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The Otolaryngology Workforce, Part I: Supply

PREDICTIONS ABOUND OF A SHORTAGE OF OTOLARYNGOLOGISTS, BUT DO THE NUMBERS SUPPORT THEM?

By **Andrew J. Tompkins, MD**

VIEWPOINT

Of all topics pertaining to medicine, perhaps none is more consequential than our workforce. It affects our ability to meet patient needs in a competent manner, speaks to how we interact and compete with one another, shows the adequacy of our training systems and how they change over time, and handles what may be required of us in the future. The otolaryngology workforce is also a factor in our ability to sustain a rewarding practice and provide for our families. Because its health affects all of us in serious ways, it requires a careful and routine analysis.

This three-part series is my attempt to provide an updated analysis of where the health of our workforce is headed. In this first part, we'll examine some evidence from published studies and updated supply models about what's really happening when it comes to supply and demand in our workforce. Our specialty was initially worried about whether we would have enough otolaryngologists when we perhaps should have been worrying about whether we might have too many.

Historical Supply Figures

To understand our current situation, we need a historical understanding of our workforce supply. While other studies preceded this, the Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS) commissioned a workforce study in the late 1990s. Among many important findings in this study was that in 1997 we had 9,017 otolaryngologists, or 3.36 otolaryngologists per 100,000 population. It was thought that this overage would correct itself over the ensuing 20 years to the managed care demand range estimate

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Innovative Recruitment

Some specialties are going above and beyond to make good matches between their programs and residency candidates

By **Linda Kossoff**

MEDICAL EDUCATION

Medical schools across the specialty spectrum are reporting increasing numbers of student applicants, overwhelming residency programs and heightening anxiety among graduates. In response to growing competition for limited spots, more individual students are applying to multiple programs, often with fit as a secondary consideration—which, in turn, increases the number of annual applicants for each program to review and consider.

What are today's residency programs doing to counteract this challenging snowball effect? They're getting innovative, developing recruitment tools with an eye toward achieving high-performing residency classes whose trainees are a suitable fit for their programs' culture and mission.

CONTINUED ON **PAGE 20**

TAKE OUR ONLINE POLL AT ENTTODAY.ORG

QUESTION:

Do you think there will be a shortage of otolaryngologists in the next five to 10 years?

Nucala
(mepolizumab)
Injection 100 mg/mL

The targeted therapy for 4 eosinophil-driven diseases

Severe eosinophilic asthma (SEA)

Chronic rhinosinusitis with nasal polyps (CRSwNP)

Eosinophilic granulomatosis with polyangiitis (EGPA)

Hypereosinophilic syndrome (HES)

NUCALA is for the:

- add-on maintenance treatment of patients 6+ with SEA. Not for acute bronchospasm or status asthmaticus.
- add-on maintenance treatment of CRSwNP in patients 18+ with inadequate response to nasal corticosteroids.
- treatment of adult patients with EGPA.
- treatment of patients aged 12+ with HES for ≥6 months without an identifiable non-hematologic secondary cause.

Important Safety Information

CONTRAINDICATIONS

NUCALA should not be administered to patients with a history of hypersensitivity to mepolizumab or excipients in the formulation.

Please see Brief Summary of Prescribing Information for NUCALA on the following pages.

Visit Nucala4EOS.com to learn more →

Important Safety Information (cont'd)

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Hypersensitivity reactions (eg, anaphylaxis, angioedema, bronchospasm, hypotension, urticaria, rash) have occurred with NUCALA. These reactions generally occur within hours of administration but can have a delayed onset (ie, days). If a hypersensitivity reaction occurs, discontinue NUCALA.

Acute Asthma Symptoms or Deteriorating Disease

NUCALA should not be used to treat acute asthma symptoms, acute exacerbations, or acute bronchospasm.

Opportunistic Infections: Herpes Zoster

Herpes zoster infections have occurred in patients receiving NUCALA. Consider vaccination if medically appropriate.

Reduction of Corticosteroid Dosage

Do not discontinue systemic or inhaled corticosteroids abruptly upon initiation of therapy with NUCALA. Decreases in corticosteroid doses, if appropriate, should be gradual and 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.

Parasitic (Helminth) Infection

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

ADVERSE REACTIONS

Most common adverse reactions (≥5%) in patients receiving NUCALA:

- Severe asthma trials: headache, injection site reaction, back pain, fatigue
- CRSwNP trial: oropharyngeal pain, arthralgia
- EGPA and HES trials (300 mg of NUCALA): no additional adverse reactions were identified to those reported in severe asthma clinical trials

Systemic reactions, including hypersensitivity, occurred in clinical trials in patients receiving NUCALA. Manifestations included rash, pruritus, headache, myalgia, flushing, urticaria, erythema, fatigue, hypertension, warm sensation in trunk and neck, cold extremities, dyspnea, stridor, angioedema, and multifocal skin reaction. A majority of systemic reactions were experienced the day of dosing.

USE IN SPECIFIC POPULATIONS

A pregnancy exposure registry monitors pregnancy outcomes in women with asthma exposed to NUCALA during pregnancy. To enroll call 1-877-311-8972 or visit www.mothertobaby.org/asthma.

The data on pregnancy exposures are insufficient to inform on drug-associated risk. Monoclonal antibodies, such as mepolizumab, are transported across the placenta in a linear fashion as the pregnancy progresses; therefore, potential effects on a fetus are likely to be greater during the second and third trimesters.

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NUCALA (mepolizumab) for injection, for subcutaneous use
NUCALA (mepolizumab) injection, for subcutaneous use
The following is a brief summary only; see full prescribing information for complete product information.

1 INDICATIONS AND USAGE

1.1 Maintenance Treatment of Severe Asthma

NUCALA is indicated for the add-on maintenance treatment of adult and pediatric patients aged 6 years and older with severe asthma and with an eosinophilic phenotype *[see Use in Specific Populations (8.4) and Clinical Studies (14.1) of full prescribing information]*.

Limitations of Use

NUCALA is not indicated for the relief of acute bronchospasm or status asthmaticus.

1.2 Maintenance Treatment of Chronic Rhinosinusitis with Nasal Polyps

NUCALA is indicated for the add-on maintenance treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients 18 years of age and older with inadequate response to nasal corticosteroids.

1.3 Eosinophilic Granulomatosis with Polyangiitis

NUCALA is indicated for the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).

1.4 Hypereosinophilic Syndrome

NUCALA is indicated for the treatment of adult and pediatric patients aged 12 years and older with hypereosinophilic syndrome (HES) for ≥6 months without an identifiable non-hematologic secondary cause.

4 CONTRAINDICATIONS

NUCALA is contraindicated in patients with a history of hypersensitivity to mepolizumab or excipients in the formulation *[see Warnings and Precautions (5.1) and Description (11) of full prescribing information]*.

5 WARNINGS AND PRECAUTIONS

5.1 Hypersensitivity Reactions

Hypersensitivity reactions (e.g., anaphylaxis, angioedema, bronchospasm, hypotension, urticaria, rash) have occurred following administration of NUCALA. These reactions generally occur within hours of administration, but in some instances can have a delayed onset (i.e., days). In the event of a hypersensitivity reaction, NUCALA should be discontinued *[see Contraindications (4)]*.

5.2 Acute Asthma Symptoms or Deteriorating Disease

NUCALA should not be used to treat acute asthma symptoms or acute exacerbations. Do not use NUCALA to treat acute bronchospasm or status asthmaticus. Patients should seek medical advice if their asthma remains uncontrolled or worsens after initiation of treatment with NUCALA.

5.3 Opportunistic Infections: Herpes Zoster

Herpes zoster has occurred in subjects receiving NUCALA 100 mg in controlled clinical trials *[see Adverse Reactions (6.1)]*. Consider vaccination if medically appropriate.

5.4 Reduction of Corticosteroid Dosage

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

5.5 Parasitic (Helminth) Infection

Eosinophils may be involved in the immunological response to some helminth infections. Patients with known parasitic infections were excluded from participation in clinical trials. It is unknown if NUCALA will influence a patient's response against parasitic infections. Treat patients with pre-existing helminth infections before initiating therapy with NUCALA. If patients become infected while receiving treatment with NUCALA and do not respond to anti-helminth treatment, discontinue treatment with NUCALA until infection resolves.

6 ADVERSE REACTIONS

The following adverse reactions are described in greater detail in other sections:
- Hypersensitivity reactions *[see Warnings and Precautions (5.1)]*
- Opportunistic infections: herpes zoster *[see Warnings and Precautions (5.3)]*

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

6.1 Clinical Trials Experience in Severe Asthma

Adult and Adolescent Patients Aged 12 Years and Older

A total of 1,327 patients with severe asthma were evaluated in 3 randomized, placebo-controlled, multicenter trials of 24 to 52 weeks' duration (Trial 1, NCT01000506; Trial 2, NCT01691521; and Trial 3, NCT01691508). Of these, 1,192 had a history of 2 or more exacerbations in the year prior to enrollment despite regular use of high-dose ICS plus additional controller(s) (Trials 1 and 2), and 135 patients required daily oral corticosteroids (OCS) in addition to regular use of high-dose ICS plus additional controller(s) to maintain asthma control (Trial 3). All patients had markers of eosinophilic airway inflammation *[see Clinical Studies (14.1) of full prescribing information]*. Of the patients enrolled, 59% were female, 85% were White, and ages ranged from 12 to 82 years. Mepolizumab was administered subcutaneously or intravenously once every 4 weeks; 263 patients received NUCALA (mepolizumab 100 mg subcutaneous) for at least 24 weeks. Serious adverse events that occurred in more than 1 patient and in a greater percentage of patients receiving NUCALA 100 mg (n = 263) than placebo (n = 257) included 1 event, herpes zoster (2 patients vs. 0 patients, respectively). Approximately 2% of patients receiving NUCALA 100 mg withdrew from clinical trials due to adverse events compared with 3% of patients receiving placebo.

The incidence of adverse reactions in the first 24 weeks of treatment in the 2 confirmatory efficacy and safety trials (Trials 2 and 3) with NUCALA 100 mg is shown in Table 1.

Table 1. Adverse Reactions with NUCALA with ≥3% Incidence and More Common than Placebo in Patients with Severe Asthma (Trials 2 and 3)

Adverse Reaction	NUCALA (Mepolizumab 100 mg Subcutaneous) (n = 263) %	Placebo (n = 257) %
Headache	19	18
Injection site reaction	8	3
Back pain	5	4
Fatigue	5	4
Influenza	3	2
Urinary tract infection	3	2
Abdominal pain upper	3	2
Pruritus	3	2
Eczema	3	<1
Muscle spasms	3	<1

52-Week Trial: Adverse reactions from Trial 1 with 52 weeks of treatment with mepolizumab 75 mg intravenous (IV) (n = 153) or placebo (n = 155) and with ≥3% incidence and more common than placebo and not shown in Table 1 were: abdominal pain, allergic rhinitis, asthenia, bronchitis, cystitis, dizziness, dyspnea, ear infection, gastroenteritis, lower respiratory tract infection, musculoskeletal pain, nasal congestion, nasopharyngitis, nausea, pharyngitis, pyrexia, rash, toothache, viral infection, viral respiratory tract infection, and vomiting. In addition, 3 cases of herpes zoster occurred in patients receiving mepolizumab 75 mg IV compared with 2 patients in the placebo group.

Systemic Reactions, including Hypersensitivity Reactions: In Trials 1, 2, and 3 described above, the percentage of patients who experienced systemic (allergic and non-allergic) reactions was 3% in the group receiving NUCALA 100 mg and 5% in the placebo group. Systemic allergic/hypersensitivity reactions were reported by 1% of patients in the group receiving NUCALA 100 mg and 2% of patients in the placebo group. The most commonly reported manifestations of systemic allergic/hypersensitivity reactions reported in the group receiving NUCALA 100 mg included rash, pruritus, headache, and myalgia. Systemic non-allergic reactions were reported by 2% of patients in the group receiving NUCALA 100 mg and 3% of patients in the placebo group. The most commonly reported manifestations of systemic non-allergic reactions reported in the group receiving NUCALA 100 mg included rash, flushing, and myalgia. A majority of the systemic reactions in patients receiving NUCALA 100 mg (5/7) were experienced on the day of dosing.

Injection Site Reactions: Injection site reactions (e.g., pain, erythema, swelling, itching, burning sensation) occurred at a rate of 8% in patients receiving NUCALA 100 mg compared with 3% in patients receiving placebo.

Long-term Safety: Nine hundred ninety-eight patients received NUCALA 100 mg in ongoing open-label extension studies, during which additional cases of herpes zoster were reported. The overall adverse event profile has been similar to the asthma trials described above.

Pediatric Patients Aged 6 to 11 Years

The safety data for NUCALA is based upon 1 open-label clinical trial that enrolled 36 patients with severe asthma aged 6 to 11 years. Patients received 40 mg (for those weighing <40 kg) or 100 mg (for those weighing ≥40 kg) of NUCALA administered subcutaneously once every 4 weeks. Patients received NUCALA for 12 weeks (initial short phase). After a treatment interruption of 8 weeks, 30 patients received NUCALA for a further 52 weeks (long phase). The adverse reaction profile for patients aged 6 to 11 years was similar to that observed in patients aged 12 years and older.

6.2 Clinical Trials Experience in Chronic Rhinosinusitis with Nasal Polyps

A total of 407 patients with CRSwNP were evaluated in 1 randomized, placebo-controlled, multicenter, 52-week treatment trial. Patients received NUCALA 100 mg or placebo subcutaneously once every 4 weeks. Patients had recurrent CRSwNP with a history of prior surgery and were on nasal corticosteroids for at least 8 weeks prior to screening *[see Clinical Studies (14.2) of full prescribing information]*. Of the patients enrolled, 35% were female, 93% were White, and ages ranged from 18 to 82 years. Approximately 2% of patients receiving NUCALA 100 mg withdrew from study treatment due to adverse events compared with 2% of patients receiving placebo.

