] range 0-110: 49.4; mean blood eosinophil count: 440 cells/μL; mean total IgE: 212 IU/mL; atopic medical history, overall: 75%; asthma: 58%; NSAID-ERD: 30%.

Trial 2[3,4]: 52-week study–448 adults (≥18 years) were randomized to receive either DUPIXENT + INCS 300 mg Q2W for 52 weeks (n=150),[c] DUPIXENT + INCS 300 mg Q2W for 24 weeks, followed by Q4W[d] through Week 52 (n=145),[c] or placebo + INCS for 52 weeks (n=153). Subjects enrolled in Trial 2 were required to be on background INCS[a] and to have CRSwNP despite prior sino-nasal surgery or prior treatment with, or who were ineligible to receive or were intolerant to, systemic corticosteroids in the past 2 years. Patients with chronic rhinosinusitis without nasal polyposis were not included in these trials. Rescue with systemic corticosteroids or surgery was allowed at investigators' discretion. The total population of patients in Trial 2 was unrestricted by minimum baseline blood eosinophil count. **Coprimary endpoints:** Change from baseline at Week 24 in NC score averaged over 28 days and bilateral endoscopic NPS. **Key secondary endpoints:** Change from baseline at Weeks 24 and 52 in NC score (at Week 52), NPS (at Week 52), daily loss of smell score, LMK-CT score, SNOT-22 score, and UPSIT score. **Prespecified pooled analysis:** Change from baseline at Week 52 in proportion of patients requiring systemic corticosteroids or sino-nasal surgery. **Patient demographics:** Mean age: 52 years; male: 62%; mean CRSwNP duration: 11 years; patients with ≥1 prior surgery: 58%; patients with SCS use in previous 2 years: 80%; mean bilateral endoscopic NPS,[b] range 0-8: 6.1; mean NC score,[b] range 0-3: 2.4; mean LMK sinus CT total score,[b] range 0-24: 18; mean loss of smell score[b] (AM), range 0-3: 2.8; mean SNOT-22 total score,[b] range 0-110: 51.9; mean blood eosinophil count: 430 cells/μL; mean total IgE: 240 IU/mL; atopic medical history, overall: 82%; asthma: 60%; NSAID-ERD: 27%.

Nasal congestion/obstruction (NC) score (range 0 to 3): reduced score indicates improvement.

[b] Higher scores indicate greater disease severity.
[c] In Trial 2, data from baseline to Week 24 are pooled from DUPIXENT Q2W treatment arms (n=295).
[d] The recommended dose of DUPIXENT for adult patients with CRSwNP is 300 mg given subcutaneously every other week.

IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS: The most common adverse reactions (incidence ≥1%) in patients with CRSwNP are injection site reactions, eosinophilia, insomnia, toothache, gastritis, arthralgia, and conjunctivitis.

DRUG INTERACTIONS: Avoid use of live vaccines in patients treated with DUPIXENT.

AM, morning; LMK-CT, Lund-Mackay computed tomography; NSAID-ERD, nonsteroidal anti-inflammatory drug–exacerbated respiratory disease; Q4W, once every 4 weeks; SCS, systemic corticosteroid; SNOT-22, 22-item Sino-Nasal Outcome Test.

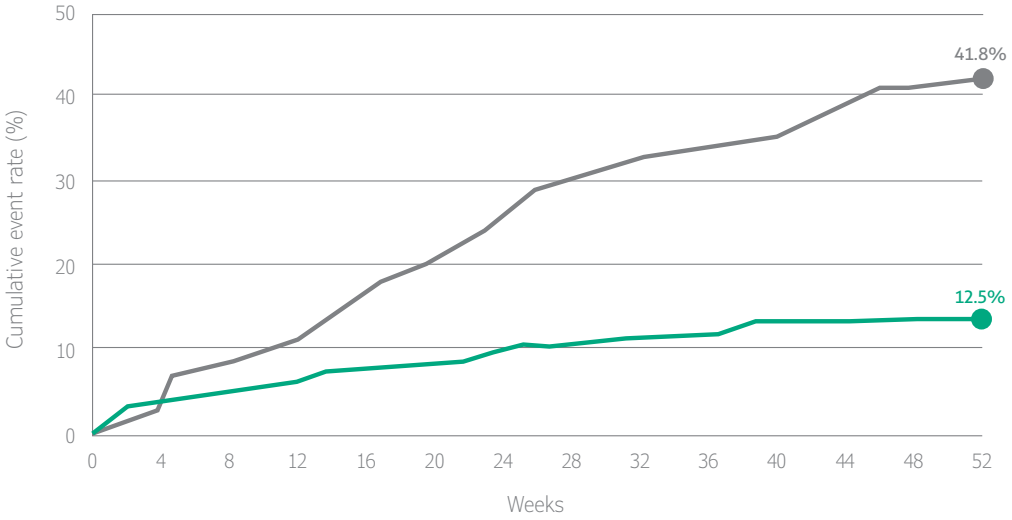
Visit DupixentHCP.com/CRSwNP

DUPIXENT® (dupilumab) Injection 300mg

DUPIXENT REDUCED STEROID USE AND SURGERY FOR THE MAJORITY OF PATIENTS

Significantly reduced SCS use or the need for sino-nasal surgery vs placebo in a prespecified multiplicity-controlled pooled analysis of Trials 1 and 2[3,a]

Time to first SCS use or CRSwNP surgery during the treatment period



76%
REDUCTION
at Week 52 with DUPIXENT vs placebo (HR: 0.24 [95% CI: 0.17, 0.35])

- **DUPIXENT 300 mg Q2W + INCS** (Day 0: n=438; Week 24: n=376; Week 52: n=100)
- **Placebo + INCS** (Day 0: n=286; Week 24: n=187; Week 52: n=61)

74% FEWER PATIENTS REQUIRED SCS USE AT WEEK 52

(HR: 0.26 [95% CI: 0.18, 0.38])[3]

- **75% REDUCTION IN SCS COURSES PER YEAR** (RR: 0.25 [95% CI: 0.17, 0.37])[3]

83% FEWER PATIENTS REQUIRED SINO-NASAL SURGERY AT WEEK 52

(HR: 0.17 [95% CI: 0.07, 0.46])[3]

[e] Individually, SCS reduction and need for sino-nasal surgery were not multiplicity-adjusted endpoints.

IMPORTANT SAFETY INFORMATION

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** Available data from case reports and case series with DUPIXENT use in pregnant women have not identified a drug-associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes. Human IgG antibodies are known to cross the placental barrier; therefore, DUPIXENT may be transmitted from the mother to the developing fetus.
- **Lactation:** There are no data on the presence of DUPIXENT in human milk, the effects on the breastfed infant, or the effects on milk production. Maternal IgG is known to be present in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for DUPIXENT and any potential adverse effects on the breastfed child from DUPIXENT or from the underlying maternal condition.

