Evidence-Based Medicine in Otolaryngology, Part 6: Patient-Reported Outcomes in Clinical Practice

Thomas L. Carroll, MD¹, Stella E. Lee, MD², Robin Lindsay, MD¹, Drew Locandro, MD³, Gregory W. Randolph, MD¹, and Jennifer J. Shin, MD, SM¹

Abstract
The assessment of patient-reported outcome measures (PROMs) in the outpatient setting is gaining momentum in clinical and research venues. Implementing this data capture into one's practice, however, is not a one-size-fits-all venture, and it is critical to determine when, how, and where to include these patient-centered assessments. This installment of the “Evidence-Based Medicine in Otolaryngology” series provides insight into the implementation process and experiences with successful incorporation of PROMs into clinical practice. Specifically, 4 differing clinical scenarios and collection techniques are described, including data acquisition protocols, formats for clinician data usage, and applications of PROM results in clinical and research scenarios.

Keywords
patient-reported outcome measures, validated instruments, clinical practice, data capture, private practice, rhinology, laryngology, facial plastic surgery

Received April 1, 2017; revised July 7, 2017; accepted August 25, 2017.

This sixth installment in the “Evidence-Based Medicine in Otolaryngology” series explores how patient-reported outcome measures (PROMs) may be integrated into clinical practice. PROMs provide quantitative insight into patients’ perceptions of their disease-specific or general health, conveying an organic and essential understanding of their firsthand experience.¹ They may also be used as the basis for enhanced clinical interactions, quality improvement initiatives, and longitudinal outcomes research. In fact, some clinicians view their patients’ PROMs as a requisite “vital sign,” a key measure of current health status that can direct ongoing management. Clinicians using these standardized methods track another key pulse of patient progress, often comparing data before and after specific clinical or therapeutic interventions.

Collecting PROMs has demonstrated benefits in the medical field at large. Physicians, nurses, and patients have reported that using them improves communication, so there may be gains for multiple stakeholders.²³ In addition, randomized controlled trial data have demonstrated that using PROMs has a positive impact on patients’ well-being, emotional status, and quality of life during cancer treatment.⁴ PROMs have additionally been used to standardize monitoring for adverse events and bolster related patient management.⁵ These tools have also facilitated earlier referral for specialist evaluation, and they have been associated with high levels of patient satisfaction.⁶ In England, the Department of Health has been expanding the use of PROMs in the National Health Service over time,⁷ and in the United States, PROMs are an accepted component of the Centers for Medicare and Medicaid Services’ Quality Payment Program.⁸

Data collection may occur through multiple mechanisms, alongside standard intake questionnaires or with staff assistance. The PROMs employed in each practice are typically chosen after careful consideration by the clinician or clinical team, often to provide reliable responses regarding a specific area of interest. PROM administration may or may not occur at every patient interaction, and ongoing evaluation of results and their applications may lead to adjustments in deciding which patients are surveyed and when. When such decisions are made, it is important to balance the anticipated benefits with the potential burden on patients and staff. It is thus crucial to consider how best to implement a PROM program and understand the available options. We therefore describe a range of techniques that have been utilized,

¹Department of Otolaryngology, Harvard Medical School, Boston, Massachusetts, USA
²Division of Sinonasal Disorders and Allergy, Department of Otolaryngology, University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania, USA
³Northwest ENT and Allergy Center, Marietta, Georgia, USA

Corresponding Author:
Jennifer J. Shin, MD, SM, Department of Otolaryngology, Harvard Medical School, 45 Francis Street, Boston, MA 02115, USA
Email: jennifer_shin@meei.harvard.edu
including 4 real-world clinical scenarios with long-term experience and development of successful practice models, to facilitate potential users’ consideration of implementing their own PROM collection programs.

**Validated Instruments and Data Capture**

Overview

PROMs are frequently quantified through validated instruments, tools that have scientifically demonstrated internal consistency, reliability, validity, and responsiveness to change. These assessments often take the form of a patient-completed questionnaire with single-select Likert items that translate into an ordinal scale. These individual item responses are then incorporated into a summary score or scores that can be utilized for clinical or research purposes. This total score is typically assessed through rounds of question implementation and serial item elimination based on psychometric results. At the completion of this process, the summary score encompasses a particular aspect of patient health status, such as nasal quality of life. Such validated instruments provide a scientific means to evaluate targeted aspects of patient conditions.