Table 2 summarizes adverse reactions that occurred in ≥3% of NUCALA-treated patients and more frequently than in patients treated with placebo in the CRSwNP trial.

Table 2. Adverse Reactions with NUCALA with ≥3% Incidence and More Common than Placebo in Patients with CRSwNP

Adverse Reaction	NUCALA (Mepolizumab 100 mg Subcutaneous) (n = 206) %	Placebo (n = 201) %
Oropharyngeal pain	8	5
Arthralgia	6	2
Abdominal Pain Upper	3	2
Diarrhea	3	2
Pyrexia	3	2
Nasal dryness	3	<1
Rash	3	<1

CRSwNP = Chronic Rhinosinusitis with Nasal Polyps.

Systemic Reactions, including Hypersensitivity Reactions

In the 52-week trial, the percentage of patients who experienced systemic (allergic [type I hypersensitivity] and other) reactions was <1% in the group receiving NUCALA 100 mg and <1% in the placebo group. Systemic allergic (type I hypersensitivity) reactions were reported by <1% of patients in the group receiving NUCALA 100 mg and no patients in the placebo group. The manifestations of systemic allergic (type I hypersensitivity) reactions included urticaria, erythema, and rash and 1 of the 3 reactions occurred on the day of dosing. Other systemic reactions were reported by no patients in the group receiving NUCALA 100 mg and <1% of patients in the placebo group.

Injection Site Reactions

Injection site reactions (e.g., erythema, pruritus) occurred at a rate of 2% in patients receiving NUCALA 100 mg compared with <1% in patients receiving placebo.

6.3 Clinical Trials Experience in Eosinophilic Granulomatosis with Polyangiitis

A total of 136 patients with EGPA were evaluated in 1 randomized, placebo-controlled, multicenter, 52-week treatment trial. Patients received 300 mg of NUCALA or placebo subcutaneously once every 4 weeks. Patients enrolled had a diagnosis of EGPA for at least 6 months prior to enrollment with a history of relapsing or refractory disease and were on a stable dosage of oral prednisolone or prednisone of greater than or equal to 7.5 mg/day (but not greater than 50 mg/day) for at least 4 weeks prior to enrollment *[see Clinical Studies (14.3) of full prescribing information]*. Of the patients enrolled, 59% were female, 92% were White, and ages ranged from 20 to 71 years. No additional adverse reactions were identified to those reported in the severe asthma trials.

Systemic Reactions, including Hypersensitivity Reactions

In the 52-week trial, the percentage of patients who experienced systemic (allergic and non-allergic) reactions was 6% in the group receiving 300 mg of NUCALA and 1% in the placebo group. Systemic allergic/hypersensitivity reactions were reported by 4% of patients in the group receiving 300 mg of NUCALA and 1% of patients in the placebo group. The manifestations of systemic allergic/hypersensitivity reactions reported in the group receiving 300 mg of NUCALA included rash, pruritus, flushing, fatigue, hypertension, warm sensation in trunk and neck, cold extremities, dyspnea, and stridor. Systemic non-allergic reactions were reported by 1 (1%) patient in the group receiving 300 mg of NUCALA and no patients in the placebo group. The reported manifestation of systemic non-allergic reactions reported in the group receiving 300 mg of NUCALA was angioedema. Half of the systemic reactions in patients receiving 300 mg of NUCALA (2/4) were experienced on the day of dosing.

Injection Site Reactions

Injection site reactions (e.g., pain, erythema, swelling) occurred at a rate of 15% in patients receiving 300 mg of NUCALA compared with 13% in patients receiving placebo.

6.4 Clinical Trials Experience in Hypereosinophilic Syndrome

A total of 108 adult and adolescent patients aged 12 years and older with HES were evaluated in a randomized, placebo-controlled, multicenter, 32-week treatment trial. Patients with non-hematologic secondary HES or FIP1L1-PDGFRα kinase-positive HES were excluded from the trial. Patients received 300 mg of NUCALA or placebo subcutaneously once every 4 weeks. Patients must have been on a stable dose of background HES therapy for the 4 weeks prior to randomization [*see Clinical Studies (14.4) of full prescribing information*]. Of the patients enrolled, 53% were female, 93% were White, and ages ranged from 12 to 82 years. No additional adverse reactions were identified to those reported in the severe asthma trials.

Systemic Reactions, including Hypersensitivity Reactions

In the trial, no systemic allergic (type I hypersensitivity) reactions were reported. Other systemic reactions were reported by 1 (2%) patient in the group receiving 300 mg of NUCALA and no patients in the placebo group. The reported manifestation of other systemic reaction was multifocal skin reaction experienced on the day of dosing.

(continued on next page)

6 ADVERSE REACTIONS *(cont'd)*

Injection Site Reactions

Injection site reactions (e.g., burning, itching) occurred at a rate of 7% in patients receiving 300 mg of NUCALA compared with 4% in patients receiving placebo.

6.5 Immunogenicity

In adult and adolescent patients with severe asthma receiving NUCALA 100 mg, 15/260 (6%) had detectable anti-mepolizumab antibodies. Neutralizing antibodies were detected in 1 patient with asthma receiving NUCALA 100 mg. Anti-mepolizumab antibodies slightly increased (approximately 20%) the clearance of mepolizumab. There was no evidence of a correlation between anti-mepolizumab antibody titers and change in eosinophil level. The clinical relevance of the presence of anti-mepolizumab antibodies is not known. In the clinical trial of children aged 6 to 11 years with severe asthma receiving NUCALA 40 or 100 mg, 2/35 (6%) had detectable anti-mepolizumab antibodies during the initial short phase of the trial. No children had detectable anti-mepolizumab antibodies during the long phase of the trial.

In patients with CRSwNP receiving NUCALA 100 mg, 6/196 (3%) had detectable anti-mepolizumab antibodies. No neutralizing antibodies were detected in any patients with CRSwNP.

In patients with EGPA receiving 300 mg of NUCALA, 1/68 (<2%) had detectable anti-mepolizumab antibodies. No neutralizing antibodies were detected in any patients with EGPA.

In adult and adolescent patients with HES receiving 300 mg of NUCALA, 1/53 (2%) had detectable anti-mepolizumab antibodies. No neutralizing antibodies were detected in any patients with HES.

The reported frequency of anti-mepolizumab antibodies may underestimate the actual frequency due to lower assay sensitivity in the presence of high drug concentration. The data reflect the percentage of patients whose test results were positive for antibodies to mepolizumab in specific assays. The observed incidence of antibody positivity in an assay is highly dependent on several factors, including assay sensitivity and specificity, assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease.

6.6 Postmarketing Experience

In addition to adverse reactions reported from clinical trials, the following adverse reactions have been identified during postapproval use of NUCALA. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. These events have been chosen for inclusion due to either their seriousness, frequency of reporting, or causal connection to NUCALA or a combination of these factors.

Immune System Disorders

Hypersensitivity reactions, including anaphylaxis.

7 DRUG INTERACTIONS

Formal drug interaction trials have not been performed with NUCALA.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Exposure Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in women with asthma exposed to NUCALA during pregnancy. Healthcare providers can enroll patients or encourage patients to enroll themselves by calling 1-877-311-8972 or visiting www.mothertobaby.org/asthma.

Risk Summary

The data on pregnancy exposure are insufficient to inform on drug-associated risk. Monoclonal antibodies, such as mepolizumab, are transported across the placenta in a linear fashion as pregnancy progresses; therefore, potential effects on a fetus are likely to be greater during the second and third trimester of pregnancy. In a prenatal and postnatal development study conducted in cynomolgus monkeys, there was no evidence of fetal harm with IV administration of mepolizumab throughout pregnancy at doses that produced exposures up to approximately 9 times the exposure at the maximum recommended human dose (MRHD) of 300 mg subcutaneous (*see Data*).

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.

Clinical Considerations

Disease-Associated Maternal and/or Embryofetal Risk: In women with poorly or moderately controlled asthma, evidence demonstrates that there is an increased risk of preeclampsia in the mother and prematurity, low birth weight, and small for gestational age in the neonate. The level of asthma control should be closely monitored in pregnant women and treatment adjusted as necessary to maintain optimal control.

Data

Animal Data: In a prenatal and postnatal development study, pregnant cynomolgus monkeys received mepolizumab from gestation Days 20 to 140 at doses that produced exposures up to approximately 9 times that achieved with the MRHD (on an AUC basis with maternal IV doses up to 100 mg/kg once every 4 weeks). Mepolizumab did not elicit adverse effects on fetal or neonatal growth (including immune function) up to 9 months after birth. Examinations for internal or skeletal malformations were not performed. Mepolizumab crossed the placenta in cynomolgus monkeys. Concentrations of mepolizumab were approximately 2.4 times higher in infants than in mothers up to Day 178 postpartum. Levels of mepolizumab in milk were ≤0.5% of maternal serum concentration.

In a fertility, early embryonic, and embryofetal development study, pregnant CD-1 mice received an analogous antibody, which inhibits the activity of murine interleukin-5 (IL-5), at an IV dose of 50 mg/kg once per week throughout gestation. The analogous antibody was not teratogenic in mice. Embryofetal development of IL-5–deficient mice has been reported to be generally unaffected relative to wild-type mice.

8.2 Lactation

Risk Summary

There is no information regarding the presence of mepolizumab in human milk, the effects on the breastfed infant, or the effects on milk production. However, mepolizumab is a humanized monoclonal antibody (IgG1 kappa), and immunoglobulin G (IgG) is present in human milk in small amounts. Mepolizumab was present in the milk of cynomolgus monkeys postpartum following dosing during pregnancy *[see Use in Specific Populations (8.1)]*. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for NUCALA and any potential adverse effects on the breastfed infant from mepolizumab or from the underlying maternal condition.

8.4 Pediatric Use

Severe Asthma

The safety and efficacy of NUCALA for severe asthma, and with an eosinophilic phenotype, have been established in pediatric patients aged 6 years and older.

Use of NUCALA in adolescents aged 12 to 17 years is supported by evidence from adequate and well-controlled trials in adults and adolescents. A total of 28 adolescents aged 12 to 17 years with severe asthma were enrolled in the Phase 3 asthma trials. Of these, 25 were enrolled in the 32-week exacerbation trial (Trial 2, NCT01691521) and had a mean age of 14.8 years. Patients had a history of 2 or more exacerbations in the previous year despite regular use of medium- or high-dose ICS plus additional controller(s) with or without OCS and had blood eosinophils of ≥150 cells/mcL at screening or ≥300 cells/mcL within 12 months prior to enrollment. *[See Clinical Studies (14.1) of full prescribing information.]* Patients had a reduction in the rate of exacerbations that trended in favor of NUCALA. Of the 19 adolescents who received NUCALA, 9 received 100 mg and the mean apparent clearance in these patients was 35% less than that of adults. The safety profile observed in adolescents was generally similar to that of the overall population in the Phase 3 studies *[see Adverse Reactions (6.1)]*.

Use of NUCALA in pediatric patients aged 6 to 11 years with severe asthma, and with an eosinophilic phenotype, is supported by evidence from adequate and well-controlled trials in adults and adolescents with additional pharmacokinetic, pharmacodynamic, and safety data in children aged 6 to 11 years. A single, open-label clinical trial (NCT02377427) was conducted in 36 children aged 6 to 11 years (mean age: 8.6 years, 31% female) with severe asthma. Enrollment criteria were the same as for adolescents in the 32-week exacerbation trial (Trial 2). Based upon the pharmacokinetic data from this trial, a dose of 40 mg subcutaneous every 4 weeks was determined to have similar exposure to adults and adolescents administered a dose of 100 mg SC *[see Clinical Pharmacology (12.3) of full prescribing information]*. The effectiveness of NUCALA in pediatric patients aged 6 to 11 years is extrapolated from efficacy in adults and adolescents with support from pharmacokinetic analyses showing similar drug exposure levels for 40 mg administered subcutaneously every 4 weeks in children aged 6 to 11 years compared with adults and adolescents *[see Clinical Pharmacology (12.3) of full prescribing information]*. The safety profile and pharmacodynamic response observed in this trial for children aged 6 to 11 years were similar to that seen in adults and adolescents *[see Adverse Reactions (6.1), Clinical Pharmacology (12.2) of full prescribing information]*.

The safety and effectiveness in pediatric patients aged younger than 6 years with severe asthma have not been established.

Chronic Rhinosinusitis with Nasal Polyps

The safety and effectiveness in patients aged younger than 18 years with CRSwNP have not been established.

Eosinophilic Granulomatosis with Polyangiitis

The safety and effectiveness in patients aged younger than 18 years with EGPA have not been established.

Hypereosinophilic Syndrome

The safety and effectiveness of NUCALA for HES have been established in adolescent patients aged 12 years and older. The safety and effectiveness in pediatric patients aged younger than 12 years with HES have not been established.

Use of NUCALA for this indication is supported by evidence from an adequate and well-controlled study (NCT02836496) in adults and adolescents and an open-label extension study (NCT03306043). One adolescent received NUCALA during the controlled study and this patient and an additional 3 adolescents received NUCALA during the open-label extension study *[see Clinical Studies (14.4) of full prescribing information]*. The 1 adolescent treated with NUCALA in the 32-week trial did not have a HES flare or an adverse event reported. All adolescents received 300 mg of NUCALA for 20 weeks in the open-label extension.

8.5 Geriatric Use

Clinical trials of NUCALA did not include sufficient numbers of patients aged 65 years and older that received NUCALA (n = 79) to determine whether they respond differently from younger patients. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or other drug therapy. Based on available data, no adjustment of the dosage of NUCALA in geriatric patients is necessary, but greater sensitivity in some older individuals cannot be ruled out.