References: 1. Data on file, Sanofi US. LIBERTY NP SINUS-52, CSR. 2018. **2.** Bachert C, Han JK, Desrosiers M, et al. Efficacy and safety of dupilumab in patients with severe chronic rhinosinusitis with nasal polyps (LIBERTY NP SINUS-24 and LIBERTY NP SINUS-52): results from two multicentre, randomised, double-blind, placebo-controlled, parallel-group phase 3 trials. *Lancet.* 2019;394(10209):1638-1650. **3.** DUPIXENT Prescribing Information. **4.** Data on file, Sanofi US. Clinical overview (chronic rhinosinusitis with nasal polyposis). 2018.

HR, hazard ratio; RR, risk ratio.

Please see brief summary of full Prescribing Information on the following pages.

SANOFI GENZYME

REGENERON

DUP.19.12.0125 02/2020

DUPIXENT® (dupilumab) injection, for subcutaneous use Rx only

Brief Summary of Prescribing Information

1 INDICATIONS AND USAGE

1.3 Chronic Rhinosinusitis with Nasal Polyposis

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

4 CONTRAINDICATIONS

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

5 WARNINGS AND PRECAUTIONS

5.1 Hypersensitivity

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

5.2 Conjunctivitis and Keratitis

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

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

5.3 Eosinophilic Conditions

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

5.5 Reduction of Corticosteroid Dosage

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

5.6 Patients with Comorbid Asthma

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

5.7 Parasitic (Helminth) Infections

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

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

6 ADVERSE REACTIONS

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

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

6.1 Clinical Trials Experience

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

Chronic Rhinosinusitis with Nasal Polyposis

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

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

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

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

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

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

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

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

Specific Adverse Reactions

Conjunctivitis

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

Eczema Herpeticum and Herpes Zoster

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

Hypersensitivity Reactions

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

Eosinophils

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

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

Cardiovascular (CV)

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

6.2 Immunogenicity

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

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

Approximately 4% of subjects in the placebo groups in the 52-week studies were positive for antibodies to DUPIXENT; approximately 2% exhibited persistent ADA responses, and approximately 1% had neutralizing antibodies.

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

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

7 DRUG INTERACTIONS

7.1 Live Vaccines

Avoid use of live vaccines in patients treated with DUPIXENT.

7.2 Non-Live Vaccines

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

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Exposure Registry

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

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

Risk Summary

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

Data

Animal Data

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

8.2 Lactation

Risk Summary

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

8.4 Pediatric Use

CRSwNP

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

8.5 Geriatric Use

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

10 OVERDOSE

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

17 PATIENT COUNSELING INFORMATION

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

Pregnancy Registry

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

Administration Instructions

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

Hypersensitivity

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

Conjunctivitis and Keratitis

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

Eosinophilic Conditions

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

Reduction in Corticosteroid Dosage

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

Patients with Comorbid Asthma

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

Manufactured by: Regeneron Pharmaceuticals, Inc., Tarrytown, NY 10591 U.S. License # 1760; Marketed by sanofi-aventis U.S. LLC (Bridgewater, NJ 08807) and Regeneron Pharmaceuticals, Inc. (Tarrytown, NY 10591). DUPIXENT® is a registered trademark of Sanofi Biotechnology
 Issue Date: September 2019 DUP.19.08.0284

Research and Quality

Cecelia E. Schmalbach, MD, MSc
AAO-HNSF Coordinator, Research and Quality

The American Academy of Otolaryngology–Head and Neck Surgery Research and Quality Business Unit goal is to develop products and services to meet the needs of our members, their staff, and their patients in support of the overarching organizational vision to be the global leader in optimizing quality ear, nose, and throat patient care. As demonstrated in the pages that follow, this objective is achieved through the expertise and voluntary commitment of our physicians. Special thanks and credit go to the Reg-ent[SM] Executive Committee, the Clinical Advisory Committees, the Guidelines Leadership and Task Force, the Patient Safety/Quality Improvement Committee, the Outcomes, Research & Evidence-Based Medicine Committee, and the CORE leadership.

Several exciting research and quality initiatives commenced this past year. Patient reported outcomes (PROs) were fully integrated into Reg-ent and are currently being piloted with several Reg-ent practices. In addition, our specialty-specific clinical pathways for hearing loss, early oral cavity cancer, and allergic rhinitis were completed. These projects are timely and impactful in ensuring that our membership is poised for the anticipated Centers for Medicare & Medicaid Services (CMS) transition from the current MIPS model toward MIPS Value Pathways.

In addition, a partnership was finalized with OM1 that will lead us into Phase II of Reg-ent, allowing our robust national registry to serve as the basis for otolaryngology clinical research, to address product surveillance, and to provide a platform with additional data sources for internal and external research endeavors in support of the AAO-HNS/F mission. This exciting new phase harnesses the true power of data, allowing Reg-ent to reach its full potential as our national otolaryngology-head and neck surgery registry.

The articles to follow highlight the above initiatives along with several other impactful programs. Together these pages showcase the true breadth and depth of our Academy research and quality platform. Ultimately, these initiatives allow the AAO-HNS/F to be proactive and to adapt in meeting the ever-changing needs of our members and patients. Thanks to the great work of our Academy research and quality leaders as well as the support from staff, we are able to fulfill the mission of achieving excellence in otolaryngology-head and neck surgery care to our patients, in a manner that is evidence-based and of the highest quality care. ■

Read more online to access the reports from the Patient Safety and Quality Improvement Committee and the Outcomes Research Evidence-based Medicine Committee.

CORE CENTRALIZED OTOLARYNGOLOGY RESEARCH EFFORTS Update!

The Centralized Otolaryngology Research Efforts (CORE) grants program plays a critical role in advancing the field of otolaryngology by providing support to research projects, research training, and career development. CORE aims to:

1. Unify the research application and review process for the specialty;
2. Encourage young investigators to pursue research in otolaryngology;
3. Serve as an interim step that may ultimately channel efforts for important NIH funding opportunities.

The CORE grant program societies, foundations, sponsors, and partners have awarded over 12 million dollars since the program's inception in 1985. In 2020, American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNSF), American Head & Neck Society (AHNS), Association for Migraine Disorders (AMD), American Rhinologic Society (ARS), and American Society of Pediatric Otolaryngology (ASPO) were involved in funding grants ranging from $10,000 to $80,000. The leadership of each participating subspecialty society is ultimately responsible for determining who is selected to receive funding each year.

This year the CORE Study Section reviewed 157 applications for $3.06M in requested funding. The 2020 CORE Study Section subcommittees included: Head and Neck Surgery, chaired by **Cherie-Ann O. Nathan, MD** (Chair-Elect: **Maie St. John, MD, PhD**); Otology, chaired by **Oliver F. Adunka, MD** (Chair-Elect: **Rick Nelson, MD, PhD**); and General Otolaryngology, chaired by **Michael J. Brenner, MD**.

The CORE Study Section was the first successful virtual meeting with members at AAO-HNSF due to the COVID-19 pandemic. The group utilized the Zoom conferencing platform to conduct all three study sections simultaneously, adhering to all confidentiality and integrity standards required of the CORE Study Section.

The 2020 CORE leadership, including the boards and councils of all participating societies, has approved a portfolio of 28 grants totaling $500,000. The AAO-HNSF specific grants accounted for 15 grants approved and $250,000 of total funding.

