

# Soundings

PUBLISHED IN THE INTEREST OF OUR MEMBERS AND THEIR PATIENTS



## President's Message

Jeffrey P. Simons, MD, FACS, FAAP



It is hard to believe that my two years serving as President of the Pennsylvania Academy of Otolaryngology-Head and Neck Surgery (PAO-HNS) are coming to an end. As an organization, we have accomplished a great deal in the past two years. I would like to summarize some of our accomplishments and current activities in my last message as President.

Early on as President of the PAO-HNS, I stated that one of my goals would be to collaborate more closely with the Pennsylvania Medical Society (PAMED) to identify areas of common interest for the members of the two groups and to help address practice management and political issues relevant to all otolaryngologists in the state. We have certainly achieved a great deal in this realm. I have met with the past and current Executive Vice Presidents of PAMED (Michael Fraser and Martin Raniowski) to work on this goal. One example of an initiative that developed from these meetings is that the leadership of PAMED agreed to offer joint membership to the PAO-HNS and PAMED for all interested resident members free of charge during the time they are residents, which provides a great way for otolaryngology residents to get

involved with organized medicine at the state level.

I have also regularly attended meetings of PAMED's Specialty Leadership Cabinet (SLC), which provides an opportunity for the leadership of all of the medical specialty societies in the state to get together to share ideas and work on issues of shared interest. There are many ways in which state specialty societies can potentially collaborate. For instance, the PAO-HNS recently worked with the Pennsylvania Allergy and Asthma Association and the Pennsylvania Academy of Dermatology on an issue involving regulation of compounding pharmacies. The State Board of Pharmacy has developed stricter rules for sterile compounding of medications. There was concern raised by several specialty societies that this issue would also apply to compounding of medications (such as allergy immunotherapy) in physicians' offices. The PAO-HNS, in addition to these other societies, communicated with the State Board of Pharmacy and the Independent Regulatory Review Commission to convey our stance on this issue. Our letter to these organizations is included in this issue of *Soundings*. It will certainly be important for the PAO-HNS to remain active in the SLC in the future.

Another aim of my time as PAO-HNS President has been to enhance our relationship with AAO-HNS, and we have certainly been successful. We have had a number of productive conference calls and meetings with the leadership of the AAO-HNS and its Board of Governors (BOG) over the past few years. We have had excellent representation in the BOG, led by Dr. Karen A. Rizzo, the PAO-HNS Governor to the BOG. We are thrilled that the Executive Vice President of the AAO-HNS, Dr. James C. Denny, will be attending the PAO-HNS 2017 Annual Meeting as a guest speaker in order to continue to foster the relationship between our two societies.

The PAO-HNS has also been instrumental in bringing the leaders of many state otolaryngology societies together. Last fall, our Executive Director Jennifer Keeler, Dr. Robert T. Sataloff, and I approached the AAO-HNS leadership with the idea of having the AAO-HNS host a meeting of the leaders and administrators of all state societies. We were delighted that the AAO-HNS and the BOG were enthusiastic and supportive of this endeavor. This past March, as part of the AAO-HNS Leadership Forum and Spring Meeting, the AAO-HNS and the BOG sponsored the inaugural State Otolaryngology Society Roundtable meeting, which was co-led by Dr. Spencer C. Payne, Chair of the BOG Governance & Society Engagement Committee, and myself. The meeting was quite successful, with the leaders of twenty-two state societies attending. It was a nice opportunity to learn about the structure and operations of many state otolaryngology societies, share common ideas and challenges, and discuss potential ways to collaborate with each other and with the AAO-HNS. The AAO-HNS and the BOG have assured us that this meeting of state society leadership will continue on an annual basis. It remains clear that the PAO-HNS has continued to be a "model" state society which many others are trying to emulate.

Over the past few years, we have continued to work on updating and expanding the PAO-HNS website. Last year we launched a "Find an Otolaryngologist" function for patients. We also have added a "Job Board" on the website for otolaryngology practices in the state to advertise job openings for physicians. The website also includes other important information for members, including a list of officers, council members, society staff, and member benefits. We also recently added a list of all past presidents on the website, going back to 1943, which

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is very interesting from an historical perspective. The state otolaryngology and ophthalmology societies were combined as the Pennsylvania Academy of Otolaryngology and Ophthalmology from 1943 until 1990. In addition, we are working to enhance the patient information section of the website. I would like to thank Dr. Michael Ondik, chair of the Website Committee, for his service to help us improve our site.

This edition of *Soundings* represents the first edition of our redesigned newsletter. The new version is more colorful and attractive. In addition to email and our website, *Soundings* has remained a very effective way for the PAO-HNS to communicate with our membership. It has a nice combination of policy and society updates as well as scientific articles that would be of interest to our members. We have opportunities for advertising both in our newsletter and on our website.

The PAO-HNS is fortunate to work with an excellent government relations firm, Milliron and Goodman, LLC, who have helped support us in Harrisburg for decades. Some of our legislative priorities include preventing taxes on medical procedures, truth in advertising for doctors, tobacco and E-cigarette use, smoking cessation, medical liability reform, and noise exposure for children. I strongly believe that the most important function of our lobbying firm is to help increase awareness of our specialty to state senators and representatives. As otolaryngologists, we can all help with this task by working together, identifying important legislative and advocacy issues, and talking with state legislators and community groups. In fact, over the next few months, the PAO-HNS will be starting a new grassroots educational campaign. We will be encouraging our members to set up meetings with their own state senators and representatives to discuss our specialty and issues that are particularly important to us as otolaryngologists. You will be hearing more about this grassroots initiative in the upcoming months.

Our next Annual Scientific Meeting will be held at the Hotel Hershey in Hershey, PA on June 16-17, 2017. Our program coordinator, Dr. David Cognetti, and the planning committee have developed an outstanding program that includes sessions on "Exploring New Frontiers in

Otolaryngology," "New Perspectives on Common Diagnoses," and "Business/ Practice Management." The meeting will also include resident research presentations (both podium and poster) and the very popular resident bowl competition (the "Conchal Bowl"). The topics will be of interest to all practicing otolaryngologists, as well as to residents, fellows, medical students, and advanced practice professionals. There are many outstanding speakers lined up for this meeting. Most importantly, it will be a great opportunity to learn, network, and socialize. I hope to see you all in Hershey this June.