10 OVERDOSAGE

There is no specific treatment for an overdose with mepolizumab. If overdose occurs, the patient should be treated supportively with appropriate monitoring as necessary.

17 PATIENT COUNSELING INFORMATION

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

Hypersensitivity Reactions

Inform patients that hypersensitivity reactions (e.g., anaphylaxis, angioedema, bronchospasm, hypotension, urticaria, rash) have occurred after administration of NUCALA. Instruct patients to contact their physicians if such reactions occur.

Not for Acute Symptoms or Deteriorating Disease

Inform patients that NUCALA does not treat acute asthma symptoms or acute exacerbations. Inform patients to seek medical advice if their asthma remains uncontrolled or worsens after initiation of treatment with NUCALA.

Opportunistic Infections: Herpes Zoster

Inform patients that herpes zoster infections have occurred in patients receiving NUCALA and where medically appropriate, inform patients that vaccination should be considered.

Reduction of 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.

Pregnancy Exposure Registry

Inform women there is a pregnancy exposure registry that monitors pregnancy outcomes in women with asthma exposed to NUCALA during pregnancy and that they can enroll in the Pregnancy Exposure Registry by calling 1-877-311-8972 or by visiting www.mothertobaby.org/asthma *[see Use in Specific Populations (8.1)]*.

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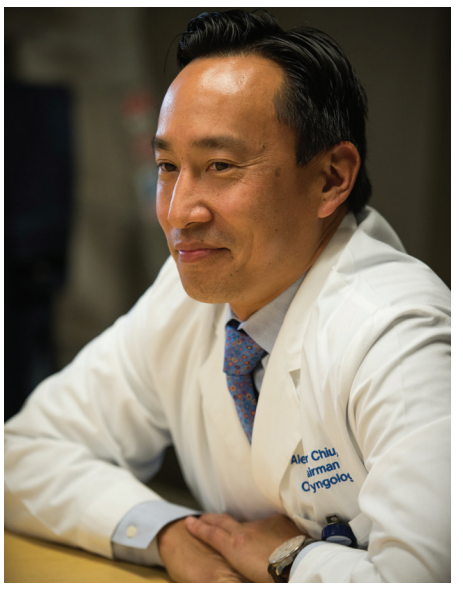
> By **Alexander G. Chiu, MD**

Time to Reengage



Every spring, our department has partnered with a local community organization to clean up an urban park down the road from our hospital. On a Saturday morning in April, we pick up trash where there are wonderful murals celebrating past Kansas Citians, a busy disc golf course, and multiple playgrounds and ball fields. The labor is tough, but there are many laughs and a lunch to follow. Our employees bring their families; it's a great way to show my kids the importance of belonging and contributing to a community.

This year, with COVID-19 cases at an all-time low here, we circulated the sign-up expecting a robust turnout. To my surprise and disappointment, in a department of over 250 employees, a grand total of two signed up. What's going on?

It got me thinking about what the pandemic has done to our social relationships. We've all gotten used to some form of social isolation. Initially, it started with the ease of working from home. There are aspects that will remain long after the pandemic is over—I certainly don't miss all the 6 p.m. hospital conferences and weekday work dinner meetings. Social gatherings have also been put on the back burner. But has the pendulum swung too far? Have we embraced the isolationism to a degree that's detrimental to our communities and future selves?

Older research has shown that people who have meaningful social connections are happier, have fewer health issues, suffer less depression, and live longer. (*PLoS Med*. 2010;7:e1000316) A study published in 2021 looked at the effects of perceived social isolation during the pandemic and showed similar results. Social isolation was associated with poor life satisfaction across all domains, as well as work-related stress and lower trust of institutions and businesses (*Humanit Soc Sci Commun*. Published online January 27, 2021. doi:10.1057/s41599-021-00710-3).

Prior to the pandemic, many communities realized that building platforms for social connections was important, especially for those who felt marginalized. More public green spaces were built, schools created classes on the importance of building and maintaining relationships, and community-based organizations built programs to encourage socializing.

Now that we're exiting the pandemic stage, it's time to brainstorm ways to build back our connections to each other and with our local communities. I imagine that greater social connections in the workplace will result in a better work environment that translates into employee engagement, less turnover, better patient satisfaction scores, and a greater buy-in to the mission.

How we do this will be a challenge. Is it okay to assume that life will go back to how it used to be, that the activities and parties can resume and we can rebuild and foster new relationships traditionally? Or have the comforts of working from home changed our employees' perception going forward? Is there a digital medium that can keep the same sense of community that in-person meetings give?

Our annual spring clean-up may have been a miss this year, but it was a necessary wake-up call. Over the next few months, we'll work together to bring our department and community back together. I encourage you all to do the same in your local environments, and I look forward to hearing about your success stories. Thanks for listening, and I wish you and your communities the best of health. ▲

—Alex

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- In April, the U.S. Food and Drug Administration announced it was seeking public comment on **a potential change that would require opioid analgesics used in outpatient settings to be dispensed with prepaid mail-back envelopes** and that pharmacists provide patient education on safe disposal of opioids. The FDA is accepting public comments from interested parties until June 21, 2022, but comments are welcome at any time.

- **Patients who have had COVID-19 and have had an altered sense of smell may also have brain damage** that explains long-term smell loss, according to a study published online in *JAMA Neurology* (doi:10.1001/jamaneurol.2022.0154). In the cohort study of 23 deceased patients and 14 matched controls, researchers found that those who had had COVID-19 had significantly more axon and microvasculopathy damage in the brain's olfactory tissue. The olfactory damage wasn't from direct viral injury and instead may be associated with local inflammation.

HEAD AND NECK

Postoperative Surveillance: Blood Test for HPV-Driven Oropharynx Cancer

A BLOOD TEST ACCURATELY PREDICTED RECURRENT and persistent human papillomavirus (HPV)-driven oropharyngeal squamous cell carcinoma (OPSCC) in patients who had undergone curative treatment for OPSCC, demonstrating it as a clinically valid and effective surveillance tool for use in clinical practice, report investigators in a study recently published in the *International Journal of Radiation Oncology Biology and Physics* (*Int J Rad Oncol Biol Phys*. 2022;112:e4).

"While detection of tumor-specific DNA circulating in a patient's bloodstream has shown potential as a powerful yet minimally invasive diagnostic tool for several cancers, this is the first study to demonstrate broad clinical utility and validity of the biomarker in HPV-driven oropharyngeal cancer," said Glenn J. Hanna, MD, director of the Center for Salivary and Rare Head and Neck Cancers at the Dana-Farber Cancer Institute in Boston, in a press release.

The study showed that a test used to detect circulating cell-free tumor tissue modified HPV DNA (TTMV-HPV DNA) in the blood was associated with a positive predictive value of 95% for identifying patients with active and occult recurrent HPV-driven OPSCC.

The findings are based on 1,076 consecutive patients across 124 U.S. sites included in the retrospective clinical case series study. All patients had completed standard definitive therapy for HPV-driven OPSCC more than three months before being administered one or more tests to detect TTMV-HPV DNA as part of their post-treatment surveillance. Ultrasensitive digital droplet polymerase chain reaction was used to analyze high-risk HPV subtypes (16, 18, 31, 33, and 35).

The effectiveness of TTMV-HPV DNA tests to predict active and occult recurrent disease was assessed by comparing the results to clinical evidence of OPSCC using nasopharyngolaryngoscopy and/or imaging (CT, MRI, or PET-CT), and/or tissue biopsy.

Overall, 80 of the 1,076 patients (7.4%) tested positive for circulating TTMV-HPV DNA (range: 7-123,148 fragments [frgs]/mL) after definitive therapy. Of these, 21 (26.2%) had known recurrence and 59 (73.8%) had no other evidence of disease or indeterminate disease status at the first positive surveillance test.

Among the 59 with positive tests but without clinically known recurrence, 55 (93.2%, TTMV range: 8-23,296 frgs/mL) had confirmed recurrence based on clinical follow-up data that identified them as subtypes HPV16 (n = 52), HPV31 (n = 1), and HPV35 (n = 2). Of the remaining four patients, two had clinically suspicious lesions with negative biopsies (one with a base of tongue ulcer and one with a pulmonary nodule (TTMV range: 9-67 frgs/mL) and two currently have no other evidence of disease (TTMV range: 16-79 frgs/mL). These last two patients are scheduled to undergo a repeat TTMV test and radiologic surveillance.

These findings indicate that the blood test had a positive predictive value of 95% (76/80) for recurrent or persistent HPV-driven OPSCC. The investigators noted that for 72.4% of patients whose cancer returned, the first indicator of recurrence was through detection of TTMV-HPV DNA through the blood test.

The investigators say the data will help inform guidance on including circulating TTMV-HPV DNA as a biomarker to detect HVP-driven OPSCC in the surveillance setting. ▲

—Mary Beth Nierengarten

HEAD AND NECK

Radioiodine Ablation Makes Little to No Difference for Low-Risk Thyroid Cancer

FOR PATIENTS WITH LOW-RISK THYROID CANCER undergoing thyroidectomy, follow up with radioiodine ablation offers no superior outcomes compared to no radioiodine, reported investigators in a study recently published in the *New England Journal of Medicine* (*N Eng J Med*. 2022;386:923-932).

The French multicenter, prospective, phase 3 trial was undertaken to assess whether no radioiodine therapy was noninferior to radioiodine therapy regarding the absence of a composite endpoint including functional, structural, and biologic abnormalities at three years. A between-group difference of <5% in event rate was defined as noninferiority.

Called the ESTIMABL2 trial, the study included patients with low-differentiated thyroid cancer who underwent thyroidectomy and were randomized to radioiodine ablation after injections of recombinant human thyrotropin or no postoperative radioiodine. A total of 730 patients were available for analysis, 363 in the radioiodine group and 367 in the no-radioiodine group. Patients were enrolled in the study between May 2013 and March 2017.

At three years, the percentage of patients without an event was 95.6% and 95.9% for the no-radioiodine group and radioiodine group, respectively. The difference of -0.3 percentage points met the criteria for noninferiority.

Structural or functional abnormalities occurred in eight patients, and biologic abnormalities occurred in 23 patients (25 events). More frequent events were noted in patients who had a postoperative serum thyroglobulin level of >1 ng/mL during thyroid hormone treatment. No differences in molecular alterations were found in patients with or without an event.

"In patients with low-risk thyroid cancer undergoing thyroidectomy, a follow-up strategy that did not involve the use of radioiodine was noninferior to an ablation strategy with radioiodine regarding the occurrence of functional, structural, and biologic events at three years," according to the investigators of the study, led by Sophie Leboulleux, MD, PhD, head of the thyroid cancer division in the department of nuclear medicine and endocrine oncology at Gustave Roussy Cancer Institute, Villejuif, France. ▲

—Mary Beth Nierengarten

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LITERATURE REVIEW

A Roundup of Important Recent Studies

GENERAL OTOLARYNGOLOGY

AMA Manual Updates Guidance on Reporting of Race and Ethnicity in Medical and Science Journals

COMMENT: This editorial provides recommendations and suggestions to "encourage fairness, equity, consistency, and clarity in use and reporting of race and ethnicity in medical and science journals." The authors support the contention that race and ethnicity are social constructs with limited utility in understanding medical research, practice, or policy; however, the terms can be useful "as a lens through which to study and view racism and disparities and inequities in health, health care, and medical practice, education, and research." This updated guidance will be added to the Inclusive Language section (Section 11.12) of the AMA Manual of Style as a dedicated subsection on Race and Ethnicity (Section 11.12.3). There are additional subsections that address reporting concerns and preferred nomenclature for sex and gender, sexual orientation, age, socioeconomic status, and persons with diseases, disorders, or disabilities. Inclusive language supports diversity and conveys respect, and these resources should be used to guide our future clinical, educational, and research practices in otolaryngology.

—Sarah Bowe, MD

CLINICAL QUESTION

What can be done to encourage fairness, equity, consistency, and clarity in use and reporting of race and ethnicity in medical and science journals?

BOTTOM LINE

Language and terminology must be accurate, clear, and precise, and must reflect fairness, equity, and consistency in use and reporting of race and ethnicity.

BACKGROUND: In 2021, the AMA Manual of Style Committee released guidelines in the *Journal of the American Medical Association* (*JAMA*) for the reporting of race and ethnicity in medical and science journals. The guidance has since been updated and will appear in the manual's Inclusive Language section.
STUDY DESIGN: Editorial.
SETTING: American Medical Association, Chicago, Ill.
SYNOPSIS: Responding to feedback on their suggested guidelines, the updated guidance is based on the contention that race and ethnicity are social constructs with limited utility in understanding medical research, practice, or policy. The authors emphasized the need for medical journal content to be accurate, clear, and precise in language and terminology, and reflective of fairness, equity, and consistency in the use and reporting of race and ethnicity. The guidance defines commonly used terms and acknowledges the changing nature of certain terms and definitions. Among the relevant items: concerns and controversies addressed in healthcare and heritage; social determinants of health; additional socioeconomic, structural, institutional, cultural, and demographic factors; reporting of race and ethnicity in research articles; use of racial and ethnic collective or umbrella terms (such as "minorities" and "multiethnic"); definitions of terms; key concerns, sensitivities, and controversies; demographics reporting; and specifics regarding usage of forms of speech and capitalizations. Key goals of the guidance are to reduce unintentional bias in literature and provide context when reporting on racial and ethnic disparities and inequities.
CITATION: Flanagin A, Frey T, Christiansen SL. Updated guidance on the reporting of race and ethnicity in medical and science journals. *JAMA*. 2021;326:621-627.