CONGRATULATIONS TO THE 2020 CORE GRANTEES! SEE FULL LIST OF GRANTEES ONLINE AT: HTTPS://WWW.ENTNET.ORG/CONTENT/2020-CORE-GRANT-RECIPIENTS

CORE GRANTS PROGRAM SPOTLIGHTS

"An Academic Career Born and Bred in CORE"

Jon-Paul Pepper, MD
Stanford University

The CORE Grants program has been instrumental to my development as a surgeon-scientist. I was awarded the Research Scholar Award from the American Associate of Facial Plastic and Reconstructive Surgery, administered through CORE. This was a critical source of initial funding for my research. The process was rigorous, and I received detailed feedback. That grant then served as a template for other foundation grants. I was also invited to participate in grant reviews with CORE in the General Section. This NIH-style review session improved my grant writing through peer review. It also connected me with other surgeon-scientists who helped to guide me. I used all of these experiences for a successful resubmission of my K08 award to NIDCR in 2019. ■

Alan Cheng, MD
Stanford University

I was a T32 resident at the University of Washington when I applied for an AAO-HNSF resident CORE grant. It seemed like a lot of work at the time, but writing a grant forced me to think through the steps and logistics of my research plans. Supported by great mentors and colleagues, I got the necessary feedback and the experience really helped prepare me when I later applied for and was fortunately awarded NIH funding. As a faculty, I have been participating in the CORE Study Section, which is another tremendous experience as you see firsthand how grants are reviewed and also network with other scientists. Overall, I believe the CORE grant mechanisms and study section are perhaps some of best ways for residents, fellows, and junior faculty to get involved and get their research programs off the ground! ■

Maie St. John, MD, PhD
University of California, Los Angeles

I am very fortunate to have been the recipient of a Surgeon Scientist CDA, and then to have served as a CORE grant reviewer for the past 10 years. CORE funding was essential in building my academic career. My CDA provided me with funding, experience, and data that allowed me to successfully compete for a K Award. These grants and my invaluable experience as a CORE reviewer paved the way for success in developing my own independent NIH/NCI/NIBIB R–funded research program. My current work continues to focus on translational research with a focus on improving therapies and outcomes for patients with head and neck cancer. I encourage our trainees and faculty to join us at CORE, as we continue to support the networking and collaborative growth that is the sustenance of our revered specialty. ■

Reg-ent℠

What's New with Reg-ent

Reg-ent and OM1

As announced in May, and published in the June *Bulletin*, page 32, the AAO-HNSF has formed a partnership with OM1, a real-world outcomes and technology company. This partnership will connect Reg-ent to OM1's real-world data and evidence platforms, thereby enhancing the value that the data repository will bring to our members. Analytic capabilities will be improved, and we can confidently move into the second phase of Reg-ent providing access to quality clinical data and therefore enhancing research capabilities within the specialty.

Patient-Reported Outcome Surveys

The Reg-ent registry is excited to announce its first patient-reported outcome measure (PROM) that encourages shared decision-making between physicians and their patients in the treatment of age-related hearing loss. Physicians who choose to enroll their patients may access this new tool via their Reg-ent dashboard. To learn more about this new offering and join other Reg-ent practices as they move the dial on patient-centered care in age-related hearing loss, make sure to join webinars being scheduled in September 2020. More details to follow, so please stay tuned to your inbox for webinar invitations. Efforts are also underway in reviewing and prioritizing additional patient reported outcome tools pertinent to the specialty to be made available through Reg-ent. To learn more about validated survey instruments currently under review, visit **https://www.entnet.org/content/outcome-tools**.

Quality and Quality Measures

Reg-ent, as a clinical data registry and CMS-designated Qualified Clinical Data Registry, is able to track patients longitudinally over time and connect clinical outcomes with healthcare processes. The registry encourages participating providers and practices to commit to mapping and reporting Reg-ent's specialty-specific quality measures, which contribute to an enhanced registry dashboard and position practices well to the future of MIPS reporting as CMS moves toward MIPS Value Pathways. We encourage all Reg-ent-participating practices to work with the Reg-ent registry to map and report Reg-ent's specialty-specific QCDR measures. Increased engagement with and reporting of Reg-ent's QCDR measures will preserve Reg-ent's QCDR status as well as provide the means for otolaryngologists to continue to define quality for the specialty. A list of the current 2020 measures available in Reg-ent can be found at **https://www.entnet.org/2020-measures** and on page 29-30 of this issue.

Registry Growth

Reg-ent registry data continues to grow, reaching a cohort of over six million unique patients and 25 million patient visits in 2020. A record number of member practices and clinicians utilized Reg-ent to comply with the Centers for Medicare & Medicaid (CMS) Merit-based Incentive Payment System (MIPS) 2019 reporting with 184 practices representing 1,244 clinicians completing reporting during the first quarter of 2020.

Large Group Executive Forum practices continued their engagement with the Reg-ent registry in 2019 with nine of their member practices choosing Reg-ent as their MIPS reporting solution, including ENT and Allergy Associates, the largest private practice in Reg-ent, with

335 clinicians who reported MIPS 2019 via Reg-ent. Reg-ent's practices remain committed as evidenced by Reg-ent's stable membership participation renewal rate this year.

We are also seeing growth with academic medical center participation. This past year, with the introduction of an EPIC solution, the University of Mississippi, Baylor College of Medicine, Temple University, UPB Brooklyn, and Oregon Health & Science University are reviewing actionable quality data in their Reg-ent dashboards. Johns Hopkins University and Thomas Jefferson University are preparing for integration with Reg-ent. Many others are now in the process of onboarding through the Reg-ent Epic app to increase quality improvement capabilities within their practice and to contribute to the growing data repository. This will ensure their ability to utilize the Reg-ent registry for research purposes and increase their ability to track their practice performance across many quality indicators, as well as assist them in preparation for the future evolution of payment and reimbursement models.

Registry Governance

The AAO-HNSF Reg-ent Executive Committee (REC) reports directly into the AAO-HNSF Board of Directors. The nine otolaryngologist members and three Ex-Officio members represent the span of the specialty and both academic and private practice. These individuals have held or currently hold leadership positions at AAO-HNSF in clinical practice guideline development, clinical research, and quality and performance improvement including measures development and implementation. Seven clinical advisory committees (CACs) representing the specialties of otolaryngology address clinical quality measure development and prioritization including identification of relevant patient reported outcome measures (PROMs) to be made available in Reg-ent. The CACS are comprised of experts from AAO-HNS committees, specialty societies, and other stakeholder groups. ■

REG-ENT℠ GOVERNANCE STRUCTURE

CLINICAL CONSENSUS STATEMENT

Ankyloglossia in Children

The new Clinical Consensus Statement (CCS): Ankyloglossia in Children was published online in *Otolaryngology–Head and Neck Surgery* on April 14, 2020. **Anna H. Messner, MD,** chaired the CCS development panel, which was composed of a panel of experts in the field of pediatric otolaryngology. The purpose of the CCS is to promote appropriate, evidence-based care of the infant and child with possible ankyloglossia and/or upper lip tie.