Finally, I feel that it is important to thank our staff for all they do to help the PAO-HNS remain a successful organization. I am grateful to Jennifer Keeler, our Executive Director, Kim Whetsell, our Assistant Executive Director, Melanie Dupont, our Member Service Specialist, and Jessica Winger, our Meeting Manager. The dedication and support of these individuals has certainly made my job easier and more enjoyable over the past two years. In just a short time, Dr. Ahmed M.S. Soliman will be succeeding me as President. Ahmed has been intimately involved with our organization for many years. As President-Elect over the past two years he has helped me immensely. He has had many great ideas for our organization and has truly been a pleasure to work with. I assure you all that the PAO-HNS will be in excellent hands and clearly has a bright future.

The PAO-HNS has continued to strive to support all otolaryngologists in the state by addressing educational, legislative, advocacy, and practice management issues. I encourage you all to get involved with our vibrant state society. There are many ways to contribute, from serving on a committee, to coming to our annual meeting, to educating state legislators in your area on issues important to otolaryngologists and our patients, to informing other otolaryngologists about the value of joining the PAO-HNS. If you have an interest in playing a more active role, please do not hesitate to contact me or the PAO-HNS staff.

We are all very fortunate to have such an active, engaged state otolaryngology society. It has been an honor to serve as your President. ■

Sincerely,  
Jeffrey P. Simons, MD, FACS, FAAP

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# Minimally Invasive Techniques to Treat Submental Fat

Michael Ondik, MD, Montgomery County ENT Institute

Submental fat is a very common aesthetic concern for patients. Anatomically, submental fat is located in two spaces; the pre-platysmal and the sub-platysmal space. Treating the deeper sub-platysmal fat generally requires an open approach that would be part of a platysmaplasty and lower face lift. Pre-platysmal fat, on the other hand, can be treated with many different minimally invasive techniques which are the focus of this review. [1]

Traditionally, tumescent liposuction has been used to remove pre-platysmal submental fat. Using a liposuction cannula, the fat is removed via one or more stab incisions. More recently, laser cannulas have also been employed using Nd:YAG wavelengths to induce thermally mediated adipolysis. The laser helps with coagulation and additionally induces skin tightening.

Radiofrequency (RF) technology can also be combined with liposuction. In this technique, RF energy travels from an electrode placed subdermally to an overlying external electrode. The subdermal electrode is also part of a suction cannula which removes the coagulated tissue. The heat generated also promises tightening of the overlying skin envelope.

One disadvantage with the above techniques is that they require skin incisions and are subject to swelling and bruising. Alternatively, there are devices which are completely non-invasive, though many require multiple treatment sessions. These include devices such as RF-assisted probes that

are passed over the skin, preferentially heating and destroying the pre-platysmal fat. The fat cells that are destroyed are removed by the body naturally. A similar technology uses cryolipolysis, a technique that targets fat cells due to the theory that they are more susceptible to cold-induced injury than surrounding cells.

There are other energy-based treatments that can be used in the submental area that focus solely on skin tightening. While these techniques may help decrease the appearance of submental fullness via their skin tightening benefit, they do not destroy or remove fat.

Finally, in the last couple of years, deoxycholic acid (Kybella, Allergan) was approved for use of treating submental fat deposits. Endogenous deoxycholic acid is a secondary bile acid which helps break down dietary fat. Kybella is a nonanimal, nonhuman formulation of deoxycholic acid that causes adipocyte lysis. It works by lysing adipocytes directly adjacent to the areas of the injections. The lysis is followed by neutrophilic inflammation and then macrophage phagocytosis. [2]

Like other minimally invasive techniques Kybella is used over multiple treatment sessions. The product is injected at multiple locations about 1 cm apart in the submental area. Studies have shown that the effect lasts for up to four years and possibly more (long-term studies are being conducted). [2]

Patients receiving the active drug had the following side effects: edema/swelling (87%), hematoma/



bruising (72%), pain (70%), numbness (66%), erythema (27%), induration (23%), and temporary marginal mandibular nerve dysfunction resulting in an asymmetric smile (4%). Paresis resolved within 4 days. [3]

Some patients also reported temporary dysphagia as well in addition to other less common adverse effects. While Kybella is indicated only for pre-platysmal submental fat and is not indicated for sub-platysmal fat or any other treatment areas, investigators are already studying the product for off-label uses. [4]

In summary, there are a host of minimally invasive technologies and treatments for submental fat. Each technique has its advantages and disadvantages which should be carefully considered when treating patients.

Disclosure: the author has no financial interest in any of the products reviewed.

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**In summary, there are a host of minimally invasive technologies and treatments for submental fat. Each technique has its advantages and disadvantages which should be carefully considered when treating patients.**

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# PAO-HNS Submits Comment on Proposed Regulations on Compounding

The PAO-HNS submitted comment on draft regulation that would impact compounding pharmacies. Please see below for the letter submitted on behalf of the organization. ■



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April 10, 2017

Kerry Maloney, Board Counsel  
State Board of Pharmacy  
RA-STRegulatoryCounsel@pa.gov

Re: State Board of Pharmacy  
Proposed Regulations: Compounding  
IRRC #3163

Dear Mr. Maloney:

As representatives of Pennsylvania Academy of Otolaryngology – Head and Neck Surgery (PAO-HNS), we are writing to share the concerns of our members regarding Regulation #16A-5419: Compounding, which could impact the potentially lifesaving care otolaryngologists provide to their patients.

The PAO-HNS represents 300 otolaryngologists in Pennsylvania, many of whom practice otolaryngic allergy.

We respectfully ask the board to clarify that the new regulations are designed for compounding commercial pharmacists and does not include physician offices.

We recognize that the proposed regulations are warranted for compounding pharmacies mass producing therapeutic compounds, especially after the 2012 incident where steroid injections were manufactured under unsafe conditions by a compounding pharmacy in Framingham, Massachusetts and caused many fatalities and illnesses. However, if compounding that occurs in physician offices must conform to these regulations, there may be an unintended and overreaching effect on clinical practitioners who engage in allergy immunotherapy.