—Review by Linda Kossoff

HEAD AND NECK

U.K. Surgeons Report Being Negatively Affected by Adverse Events

COMMENT: We are aware of our own and our team members' responses to adverse surgical outcomes and events. This article looks at those reactions and subsequent effects on surgeon/team decisions and performance.

—Sujana Chandrasekhar, MD

CLINICAL QUESTION

What is the impact of adverse events, such as medical errors and complications, on U.K. surgeons' health and well-being?

BOTTOM LINE

Surgeons in the U.K. are affected negatively by adverse events but are ill-prepared to deal with them.

BACKGROUND: For surgeons, adverse events such as medical errors and complications can result in guilt, anxiety, reduced confidence, burnout, depression, suicidal ideation, and/or reduced quality of life. Although the literature on adverse events typically groups doctors together, some aspects of medical practice are unique to, or are predominant aspects of, surgery.
STUDY DESIGN: Online survey.
SETTING: Department of Psychology, Faculty of Science and Technology, Bournemouth University, Bournemouth, U.K.
SYNOPSIS: Participants in an online survey on adverse events were asked to recall a recent surgical event consistent with complication or error, depending upon the survey version they had been randomly assigned. Survey items addressed participants' event experience, including its impact on their health and well-being. A total of 445 surgeons (315 male, median age 47 years) working across different grades, specialties, and settings, completed the survey. Reported impacts from the recalled event included increased anxiety (48.3%), sleep problems (42.5%), anger or irritability (32.1%), increased depression (11.7%), and increased alcohol consumption (10.6%). The impact of the event on physical health was generally low. The error group was more likely to experience anxiety and sleep problems. Only 2.7% indicated having accessed a support service following the event. When controlling for event severity, preparedness scores differed depending on whether the event was due to an error or a complication, with lower scores in the error group. Participants felt ill-prepared by their training for the impact of adverse events. Study limitations included its retrospective nature.
CITATION: Turner K, Bolderston H, Thomas K, et al. Impact of adverse events on surgeons. *Br J Surg*. 2022;109:308-310.

—Review by Linda Kossoff

LARYNGOLOGY

Non-Steroidal Anti-Inflammatory Drugs Not Associated with Post-Tonsillectomy Hemorrhage Rates in Adults

CLINICAL QUESTION

What can be learned from a single-institution investigation into the incidence and management of adult post-tonsillectomy hemorrhage (PTH) rates, and any possible association between use of non-steroidal anti-inflammatory drugs (NSAIDs) and PTH in adults?

BOTTOM LINE

In a retrospective cohort study of 1,057 adult patients, the incidence of PTH was low, and no association between NSAID use and PTH rate was found.

BACKGROUND: Tonsillectomy is performed on 100,000-plus patients age 15 and older in the U.S. annually. The rate of PTH in adults ranges widely in the literature. Many otolaryngologists hesitate to incorporate NSAIDs into their post-tonsillectomy pain regimen due to a lack of study and these drugs' role in inhibiting platelet aggregation.
STUDY DESIGN: Retrospective chart review.
SETTING: Department of Otolaryngology–Head and Neck Surgery, Naval Medical Center Portsmouth, Portsmouth, Va.
SYNOPSIS: Researchers conducted a retrospective chart review and identified 1,057 adult patients who had undergone tonsillectomy at a single institution between Jan. 1, 2012, and Dec. 31, 2019, who did not have a bleeding disorder and/or were not taking coagulants pre-operatively. A total of 432 patients were prescribed NSAIDs for their postoperative regimen. In total, 126 (11.9%) of the 1,057 tonsillectomy patients had bleeding events, representing a higher rate of postoperative hemorrhage than is typically reported in the literature. Of the 126 patients, 29 experienced multiple events. Most of these patients did not require operating room (OR) intervention, two-thirds had bedside interventions, and roughly a quarter did not require any intervention. OR Intervention was most successful in avoiding additional hemorrhage. A subgroup analysis showed that bleeding rates in patients with and without prescriptions for preoperative NSAIDS were 12.5% and 11.9%, respectively, indicating no association between PTH and NSAID use. Authors noted that different NSAIDs have varying effects on platelet aggregation. Study limitations included the representation of only ibuprofen and naproxen in the study and the inability to collect data regarding smoking status.
CITATION: McLean JE, Hill CJ, Riddick JB, et al. Investigation of adult post-tonsillectomy hemorrhage rates and the impact of NSAID use. *Laryngoscope*. 2022;132:949-953.

—Review by Linda Kossoff

RHINOLOGY

Upper Lateral Cartilage Mucosal Flap Enables the Successful Closure of Larger Septal Perforations

CLINICAL QUESTION

What are the surgical technique and closure outcomes of larger septal perforation repair incorporating mucosa from undersurface of the upper lateral cartilage into a superiorly positioned advancement flap?

BOTTOM LINE
The ventral surface of the upper lateral cartilage can provide additional mucosa for incorporation into a superior advancement flap to achieve successful closure for larger septal perforations.

BACKGROUND: Frequently published surgical techniques for closure of nasal septal perforations use bilateral or unilateral nasal mucosal flaps. Repairs using nasal mucosa are considered the most physiologic, but flap procedures are technically difficult and outcome has not been standardized. Regardless of the procedure used, a major perforation closure determinant is defect size.
STUDY DESIGN: Retrospective case series.
SETTING: Department of Otolaryngology–Head and Neck Surgery, Mayo Clinic in Arizona, Phoenix, Ariz.
SYNOPSIS: Of 299 patients receiving mucosal flap septal perforation repairs between January 2009 and December 2020, researchers identified 66 who underwent repair using a left-sided upper lateral cartilage mucosal (ULM) flap. Prior septal surgery was the most common (28.8%) etiology, and mean perforation length and height were 18.9 and 14.4 mm, respectively. Patients' presenting symptoms included crusting (90.9%), obstruction/congestion (89.4%), epistaxis (69.7%), whistling (15.2%), and facial pain/pressure (16.7%). All repairs were performed endonasally using a three-layer repair technique. Authors noted that most septal perforations demonstrate greater horizontal length than vertical height, so attempted closure is well suited to procedures using horizontally oriented flaps superior and/or inferior to the perforation. They also noted that the superior ULM maneuver can add 1 cm of mucosa to the anterior–superior aspect of the repair. Complete perforation closure was noted in 91.2% of patients followed for six months or more. Twelve patients underwent secondary surgery for persistent nasal obstruction. Postoperative dorsal height was noted in seven patients. Study limitations related to postoperative follow-up time and the number of patients with validated outcomes.
CITATION: Bansberg SF, Taylor CM, Howard BE, et al. Repair of large nasal septal perforations using the upper lateral cartilage mucosal flap. *Laryngoscope*. 2022;132:973-979.

—Review by Linda Kossoff

LARYNGOLOGY

Vocal Fold Lipoaugmentation Provides Long-Term Voice Improvements for Glottal Insufficiency

CLINICAL QUESTION
What is the long-term effectiveness of vocal fold (VF) lipoaugmentation as a treatment for patients with glottal insufficiency?

BOTTOM LINE
Most patients who receive VF lipoaugmentation for glottal insufficiency experience a long-term benefit, although improvements in voice and swallowing taper over time.

BACKGROUND: Autologous fat injections into VFs have been used to treat glottal insufficiency. These differ from synthetic injectables in that they can avoid granuloma formation and negative voice changes and conform more naturally to existing structures. Although lipoaugmentation offers a long-term solution, direct comparisons of outcomes are complicated.
STUDY DESIGN: Systematic review.
SETTING: Department of Otolaryngology–Head and Neck Surgery, Brooke Army Medical Center, JBSA Fort Sam Houston, Texas.
SYNOPSIS: Researchers conducted a systematic search to identify articles related to VF lipoaugmentation effectiveness duration. Thirty-one articles comprising 764 patients were included in the final analysis. Eleven of the studies tracked patients for longer than one year. Primary endpoints included duration of effectiveness per patient-reported outcome measures, objective findings, and additional procedures performed. Indications for augmentation were VF paralysis (690 patients) and atrophy (74 patients). Researchers identified a broad range of autologous fat harvest sites, including the abdominal region (21 studies, 529 patients), thigh/abdomen (5 studies, 91 patients), and buccal/submental region (2 studies, 33 patients). Fat processing techniques and voice quality assessment tools varied widely. Objective measure report-

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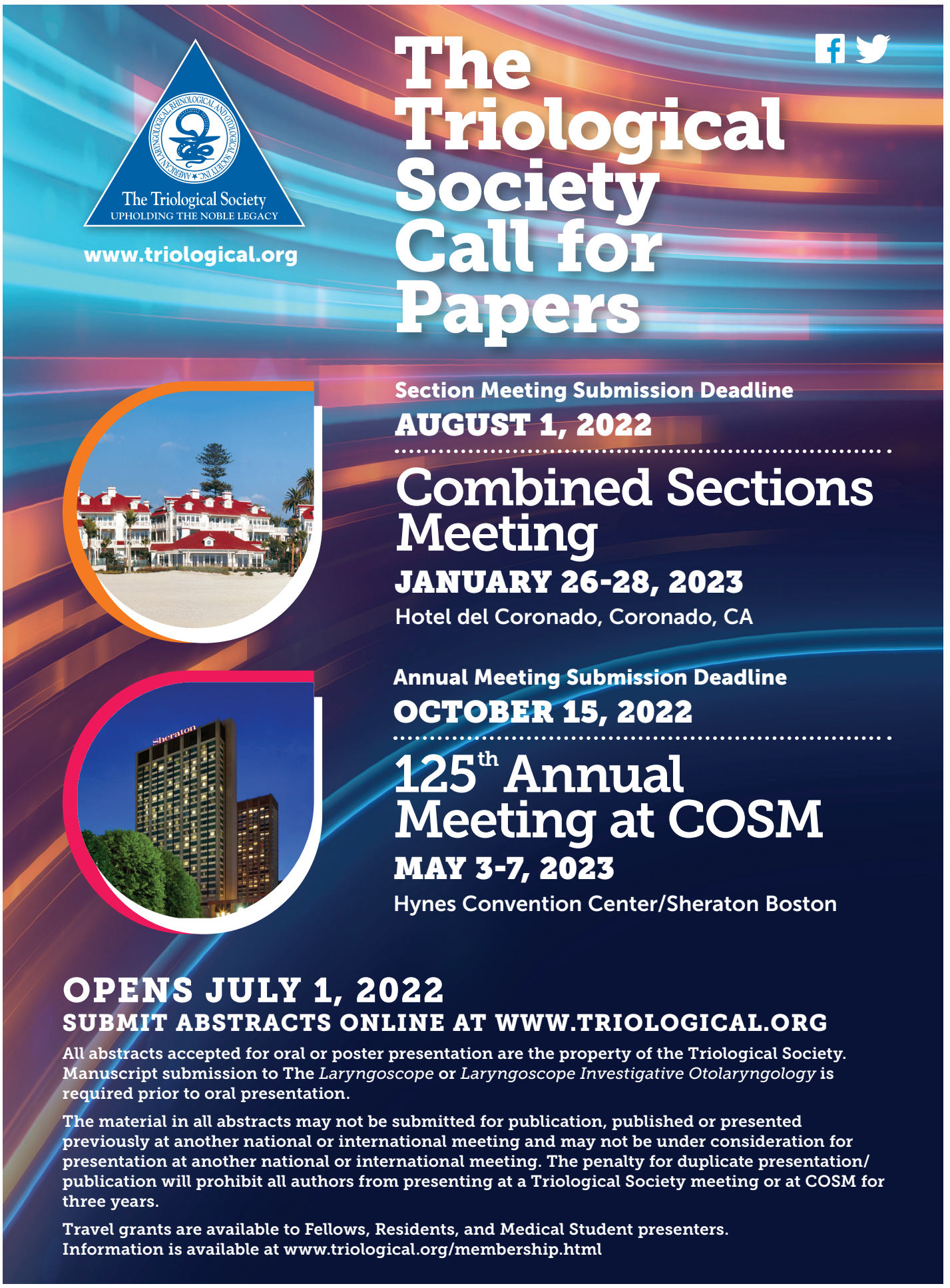

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ing was not uniform across studies and included a variety of outcomes. Long-term improvement in voice outcomes was seen, with only 11 in 764 patients (1.4%) reporting no improvement in voice and/or swallowing. Within the first year, 71 of 608 patients (11.7%) reported a regression toward baseline. Beyond one year up to eight years, 27 of 214 patients (12.6%) reported regression from initial improvement. Study limitations included limited available data and variable report mechanisms.

CITATION: Luke AS, Logan AM, Gawlik AE, et al. Autologous lipoaugmentation long-term clinical outcomes: A systematic review. *Laryngoscope*. 2022;132:1042-1053.

—Review by Linda Kossoff

OTOLOGY/NEUROTOLOGY

Vestibular Schwannoma Position Relative to Internal Auditory Canal Helps Predict Postoperative Facial Function

CLINICAL QUESTION

What is the impact of vestibular schwannoma (VS) position relative to the internal auditory canal (IAC) on postoperative facial nerve function and extent of surgical resection?

BOTTOM LINE

VS position relative to the IAC axis can be used along with tumor size to predict postoperative facial outcomes.

BACKGROUND: Treatment of VS, a benign tumor commonly arising from the vestibular branch of the eighth cranial nerve, must balance hearing/facial function preservation with tumor removal or cessation of growth. Facial paralysis risk following surgical resection in patients with VS has been correlated with tumor size, position, and growth direction.

STUDY DESIGN: Retrospective chart review.

SETTING: Department of Otolaryngology–Head and Neck Surgery, Southern California Permanente Medical Group, San Diego, Calif.