Data capture can be tailored to the clinician, practice, and/or health system. It is not a one-size-fits-all venture, and what is “best” for any provider may vary. PROMs may be assessed on paper or electronically, and data collection may occur at every visit or solely before and after interventions. PROM results may be used in the clinic immediately or reserved in a repository for subsequent quality improvement inquiries. Otolaryngology-related PROMs are further described online. Multiple effective permutations are in use, and this installment presents the experience of representative otolaryngology practices whose lead physicians share their rationale, data collection process, and data applications (Tables 1 and 2). In addition, obstacles to data collection are reported and how or if they were overcome, as well as the resources and support staff needed to capture data reliably. Response rates among patients are also described, and each provider highlights points that have been key in the success of one’s PROM program.

**Scenario 1: Pre- and Postintervention PROM Assessment via Paper Forms**

A private practice group of 7 physicians uses paper forms to collect pre- and postintervention data relevant to 4 common interventions: hearing aid dispensing, immunotherapy, nasal/sinus surgery, and pressure equalization tubes. Audiologists collect the Hearing Healthcare Questionnaire at the initial consultation for hearing aids and 6 months after dispensing for adults. For immunotherapy, allergy technicians administer the Rhinoconjunctivitis Quality of Life Questionnaire before immunotherapy begins and yearly for 3 years. The Sinonasal Outcome Test (or SNOT-22) is collected at the preoperative consultation and at the 6-month follow-up visit after nasal and/or sinus surgery. Last, for children undergoing myringotomy and tubes, the Otitis Media–6 instrument is administered to parents preoperatively and 6 months postoperatively. For these latter perioperative inquiries, a surgical scheduler shares the forms preoperatively, and a dedicated staff member contacts patients postintervention. These validated instruments were chosen to match the group’s high-volume interventions.

The group has determined that engaging multiple team members (ie, audiologists, allergy technicians, surgery scheduler) makes the initial data collection straightforward. However, follow-up data have been more difficult to obtain with reliable consistency. Through trial and error, they discovered that the highest rate of data completion could be achieved through follow-up phone calls from a dedicated office staff member assigned specifically to the task, since email and regular mail return rates were poor.

In this practice model, patients complete paper forms, and the data are then manually entered into Excel spreadsheets for subsequent longitudinal analysis. Based on their experience, surveys at these limited intervals do not typically burden the clinicians or the patients; however, the collecting staff are aware of the extra workload when the volume is high. This effort takes an average of 2 to 3 hours per week and is built into the standard workday. No additional training sessions have been required after the initial implementation, and no overtime has been required.

Meaningful clinical changes were implemented after assessing the PROM results and analyzing these results with intended benchmarks. For example, hearing health improvement was initially found to be lower than expected after intervention with amplification, which led to a performance improvement initiative within the audiology department. The results led to the realization that one provider was not providing counseling in line with the group’s clinical expectations; a staffing change resulted in significantly improved group outcome scores. The audiologists also reassessed the use of current technology to increase the accuracy of hearing aid fitting. In addition, by using common outcome measures among all physicians after sinonasal surgery, this group was able to compare its own clinical outcomes with published results. These outcomes met or exceeded previously published results, and because this group is part of a larger clinical network, documenting such positive clinical outcomes for common interventions was deemed to add value to the organization at large.

**Scenario 2: PROM Assessment at All Outpatient Visits via Paper Forms Imported into the Electronic Medical Record**

Routine PROM assessment has been incorporated into an academic subspecialty practice with 2 physicians, 4 speech and language pathologists, and 1 physician’s assistant; these providers work together in a coordinated, multidisciplinary fashion to deliver comprehensive laryngologic care. In this practice, data are collected with the twofold intention of following patients symptomatically over time and collecting...
### Table 1. Practice Types and Data Collection Techniques: Scenarios 1 and 2.

|-------------------------------------|-------------------------------------------|---------------------------------------------------|-----------------------------------------------|-------------------------------------------------|-------------------------------------------------|-----------------------------|-------------------------------|
| **Scenario 1: Pre- and postintervention PROM assessment via paper forms**
  