If physicians who engage in practice of allergy/immunology must follow same criteria as commercial compounding pharmacies that manufacture products, many of them will have to stop providing allergen immunotherapy to the patients who are currently on active treatment plans. These practices would have to invest thousands of dollars in order to meet commercial pharmacy compounding standards and to do so would disrupt patient care. Disruption of immunologic treatment can have a devastating rebound effect on allergy and asthma patients and can significantly increase the cost of treatment.

We would like to point out the following reasons why such stringent regulations are unnecessary and impractical in case of allergy immunotherapy:

1. Allergy serum preparation involves making individualized mixtures for specific patients. It is not a massive compounding process. The process of making serum for allergies does not alter the nature of a given compound nor does it produce a totally new compound. It is simply a dilution process, much like the dilution of medications that nurses perform at the patient's bedside for injections.

**Mr. Kerry Maloney**

**April 4, 2017**

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2. Allergens used in an injection mixture are typically standardized allergens. Manufacturers follow FDA guidelines for standardization. This eliminates discrepancies in dosing outcomes after dilution.
3. The solution media where these antigens are stores typically contain Phenol (0.4%) which is a bacteriostatic agent. In fact, the allergy industry has been able to get longer shelf life approval for antigens because of presence of phenol as opposed to other preparations that expire every 28 days according to the United States Pharmacopeia (USP).
4. Skin allergy testing panels are also made and refreshed in the office. This often requires on-the-spot modification of mixture and dose selection appropriate for patient needs. This flexibility of individualized care would be compromised if the ability to mix and prepare solutions was taken away from facilities that provide these tests.
5. Allergy testing and immunotherapy has been around for 100 years. It is a well-established and safe practice that has not been associated with infectious side effects. This immunomodulation is one of the most effective remedies for patients with severe allergies and asthma. It is particularly effective when mixtures are individualized for each patient. The sterile techniques followed by health care personnel are the same as what is required of them in every facet of health care. In fact, to the best of our knowledge, infectious dissemination has not been an issue in decades.

In addition to immunotherapy, otolaryngology offices may encounter on a given day acute scenarios where mixing solutions and injections are required. For instance, injections to the middle ear, temporomandibular joint space, or intramuscular trigger points may be required to alleviate incapacitating symptoms such as dizziness, tinnitus, and pain. Analgesics, steroids, and antibiotics such as gentamicin are typical injections that may be mixed or diluted prior to injection.

Otolaryngology is not the only specialty potentially impacted if these regulations include practitioners' offices, but we are sharing these specific examples to highlight the potential threat to patient safety, access to care, and physicians' ability to deliver the life improving services that we all are committed to provide.

Thank you for the opportunity to comment on this very important issue. If you have any questions, please contact our executive offices at [otopa@pamedsoc.org](mailto:otopa@pamedsoc.org) or call (717) 558-7750 ext. 1519.

Sincerely,



Jeffrey Simons, MD, FACS  
President



Mahmoud Max Ghaderi, DO, FAOCO  
Chair, Allergy Committee

cc: Independent Regulatory Review Commission  
via email, [irrc@irrc.state.pa.us](mailto:irrc@irrc.state.pa.us)

# Update on Recurrent Respiratory Papillomatosis

Nicole Aaronson, MD and Jeffrey P. Simons, MD, Children's Hospital of Pittsburgh of UPMC, University of Pittsburgh School of Medicine



Recurrent respiratory papillomatosis (RRP) is the most common benign lesion of the larynx in children and is the second most common cause of chronic pediatric hoarseness. [1] As many as 1,000 new cases of RRP are diagnosed annually, and its overall prevalence is estimated at 0.75 to 4 cases per 100,000.

Recurrent respiratory papillomatosis (RRP) is the most common benign lesion of the larynx in children and is the second most common cause of chronic pediatric hoarseness. [1] As many as 1,000 new cases of RRP are diagnosed annually, and its overall prevalence is estimated at 0.75 to 4 cases per 100,000. Each patient requires an average of 4.4 surgeries per year with 19.7 surgeries per patient overall. [2] Despite this disease burden, many pediatricians have had only limited training on RRP, its etiology, treatment, and prevention. [3] This awareness deficit often results in delayed diagnosis with a majority of RRP patient failing to receive a definitive diagnosis until approximately one year after symptom onset. [4]

Human Papilloma Virus (HPV) subtypes 6 and 11 have been identified as the causative agent for RRP. Viral infection results in an exuberant proliferation of squamous epithelium particularly at epithelial junctions. [5] There are 3 peaks of disease onset, 2 during adulthood and one during childhood at age 7. [6] Disease transmission to children can occur during birth when an active condyloma is present, in utero due to exposure to HPV-infected amniotic fluid, or as a result of child abuse. [7]

RRP usually presents as hoarseness, although inspiratory followed by biphasic stridor often occurs as the disease progresses. The disease course can be quite variable. Some patients achieve spontaneous remission, while

others require multiple procedures in order to maintain airway patency. The Derkay grading system has been used to assess disease severity and predict the likely inter-surgery interval. In this grading system, each anatomic subunit is assigned a score of 0 to 3 points based on presence of no lesions, surface lesions, raised lesions, or bulky lesions. Anatomic subunits include: the lingual and laryngeal surfaces of the epiglottis, each arytenoid, each aryepiglottic fold, each true vocal cord, each false vocal cord, the anterior commissure, the posterior commissure, the subglottis, the upper, middle, and lower thirds of the trachea, the right and left mainstem bronchi, the tracheostomy stoma, the nose, the pharynx, the palate, the esophagus, and any other site on which lesions are identified. A patient with overall score of more than 20 will likely need surgery 120 days sooner than a patient with a score less than 20. [8]

Quality of life for RRP patients, especially those infected with HPV subtype 11, is relatively poor compared with their healthy peers as perceived by patients and their parents, with less participation in social interactions. [9] Extra-laryngeal spread, which occurs in 30% of children, most commonly to the trachea or bronchi, portends a poorer prognosis. HPV-11 infection tends to result in a more aggressive disease course than HPV-6 infection with higher rates of pulmonary spread and more frequent need for

tracheotomy. [10] While malignant degeneration is rare, it has been shown to occur in up to 5% of cases, most often in patients with pulmonary involvement and with younger age at onset of disease. [11]