The panel was able to reach consensus on 41 statements after three iterative Delphi method surveys related to the clarification of diagnosis, management, and treatment of ankyloglossia in children up to 18 years of age. An additional 17 statements were near consensus, and 28 statements failed to achieve consensus. The statements were grouped into the following categories: ankyloglossia (general), buccal tie, ankyloglossia and sleep apnea, ankyloglossia and breastfeeding, frenotomy indications and informed consent, frenotomy procedure, ankyloglossia in older children, and maxillary labial frenulum. Areas where knowledge gaps and lack of evidence exist identified opportunities for future research. In the meantime, this information should prove helpful for otolaryngologists treating patients with ankyloglossia. The AAO-HNSF recognizes the valuable contributions made by Dr. Messner and the panel in the development of this new CCS.

Read CCS: Ankyloglossia in Children now by visiting **https://journals.sagepub.com/doi/full/10.1177/0194599820915457.**

A podcast, moderated by **John H. Krouse, MD, PhD, MBA,** Editor in Chief of *Otolaryngology–Head and Neck Surgery,* with **Jennifer J. Shin, MD, SM,** and Dr. Messner, is also available at **http://sageotolaryngology.sage-publications.libsynpro.com/oto-clinical-consensus-statement-ankyloglossia-in-children** ■

CPG
Clinical Practice Guidelines

CCS
Clinical Consensus Statement

AAO-HNS Clinical Practice Guidelines and Clinical Consensus Statements Focused on Quality Improvement

With the goal of improving quality of care in otolaryngology, the AAO-HNSF has continued to develop guidance documents, in the form of Clinical Practice Guidelines (CPGs) and Clinical Consensus Statements (CCSs), on a range of topics prioritized by the Guideline Task Force (GTF). The GTF leadership and methodologists, David E. Tunkel, MD (GTF Chair), Richard M. Rosenfeld, MD, MPH, MBA (Senior Advisor and Methodologist for Quality Measures and Guidelines), Seth R. Schwartz, MD, MPH, and Stacey L. Ishman, MD, MPH, have led the methodological oversight of these documents. Their leadership, as well as that of each CPG and CCS chair, has helped produce publications that are highly cited and accessed not only by AAO-HNS members, but also by clinicians across multiple specialties, as well as by patients and the public. As the AAO-HNSF continues to develop new CPGs and CCSs, and update previously published CPGs, the catalogue of CPGs has also facilitated the development of quality measures. This has furthered the AAO-HNSF's goal to take the lead in defining "quality care" for the specialty.

CCSs that have been published or initiated in 2019 and 2020 include:

- CCS: Balloon Dilation of the Eustachian Tube (June 2019)
- CCS: Ankyloglossia in Children (April 2020)
- CCS: Drug Induced Sleep Endoscopy (In progress)

CPGs that have been published and initiated in 2020 include:

- CPG: Nosebleed (Epistaxis) (January 2020)
- CPG: Meniere's Disease (April 2020)
- CPG: Opioid Prescribing for Analgesia After Common Otolaryngology Operations (In progress)
- CPG: Tympanostomy Tubes in Children (Update) (In progress)
- CPG: Surgical Management of Rhinosinusitis (In progress)

To support the dissemination and implementation of a CPG that is published as a supplement in *Otolaryngology–Head and Neck Surgery*, the AAO-HNSF produces resources including a plain language summary, executive summary, patient handouts (printable, customizable, and available in Spanish), slide set, podcast episodes, and, in collaboration with Guideline Central, a quick-reference pocket guide and app. In addition, CPGs and CCSs are presented at the AAO-HNSF Annual Meeting & OTO Experience prior to publication and are shared with relevant organizations in order to request endorsement.

To access the published CPGs, CCSs, and supplemental resources, visit www.entnet.org/CPG. ■

AAO-HNSF

QUALITY MEASURES

EVIDENCE-BASED CARE

WHY QUALITY MEASURES ARE IMPORTANT

Quality measures are used to monitor patient care, connect clinical outcomes with healthcare processes, and meet third-party payer requirements. AAO-HNSF is committed to providing quality measures that meet our members' requirements for public reporting to both the Centers for Medicare & Medicaid Services (CMS) and private payers and to track patient care over time.

Reg-ent offers 17 specialty-specific AAO-HNSF-developed QCDR measures.

AAO-HNSF Qualified Clinical Data Registry (QCDR) measures are developed internally and only available to Reg-ent participants. These are specialty-specific measures that have been approved by CMS for reporting in the Merit-based Incentive Payment System (MIPS).

AAO-HNSF QCDR MEASURES

AGE-RELATED HEARING LOSS	
AAO16	Age-related Hearing Loss: Audiometric Evaluation+
AAO17	Age-related Hearing Loss: Advanced Diagnostic Imaging of Bilateral Presbycusis or Symmetric SNHL+
ALLERGIC RHINITIS	
AAO23	Allergic Rhinitis: Intranasal Corticosteroids or Oral Antihistamines
AAO24	Allergic Rhinitis: Avoidance of Leukotriene Inhibitors+
BELL'S PALSY	
AAO13	Bell's Palsy: Inappropriate Use of Magnetic Resonance Imaging or Computed Tomography Scan (Inverse Measure)+
DYSPHONIA	
AAO34	Dysphonia: Postoperative Laryngeal Examination
OTITIS MEDIA WITH EFFUSION	
AAO21	Otitis Media with Effusion: Hearing Test for Chronic OME > 3 months
AAO31	Otitis Media with Effusion (OME): Avoidance of Inappropriate Use of Medications+
TYMPANOSTOMY TUBES	
AAO12	Tympanostomy Tubes: Topical Ear Drop Monotherapy Acute Otorrhea+
AAO20	Tympanostomy Tubes: Hearing Test
AAO36	Tympanostomy Tubes: Resolution of Otitis Media with Effusion in Adults and Children*
NEUROTOLOGY	
AAO29	Quality of Life for Patients with Neurotology Disorders*
AAO32	Standard BPPV Management+
AAO35	Benign Positional Paroxysmal Vertigo (BPPV): Dix-Hallpike and Canalith Repositioning
RHINOPLASTY	
ASPS16	Airway Assessment for Patients Undergoing Rhinoplasty+
ASPS17	Patient Satisfaction with Rhinoplasty Procedure*
ASPS18	Shared-decision Making for Post-operative Management of Discomfort Following Rhinoplasty+

*+Denotes high priority measure *Denotes outcome measure*

Reg-ent℠

ENT CLINICAL DATA REGISTRY

Reg-ent offers 40 public QPP measures applicable to otolaryngology-head and neck surgery.

Quality Payment Program (QPP) measures are available publicly to any clinician reporting to MIPS and several were developed by AAO-HNSF. These QPP measures are also available in the Reg-ent registry. Reg-ent participants who are using the web tool for MIPS reporting do not have access to the QCDR measures but are able to use QPP measures.