  **Pre- and postintervention only:** Before and 6 mo after hearing aid dispensing, sinus surgery, septum surgery, and myringotomy and tubes; before and 1 y after immunotherapy | Hearing aid use, HHQ; immunotherapy, RQLQ; nasal/sinus surgery, SNOT-22; ear tubes, OM-6 | None | Paper form for initial survey, follow-up phone survey. Manual data entry into Excel. | Initial surveys handed out by audiologist, allergy technician, or surgical scheduler. Office staff makes phone call for follow-up survey. | Outcome study results are formally reviewed with all providers as a quarterly standing agenda item. | Excel file | Private practice (7 physicians) |
| **Scenario 2: PROM assessment at all outpatient visits via paper forms imported into the EMR**
  
  **All patients, all visits:** Laryngology-specific practice | VHI-10, RSI, Singing VHI-10 | Complete history, including voice-specific history | Paper forms collected then scanned into EMR. Total PROM scores are added to patient note for each visit. | The front desk gives the patient the paperwork on arrival and collects before the visit begins. | Paper forms are reviewed by the clinical team before patient is seen, to determine new patient issues or changes from prior in return visit. | Scanned copy of form in EMR | Academic, tertiary |

Abbreviations: EMR, electronic medical record; HHQ, Hearing Healthcare Questionnaire; OM-6, Otitis Media–6; PROM, patient-reported outcome measure; RQLQ, Rhinosinusitis Quality of Life Questionnaire; RSI, Reflux Symptom Index; SNOT-22, Sinonasal Outcome Test; VHI-10, Voice Handicap Index–10.

*Paper, tablet, or EMR.*

*Data collection began in 2014 for each group ("When did your data collection begin?").
Table 2. Practice Types and Data Collection Techniques: Scenarios 3 and 4.

<table>
<thead>
<tr>
<th>From Whom/When Do You Collect Data?</th>
<th>What Validated Instruments Do You Collect?</th>
<th>What Other Information Do You Collect besides PROMs?</th>
<th>How Do You Collect Your Data and Then Capture It?</th>
<th>How/When Are Patients Approached to Complete Data Entry?</th>
<th>How Does the Raw Data Come to the Physician for Review?</th>
<th>How/Where Is the Data Stored?</th>
<th>How Is Your Practice Setting?</th>
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<tr>
<td><strong>Scenario 3: PROMs on paper collected at all visits with electronic database capture</strong></td>
<td>SNOT-22 for CRS patients and RQLQ for allergic rhinitis patients</td>
<td>Complete history and physical, response to medications</td>
<td>Paper form collected then manually input into flowsheets in EMR that are programmed in for data collection</td>
<td>The front desk gives the paperwork on arrival and collects before the visit begins. After completion, answers are input into the computer.</td>
<td>Before the patient is seen, the PROMs help the physician understand the patient’s progress. The data are also viewed in aggregate for research studies.</td>
<td>Research data in REDcap, hosted on-site at the hospital.</td>
<td>Academic, tertiary</td>
</tr>
<tr>
<td><strong>All patients with CRS:</strong> SNOT-22 obtained, olfactory testing (Brief UPSIT) before and after surgery (postoperative 1 mo)</td>
<td>SNOT-22 for CRS patients and RQLQ for allergic rhinitis patients</td>
<td>Complete history and physical, response to medications</td>
<td>Paper form collected then manually input into flowsheets in EMR that are programmed in for data collection</td>
<td>The front desk gives the paperwork on arrival and collects before the visit begins. After completion, answers are input into the computer.</td>
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<td>Academic, tertiary</td>
</tr>
<tr>
<td><strong>Scenario 4: Electronic database and EMR system capture in clinic and via email</strong></td>
<td>NOSE, SOS, EQ-5D, FACE-Q</td>
<td>Nasal history, standardized nasal examination, PNIF (objective measure)</td>
<td>Electronic with REDcap through tablets and emails</td>
<td>Tablets with questions provided at check-in for preintervention or interim visits. Postintervention email surveys sent at 2, 4, 6, 12, 24, and 36 mo.</td>
<td>A report is generated from REDcap to the provider upon patient submission. View aggregate data every 12 mo and the data of selected cohorts for specific research projects.</td>
<td>REDcap data collection is hosted on-site at the hospital.</td>
<td>Academic, tertiary</td>
</tr>
<tr>
<td><strong>All new patients with nasal concerns:</strong> cosmetic and nasal obstruction—pre- and postintervention</td>
<td>NOSE, SOS, EQ-5D, FACE-Q</td>
<td>Nasal history, standardized nasal examination, PNIF (objective measure)</td>
<td>Electronic with REDcap through tablets and emails</td>
<td>Tablets with questions provided at check-in for preintervention or interim visits. Postintervention email surveys sent at 2, 4, 6, 12, 24, and 36 mo.</td>
<td>A report is generated from REDcap to the provider upon patient submission. View aggregate data every 12 mo and the data of selected cohorts for specific research projects.</td>
<td>REDcap data collection is hosted on-site at the hospital.</td>
<td>Academic, tertiary</td>
</tr>
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Abbreviations: CRS, chronic rhinosinusitis; EMR, electronic medical record; FDA, Food and Drug Administration; NOSE, Nasal Obstruction Symptom Evaluation; PNIF, Peak Nasal Inspiratory Flow; PROM, patient-reported outcome measure; RQLQ, Rhinosinusitis Quality of Life Questionnaire; SNOT-22, Sinonasal Outcome Test; SOS, Snoring Outcomes Survey; UPSIT, University of Pennsylvania Smell Identification Test.