SYNOPSIS: Researchers reviewed the charts of 127 patients who underwent retrosigmoid (17%) and/or translabyrinthine (82%) resection of tumors, with a greatest tumor dimension of >25 mm, including both IAC and cerebellopontine angle components. Tumor measurements included greatest dimension, dimension anterior to the IAC axis, dimension posterior to the IAC axis, and a ratio of posterior-to-anterior dimension (PA ratio). Short term, 76 (60%) patients had good facial function, and 51 (40%) had poor function. Long term, 90 (71%) patients had good facial function; 37 (29%) had poor function. Ninety-two (72%) patients underwent gross total resection of their tumors. Although patients with good function had larger PA ratios than patients with poor function, early and long term, greatest dimension was the more significant independent predictor of facial outcomes. Patients with poor facial function in early follow-up who recovered to good function long term had significantly larger PA ratios and smaller anterior dimensions than patients who did not recover. Findings suggest that PA ratio and anterior dimension could be considered with tumor size when predicting facial outcomes. Study limitations included its retrospective nature and the limited number of patients included.

CITATION: Hobson CE, Saliba J, Vorasubin N, et al. Vestibular schwannoma cerebellopontine angle position impacts facial outcome. *Laryngoscope*. 2022;132:1093-1098.

—Review by Linda Kossoff

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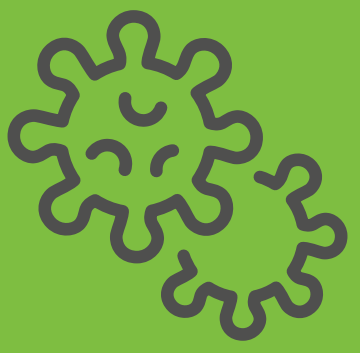

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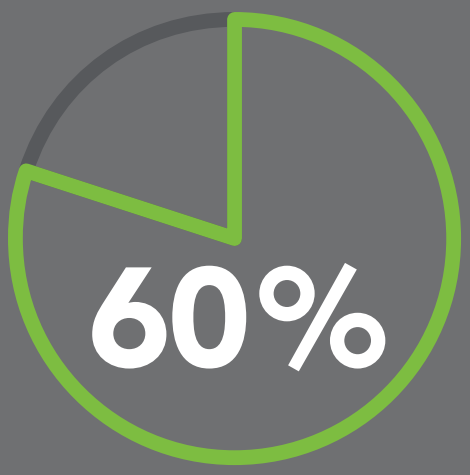

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A Better Night's Sleep?

Obstructive sleep apnea management is evolving through wearables to implantables

By **Thomas R. Collins**

One-third of the U.S. population reports tracking their sleep. We also know that insufficient sleep or poor sleep is common and related to health, so many people are motivated to understand their health and sleep better.

—Jolie Chang, MD

Treatment for obstructive sleep apnea (OSA) continues to advance, from the increasingly sophisticated realm of wearables, to evolving approaches in OSA patients who also have insomnia and post-traumatic stress disorder (PTSD), to new techniques for implantable devices. Expert panelists discussed the advances in a session at the 2022 Triological Society Combined Sections Meeting.

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Updated Wearables

Jolie Chang, MD, chief of sleep surgery and general otolaryngology at the University of California, San Francisco, said that the field is well positioned to use wearable sleep-tracking technology, as well as "nearables," or items that measure sleep when placed near a patient, such as smart beds and certain smart phone apps.

"One-third of the U.S. population reports tracking their sleep," she said. "We also know that insufficient sleep or poor sleep is common and related to health, so many people are motivated to understand their health and sleep better."

Tracking sleep with wearables, which use sound and movement to estimate the quality of sleep, to help with sleep-disordered breathing makes sense because it's a relatively common condition and patients are already armed with the tools needed to track it. "Providers and patients are set to benefit from sleep-tracking technology," Dr. Chang said. "Patients are doing it anyway—they're showing up at the clinic and saying, 'Look at my sleep quality. It's really been dipping since COVID-19,' or, 'My restfulness numbers are bad these days.' A lot of patients are asking us about their metrics."

When it comes to OSA, the use of sleep-tracking metrics seems to result in an increased use of continuous positive airway pressure (CPAP) (*Sleep*. 2015 Aug 1;38:1229-1236). These technologies can also help provide a sense of how well therapy has affected outcomes—for example, by measuring changes in snoring volume.

On the other hand, Dr. Chang said these consumer wearables and apps aren't true medical devices and their data collection typically hasn't been validated by polysomnography. In addition, they use proprietary algorithms that change routinely.

Most wearables are being studied in healthy populations rather than in those with sleep disorders, which could affect the reliability among those with sleep disorders. There has been some individual use of apps in sleep disordered patients. The SnoreLab app, which captures sound to quantify snoring levels during sleep, can be helpful in gauging progress after hypoglossal nerve stimulation surgery and during setting titration, Dr. Chang said. She reviewed an example case of one patient who had a very high snoring score of 93 on the app, which dropped to 25 after receiving his implant.

The most promising aspects of wearable and other app-related technology, at this point, might be the patient-directed motivation to improve sleeping habits and to boost treatment compliance, Dr. Chang said. "It's limited currently by the lack of validation and accuracy, but may be helpful in longitudinal care," she said.

OSA and Insomnia

Treating patients who have obstructive sleep apnea with comorbid insomnia involves a complex layering of considerations, since their sleep can be disrupted for a variety of reasons that can feed off one another, said Reena Dhanda Patil, MD, associate professor of otolaryngology and director of the Veterans Affairs Otolaryngology–Head and Neck Cancer Service at the University of Cincinnati in Ohio. These patients often have PTSD as well, she said. The sleep apnea can lead to frequent awakenings, causing insomnia, which can lead to anxiety about not being able to sleep, and on and on, she said.

"When you lump the two together you get everything," she said. "It's hard to figure out what's being caused by what." Insomnia is seen in about 50% of OSA patients, she said.

This means that when patients are considering hypoglossal nerve stimulation for their OSA, the implantation is only part of the challenge, she said. The underlying issues with sleep must be addressed for the implant to work, Dr. Dhanda said. "The device isn't magic. It only works if you sleep,'" she said.

Dr. Dhanda believes that OSA patients would benefit if cognitive behavioral therapy were more readily available to them. "Our psychology colleagues are very important," she said. "It [cognitive behavioral therapy] is the best therapy for insomnia that's out there, but it unfortunately isn't as easy to access as a sleeping pill. You can easily write someone a prescription for zolpidem, but you can't easily find them a really competent CBT provider unless you search for one."

Hypoglossal Nerve Stimulation

Maria Suurna, MD, an associate professor and the director of sleep surgery at Weill Cornell Medicine in New York City, said techniques for hypoglossal nerve stimulation are advancing. A two-incision approach, rather than using three incisions, has been shown to be noninferior and a safe and effective option for implantation of a device made by Inspire. Fewer complications and a shorter recovery time have been reported (*Otolaryngol Head Neck Surg*. Published online November 30, 2021. doi:10.1177/01945998211062150).

Although the United States differs from other countries by mostly limiting insurance coverage for the procedure to those with a body mass index (BMI) of 32 or below, Dr. Suurna noted that a registry study found that others might benefit as

CONTINUED ON **PAGE 19**

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Tympanoplasty Tips

Otology experts share advice on the many ways to surgically repair a hole in the eardrum

By **Thomas R. Collins**

How each of us do it is going to be different, and being different doesn't mean that it's less effective. It just means that through trial and error, it's what you have figured out to be the most efficient way to operate.

—Kevin Brown, MD, PhD

Tympanoplasty is a procedure that can be performed in a variety of ways, with considerations, subtleties, and preferences that differ according to the surgeon and the patient. Expert physician panelists shared their thoughts on the procedure at a session during the 2022 Triological Society Combined Sections Meeting, with the goal of helping others make their procedures more successful.

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Expert Advice

"As much as any otologic procedure we do, tympanoplasty is something that has a very personal quality to it," said Kevin Brown, MD, PhD, chief of otology and neurotology at the University of North Carolina at Chapel Hill. "How each of us do it is going to be different, and being different doesn't mean that it's less effective. It just means that through trial and error, it's what you have figured out to be the most efficient way to operate."

The panelists offered these tips:

Remove mucosa and sclerosis from the membrane. "You need to be prepared to sacrifice part or all of the eardrum in the interest of removing mucosalized or sclerotic tympanic membrane, because otherwise that will interfere with your healing," Dr. Brown said.

Recognize skin ingrowth. "If it isn't identified at the time of surgery, the skin can actually grow under the remnant of the tympanic membrane; if you try to do a medial graft and don't recognize that, it's definitely going to fail," said Joni Doherty, MD, PhD, an associate professor of clinical otolaryngology–head and neck surgery at the University of Southern California in Los Angeles.

A cartilage graft can be a helpful option. "Sometimes the fascia and perichondrium can undergo atrophy," Dr. Doherty said. "Cartilage is more resistant to resorption, it's more rigid, it has good long-term survival, and it's nourished largely by imbibement from perichondrium or from the vascularized mucosa that grow underneath it."

Situations in which cartilage should be considered are when there is atelectasis, a retraction pocket or cholesteatoma, or a high-risk of perforation or risk of procedure failure. These cases can include revision procedures, anterior perforations, or otorrhea at the time of the surgery, she said.

Studies have found a 92% closure rate for cartilage tympanoplasty, with hearing results that are comparable to procedures using fascia and perichondrium grafts, said Dr. Doherty. But a systematic review and meta-analysis found that further study is needed to assess cartilage grafts in cases of larger perforations (*Ear Nose Throat J*. doi: 10.1177/01455613211015439).

Consider an endaural approach in certain situations. Surgeons should be comfortable using an endaural approach, which incorporates the endaural incision to the traditional transcanal flap incision, allowing for improved visualization and access, said Rick Nelson, MD, PhD, an associate professor of otolaryngology–head and neck surgery at the Indiana University School of Medicine in Indianapolis.

An endaural approach should be considered with large perforations when there is a need for canalplasty to improve visualization of the entire perforation, in the case of attic disorders such as malleus fixation or small cholesteatoma, and when circumstances dictate during surgery that it would be necessary or helpful to transition from a transcanal to endaural procedure, he said.

This is especially true when there are problems completely visualizing the tympanic membrane perforation, which has been the case in revisions that he has handled when it's apparent that a poor view led to technical issues with the procedure. "Some of these are technical [mistakes] that I've seen on revision tympanoplasties, particularly when there's a large canal hump," said Dr. Nelson. "It was clear to me that the surgeon may not have been able to even see the perforation in its entirety."

Closure of the perforation alone can be a success in some cases. "Closure of the perforation without having a significant improvement in hearing can still be considered a success because there are circumstances that one encounters where the degree of tympanosclerosis is so significant and severe that you may not be able to improve their hearing," said Dr. Brown.

Don't overlook the importance of the injection. "The injection really is a critical component of the operation," Dr. Brown said. "It's something that you should do slowly and very carefully because it makes everything easier thereafter."

Be extra careful with packing in cases of lateral tympanoplasty. This is the preference of Michael Hoffer, MD, a professor of otolaryngology at the University of Miami in Coral Gables, for near-total perforations. "We place a very big emphasis on how we pack the canal after the lateral technique," he said. "It's much more critical than when you're packing after a medial technique. If you pack wrong, then anterior blunting [blunting of the anterior tympanomeatal angle, which can interfere with hearing] is going to occur."

Be diligent with the graft specimen you use in lateral procedures. "Don't get lazy on your tympanoplasty material," Dr. Hoffer said. "Get a good piece of fascia." ▲

Thomas R. Collins is a freelance medical writer based in Florida.

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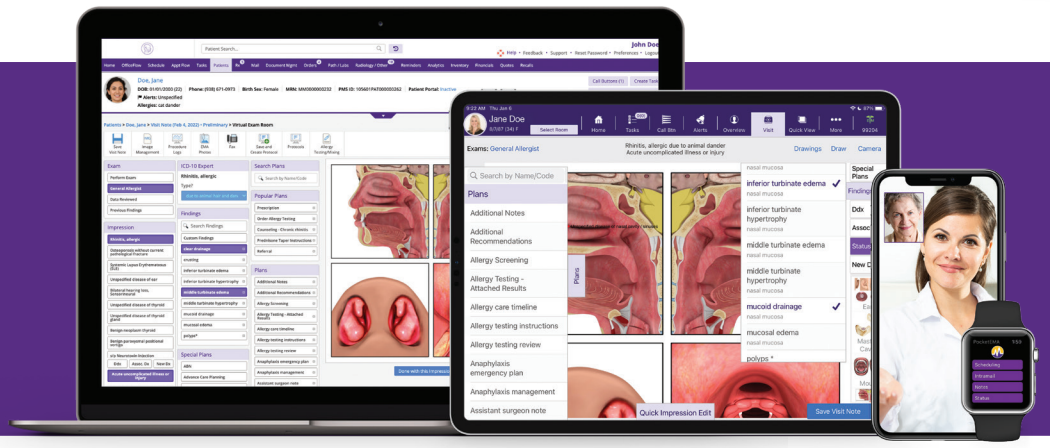

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> By **Andrew J. Tompkins, MD**

VIEWPOINT

The Otolaryngology Workforce

CONTINUED FROM **PAGE 1**

What struck me about [a recent] study is that we were edging closer to the time periods of predicted supply shortfalls, yet our supply (and supply per 100,000 population) was increasing.

—Andrew J. Tompkins, MD

of 1.8 to 3 otolaryngologists per 100,000 due to the aging of the workforce and population growth (*Otolaryngol Head Neck Surg*. 2000;123:341-356).