QPP MEASURES FOR ENT

ACUTE OTITIS EXTERNA

QPP 093 Acute Otitis Externa: Systemic Antimicrobial Therapy - Avoidance of Inappropriate Use+

ADULT SINUSITIS

QPP 331 Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse)+

QPP 332 Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use)+

QPP 333 Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse)+

ASTHMA

QPP 398 Optimal Asthma Control*

QPP 444 Medication Management for People with Asthma+

FALLS

QPP 154 Falls: Risk Assessment+

QPP 155 Falls: Plan of Care+

OTITIS MEDIA WITH EFFUSION

QPP 464 Otitis Media with Effusion: Systemic Antimicrobials - Avoidance of Inappropriate Use+

SLEEP APNEA

QPP 277 Sleep Apnea: Severity Assessment at Initial Diagnosis

QPP 279 Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy

GENERAL QPP MEASURES

MEDICATION

QPP 130 Documentation of Current Medications in the Medical Record+ˆ

QPP 238 Use of High-Risk Medications in the Elderly+ˆ

OPIOID THERAPY

QPP 408 Opioid Therapy Follow-up Evaluation+

QPP 412 Documentation of Signed Opioid Treatment Agreement+

QPP 414 Evaluation or Interview for Risk of Opioid Misuse+

QPP 468 Continuity of Pharmacotherapy for Opioid Use Disorder (OUD)+

PERIOPERATIVE CARE

QPP 021 Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second Generation Cephalosporin+

QPP 023 Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients)+

PREVENTIVE CARE & SCREENING

QPP 110 Preventive Care and Screening: Influenza Immunizationˆ

QPP 111 Pneumococcal Vaccination Status for Older Adultsˆ

QPP 128 Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Planˆ

QPP 226 Preventive Care and Screening: Tobacco Use: Screening and Cessation Interventionˆ

QPP 317 Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documentedˆ

QPP 402 Tobacco Use and Help with Quitting Among Adolescents

QPP 431 Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling

RESPIRATORY DISEASES

QPP 065 Appropriate Treatment for Children with Upper Respiratory Infection (URI)+ˆ

QPP 066 Appropriate Testing for Children with Pharyngitis+ˆ

QPP 116 Avoidance of Antibiotic Treatment in Adults With Acute Bronchitis+

SURGERY

QPP 355 Unplanned Reoperation within the 30 Day Postoperative Period*

QPP 356 Unplanned Hospital Readmission within 30 Days of Principal Procedure*

QPP 357 Surgical Site Infection (SSI)*

QPP 358 Patient-Centered Surgical Risk Assessment and Communication+

OTHER

QPP 047 Advance Care Plan+

QPP 261 Referral for Otologic Evaluation for Patients with Acute or Chronic Dizziness+

QPP 265 Biopsy Follow-Up+

QPP 374 Closing the Referral Loop: Receipt of Specialist Report+ˆ

QPP 404 Anesthesiology Smoking Abstinence*

QPP 435 Quality of Life Assessment For Patients With Primary Headache Disorders*

QPP 440 Basal Cell Carcinoma (BCC)/Squamous Cell Carcinoma (SCC): Biopsy Reporting Time - Pathologist to Clinician+

*+Denotes high priority measure *Denotes outcome measure ˆDenotes eCQM*

Visit www.entnet.org/2020-measures to view the full list of quality measures available through Reg-ent.

AMERICAN ACADEMY OF OTOLARYNGOLOGY–HEAD AND NECK SURGERY FOUNDATION®

FROM THE EDUCATION COMMITTEES

Cancer Immunotherapy Update

Larissa Sweeny, MD, and Nicole C. Schmitt, MD,
For the Head and Neck Education Committee

Immunotherapy has the capability of restoring a patient's own anti-tumor immunity as a means to target cancer. The emergence of checkpoint inhibitors in recent years has promoted immunotherapy as a major breakthrough in cancer therapy. Checkpoint inhibitors have revolutionized treatment of advanced head and neck cancer (HNC), known to have a poor prognosis and low survival rate. When pembrolizumab was approved by the U.S. Food and Drug Administration (FDA) for treatment of refractory recurrent and metastatic HNC in 2016, it became the first new therapeutic agent for treatment of HNC in a decade.

In 2019 the findings from the KEYNOTE-048 trial, a phase III clinical trial, established pembrolizumab as a first-line therapy for patients with unresectable recurrent or metastatic HNC. The trial found for tumors with a PD-L1 score of 1 or greater, patients responded to single agent pembrolizumab, with superior overall survival compared to combination platinum, 5-FU, cetuximab regimens and with fewer adverse events.[1] Another significant finding from the trial was that pembrolizumab plus platinum and 5-FU had better overall survival regardless of PD-L1 status compared to the combination platinum, 5-FU, cetuximab regimen.[1]

These findings led to the FDA approval of pembrolizumab as a first-line agent in the treatment of recurrent or metastatic HNC with a PD-L1 staining score of 1 or greater. For patients with a lower PD-L1 staining score, first-line pembrolizumab plus platinum and 5-FU is the new standard.

Pembrolizumab is now under investigation for use in locally advanced HNC and in combination with radiation therapy. With these recent findings of immune checkpoint inhibitors improving survival and reducing toxicity, their use in earlier stage disease and deintensification has great potential. Here are some highlights of exciting new avenues for immunotherapy in our field:

- The COVID-19 pandemic has certainly highlighted limitations of immunity in the elderly, and geriatric patients are often not eligible for treatment with nephrotoxic, platinum-containing regimens. A phase II trial of pembrolizumab + radiation for cisplatin-ineligible HNC showed toxicities comparable to those seen with radiation alone and very favorable one-year survival rates.[2]
- For patients with high-risk head and neck squamous cell carcinoma who can tolerate cisplatin, immune checkpoint blockade has been added to definitive chemoradiation regimens, with the intent of improving survival. One study adding pembrolizumab to radiation and weekly cisplatin showed good safety and feasibility, with all patients receiving the intended dose of radiation and most receiving the goal dose of cisplatin.[3] Two large randomized, placebo-controlled studies adding anti-PD-1 or anti-PD-L1 therapy to cisplatin chemoradiation for patients with high-risk HNC are underway.[4,5]
- Several "window of opportunity" trials are using checkpoint inhibitors alone or with other immunotherapies prior to surgical resection of HNC, allowing us to better understand responses and potentially improve long-term survival. Three phase II studies have used pembrolizumab or nivolumab in the neoadjuvant setting and along with postoperative chemoradiation in HNC. Pathologic responses were >40%, with some patients demonstrating a complete pathologic response.[6-8] PD-1 blockade was well tolerated and did not usually delay the timing of surgery. A phase III study investing neoadjuvant and adjuvant pembrolizumab for patients with high-risk, resectable HNSCC (KEYNOTE-689) is currently underway.