*Data collection began in 2014 (“When did your data collection begin?”).  
Data collection began in 2013 (“When did your data collection begin?”).
clinical research outcomes for analysis. The Voice Handicap Index–10 (VHI-10)\textsuperscript{17} and the Reflux Symptom Index\textsuperscript{18} are assessed for each patient at every visit, with the exception of patients who have been on postoperative voice rest. If the patient is a singer, she or he also completes the Singing VHI-10 each time.\textsuperscript{19} All forms are on 1 piece of paper, which has the VHI-10 on the front and the Reflux Symptom Index and the Singing VHI-10 on the back. These PROMs were selected on the basis of their prior dissemination in the field.\textsuperscript{20-22} The forms are maintained by the front desk staff, who maintain copies of the surveys and distribute them to patients upon arrival to the outpatient clinic.

In this practice, providers estimate that questionnaires can take up to 10 minutes for a new patient, while return patients who have seen the questions numerous times may finish more quickly. This practice’s hospital system uses a large vendor-based electronic medical record (EMR) system, and the paper intake questionnaire process is not integrated. The medical assistants incorporate the total score for each PROM into the EMR via manual input into the section of the “vital signs” screen. In addition, the paper forms are scanned into the EMR for future reference. This group does not throughput its data into a dedicated, electronic research database, and the repository rests solely within the EMR.

Patients are counseled that these survey results are vital signs for the clinician, and the estimated response rate is extremely high, as patients are typically not seen until their surveys are complete. One primary obstacle experienced by this practice in collecting data, however, has been for patients who cannot read or speak English. The PROM results could have inaccuracies if an interpreter coaches a patient to an answer or if a family member answers for him or her. It also takes longer for a translator to help a patient fill in these forms. This concern could be overcome with funding for translation services or validation in additional languages.

Ideally, this group would have the PROM data entered automatically into the EMR, as well as deposited into a research database with other keywords from the EMR note, such as the diagnosis or chosen treatment. This group’s other obstacle is being able to easily retrieve the data, as they are not yet placed categorically into a database.

Scenario 3: PROMs Collected on Paper Collected at All Visits with Electronic Database Capture

The third practice engaged in PROM collection is that of a subspecialty rhinologist who works closely with residents and fellows in the outpatient setting of a large, academic group otolaryngology practice. They subscribe to using short surveys that are easy for patients to answer, and they have engaged in PROM collection based on the belief that objective measures and quality metrics are critical to following their patient outcomes and physician-related performance. Data are collected from every patient depending on disease type. The SNOT-22 is the primary instrument utilized, given the rhinology focus of the practice. This PROM was selected because it is a well-known validated symptom survey that can be used to monitor outcomes in chronic rhinosinusitis.\textsuperscript{23} Data for research purposes are subsequently entered into a REDCap database that is compliant with the Health Insurance Portability and Accountability Act and approved by the local institutional review board. REDCap is an electronic data capture platform designed for academic clinical and translational database development.\textsuperscript{24} In this setting, it is managed by the physician’s residents and research staff, which includes a research coordinator who ensures the integrity of the data and its collection, serving as a highly valued member of the team. They are currently using the data to complement a range of basic and translational research studies.