Treatment for RRP has been frustrating for many otolaryngologists. There is currently no cure. Surgery remains the first-line therapy, but rather than complete excision, debridement of as much papilloma tissue as possible without damaging underlying structures is the goal. The carbon dioxide laser had been the previous gold standard, but has been largely supplanted by the microdebrider in recent years due to concerns of viral transmission via smoke inhalation and fire risk. Interferon, which had once been the predominant adjuvant antiviral therapy, is now used in less than 4% of pediatric patients due to concerns over side effects and poor long-term remission rates. [12] Despite attempts at disease control rather than eradication, laryngeal sequelae still occur in almost half of RRP patients. The most frequent complications are anterior commissure synechiae followed by glottic stenosis. Patients with an advanced Derkay score are more likely to experience these complications. [13]

Due to these complications and need for repeat therapy, therapies that can produce long-lasting remission are under investigation and have been employed. Although off-label and

requiring informed consent, cidofovir injection at the time of papilloma excision has become relatively common in patients who require repeat surgical debridements at least every 2 to 3 months. Dosing is kept below 3 mg/kg in order to help minimize the risk of acute kidney injury. [14] In one study, 30% of RRP patient treated with cidofovir demonstrated complete disease remission, while an additional 65% showed significant disease regression with minimal residual disease. [15]

Bevacizumab, an anti-angiogenesis monoclonal antibody, has also been under investigation as an adjuvant treatment for RRP. Repeat bevacizumab injections have been shown to increase the inter-surgery interval as well as the Derkay score. [16] The 532-nm KTP laser has been utilized to treat RRP due to its ability to target the blood supply of the papilloma. Recent studies have attempted combined use of the KTP laser and bevacizumab in order to prevent disease recurrence through synergistic anti-angiogenic effects. [17]

Photodynamic therapy (PDT) with meso-tetra (hydroxyphenyl) chlorin (m-THPC) photosensitizer had also shown significant regression of papilloma, but further follow-up revealed that remission was not sustained over time. [18] Similarly, indole-3-carbinol, a mediator of estrogen metabolism, has been shown to induce remission in up to one-third of RRP patients, although remission was sustained in less than half of these patients when they stopped therapy. [19]

Laryngeal papillomas have been shown to overexpress both epidermal growth factor receptor (EGFR) and cyclooxygenase-2 (COX-2). As result, EGFR inhibitors and celecoxib, a COX-2 inhibitor, have both been trialed as adjuvant therapies. Each of these therapies has demonstrated some benefit among a portion of patients with RRP, but more investigation and evidence is required before these medications can be recommended to be used in a widespread fashion. [20,21]

MMR (Measles, Mumps, and Rubella) and HPV vaccination of patients with active RRP have been postulated to slow the course of the disease progression. While early data suggested that the MMR vaccine was beneficial, this data has not been able to be successfully reproduced. [22] The HPV vaccine has been shown to be effective in several case reports, which describe a longer inter-surgery interval for individual patients following vaccination. [23,24]

**While the development of new treatments to promote remission, and ideally cure, of RRP are important, widespread HPV vaccination will be the key to preventing this disease.**

However, one 9-patient study evaluating the HPV vaccine in patients with active RRP showed no significant improvement in inter-surgery interval, inter-relapse interval, or number of surgeries when comparing the years prior to and following HPV vaccination. [25]

While the development of new treatments to promote remission, and ideally cure, of RRP are important, widespread HPV vaccination will be the key to preventing this disease. As HPV vaccination becomes more standard, the HPV burden within the population at large, and most importantly women of child-bearing age, will decrease which in turn will decrease the rates of childhood RRP infection. Because pediatricians play a crucial role in encourage childhood vaccinations, it is important that they are well-informed about the role of HPV vaccination in preventing RRP.

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# The Ovine Model for Surgical Simulation

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Simulation has gained wide acceptance in medical student and resident education – providing trainees with first-hand exposure to emergency situations and complex procedures while minimizing risk to patients. This is particularly true for surgical training, where simulation allows trainees to acquire mechanical skills and teachers to document technical competence in a standardized fashion. [1] The Accreditation Council for Graduate Medical Education (ACGME) otolaryngology residency program requirements mandate that residents “must demonstrate knowledge of anatomy through procedural skills demonstrated in cadaver dissection, temporal bone lab, and/or simulation labs.”. [1,2]

A wide variety of models for head and neck surgical training have been proposed, ranging from virtual reality to live animals. [3] None is ideal. Fresh human cadavers offer the most obvious surrogate for living patients. Unfortunately, the 2007 United States Safe Tissue Act has markedly limited access to human tissues. [4] Further, human tissues are expensive and pose the greatest risk of disease transmission of any proposed teaching model. [5] Animal rights concerns, anesthesia and facility expenses limit the usefulness of live animals in surgical education. [6]

Tissues from non-living laboratory or farm-raised animals thus have gained popularity. Porcine and avian models for soft tissue surgery as well as goat, sheep and dog models for airway reconstruction have been explored with mixed results. [7–10] Endoscopy using excised, mounted larynges is useful for surgical manipulation, but this model does not contain the structure needed to learn suspension laryngoscopy and intubation skills. [11–18] Our group has explored the use of a fresh, saline-perfused sheep head and neck model for surgical simulation. We believe the ovine model provides a versatile, flexible and inexpensive teaching tool for simulation of a wide range of Otolaryngology-Head and Neck surgeries.

Cervical and facial dissections are easily performed on an operating table with the ovine head and neck stabilized with sand bags and/or adhesive tape. Dissection may be conducted with the naked eye, loupe magnification or operating microscope using conventional operating room cold-steel

instruments. Blepharoplasty, parotidectomy, tracheotomy, medialization laryngoplasty, laryngofissure, anterior cartilage grafting, and tracheal resection can be easily performed.