A follow-up study was commissioned and published in 2004. The authors made some interesting observations—in particular, that the workforce supply trends were the opposite of those that had previously been projected. The total number of otolaryngologists and number per 100,000 population were *increasing* in all areas of the country. We had risen from 3 otolaryngologists per 100,000 in 1995 to 3.2 per 100,000 in 2002 (*Otolaryngol Head Neck Surg*. 2004;131:1-15). An American College of Surgeons Bulletin article in 2012 also supported the idea that our supply per 100,000 was increasing, with 2.72 otolaryngologists per 100,000 population in 1981 rising to 3.32 per 100,000 in 2006 (*ACS Bulletin*. March 1, 2012). A slight decline to 3.26 was noted around 2009. And it was then that the shortage narrative surfaced.

Several studies peering into the horizon sounded alarm bells about the otolaryngology supply. While the American Association of Medical Colleges (AAMC) issued attention-grabbing headlines, starting in the 2010s, about looming shortages of tens of thousands of physicians, we had specific studies highlighting our apparently dire situation.

Predictions of severe specialty shortages over the next 20 years began as early as 2002 (*Acad Med*. 2002;77:761-766). New modeling forecast a shortage of between 1,600 (*HRSA*. 2016;1-14) and 2,300 (*Otolaryngol Head Neck Surg*. 2012;146:196-202) otolaryngologists per 100,000 by 2025, and 2,500 by 2030 (*Ann Surg*. 2009;250;590-597). New demand estimates from the 2012 paper also showed that we now needed 3.11 otolaryngologists per 100,000 population, which accounted for part of our expected shortfall.

One of the more recent analyses of our workforce supply, published in 2016, showed that we had 10,522 otolaryngologists in 2011 and 10,800 in 2014 (*Laryngoscope*. 2016;126:S5-S11). Despite these supply increases, we were still projected to have a shortfall. What struck me about this last study is that we were edging closer to the time periods of predicted supply shortfalls, yet our supply (and supply per 100,000 population) was increasing. I began to question the supply numbers we'd been relying on. Every study, save this most recent study, had used American Medical Association (AMA) supply data.

This begged the question as to whether AMA data are even accurate. I believe there's reason to be skeptical.

To try to understand the accuracy of the AMA supply data, I looked at the American Urological Association (AUA) census data, which has been gathered since 2014. The AUA uses two internal databases implying some level of active practice (AUA roles and board certification data) as well as the NPI file data to construct a list of possible practicing urologists and then further ensures ongoing practice by confirming names on at least two of these databases. Physicians not meeting this criteria are then systematically checked to ensure each individual is still practicing—if physicians aren't found, they aren't included. The AAMC publishes a specialty data report every other year (https://www.aamc.org/data-reports/workforce/report/physician-specialty-data-report), using the AMA physician master file that most of the previous studies used. Data were available for recent odd years for comparison.

The total urology workforce was approximately 28% greater than the AMA numbers would suggest (https://www.auanet.org/research/research-resources/aua-census/census-results). The AMA supply data are based on an "actively practicing" definition of 20+ hours of work per week. The AUA also calculates "actively practicing" urologists, although their criteria for active practice is more stringent at 25+ hours per week. And, under these more stringent definitions, the AUA workforce supply analysis was still between 1% and 11% greater than the AMA supply numbers over the three comparison years (Table 1).

The 2016 *Laryngoscope* study used our internal AAO-HNS and American Board of Otolaryngology Head and Neck Surgery (ABOHNS) data, not AMA data. Maybe this study's numbers were more spot on.

Current and Future Supply Modeling

To understand our current situation, I looked at all of our residency programs and counted each resident by graduation year, accounting for research years. In 2021, we graduated 330 residents. Had you looked at the 2016 National Resident Matching Program (NRMP) match positions, you would have predicted 304 graduates, but this number wouldn't account for DO or military programs, which are not included, or those who take research years or drop out. The difference between NRMP position prediction and reality was 8.6%.

I then applied this 8.6% difference to the predicted graduate number, based on NRMP positions five years prior, back to the 2011 graduation year, in order to derive a predicted actual graduate number for these preceding years (National Resident Matching Program, Results and Data: 2006-2016 Main Residency Match. National Resident Matching Program, Washington, DC. 2006-2016.). Using the 2016 *Laryngoscope* study supply inputs, yearly U.S. population numbers from the United Nations (https://www.macrotrends.net/countries/USA/united-states/population), and the AMA attrition rate of 1.7% (from the 2016 study), we can see that our numbers appear to be increasing both in absolute terms and also on a per 100,000 population basis. We now appear to stand at 3.5 otolaryngologists per 100,000 population—well over previous demand predictions (Table 2).

While the AMA attrition rate may be inaccurate, the 1.7% rate would have to be 41% greater, at 2.4% annually, in order to have a stable per capita supply that's still above previous demand estimates. A 2020 workforce paper (*Otolaryngol Head Neck Surg*. 2020;162:649-657) used 2019 ABOHNS supply data to show the geographic dispersion of practicing otolaryngologists, which yielded a total of 11,124 based on their calculated per capita ratio and census data. Remarkably, inserting this supply number into the above table yields an attrition rate of 2%, still not enough to stem an oversupply of otolaryngologists on a total number and per capita basis.

One of the reasons for our increasing supply ratio is that U.S. population growth has been on a steady decline for decades, with 2021 being the lowest year on record (https://www.census.gov/library/stories/2021/12/us-population-grew-in-2021-slowest-rate-since-founding-of-the-nation.html). The U.S. Census Bureau projects our population growth rate to continue at a steady decline over the

TABLE 1

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next four decades, to 0.4% annually by 2060 (https://www.census.gov/content/dam/Census/library/publications/2020/demo/p25-1144.pdf). Most previous modeling for otolaryngology demand with a projected supply need assumed an annualized growth rate of 0.7%. But we may not see that level of growth again in our lifetimes.

Our supply situation may become more heated in the coming years. Based on my trainee analysis, graduates will increase from 330 in 2021 to 367 in 2025. We have added nine new otolaryngology training programs in the last six years, three of which will start accepting new residents in 2022. Other programs have increased their complements. This rate of growth is more than double that of the previous two decades, at a time when we appear to be in oversupply. This growth belies the notion that our graduate numbers are stable or that we need more GME funding to grow residency slots—our programs are happily doing so anyway.

Projecting our supply per 100,000 population out to 2025 is also instructive. Using the directly measured resident graduate numbers, the AMA attrition rate of 1.7%, and a stable population growth of 0.5%, we should have an expected supply of 3.61 otolaryngologists per 100,000 in 2025. Remember: We were to have significant supply shortages by 2025, below the demand estimate of 3.11 otolaryngologists per 100,000 population.

We aren't suffering from a deficit—we're growing in number, and far too quickly.

Fellowship Growth

We've also witnessed a steady increase in fellowship training. Studies show that the pursuit of fellowship has increased from an already historically elevated 46% in 2011 to 62% in 2019 (*Otolaryngol Head Neck Surg*. 2021;165:655-661). Without question we expanded our reach into the head and neck, but have we gone too far? Evidence shows that we almost assuredly have.

In 2013, a neurotology workforce study was conducted, estimating that, due to supply numbers and shifting treatment paradigms, we had a 10% to 15% oversupply of neurotologists (*Otol Neurotol*. 2013;34:755-761). Over the subsequent seven years, however, while the U.S. population saw a 4.6% increase, the number of neurotology fellowship positions increased by 37% (https://apps.acgme.org/ads/Public), fueling a 49% increase in the neurotology workforce by 2020 (*Otol Neurotol Open*. 2021;1:e007).

This trend isn't unique to neurotology. Head and neck oncology appears to be on a similarly compromising path. In 1997, we graduated seven accredited head and neck fellows per year, a number that grew to 43 fellows per year by 2017, with 50 positions offered (*Head Neck*. 2020;42:1024-1030). Some of this increase was due to assimilation of non-accredited programs, and our ability to expand into skull base and reconstructive surgery has justified some growth. But our incidence of head and neck cancer per 100,000 population has been on a steady decline over this same time period. We may be overestimating the career demand for current graduating fellows.

Rhinology fellowship spots have grown by 14%, compounded annually, from 2006 to 2017 (*Laryngoscope*. 2020;130:1116-1121). Modeling in this paper predicts that we'll surpass demand by 2024, with a 40% excess supply of rhinologists in 15 years if nothing changes, assuming that our current rhinologist-to-population ratio is appropriate. But is it? A 2017 survey of rhinology fellowship directors showed that most believe that we've been training too many rhinologists—a strong majority (59%) thought this was true with respect to the private practice supply, 85% with respect to academia, and 62% for general

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Over the subsequent seven years, however, while the U.S. population saw a 4.6% increase, the number of neurotology fellowship positions increased by 37%, fueling a 49% increase in the neurology workforce by 2020.

—Andrew J. Tompkins, MD

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4:00 – 5:00 pm (PST) Challenging Cases in Laryngology Panel (1.0 CME Credit)

- **Lee M. Akst, MD**, Director**,** Division of Laryngology; Associate Professor, Johns Hopkins Medicine Department of Otolaryngology – Head and Neck Surgery
- **Amanda Gillespie, PhD,** Director, Speech Pathology; Co-Director, Emory Voice Center; Assistant Professor, Emory University School of Medicine
- **Shigeru Hirano, MD, PhD,** Professor and Chair, Department of Otolaryngology – Head and Neck Surgery, Kyoto Prefectural University of Medicine
- **Clark A. Rosen, MD,** Co-Director of the UCSF Voice and Swallowing Center, Chief of the Division of Laryngology, Professor of Otolaryngology – Head and Neck Surgery
- **Sarah L. Schneider, MS, CCC-SLP,** Co-Director, UCSF Voice and Swallowing Center, Director, Speech-Language Pathology, Assistant Clinical Professor, Department of Otolaryngology – Head and Neck Surgery

- **Moderator: Vyvy N. Young, MD, FACS,** University of California San Francisco, Associate Professor of Otolaryngology – Head and Neck Surgery

Lewis F. Morrison, MD

Shigeru Hirano, MD, PhD

5:00 – 6:00 pm (PST) Morrison Endowed Lecture
"Regenerative and Anti-aging Treatment of the Vocal Fold" (1.0 CME Credit)

- **Shigeru Hirano, MD, PhD** - 2022 Endowed Lecturer
  Professor and Chair of Department of Otolaryngology – Head and Neck Surgery, Kyoto Prefectural University of Medicine

> By **Andrew J. Tompkins, MD**

The Otolaryngology Workforce

CONTINUED FROM **PAGE 17**

healthcare delivery (*Am J Rhinol Allergy*. 2019;33:8-16).

And these thoughts aren't unique to rhinology. Academic pediatric otolaryngologists had similar thoughts in 2014. Again, a strong majority (70%) said that job prospects nationwide were going to look worse over the coming three years. Over 85% believed this to be true for their local community, where they had more intimate knowledge, with 68% saying job prospects over the next three years would be limited or extremely limited (*JAMA Otolaryngol Head Neck Surg*. 2016;142:823-827). This study looked out only to 2017. Since then, we've increased the number of pediatric otolaryngology fellowship spots by 30%.

Two things happen with fellowship training—a new skillset is produced that needs to be maintained/sharpened, and unused, previously acquired skillsets wane. This trade-off affects more than just the supply of generalists. It can present a safety issue for patients when oversupply leads to underutilization of a newly acquired skillset. On the flip side, a waning skillset decreases the ability to fully meet actual demand. In short, what appears to be happening is that we're creating excess supply while making that supply less generally capable.

Advanced Practice Provider Growth

Advanced practice providers (APPs)—physician assistants and nurse practitioners—increase our productivity, which increases our effective supply. The 2012 workforce paper modeled out APP growth to 2025, estimating we would have between 2,944 and 3,351 APPs in our specialty by 2025 (*Otolaryngol Head Neck Surg*. 2012;146:196-202). Two recent studies showed APP growth rates in our field between 2012 and 2017, which demonstrated between 8.7% and 16.6% annualized growth over that time period (*Otolaryngol Head Neck Surg*. 2021;165:69-75; *Otolaryngol Head Neck Surg*. 2021;165:809-815). These growth rates are well in excess of the 2012 paper's supply modeling. It's important to note, though, that modeling APP growth has proved difficult because few direct supply measurements exist, and the two recent APP studies noted above counted only independent Medicare billing. That means APP supply may be below the 2012 estimates, or well above

And these productivity increases allow us to meet the same patient demand with fewer otolaryngologists. According to a 2016 survey, the average physician assistant had 5,000 office visits and performed 400 procedures a year (*Laryngoscope*. 2018;128:2490-2499). A recent pediatric otolaryngology APP assessment showed that 90% of academic practices used APPs, who, on average, handled 16% of total visits (*Int J Pediatric Otorhinolaryngol*. 2020;129:1-4). Unfortunately, none of our prior otolaryngology supply modeling accounted for APP use and the resultant productivity gains in their shortfall predictions.

The Challenges of Rural Care

The challenge of rural healthcare—lack of delivery of talent when and where it's needed—could be its own article. Our studies are quite clear: Otolaryngologists tend to cluster in urban centers (*Otolaryngol Head Neck Surg*. 2020;162:649-657). Urban employment

THE TRIOLOGICAL SOCIETY

124TH ANNUAL MEETING AT COSM

APRIL 29-30, 2022 * HYATT REGENCY, DALLAS

The 124th Annual Meeting will feature general, concurrent and panel presentations designed to appeal to all otolaryngologist-head and neck surgeons, residents and medical students. Scientific sessions will be held all day Friday and Saturday morning. State-of-the-art clinical and research poster presentations will appeal to general and subspecialty otolaryngologists, and numerous opportunities will be available for review of posters and discussion with authors. Scientific session highlights include the annual Ogura Lecture to be given by Lara Jehi, MD MHCDS, Chief Research Information Officer at Cleveland Clinic. All COSM registrants are invited to attend her special lecture on "Artificial Intelligence and Quantum Computing in Medicine" on Friday morning at 8:50 am. The scientific program includes panels on "Patient Safety and Quality in Pediatric Airway", "Expanded Indications for Cochlear Implantation", "Facial Plastic Surgery: New Approaches in our Practices", "The Role of the Otolaryngologist in Managing Chronic Cough", "Lessons from COVID-19", "Advancing Efficiency/Reducing Waste in Otolaryngology: Examples from the Front Lines".