Although we need to await the results of these phase III studies, it is likely that PD-1 checkpoint inhibitors will soon be integrated into standard therapy for previously untreated, locally advanced HNC. ■

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OUT OF COMMITTEE

Telemedicine

Collaboration among Patient Safety and Quality Improvement Committee, Telehealth Committee, and Practice Management Education Committee

Steven T. Kmucha, MD, JD, Lance A. Manning, MD, and Douglas M. Hildrew, MD

With the goal of reducing disease exposure and transmission, telemedicine became an immediate necessity in 2020 due to COVID-19. This enormous and rapid leap forward in the utilization of telemedicine technology also provides an opportunity to address other challenges that physician practices face. As such, it is important to understand the many rapidly changing logistical, legal, regulatory, and financial implications as early as possible.

Telemedicine implementation is a team effort that requires training, open communication, and commitment for long-term success. While there may have been an urgent need to get telemedicine services up and running due to the rapid onset of the COVID-19 pandemic, telemedicine needs and services often change significantly over time. In the beginning, it is important to have open discussions about concerns, timing, goals, and objectives so that your entire team is aligned. It is equally important to list and share the anticipated benefits and challenges of the telemedicine program. A clear and thorough evaluation, sharing, and understanding of your practices' needs and processes will make implementation easier and hopefully minimize future problems. Creating a brief list of specific short- and long-term goals with accessible metrics and a process for tracking your progress will help guide you and your staff to easily identify successful achievement of these important milestones. Obtaining timely feedback from schedulers, nursing and medical assistant staff, physician extenders, and other members of the care team who may not have been part of the initial discussions and early phases of implementation will help you all to quickly identify opportunities for improvement in telemedicine training, new workflow procedures, triage protocols, and patient education materials.

For those in larger organizations, getting support from the leadership team and administration is a key element of the long-term success of a telemedicine program. Without broader support, it can be challenging to continue to get the necessary resources and to prioritize the staff time needed to make implementation or continuation successful. Be sure to share the operational and quality issues that have been identified as well as how these can be aligned with group and/or organizational goals and the metrics. Sharing which tools of telemedicine are working best for your team and patients with your organizational administrators can help everyone understand how this technology can improve operational efficiencies and thereby deliver a positive return on investment. It is important to align expectations and goals for how everyone will work together and communicate to optimize implementation and improve practice workflow, documentation, and patient satisfaction. It is important early in the process to discuss the level of support and training that will be needed and to think creatively about when, where, and how the platform can provide additional value by optimizing practice efficiency.

Telemedicine appointments will likely require an adjusted workflow to ensure that you are offering a positive experience for patients and the care team. Daily logistics such as physical workspace arrangements, appointment scheduling procedures, triage, staff time, and communication may have to be altered to integrate telemedicine as seamlessly as possible into your practice. Consider how to incorporate telemedicine appointments with the least amount of workflow disruption. It is important to try to understand and operationalize the preferences and needs of patients, such as what types of technology and communication barriers they may be encumbered by when engaging in a telemedicine visit.

Telemedicine visits can only be truly successful when patients are empowered to use them. It is critical to ensure that patients are educated and engaged through a patient-centered approach to maximize the positive impact of these new telemedicine services. As you plan and discuss when and how to inform patients about telemedicine services, it is important to ensure that the entire team is prepared to answer patient questions such as how to access the platform and how to schedule an appointment. Define appropriate appointment expectations and limitations and be prepared to kindly communicate these in order to promote awareness, receptivity, and participation.

With the rollout of a telemedicine program, much of the energy will be focused on making patients and referring physicians aware of the availability of the new service, scheduling appointments, supporting clinicians and patients as they start using the technology, ensuring appropriate E/M documentation, currently approved CPT codes and respective site of service codes, and ensuring a path to payment. It will be important to monitor the impact of your program by tracking the key success metrics mentioned earlier, including timely and

correct reimbursement for services rendered as the reimbursement, documentation, and coding requirements from both private payers and Medicare and Medicaid are rapidly changing. It is also critical to be sure that you continue to collect and respond to feedback from administrative staff, patients, and clinicians about their experiences with the program to ensure that efficiencies are optimized and that you are responding well to the dynamic nature of the legal, regulatory, and logistical telemedicine environment.

New technologies are rapidly and fundamentally changing the way patients interact with healthcare providers and the way that providers interact and communicate with each other for the benefit of the patient. Successful implementation and smooth interoperability of these many digital health technologies are imperative for improving patient outcomes and ensuring financial stability for healthcare practices. With the evolving COVID-19 pandemic, its impact on access to medical care and the high risk of otolaryngology provider exposure, the incorporation of telemedicine services into otolaryngology practice has been unavoidable. In addition, it should be our mission to provide the safest experience possible for our patients—something that remote triage and management by way of telemedicine is particularly adept at. Otolaryngologists require ongoing support, frequent regulatory updates, and continued telemedicine education to best navigate this transition, to implement telemedicine into their practices, and to enhance their ability to care for patients both short-term and long-term. The tools and guidelines being created now are already helping many to use telemedicine and will continue to help define its role and to help shape and improve the future of otolaryngology practice. There are many potential resources for up-to-date telemedicine information and guidance. On the AMA website you can find the AMA Quick Guide to Telemedicine in Practice and the Telehealth Implementation Playbook and the AMA STEPSforward Module on Telehealth. Likewise, the Centers for Medicare & Medicaid Services provides updated information and toolkits on their website. Other potential resources include the American Telehealth Association, medical liability companies, private partners, and your state and regional medical associations. The AAO-HNS provides numerous resources relevant to telemedicine in otolaryngology practices: podcasts, informational documents, advance releases of important journal articles, webinars, frequENTcy, *OTO News*, ENTConnect, and online courses. To access the AAO-HNS resources on telemedicine, visit **https://www.entnet.org/content/coronavirus-disease-2019-resources.**

And while there are a number of potential unique risks and liabilities associated with telemedicine services, these have been fully addressed in other publications. See the three-part series from **Steven T. Kmucha, MD:**

Physician liability issues and telemedicine: Part 1 of 3. *Ear Nose Throat J.* 2015;94(10-11):428-429.

Physician liability issues and telemedicine: Part 2 of 3. *Ear Nose Throat J.* 2015;94(12):466-469.

Physician liability issues and telemedicine: Part 2 of 3. *Ear Nose Throat J.* 2016;95(1):12-14. ■

AAO-HNS COVID-19 Podcast Series Episode 5: Telemedicine

[published April 2]

Lance A. Manning, MD, Chair of the AAO-HNS Practice Management Education Committee and Chair Elect of the Board of Governors is joined by **Douglas M. Hildrew, MD,** Chair of the AAO-HNS Telemedicine Committee and Assistant Professor of Surgery at the Yale School of Medicine, Division of Otolaryngology-Head & Neck Surgery, and **Lawrence M. Simon, MD,** former AAO-HNS CPT Advisor, member of the AMA's CPT Editorial Panel, and Regional Director for Blue Cross and Blue Shield of Louisiana, for a discussion on the rapid adaptation of telemedicine and related issues due to the coronavirus pandemic.
https://directory.libsyn.com/episode/index/id/13826069

AcademyU Free eCourse: Telemedicine during the Pandemic

Free for members and nonmembers: This timely new course provides a guide for immediate implementation of telemedicine in your practice in response to the COVID-19 pandemic. This course was developed in collaboration with the Practice Management Education Committee and Telemedicine Committee.
http://academyu.entnet.org/diweb/catalog/item/id/5098818/q/f2=1&c=177&o=-esd ■

Data-Driven Multidisciplinary Tracheostomy Care—Preventing Harm and Improving Lives

OREBM Publication Spotlight

Michael J. Brenner, MD, Joshua R. Bedwell, MD, and Vikas Mehta, MD

Management decisions around tracheostomy have been at the forefront of international dialogue in the midst of the COVID-19 pandemic. In this *Bulletin* segment, our committee shares highlights from key developments in this space, with detailed analysis of the largest implementation to date of a prospective multidisciplinary tracheostomy team approach. We provide concise summaries of salient findings from current studies that may inform high-stakes decision making and surgical practice in otolaryngology.