For endoscopic procedures, the ovine head and neck preparation is supported in the supine position with adhesive tape passed around the operating table to provide counter-traction. Adult laryngoscopes are readily inserted and suspended. This is in contrast to porcine and canine live models which have jagged teeth and deep larynges that make suspension laryngoscopy difficult. [19,20] Rigid rod telescopes can be used to examine the larynx and trachea in detail. Standard microlaryngeal instruments can be used to for a variety of endolaryngeal procedures including vocal fold injection, vocal fold biopsy, and microflap elevation. Flexible nasopharyngolaryngoscopy and transnasal fiberoptic intubation are also possible. The smooth mucous membranes of the fresh sheep with associated mucoid secretions closely resemble the conditions found in human endoscopy. They cause fogging and white-out phenomena not found in current computerized simulators.

An ideal model for surgical simulation in Otolaryngology - Head Neck Surgery should: 1) be readily available to most training programs; 2) be inexpensive; 3) have a low risk of disease transmission; 4) avoid undue ethical concerns; 5) accurately reflect normal human anatomy; and 6) be useful for the full range of head neck surgical procedures. While no single model is ideal, the ovine head and neck preparation satisfies many of these requirements.

Handling of fresh ovine tissue requires an understanding of zoonotic disease. Although sheep rarely transmit infections to humans, the main concern with using mature farm animals is Query Fever (Q fever), a treatable but potentially dangerous disease. [26] Acute symptoms include fever, headaches, myalgia, cough, gastrointestinal distress, and chest pain. The causative bacteria, *Coxiella burnetii* reside primarily in the amniotic fluid and placental tissue of pregnant sheep. Human contamination with this may occur from aerosolized dried amniotic and placental material found in barnyard dust. [22] Selection of tissues from male or prepubescent female sheep reduces the risk for *Coxiella burnetii* exposure and should be considered if a program chooses to use farm-raised animals. [23] Use of personal protective equipment and Q fever testing of all trainees before starting and annually is recommended.

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## Leadership Forum Update

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The AAO/HNS recently held its Annual Leadership Forum and BOG Spring Meeting in Alexandria, Virginia from March 10th to the 13th. Its purpose was to share leadership and practice tools for physicians caring for otolaryngology patients. Physician attendees learned about cultural competence, the diverse workplace, and emotional intelligence, and how these affect their practice through interactive sessions led by their peers and subject matter experts. There was an inaugural State Otolaryngology Society Roundtable discussion on March 10th, where leadership from several state societies discussed their concerns regarding how information was shared and ways communication abilities could be enhanced. Dr. Jeffrey Simons and Dr. Robert Sataloff led this discussion. This roundtable discussion received significant positive feedback from state OTO societies and leadership encouraged making this roundtable dialogue an annual event.

Outcome objectives from the weekend meetings included recognizing the value of diverse workplaces and the challenges faced by minorities in academics. It also included providing culturally competent health care in practices, practicing emotional intelligence or EQ as an important skill for managing people in the workplace, and maintaining well-being and potentially improving patient outcomes. The use of the Reg-ent data Registry to receive credit for MIPS was also discussed.

Several political and practice advocacy issues were discussed as well including the Academy's support of establishing a category of basic hearing aids available over-the-counter for individuals with mild to moderate hearing loss. Criteria for a consumer's purchase of an over-the-counter hearing aid should include a medical evaluation by a physician to rule out a medically



treatable cause of hearing loss, a standardized hearing test via a hearing health professional or appropriate online technological source to confirm the hearing loss, and continuing current FDA hearing aid packaging requirements and consumer protections. Repeal of the independent payment advisory board was encouraged by the AAO. Re-authorization of the early hearing protection and intervention program was encouraged for an additional five years. And to ensure patient's safety is preserved, the AAO opposes legislation that would provide audiologists with unlimited direct access to Medicare patients without a physician referral and/or inappropriately include audiologists in the Medicare definition of physician. The AAO continues to encourage evaluation of the affordable care act to ensure sustainability of an efficient and affordable health care delivery system in the United States. It supports the reintroduction and advancement of Truth in Advertising legislation. It also opposes any legislation that would exempt cigars from regulation under the Tobacco Control Act.

# An Update in Human Papilloma Virus Related Head and Neck Cancer: Understanding Current Guidelines

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Human Papilloma Virus (HPV) has resulted in an increase in the incidence of oropharyngeal squamous cell carcinoma (SCC), resulting in a subpopulation of patients that are generally younger with improved prognosis compared with those with HPV-negative tumors traditionally associated with heavy tobacco and alcohol use. As an increasing number of patients are diagnosed with HPV-related head and neck cancers, physicians are finding themselves navigating sensitive, potentially challenging topics, while dealing with a disease process that remains somewhat elusive. No guidelines are currently available to assist with addressing this relatively new disease process. However, general principles applied to patient education and management of HPV related cervical cancer may be applied toward HPV positive head and neck cancer. Although public knowledge regarding HPV is improving, mainly as a result of cervical HPV screening and the availability of HPV vaccines, general knowledge continues to be limited in comparison to other sexually transmitted infections. It is important to approach this potentially sensitive topic with evidence based guidance. In this article, we will review the current literature in hopes of helping navigate questions both providers and patients may have regarding HPV infection and HPV-related oropharyngeal SCC. We would also refer interested clinicians to the recently published AHSNS Practice Guidelines on the management of the Human Papilloma Virus. [1]

## Pathogenesis and Epidemiology

HPV is a double-stranded DNA virus with over 150 serotypes, which can be subdivided into high and low risk. HPV-6 and HPV-11 are the lower risk subtypes associated with benign disease, such as anogenital warts or respiratory papillomatosis. On the other hand, serotypes HPV-16 and HPV-18 are associated with cervical, anogenital, and oropharyngeal cancer. Viral oncogenesis is mediated via HPV viral proteins E6 and E7, which disrupt the cell's regulatory cycle. The E6 protein binds

and degrades p53, a tumor suppressor gene product, allowing for cell cycle escape. E7 inhibits retinoblastoma (Rb) protein another tumor suppressor protein. [2,3] HPV is the most common STI in the US and the majority of sexually active individuals are estimated to have had at least one HPV infection during their lifetime. [4] Oral HPV infection is acquired via orogenital or oral-oral contact with an infected partner. Oral HPV infection has been shown to have a bimodal age distribution with peak prevalence at ages 30-34 and 60-64. The prevalence of oral HPV has been shown to be 2-3 times higher in men than women, with an overall prevalence of 10% in males and 3.6% females. [5] This discrepancy is thought to be secondary to higher transmissibility in orogenital contact with women or differences in immunity between sexes. [6,7] HPV infection is commonly asymptomatic and, in most cases, clears within 1 year without intervention. [8,9]