Triological Society Fellows are invited to attend the New Fellow Ceremony and reception on Friday at 7:00 am.

	Wednesday April 27	Thursday April 28	Friday April 29	Saturday April 30	Sunday May 1
AM	AAFPRS AHNS-C	AAFPRS AHNS-C ARS	ALA ARS TRIO-C	ABEA AOS ASPO TRIO	ABEA ANS ASPO-C
PM	AAFPRS AHNS-C	AHNS-C ALA ARS	ABEA AOS ASPO TRIO	ALA ANS ASPO-C	

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TABLE 2

YEAR	PREDICTED*	ACTUAL**	U.S. POPULATION	OTOLARYNGOLOGISTS	ATTRITION	OTO/100K
2011	264	287	311,584,047	10,522	179	3.38
2012	270	293	314,043,885	10,630	181	3.38
2013	273	296	316,400,538	10,742	183	3.40
2014	275	299	318,673,411	10,800	184	3.39
2015	280	304	320,878,310	10,915	186	3.40
2016	283	307	323,015,995	11,033	188	3.42
2017	285	309	325,084,756	11,153	190	3.43
2018	292	317	327,096,265	11,273	192	3.45
2019	295	320	329,064,917	11,398	194	3.46
2020	299	325	331,002,651	11,525	196	3.48
2021	304	330	332,915.07	11,653	198	3.50

*Predicted residency graduates based on NRMP data from five years prior

** Actual based on 8.6% higher rate on direct measure for 2021 class

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is a growing trend by age bracket, with younger surgeons pursuing more urban employment (2019 Urology Census, Page 24). Fewer medical students now hail from rural areas, where they would be more likely to practice (*Health Aff.* 2019;38:2011-2018). We aren't uniformly dispersed by either county or hospital referral region (*Otolaryngol Head Neck Surg.* 2020;162:649-657), and some of our supply gap areas are massive. The question is, can we do better?

Access to care, more specifically convenience and timeliness, affects outcomes. Almost 98% of head and neck surgeons practice in urban settings (*Head Neck.* 2020;42:1024-1030). Given this number, is it any wonder that we see disparate Kaplan-Meier curves for rural patients, most notably for minority rural patients? A recent 10-year analysis that included tens of thousands of head and neck cancer patients (excluding oropharyngeal cancer) demonstrated this result (*Cancer Epidemiol Biomarkers Prev.* 2020;29:1955-1961). Differences persisted after controlling for socioeconomic status, demographics, and clinical factors. Stop and think about this for a moment. These aren't curves—they represent thousands of people who might live with better access and care coordination.

Maximizing the impact of our workforce is perhaps one of the biggest quality improvement initiatives we could undertake. Rural patients ideally need well-trained general otolaryngologists and convenient access to specialty care. We seem to be trending away from the well-trained generalist, however, toward an overabundance of subspecialty care concentrated in urban settings. How much of this migration is driven by generational preferences, or by fellowship training? And are our patients paying the price in both locations due to market saturation of fellows in urban centers and nonavailability of generalists with maximized skillsets in rural settings?

A Cautionary Note

Some may think that my analysis is too bleak. After all, haven't we always had good jobs available? Hasn't everyone predicted a shortfall in supply? Didn't I just read that we'll need over 100,000 more physicians in just 12 more years? My answer would be to examine the situation with emergency medicine (EM).

Like otolaryngology, EM was in demand and shortages were predicted. But after years of skyrocketing training program growth and APP involvement, researchers now think that in just eight years there will be over 10,000 more EM physicians than jobs available if nothing changes (*Ann Emerg Med.* 2021;78:726-737). Adaptive changes produce only a modest reduction in this number. (Coincidentally, this amounts to a 13% excess supply in their workforce, which matches our supply excess between the above supply and demand estimates of 3.61 and 3.11 for 2025). If you started medical school right now and wanted to go into EM, you might not find a job.

Correcting this oversupply of EM physicians relies on transparent, widely disseminated knowledge and an adaptable system. As you'll see in the next article, I don't believe we have enough transparency in our field, and our system, as presently designed, isn't accountable.

We have serious issues to investigate if we want to optimize our workforce and care delivery. We should question historical narratives, take ownership of our own data, and seek to understand the truth about what's happening in the otolaryngology market. To that point, we should also rethink the basic supply metric itself—the number of otolaryngologists per 100,000 population. The truth of our supply adequacy lies in different metrics.

(*Next Month: Rethinking Supply*) ▲

Dr. Tompkins is a private practice otolaryngologist in Columbus, Ohio.

> **Rural patients ideally need well-trained general otolaryngologists and convenient access to specialty care. We seem to be trending away from the well-trained generalist, however, toward an overabundance of subspecialty care concentrated in urban settings.**
>
> ***—Andrew J. Tompkins, MD***

A BETTER NIGHT'S SLEEP

CONTINUED FROM **PAGE 12**

well. Results for those with a BMI of 32 to 35 were noninferior to those with a BMI of 32 or below when it came to change in apnea-hypopnea index, she said. Those with the higher BMI, however, were less likely to achieve mild or no sleep apnea (*Laryngoscope.* 2021;131:2616-2624).

A newer device with no implantable battery called the Genio is currently in clinical trials in the United States, Dr. Suurna said. Most trials exclude patients with complete concentric collapse (CCC) at the velopharynx, but the procedure using the Genio might be an option for these patients, she said. A study on patients with CCC and patients without CCC is also underway in Australia and New Zealand. No results have been released, but a case report shows good results for one patient with CCC who had severe sleep apnea (*Clin Case Rep.* 2021;9:2222-2224). "Hopefully we'll be able to implant patients with complete concentric collapse in the future," Dr. Suurna said.

In another encouraging sign for the field, combining ansa cervicalis stimulation, a neurostimulation mechanism for generating caudal pharyngeal traction, combined with hypoglossal nerve stimulation resulted in a greater cross-sectional measurement of the airway and in expiratory airflow (*Chest.* 2021;15:1212-1221).

It's important to select patients carefully when deciding whether to move forward with hypoglossal nerve stimulation, said Dr. Dhanda. Their sleep habits, mental health history, pain issues, use of sleep aids, and nocturia all need to be considered. Physicians should try to answer the question of why CPAP didn't work for these patients. "I'm almost always on the phone with, emailing, or messaging their referring physicians to figure out how we can help them with some of these issues," she said. ▲

Thomas R. Collins is a freelance medical writer based in Florida.

> By **Linda Kossoff**

Innovative Recruitment

CONTINUED FROM **PAGE 1**

Students often feel pressure to pursue activities they perceive as more valuable to programs to match at the expense of following their own passions and interests. Programs have difficulty determining which applicants have a genuine interest in their program.

—Ilana Rosman, MD

Although such steps have been needed for some time, COVID-19 seems to have sped up development. "The medical education environment was already evolving and changing, and COVID presented an opportunity to improve the system. Many medical and surgical specialties explored and implemented unique programs or initiatives," said Sonya Malekzadeh, MD, residency program director and professor of otolaryngology–head and neck surgery at Georgetown University Medical Center in Washington, D.C. Moreover, these specialties are taking cues from each other, incorporating numerous practices to employ in their own programs to everyone's benefit. The common goal is to achieve the best matches by providing less stressful and more promising pathways to placement for applicants, and a more effective and holistic recruitment review process for programs.

Supplemental and Specialized Applications

Today's high volume of applications means more time and money spent, not to mention increased stress. But that's not all, said Ilana Rosman, MD, associate professor in internal medicine (dermatology) and pathology and immunology, and dermatology residency director at Washington University School of Medicine in St. Louis. "The volume also contributes to suboptimal outcomes, particularly related to applicant–program fit and medical education," she noted. "Students often feel pressure to pursue activities they perceive as more valuable to programs to match at the expense of following their own passions and interests. Programs have difficulty determining which applicants have a genuine interest in their program."

To help address these challenges, the dermatology specialty participated in the supplemental Electronic Residency Application Service, or ERAS, application pilot program offered through the Association of American Medical Colleges. "Completed in addition to the traditional MyERAS application, the supplemental application asked applicants to describe their five most meaningful activities or experiences and allowed them an opportunity to provide additional information about their journey to residency," Dr. Rosman explained. "They were also able to denote up to three preferred programs and three preferred geographic regions."

According to Dr. Rosman, the supplementary application proved useful. "Certain qualities, including sustained engagement in activities, leadership experience, and commitment to diversity and inclusion are important to us," she said. "It was easier to identify applicants with these elements."

The plastic surgery specialty applied a different application approach to residency recruitment through a piloted process called the Plastic Surgery Common Application (PSCA) (https://acaplasticsurgeons.org/Resources/match-faq.cgi). Built separately from the ERAS, the PSCA was administered at no cost to applicants. "We believe that applying to residency shouldn't be prohibitively expensive," said Brian C. Drolet, MD, an associate professor and vice chair of education in plastic surgery and program director of integrated plastic surgery residency at Vanderbilt University School of Medicine in Nashville. "Cost is a major barrier to many residency applicants, and there are major equity issues inherent in the current process. The PSCA seeks to eliminate these financial barriers." The goal, he added, is to ultimately use the PSCA only, "and save applicants an average of $1,500 in application fees."

The PSCA was strategically designed to focus on quality over quantity. "ERAS applications can be 50 pages or longer, and many plastic surgery programs will get more than 300 applications for one or two positions," Dr. Drolet said. "There's no way that programs can look holistically at applicants; instead, they're screened by arbitrary and often inappropriate metrics. We think that students should focus on depth of engagement and demonstrate truly meaningful accomplishments." He believes the best way to find a good match is to "interview a group of applicants who demonstrate a strong likelihood upfront, and that only happens when applications are reviewed holistically rather than screened based on Step scores or number of publications."

Preference Signaling

Otolaryngology is among the specialties dealing with more applicants for residency positions than there are positions available, said Marc Thorne, MD, MPH, associate chair for education and quality, clinical professor in otolaryngology–head and neck surgery, and division chief of pediatric otolaryngology at the University of Michigan Medical School (UMMS) in Ann Arbor, as well as the current chair of the Otolaryngology Program Directors Organization (OPDO). "Our specialty has led in attempting to innovate and improve in the residency recruitment process over the last several years. Otolaryngology–head and neck surgery was the first specialty to institute the process of preference signaling, in which the OPDO serves as a trusted source for prospective otolaryngology residents who wish to signal their special interest in a small number of programs," he explained.

The preference signaling process was introduced in the 2021 residency application cycle. At the time of submission, otolaryngology applicants were permitted to signal up to five programs of interest. The programs then received a list of applicants who submitted signals to consider during interview offer deliberations (*Acad Med*. Published online October 5, 2021. doi:10.1097/ACM.0000000000004441). According to Dr. Thorne, preference signaling has resulted in applicants receiving significantly more interview offers from programs in which they were most interested. The practice has since been adopted by several other specialties. The program has been so successful, in fact, that the ERAS "is exploring incorporation of signaling into the formal application system," noted Dr. Malekzadeh, who, as immediate past chair of the OPDO, was among the leaders who developed the process.

Maya Hammoud, MD, MBA, research professor of obstetrics and gynecology, professor of learning health sciences, chief of the women's health division, and associate chair for education at UMMS, described her specialty's plans for a variation on preference signaling. "Instead of signaling five or fewer programs, we would use a two-tiered signal in which the applicant gets three gold tokens and 15 silver tokens for a total of 18 programs signaled because we're a much bigger specialty," she explained. "We think that this might help eventually reduce the number of applications; now, students are applying to as many as 70 programs." The token process would be implemented for the 2023 Match, she added.

Standard Interview Date

Residency application is stressful enough without adding the uncertainty of not knowing when or if an interview offer might be on the way. By establishing a common or standard interview date, specialties such as otolaryngology and OB-GYN have created a finite window of time in which residency applicants can expect to receive an interview offer (*J Surg Educ*. 2021;78:1091-1096).

"Prior to the common interview date, otolaryngology applicants would anxiously hover over emails waiting for interviews to trickle in," said Dr. Malekzadeh. "It wasn't uncommon to hear

CONTINUED ON **PAGE 22**

Pandemic Clarifies the Long-Term Path:

What Running a Practice and an Ultra Marathon Have in Common

Don't go it alone. That may seem like strange advice from an ultra-marathon runner like Dr. David Lehman, accustomed to going solo for distances up to 100 miles or more. But he has a team of people backing him up, both as a runner and in his professional life.

In the following Q&A, Dr. Lehman shares his advice for overcoming such hurdles and his inspiration for keeping long-term goals in mind, despite more immediate, inevitable setbacks.

Q: Can you share an example of a hardship you faced and how you handled it?

Dr. Lehman: There are some situations in life where you don't have a choice whether you succeed or not. Hardships will come up, and sometimes you don't have the time or luxury to decide if you want to go forward. You just have to keep moving – relentless forward progress.

As an example, I once got lost running a 125-mile ultra-marathon on a poorly marked trail through the swamp at night. I was on my own, soaking wet, in 40-degree weather. It dawned on me that if I didn't find my way out, I could die from hypothermia that night.

I knew no one was coming to get me, as the race was unsupported, and I was well outside of cell phone range. Rather than panic, it gave me this really bizarre sense of calm. I realized I didn't have a choice — I had to stay calm and figure it out.

Often in medicine, we don't have a choice either. We have to give everything we have to care for a patient. Once a person is under our care, we really have no other option but to do absolutely everything we can to get the best possible outcome.

That's also how I want my own doctor to think.