Forthcoming Publications

McGrath BA, Wallace W, Lynch J, et al. Improving tracheostomy care in the United Kingdom: Results of a guided quality improvement program in 20 diverse sites. *Br J Anaesth.* Forthcoming.

Brenner MJ, Pandian V, Milliren C, et al. Global Tracheostomy Collaborative: data-driven improvements in patient safety through multidisciplinary teamwork, standardization, education and patient partnership. *Br J Anaesth.* Forthcoming.

Cherney RL, Pandian V, Eastman D, et al. The Trach Trail: a systems-based pathway to improve quality of tracheostomy care and interdisciplinary collaboration. *Otolaryngol Head Neck Surg.* Forthcoming.

McGrath BA*, Brenner MJ*, Warrillow S, et al. Tracheostomy in the COVID-19 era: global and multidisciplinary guidance. *Lancet.* Forthcoming.

The impetus for change:

Tracheostomy is a marker for medical complexity with significant adverse events occurring in 10% to 20% of patients.[1,2] A landmark study found that in ICUs, tracheostomy was implicated in up to half of all airway-related deaths and instances of hypoxic brain injury.[3] Other well known complications include tracheostomy tube occlusion, accidental dislodgement, hemorrhage, infection, pneumothorax, granulation tissue, airway stenosis, tracheoinnominate artery fistula, tracheoesophageal fistula, and aspiration.[1] The United Kingdom's National Confidential Enquiry into Patient Outcomes and Death further illuminated the concerning shortfalls in care, documenting lack of coordinated efforts, insufficient education and protocols, and systems failures as root causes of preventable harm.[2]

These reports catalyzed international efforts to improve the standard of care for patients with tracheostomy. The UK National Tracheostomy Safety Project (NTSP, www.tracheostomy.org.uk) and the Global Tracheostomy Collaborative (GTC, www.globaltrach.org) evolved to provide structures for coordinating improvement efforts across institutions, facilitating data capture and analysis. Five key drivers of outcomes were identified to improve patient care: multidisciplinary ward rounds, standardized protocols, interdisciplinary education, patient and family involvement, and data-driven solutions.[4] Multidisciplinary tracheostomy teams at individual sites have achieved dramatic reductions in adverse events and improved patient outcomes. However, widespread dissemination and adoption of successful practices have lagged, with questions remaining as to whether such improvements are generalizable across institutions. Prior studies have been limited by emphasis on outcomes of adverse events and mortality with far less data available on patient quality of life and economic measures.

Largest prospective study to date on multidisciplinary tracheostomy care

Design

McGrath, et al. reports in the *British Journal of Anesthesia* on a three-year, 20-hospital, multipronged quality improvement initiative involving 2,405 tracheostomy patient admissions. The hospitals were distributed throughout the United Kingdom including adult, pediatric, and combined sites. The outcomes evaluated included overall hospital length of stay, ICU stay, ventilator duration, time to cuff deflation, time to first vocalization, time to first oral intake, prevalence of anxiety and depression, and economic impact. Mixed methods analysis, data tracking, and benchmarking were combined to evaluate effects of implementation. Sites were enrolled in three waves, with respective institutions undertaking incremental adoption of interventions identified to improve outcomes. A total of 18 interventions relating to themes of patient safety, patient-focused quality of care, and organizational efficiency were adopted.

Methodology

Individual sites captured patient-level data prospectively using a GTC-specific REDCap database, with additional linked data obtained from critical care datasets and local incident reporting. Qualitative data collection involved use of validated survey instruments and interviews for both patients and staff. The authors performed appropriate quantitative and qualitative analyses, including nonparametric linear regression to identify predictive variables, and the use of NVIvo for qualitative analysis of interview and survey data. Economic evaluation was calculated using NHS national schedule of cost, with independent financial analyses conducted to minimize risk of bias. The time course

Summaries of current studies may inform high-stakes decision making and surgical practice in otolaryngology regarding tracheostomy care.

of implementation was monitored, with most sites requiring 12 months to achieve implementation of objectives.

Results

Study findings included significant improvements for all 20 sites enrolled. A total of 727 clinical patient safety events were reported, with significant reductions in adverse events over time. Patients spent fewer days in the ICU, days on the ventilator, days with tracheostomy, and days in the hospital (all p <.01). Several patient-centered quality of life outcomes improved, including a dramatic reduction in the time to first oral intake (from 26 to 9 days, p<0.01), and time to cuff-deflation and vocalization (each reduced by 1 week, p<0.05). Measures of patient mental health similarly benefitted, with reduced anxiety (down from 35.9% to 20%, p<0.01) and depression (from 38.7% to 18.3%, p<0.01). The economic analyses demonstrated £15,200 savings per patient, with projected savings to NHS of £275 million annually (US $341 million). Limitations included inclusion of sites only in the United Kingdom and lack of random assignment, as the study was a quality improvement implementation.

GTC reports on >5000 prospective tracheostomy admissions: the Trach Trail

Two other studies provide important supporting data regarding the power of multidisciplinary team-based care to transform tracheostomy care. The GTC international report details findings of prospective data collection on over 5000 patients with tracheostomy, presenting a model of risk and identifying powerful predictors of adverse events, length of stay, and mortality, such as comorbidities and admitting diagnosis. It also highlights an association of bleeding events after tracheostomy with mortality. The Trach Trail represents a systems-based pathway implemented at University of Michigan that reduced ICU length of stay. The findings are particularly significant given that ICU capacity strain (involving ICU beds, staff, and ventilators) have proven a critical choke point in the COVID-19 era.

Tracheostomy in the COVID-19 Era: Global and Multidisciplinary Guidance

Finally, the consensus guidance document, in press for *The Lancet Respiratory Medicine,* brings together thought leaders from the United States, the United Kingdom, Italy, Spain, France, Germany, Switzerland, Australia, Hong Kong, Beijing, Shanghai, and Wuhan China, examining practices through lenses of pandemic history, medical ethics, resource scarcity, and patient advocates alongside stakeholders in diverse clinical disciplines (otolaryngology, anesthesia critical care, pulmonology, intensive care, infectious disease, virology/immunology, respiratory therapy, speech and language pathology, and nursing). A modified Delphi technique was used to generate recommendations regarding indications for tracheostomy, case selection, timing of tracheostomy, setting/location, procedural approach/personal protective equipment (PPE), and optimal management strategies following tracheostomy.