## HPV-related Oropharyngeal Squamous Cell Carcinoma

Although oral cavity and laryngeal squamous cell carcinomas (SCC) have been declining with decreased use of tobacco products, oropharyngeal carcinoma incidence has increased within the last 20 years. [10] This surge has been largely attributed to an increase in HPV-related disease, while evidence shows that HPV-negative disease has been declining. [11] Currently, 70-90% of newly diagnosed oropharyngeal SCC in the US are estimated to be HPV-positive. [12] Persistent oral HPV infection is postulated to be a precursor of HPV-positive oropharyngeal cancer. However, the progression from infection to carcinoma is a continuing area of investigation. [13] Some studies have shown the latency period between initial onset of infection and development of carcinoma may be 10-30 years. [14] However patients with HPV-positive SCC often present with cystic nodal disease, given the asymptomatic nature of the primary infection. [15] HPV-associated SCC can present as a small primary tumor, undetectable on physical examination, with associated large

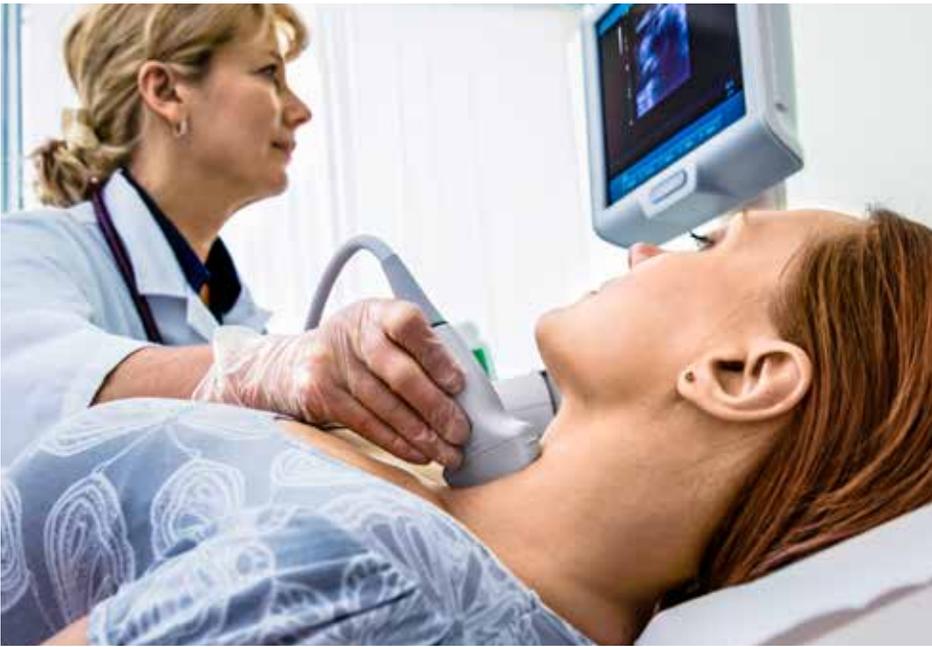
nodal metastases resulting in an overall late stage at diagnosis. Despite its late stage, HPV-related SCC often carries a better prognosis with respect to survival and recurrence rates when compared to that of HPV-negative disease. [16-18] Improved outcomes may be due to fewer genetic mutations and an improved response to chemoradiation. [19-23] This improved prognosis has been noted even in the setting of disease progression. [24-25] The discordance between staging and prognosis, has resulted in a change in AJCC guidelines in the upcoming 8th edition. [26]

## Testing and Surveillance

Due to the increased rate of HPV-related cancer there is a mounting level of evidence supporting routine HPV testing in oropharyngeal SCC, especially given the high prevalence of HPV positivity in newly diagnosed oropharyngeal cancers. [12,27] Therefore, routine testing of HPV biomarker should be done in all oropharyngeal tumors, particularly given the fact that testing holds significant prognostic value. However, the prognostic value of HPV testing in other subsites remains unclear. There remains a high degree of variability with respect to the rate of HPV-related disease in non-oropharyngeal subsites. [28,29] The majority of the literature indicates a low fraction of HPV positive non-oropharyngeal malignancies. [30-32]

Unknown primary HNSCC are however an exception; as the rate of HPV positivity in this disease entity has been previously documented to range from 20-90%. Recent studies have shown >90% of tested unknown primaries may be HPV positive. [33] These studies have also indicated that the overall frequency of unknown primaries have increased within the last decade, paralleling the rise in HPV related disease as seen in the oropharynx. [34] In such cases, further biopsies of suspicious lesions or resection of oral cavity subsites may be prudent to identify a primary tumor. Alternatively, if chemoradiation therapy is pursued, it may be directed to the oropharynx as well.

Tumors should be tested using HPV



in-situ hybridization (ISH) and/or p16 immunohistochemistry (IHC). [35] IHC staining for p16 is an accurate surrogate marker for HPV positive disease in the oropharynx although it is not specific for HPV in other tumor sites. The p16 protein has been shown to be significantly upregulated in HPV positive tumors of the oropharynx, likely due to inhibition of Rb by viral proteins leading to increased production of p16. [36] However, p16 overexpression is seen in other malignancies involving the salivary glands, skin, breast, or gastrointestinal tract and should be interpreted with caution. Therefore, in some cases, both HPV ISH and p16 IHC may be useful in confirming HPV positive cancer.