The physician lead in this program estimates that it takes <5 minutes for the patients to fill out the disease-specific PROM. The estimated response rate is also very high. Similar to the preceding vignette, PROMs are an expected part of patient assessment and treated like a vital sign. Patients receive the questionnaires either by mail prior to their appointment or at check-in for their visit. The forms are filled out, and then the data are entered into the EMR flow sheet by a medical assistant. Each item is entered into the system, and the scores are calculated electronically. The progress of the patient can subsequently be reviewed via the EMR flow sheets, which saves time for the clinician and trainees, as there are clear records of specific symptom severity over time. The team reports that using PROMs for clinical updates helps caregivers target patient symptoms more accurately, determining which continue to be problematic or, alternatively, which significantly improved after each intervention.

Obstacles reported in this clinical setting include difficulty in expanding the use of identical PROMs to all faculty in the practice who perform sinus surgery and/or see patients with chronic rhinosinusitis with polyps. Adding tablet-based input methods for patients would be this practice’s ideal next step. There is also a plan to incorporate the data into quality metric reports that can be utilized to assess patient outcomes.

Scenario 4: Electronic Database and EMR System Capture in Clinic and via Email

This practitioner is a facial plastic surgeon in a tertiary subspecialty practice who has been motivated by the observation that outcomes assessment of patients with nasal obstruction has been hampered by infrequent objective and quantitative evaluation of nasal function. The goal of the database is to improve the level of evidence supporting the treatment of nasal obstruction and to create treatment algorithms for the care of patients with nasal obstruction, ensuring that each patient is receiving the most appropriate treatment for one’s anatomic issue. The answers obtained offer immediate clinical advantages while building the research database. The Nasal
Obstruction Symptom Evaluation (NOSE) instrument allows for prospective evaluation of patients with nasal obstruction.25 However, in practice, PROMs can be underutilized in the field of nasal valve dysfunction, and surgical treatments are supported only by level 4 evidence. A review of the published literature identified the NOSE survey as the most useful PROM for nasal obstruction.25,26 The practice also integrated the EQ-5D after discussing the manuscripts authored by our rhinology colleagues to examine global quality of life and perform cost-utility analyses.27 The FACE-Q was incorporated after contacting the developers of the instrument and reviewing the merits of its use.28,29

In this practice, an electronic database is created, as PROMs are obtained via tablets and follow-up emails. There is no paper used in this model. REDCap is used as part of an integrated system to prospectively collect data from patients undergoing evaluation and surgical treatment for nasal obstruction. This database protocol was approved by the local Human Studies Committee. The office staff provides patients with a tablet in the clinic, and they are asked to complete the electronic consent form and questionnaires. In this practitioner’s experience, it takes patients approximately 10 minutes to do so. The forms require completion of all fields, and patients do not have the option of skipping items or commenting on items outside the given question, as may occur with paper forms. The program performs automatic tabulation of the NOSE, the EQ-5D, and FACE-Q30 scores upon completion of the surveys. A detailed standardized nasal history, examination, and peak nasal inspiratory flow pressure results are documented on a standardized nasal examination template and Nasal Anatomical Worksheet by the provider.31 The operative information is directly entered into REDCap by the surgeon. Postoperative surveys are completed by the patients via email, which are automatically sent at specific time points after the date of surgery or collected via the tablet at postoperative visits.

“Smart Docs” were created in the provider’s EMR that mirror all of the REDcap documents, with the goal of integrating the systems to avoid manual data input into both systems. Using available research funding, a programmer was hired to build the original system. A clinical research coordinator makes needed changes or additions to the database. The institution also has a designated person to ensure Health Insurance Portability and Accountability Act compliance and appropriate data storage. Both these roles are felt to be a requirement for the success of the project. Response rates in this model have been approximately 85% at all intervals.