Conclusions

The results of these collective studies are particularly relevant to otolaryngologists and other specialists involved in tracheostomy care in the United States and beyond. The COVID-19 pandemic has led to a surge in critically ill patients, a significant number of whom may go on to require tracheostomy. Given what we know about the baseline prevalence of tracheostomy-related adverse events and effects on patient quality of life, there is much room for improvement. Dr. McGrath and colleagues have demonstrated the feasibility of improving quality and safety of tracheostomy care in geographically and politically diverse sites, with differing size, operations, and governances. The program is the first to demonstrate improvement at such scale and shows the potential for multidisciplinary interventions to prevent harm, improve the patient experience of living with a tracheostomy, and reduce expenditures. ■

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Eosinophilic Esophagitis: Implications for the Otolaryngologist

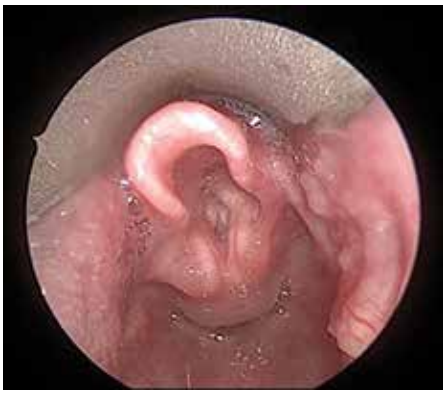
Margo McKenna Benoit, MD; Mathieu Bergeron, MD; Anatoli F. Karas, MD; Esther Prince, MD; and John J. Faria, MD

Eosinophilic esophagitis (EoE) is a clinicopathological disorder characterized by eosinophil predominant inflammation of the esophagus (>15 eosinophils/hpf) and esophageal dysfunction. The prevalence in children in the United States is 10-50/100,000 and EoE has become increasingly recognized in children and adults over the past two decades. The disease is characterized by periods of remission and relapses and includes vague presenting symptoms, making it difficult to diagnose. Due to its nonspecific presentation, up to 15% of patients with EoE may initially present to an otolaryngologist, therefore making it an important differential diagnosis in our clinics.

Presenting symptoms vary with age. Infants and toddlers typically present with feeding difficulties, vomiting, food refusal, or failure to gain weight. School-aged children will usually present with vomiting, regurgitation, and abdominal pain, while adolescents will tend to present with food impaction, dysphagia, and abdominal pain. However, patients with EoE develop coping mechanisms to compensate for their symptoms. It is of utmost importance to keep a high degree of suspicion and to question any changes in food habits. Changes in food habits include cutting food into smaller pieces, pocketing of food in the mouth, or drinking larger amounts of liquids with meals to help alleviate symptoms. A personal or atopic family history such as atopic dermatitis, asthma, eczema, or IgE-mediated food allergies, as well as family history of EoE, should increase the clinical index of suspicion for EoE. Atopic disorders and EoE are thought to share similar underlying mechanisms.

While EoE usually presents with gastrointestinal symptoms, it can also have extraesophageal manifestations refractory to conventional treatment. Several otolaryngologic symptoms are associated with EoE, and these may be the initial presenting symptoms in the absence of traditional gastrointestinal symptoms. Nasal symptoms and rhinosinusitis are reported in up to 25% of children with EoE. To a lesser extent, the same applies for laryngeal symptoms (chronic cough, hoarseness, dysphonia), recurrent laryngotracheobronchitis (croup), and other airway manifestations such as "active airway" or failed airway reconstruction. Of note, it is now a standard of care to rule out EoE prior to attempting laryngotracheal reconstruction as such disorder doubles the odds of a failed reconstruction. It has also been noted that patients with EoE are more likely to undergo ENT surgery. For example, 15% of patients with EoE will have bilateral myringotomy with tubes versus 6.8% of the general population. Up to 30% of patients with EoE will require multiple sets of tubes, which represents approximately 10% more than the general population.

Revised diagnostic criteria for EoE were published in 2018, refining presenting symptoms and the role of esophageal biopsies. More importantly, the diagnostic algorithm removed the need for the use of proton pump inhibitors (PPI) prior to performing an EGD. It was felt that PPIs were better classified as treatment of EoE rather than part of the diagnostic criteria. EoE should be suspected on a clinical basis with chronic symptoms of esophageal dysfunction such as food impaction, heartburn, abdominal pain, and/or cough. When EGD is indicated, the examination should focus on endoscopic signs of EoE, such as longitudinal furrowing, esophageal rings, edema, exudates, or strictures. It is also recommended to quantify the findings using a validated tool, like the EoE Endoscopic Reference Score. Normal mucosa does not exclude EoE. During an EGD, esophageal biopsies should be taken whenever EoE is suspected. EoE is considered a patchy disease and 2-4 biopsies should be taken from the proximal and distal esophagus focusing on areas that appear suspicious. A diagnosis of EoE is made when biopsies demonstrate greater than 15 eosinophils/hpf and the patient has symptoms compatible with this disorder. Of note, the presence of esophageal eosinophilia on biopsies without the presence of symptoms of EoE does not necessarily lead to its diagnosis. All patients



with esophageal eosinophilia should be evaluated for other causes of esophageal eosinophilic. These conditions include gastroesophageal reflux and Crohn's disease as well as other diseases.

EoE management includes both medical and dietary therapies. PPI and swallowed steroids (budesonide and fluticasone) are the cornerstone of the medical treatment. Swallowed fluticasone has demonstrated to improve symptoms and histology with uncommon and often mild side effects (candida overgrowth). Biological therapy demonstrated some histological benefit, especially those that targeted the Th2 axis.

Dietary therapy should be considered and discussed in all patients with a diagnosis of EoE. Consultation with a dietician is highly recommended. Therapy options may include a total elimination diet (amino acid-based formula), selective elimination diet (eliminating major food allergens), and directed diet (eliminating foods based on allergy skin testing). The use of dietary therapy may lead to complete or near-complete resolution of both clinical and histological abnormalities. A response to any treatment supports but is not required for diagnosis.

EoE is a complex disorder with a non-specific presentation and affects a wide range of ages. Investigation and treatment require a multidisciplinary approach, with a pivotal role from a dietician, gastroenterologist, and allergist. Otolaryngologists should consider EoE whenever a patient presents refractory aerodigestive symptoms unresponsive to conventional treatment. ■

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

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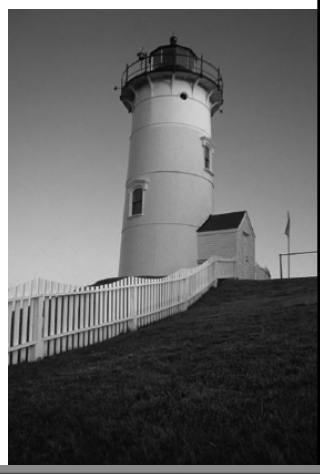

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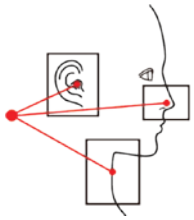

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