There are currently no screening tests to detect active viral oral HPV infection. The clinical significance of persistent oral HPV infection is unclear as well, as most infections clear spontaneously. There have been promising clinical investigations in the use of oral rinses or swab tests for detection. [37-38] The influence of HPV tumor status on timing and behavior of recurrent disease continues to be an area of active research without clear consensus. Lastly, the utilization of HPV DNA detection may play a future role as a surveillance biomarker considering that HPV DNA in both plasma and oral rinses has been associated with increased risk of recurrence and decreased survival. [39-40]

### Patient Education

Patients newly diagnosed with oropharyngeal SCC will ask difficult questions of their providers, especially

in the setting of HPV positivity. It is the clinicians' role to help patients navigate these issues without judgement, and more and more this the role of the otolaryngology-head and neck surgeon. Feelings of self-blame may be encountered and patients may have questions regarding the implications their diagnosis has on current or future personal relationships. Learning that HPV is a sexually transmitted infection may cause patients to feel as if their cancer may be a direct result of their sexual behavior. They should be reassured that HPV is the most common sexually transmitted infection and therefore not reflective of sexual promiscuity, or infidelity on the part of their significant others. It is important to discuss that HPV is considered a marker of sexual activity, and most individuals are exposed to HPV during their lifetime, with the majority clearing the infection within 1 year. There is no treatment for an active HPV infection, though treatment of the cancer will likely clear the HPV infection as well. Orogenital contact with only a single sexual partner is required for transmission of the virus.

It is important to also stress the latency period from onset of infection to malignant transformation, as noted, to be up to 30 years. [14] Patients may further ask themselves why their infection persisted instead of clearing spontaneously. Risk factors contributing to persistent infection, and preventive measures aimed at decreasing persistence, are still under investigation, though there is an association with older age and active smoking. [41] Therefore smoking cessation likely plays a role

in decreasing risk of persistent disease thereby potentially decreasing risk of carcinoma. The majority of the studies regarding the efficacy of the HPV vaccine have thus far evaluated its effect in cervical infection and cancer. However, these vaccines must be administered prior to exposure to the disease in order to prevent infection as they not been shown to eradicate active infection. [42] Vaccines are currently recommended by the CDC for boys and girls between the ages of 9 to 12 years old and also prior to sexual activity up to 26 years of age.

Patients may be concerned of the effect their diagnosis may have on their level of intimacy with their partners. Casual contact (sharing drinks, kissing) does not cause disease transmission. Prior studies have not demonstrated individuals with partners having HPV related disease to have increased rates of persistent oral HPV infection. [43] They may however, based on their exposure, still be at an increased risk of HPV related cancers. Patients should also be counseled about barrier contraception, which may help prevent the transmission of the virus. Studies have shown that the majority of patients discuss their diagnosis with their partners while only a minority (20%) report this having a negative influence on their relationship. [44,45] Although Otolaryngologists may not often extensively discuss psychosocial concerns with their patients, it is important to educate patients so that they may properly cope with and understand their diagnosis.

### Conclusion

Addressing HPV related cancer with patients is challenging given the continually evolving nature of our understanding of the disease process and its clinical significance. Although improved prognosis of HPV-positive tumors may offer reassurance to both patients and clinicians, patients with HPV related SCC may still have aggressive disease and are at risk of recurrence. Prognostic indicators that may be utilized to identify patients at risk of recurrence are still under investigation. Therefore, patients with HPV related SCC should still receive standard of care treatment for oropharyngeal SCC. Clinical trials are underway to evaluate and address the efficacy of decreased treatment regimens in HPV positive disease. Further studies are still needed to better understand the implications of HPV positivity in head and neck cancer in order to develop guidelines for prevention, tailored treatment, and surveillance of oropharyngeal carcinoma.

*continued on page 12*

# An Update in Human Papilloma Virus Related Head and Neck Cancer: Understanding Current Guidelines *continued from page 11*

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# Advances in Otology: 2016 Year in Review

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While there were numerous notable advancements in otology documented in the literature during the past year, advancements in two areas of the field are particularly notable – endoscopic ear surgery and cochlear implantation. First, the application of the endoscope to ear surgery, which has been gaining traction over the past several years, continues to show promise. Compared to microscopic ear surgery, endoscopic ear surgery has the advantage of advancing the point of visualization down the ear canal thus bypassing obstructions, such as the anterior canal wall overhang. Anterior perforations, while traditionally addressed with lateral graft tympanoplasty techniques that commonly require canalplasty when using the microscope for visualization, have been shown to be well suited to repair using an endoscopic myringoplasty technique (93% perforation closure rate). [1] Furthermore, using the endoscope to guide removal of cholesteatoma in pediatric patients has been shown to lower rates of residual disease. [2] Such improvements may be the result of improved visualization of the middle ear and epitympanum that result from use of the endoscope. [3] One criticism of the use of endoscopes in ear surgery is that dissection is limited to a one-handed technique. While endoscope holders can be used, concerns have been raised about their feasibility in ear surgery because if a patient were to move the endoscope would remain stationary, potentially resulting in injury. However, investigators in India, using a modified microscope as an

endoscope holder had no problems in over 150 cases of cartilage tympanoplasty most of which were performed under sedation and local anesthesia. [4]

Notable advancements in cochlear implantation were also documented in the literature in 2016. While it has long been believed that adult patients with bilateral cochlear implantation perform better than patients with unilateral cochlear implantation (in patients who meet candidacy criteria in both ears), a randomized controlled trial of patients segregated into these two groups had not been previously performed. A group from the Netherlands randomized patients into these two groups, and found that patients in the bilaterally implanted group had better speech scores in challenging listening-in-noise situations and better scores on sound localization tests. Furthermore, patients with bilateral implants reported improvements in hearing over

the unilaterally implanted patients on standardized questionnaires. [5] Results from the US trial of the Hybrid cochlear implant, a cochlear implant device designed for patients with residual low frequency hearing (to be acoustically stimulated) and poor high frequency hearing (to be electrically stimulated), were published last year. [6] Significant improvement in speech scores, as tested using single words as well as sentence tests in noise, were noted postoperatively. While 44% of patients lost over 30dB following cochlear implantation with this device, patients who were limited to using the device in electric only mode still performed better than they had preoperatively.

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Compared to microscopic ear surgery, endoscopic ear surgery has the advantage of advancing the point of visualization down the ear canal thus bypassing obstructions, such as the anterior canal wall overhang.