Q: How has the COVID-19 pandemic specifically affected you and your ENT colleagues?

Dr. Lehman: We are all comfortable wearing masks now. I wonder why we didn't use them all along, before COVID-19.

Otolaryngology is the highest-risk outpatient specialty for potential exposure to an aerosolized, infectious agent like SARS-CoV-2. When we examine patients, we do so only 6 to 10 inches from their faces. About half of our patients present with respiratory symptoms, and we're performing procedures that might make people cough or sneeze.

We knowingly put ourselves at significant risk yet forge ahead. Knowing we have a tool (an N95 mask) that can reduce that risk and allow us to perform to the best of our ability is invaluable.

Q: How has the COVID-19 pandemic helped you focus on the long view?

Dr. Lehman: The pandemic has been an opportunity to take a step back and look at the bigger, long-term picture. Taking the macro view is essential as an ultra-marathon runner.

You can't just plan for tomorrow — you have to look a hundred miles ahead. You also realize that covering so much ground means facing a lot of challenges and hardships along the way. You have to become comfortable with discomfort. "Obstacles are stepping stones that guide us to our goals" — one of my favorite Phish lyrics that makes me view hard times with a better perspective.

Q: How does that apply to medicine?

Dr. Lehman: The same applies in medicine, particularly with the major changes we've faced in the past few years. It's about anticipating and preparing for the hurdles, which makes it easier to get over or around them.

Q: I've heard you say that the right tools can help you succeed. Can you expand on that?

Dr. Lehman: Electronic medical records, for example, can help you tremendously in the long run. The key is using an efficient and user-friendly EHR system and practice management software that work together seamlessly. These tools, when designed for ENTs by ENTs like ModMed®, can be even more user-friendly.

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Q: How essential is teamwork to you as a runner and as an ENT?

Dr. Lehman: The difference between success and failure is often the people around you.

Support makes a difference. Some ultra-marathon runners have a team that waits a few miles ahead to provide food, water, and other assistance as needed.

There have been races I shouldn't have finished. The only reason I did was because of the people who supported me along the way, especially when things got more challenging.

It's the same with otolaryngology. As an ENT I need the help of my nursing staff, OR staff, and everyone else who supports me in optimizing care for our patients.

Q: How important is flexibility going forward?

Dr. Lehman: Medicine is always evolving — there are always new advances. There's always something better we can do, and you have to evolve and adapt.

Running can also be different one day to the next, based on your body, the weather, the conditions of the trail, and more. You need to be ready to adapt to those situations. Finishing a 100-mile race is often more about recognizing and anticipating that things will not go to plan, and then persevering and overcoming those obstacles, than just running fast or far.

Dr. Lehman is an otolaryngologist in private practice in West Palm Beach and senior medical director at ModMed, the specialty-specific software solutions and revenue cycle management services firm in Boca Raton, Florida.

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> By **Linda Kossoff**

Innovative Recruitment

CONTINUED FROM **PAGE 20**

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> **Through the combination of changes, we were able to interview more applicants and allow them to learn more about our program before deciding to spend additional money to visit.**
>
> *—Cheryl O'Malley, MD*

of students asking parents and friends to monitor their emails or pulling off to the side of the road to respond to an invitation. It created a lot of unnecessary anxiety."

"We set the standard interview offer date to about three to four weeks after applications open to give the programs opportunity to holistically review and discuss the applicants," said Dr. Hammoud. "We found that when we offer interviews on only one day, the applicants don't over-interview. They have all the offers at once and can decide which program they really want."

Technology-Based Tools

The COVID-19 pandemic expanded the use of technology-driven communication in residency recruitment. "There has been much more intentional effort to expose applicants to programs through social media and other virtual events," noted Dr. Hammoud. "Our national organization, the American College of Obstetrics-Gynecology (ACOG) and CREOG [Council on Resident Education in Obstetrics and Gynecology] sponsored a virtual residency fair largely driven by interns and medical students. They highlight programs and offer best practices on social media platforms like Twitter and Instagram."

In 2018, the internal medicine residency program at the University of Arizona College of Medicine–Phoenix started conducting all-virtual interviews. Then-program director Cheryl O'Malley, MD, associate professor and associate dean of graduate medical education at the university, found inspiration from the 2015 book *Work Rules* by Lazlo Bloch, former senior vice president of people operations at Google. "He described Google's approach to recruitment, and I realized that young professionals are looking for a program that aligns with their values," she said. "One of our values is innovation, so having a new, thoughtful approach to interviewing that was also creative and responsive to evolving challenges and opportunities aligned with our values. I'd always interviewed all applicants and found it an important time to highlight our family-feel and personal interest in them, so we needed to maintain that, while minimizing the impact of interviews on patient care and education. It was a risk, but through the combination of changes, we were able to interview more applicants and allow them to learn more about our program before deciding to spend additional money to visit."

Early Match, Early Acceptance

Spurred by its exploding number of applicants, obstetrics–gynecology has been at the forefront of recruitment innovation. In 2020, the Association of Professors of Gynecology and Obstetrics received a grant from the American Medical Association (AMA) dedicated to the purpose. Dr. Hammoud is the primary investigator for the grant.

Among the ideas that Dr. Hammoud and her colleagues explored was an early results acceptance program (ERAP). With ERAP, students apply to a limited number of programs; in turn, the programs allot a portion of residency openings to these applicants (*JAMA*. 2020;323:503-504). "We end up doing a quick first-stage match; that applicant doesn't go into the regular match group," said Dr. Hammoud. "We get these early matches out of the system using less money and fewer resources. It also encourages our programs to do the holistic review, because they have more time to look at applications."

A 2021 survey study to gauge OB-GYN stakeholders' interest in ERAP showed broad support for the program, and survey responses suggested that an ERAP in the specialty could reduce applications by approximately 33% (*JAMA Netw Open*. 2021;4:e2124158). Currently, the neurology, neurosurgery, ophthalmology, and urology specialties participate in an early match process for residency program applicants.

Situational Judgment Tests

Professional and interpersonal skills are essential in a medical career but aren't easily evaluated via standard applications or even interviews. In 2020, Michael Cullen, PhD, senior director of assessment, evaluation, and research in graduate medical education at the University of Minnesota Medical School in Minneapolis, along with a team of researchers, developed a 45-minute, online situational judgement test (SJT) designed to measure conscientiousness, integrity, accountability, teamwork, stress tolerance, aspiring to excellence, and patient-centered care as they would present in the residency setting (*Teach Learn Med*. 2020;32:508-521). In the test, the applicant is presented with situations they're likely to encounter as a resident or fellow and then given lists of possible responses and/or actions, each of which must be rated on a scale of 1 to 7 ("completely ineffective" to "highly effective"). The SJT is automatically scored, requiring no input from faculty, and comes with a development report for matched trainees, which can be used for setting professionalism goals for trainees.

Applicants in dozens of residency and fellowship programs in psychiatry and other specialties took part in the SJT pilot. In their study paper, researchers concluded that the tests "show promise as a method for assessing noncognitive attributes in residency program applicants." Dr. Cullen cited the SJT as another tool that could be used to achieve a more holistic review of candidates without adding the need for faculty input.

The Future of Recruitment

As the number of residency applicants continues to rise, medical education leaders are working on additional ways to improve and refine the recruitment process. Dr. Hammoud and her colleagues are working with the AMA on a proposed system alignment check index system that would help students pinpoint programs to which they are most aligned. Programs would apply "weights" in six key aspects of their offerings and applicants would use that information to self-evaluate their suitability. "It's kind of like a dating app," said Dr. Hammoud, "but because the applicant is self-evaluating, it's to their advantage to be accurate. No one else sees it but them."

Dr. Rosman would like to see continued collaboration between specialties to address the challenges of the application process. "Many of the pain points are similar across specialties," she emphasized. "Working together, we can come up with innovative ways to solve problems within the current system."

To encourage development of a system where applicants could apply to far fewer programs and reviewers could be more thoughtful, Dr. Thorne supports greater transparency among programs regarding their selection criteria and the attributes they value most highly. "Applicants may benefit from seeing data about their likelihood of matching at a limited number of programs they identify ahead of the process as their preferred destination," he said. "This may support a cap on applications in the future." ▲

Linda Kossoff is a freelance medical writer based in California.

Consider an Investigational Immunotherapy Trial for Patients With

Head and Neck Squamous Cell Carcinoma and Cutaneous Squamous Cell Carcinoma.

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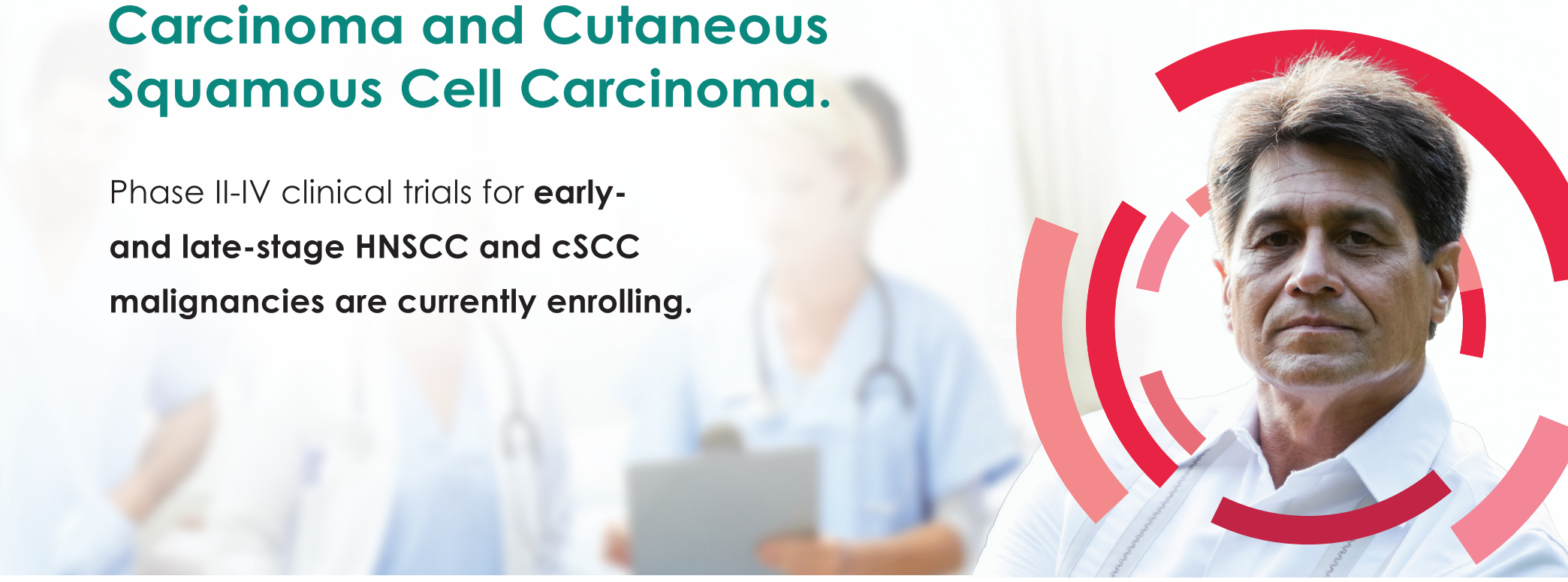

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Cutaneous Squamous Cell Carcinoma

KEYNOTE 630

- A study of pembrolizumab monotherapy following surgery and radiation therapy for patients with high-risk, locally advanced cSCC

Head and Neck Squamous Cell Carcinoma

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- Primary tumor must be in the oropharynx, oral cavity, hypopharynx, or larynx*

Treatment-Naïve Trial

KEYNOTE 689

- A study of pembrolizumab as neoadjuvant and adjuvant therapy plus surgery and RT ± cisplatin for patients with previously untreated, resectable, locoregionally advanced HNSCC (Stage III or IVA)

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LEAP-009

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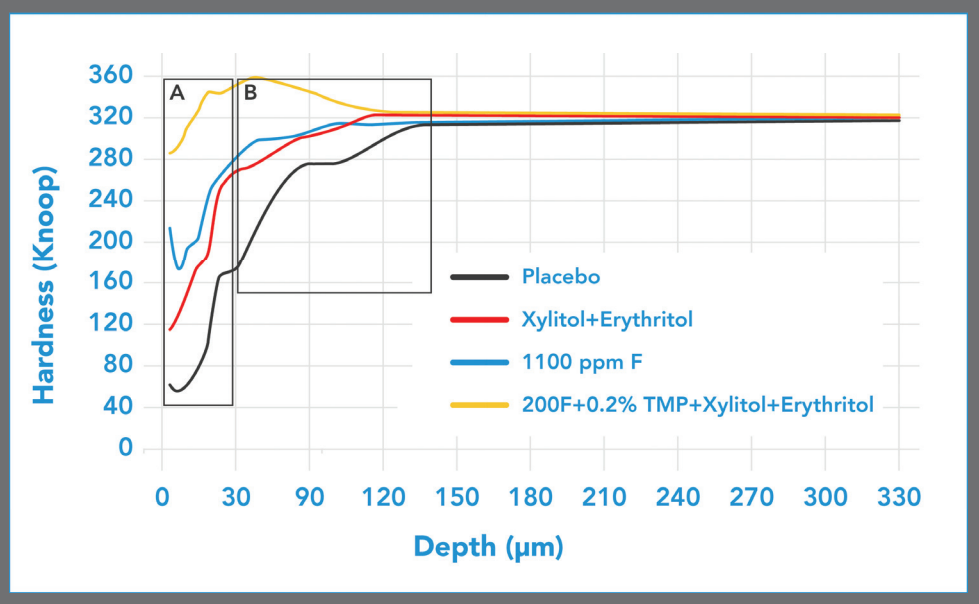

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