# Rethinking Grassroots Advocacy in 2017 & Beyond



With every freshmen class, challenges lie ahead. There is a learning curve, new set of priorities, and competing interests. Without outspoken advocates, issues can quickly get lost in the thousands of bills introduced each legislative session.

## The Pennsylvania Academy of Otolaryngology is implementing a grassroots advocacy program to recalibrate our membership for future and existing legislative fights.

Therefore, below are some key points to help you become a physician advocate. Furthermore, the PAO-HNS would like you to discuss a few key issues. None of these issues are pressing today, but we are certain that they are a continually discussed and debated subject that certainly could use your expertise. The points we would like you to touch on with you State Representatives and Senators are

- Hearing aid sales over the internet. Explain the risks.
- E-cigarettes – remind your Senator of the harmful effects and what you have seen because of it.
- Smoking cessation & Second hand smoke exposure, particularly for minors. ■

Over the course of the two-year session, the Pennsylvania General Assembly will consider multiple pieces of legislation that could have a significant impact – positive or negative – on you. Whether you're supporting or opposing a bill, grassroots advocacy is now more important than ever.

Once upon a time, it was not out of the ordinary for incumbents to serve twenty or thirty plus years. Long-serving veteran members were often valued not only for their experience and expertise on issues, but also as legislative champions.

Politics, scandals, retirements and frustration with the legislative process have paved the way for an influx of new members. Since 2000, there has been a turnover of 85 percent, 76 percent since 2005 and 52 percent since 2010. This session alone there are nearly 30 first-timers. To put this in context, less than 1 percent of the current legislature was elected during the '70s, 3 percent during the '80s and 11 percent during the '90s.

With every freshmen class, challenges lie ahead. There is a learning curve, new set of priorities, and competing interests. Without outspoken advocates, issues can quickly get lost in the thousands of bills introduced each legislative session.

During the course of any given two-year legislative session, on average 4,300 or more bills are introduced. Of those, only 330 or roughly 7 percent are actually signed into law. Take away the bills designating roads and bridges and it's even less!

Think that grassroots advocacy isn't important? Think again. Educating,

advocating and putting a face on an issue can make all the difference in sending a bill to the governor's desk or defeating an issue. At the end of this article, we provide you with some tips for future advocacy plans.

Community and grassroots advocacy is the most powerful tool and an important complement to the lobbying efforts of the Milliron Goodman team. Elected officials want to hear from their constituents – the people that elected them and can re-elect them. Building strong, personal relationships with legislators and their staff is one of the most important aspects of advocacy.

In the short-term, you are putting a face on an issue that allows legislators to connect beyond the facts and figures. In the long-term, you are developing legislative champions that will seek your advice and complement our voice in the Capitol.

We strongly encourage you to get to know your legislators – whether it's a reception to introduce yourself, having coffee or lunch to discuss an issue, or inviting your legislator on a tour of your facility. All are examples of community and grassroots advocacy and effective ways to build relationships with your legislators. Keeping us "in the know" on your advocacy helps produce the results you're looking for.

If you're already engaged, we would like to thank you. If you would like to get involved, please feel free to contact us at 717.232.5322. ■

# Guide to Grassroots Advocacy

What can you do to help? We'd like to share a few grassroots tips we've learned along the way. Take a look:

## 10 TIPS ON EFFECTIVE GRASSROOTS ADVOCACY

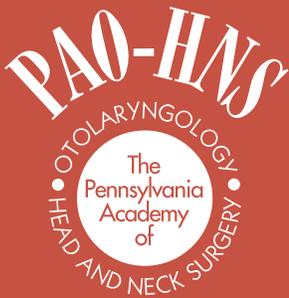
- 1** Before contacting your legislators, do a little homework. Research their biography, committee assignments, cosponsor memos and legislation sponsored. This will offer some insight into their legislative interests. You might also discover that you attended the same school or have a hobby in common. Contact Milliron & Goodman, so we can help you. The Pennsylvania General Assembly website [1] is also a great place to start.
- 2** If you do not know or have never met your legislators, you should attempt to make your first meeting a friendly, get-acquainted occasion. This could be as simple as introducing yourself as a constituent at a town hall meeting or legislative reception. Follow-up by scheduling a personal meeting.
- 3** Take advantage of additional opportunities to connect with your legislators – whether inviting your legislators to attend an open house, an award ceremony, or a ground-breaking for a new project. Likewise, opportunities might arise through involvement with professional organizations, civic or charitable organizations, or political parties.
- 4** The hometown connection is essential to getting a legislator's attention, so always identify yourself as a



- constituent – where you live and how you are connected to the community.
- 5** You are the expert on your profession and knowing what you or the community needs. You are meeting with the legislator as a constituent. You do not have to be an expert in legislative advocacy. You are setting the stage for the Milliron Goodman team to follow-up with the legislator on the issue(s) you raise. **Remember to let your legislators know that Milliron Goodman is representing your interests in Harrisburg and to let us know of communications and/or meetings with your legislators.**
  - 6** If discussing an issue, be brief, clear and accurate. Telling your story by sharing your experiences, struggles and solutions is the most persuasive message. Allow the legislator to offer his or her view on the issue and ask questions. If the legislator asks questions that you cannot answer, be honest and provide the requested information later.
  - 7** Your legislator may not always agree with your position. Be persistent, but not argumentative. Provide points supporting your issue. Ask thought provoking questions that will encourage him or her to contemplate your position. Keep in mind that a legislator who opposes you on an issue today may become a valued ally on an unrelated issue tomorrow.
  - 8** Get to know your legislator's staff. They usually have more time to devote to your issues and are often influential with the legislator.
  - 9** Always express appreciation. Follow-up with a thank you letter that briefly restates your main points and includes any information you offered to provide.
- Once acquainted with your legislators, it is important to maintain an ongoing relationship. Stay informed about your legislator's activities by subscribing to his or her newsletter. Share your opinion on legislation concerning you and send your legislator literature referencing your issues. Attend and participate in town hall meetings. Invite your legislators to your office to meet with your colleagues. Participate in projects undertaken by your legislators. Attend fundraisers or get involved personally in their election campaigns.

### REFERENCES

[1] <http://www.legis.state.pa.us/>



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