One obstacle included a failed attempt at emailing the preinitial visit PROMs to the patient, as the response rate was low. The biggest obstacle, however, after having the needed support staff, can be the initiating clinician him- or herself; the provider had to make the commitment to enter the data on every patient and make it a part of the normal clinical flow. Ultimately, this commitment was made, and multiple manuscripts have been published with the collected data.

Discussion

Within otolaryngology, capturing patient data for research is a familiar proposition, and more recently, we have seen PROM collection utilized to support patient care. PROMs have been integrated into a variety of clinical practice scenarios, from private practice to tertiary academic centers and among multiple specialties.32 Translation of patients’ personal experience into a format amenable to a database or EMR may occur through a variety of mechanisms. Paper forms are commonplace, and EMR and tablet capture are additional options. With the integration of EMRs into most health care systems, the potential for incorporating self-reported data into the patient’s clinical record has promise, as does incorporating these data into a separate searchable and analyzable repository. It is likely that the more that PROMs are integrated with clinical workflow, the greater the response rates and data acquisition will be.

Common themes regarding potential obstacles to PROM implementation have centered mainly on the process of data capture and the expansion of collection. Some form of staff-based manual entry, whether via paper forms or electronically, is still used for data capture in the presented scenarios. Our author team has collectively fostered staff motivation for these activities in the following ways: (1) emphasizing the immediate utility of the information for patient care, (2) encouraging and acting on feedback from staff about the collection process, and (3) including them in manuscripts that arise from collected data. This last component helps foster the careers of those who wish to advance (eg, to physician assistant school, higher administrative positions). The staff also responds to understanding that PROM results help to facilitate an optimal understanding of patients’ progress after medical or surgical intervention and thus serve patients in their care over time. The staff’s role in data capture has been incorporated into the normal clinic work flow so that there is not a requirement for additional paid hours or additional staff. While additional training is required at the outset to teach the staff how to perform the data entry (eg, obtaining REDcap access), this training process is such that it also falls within the standard work hours. Accuracy of data entry is checked during a review of the results with the related patient. We have not observed any negative impact on patient volume, referrals, or financial reports after implementation. In fact, some of the authors believe that their use of PROMs distinguishes them in a competitive market, as they use the results as an active springboard for patient discussions. Physicians themselves may personally be required to input some data that are not part of their outpatient PROM collections (ie, surgical data). In most instances described, however, the medical assistant, practice administrator, or research assistant performed this vital role, and engaging clinical staff has contributed to program success. There have been reports of additional means to streamline this process to minimize staff involvement and provider time investment through solely electronic interfaces that incorporate multiple related subspecialties in our field.33 As we surmount the range of obstacles, PROM data can increasingly contribute
to evidence-based practice, the foundational motivation for this article and series.\textsuperscript{34-38}

With regard to the spread of PROM collection, it would be beneficial to increase the availability of common, uniform PROMs that could be integrated into, and selected automatically from, electronic systems so that multiple providers, practices, and institutions could contribute to a shared or overlapping data set. Subspecialty-specific efforts could use specific administrative codes to prompt targeted PROM administration. At this stage, most efforts are in the initial decade of evolution, and qualitative observations can support ongoing educational efforts. Ideally, however, as we share our common experiences, we can form the basis for future studies that provide vetted, hypothesis-driven data to better guide the efforts of practices who wish to engage. These data could, in turn, drive more rational and patient-centered clinical care as we move forward into our health care horizon.

Conclusions

PROMs have been incorporated into a variety of clinical settings, including private practices and academic programs. Techniques for data collection differ and include paper forms, spreadsheets, EMRs, and formal data repositories.

Acknowledgments

J.J.S. thanks Maureen Corrigan for assistance with formatting, as well as Thomas Lin for support during the preparation of this manuscript.

Author Contributions

Thomas L. Carroll, draft writing, revisions for intellectual content, final approval; Stella E. Lee, draft writing, revisions for intellectual content, final approval; Robin Lindsay, draft writing, revisions for intellectual content, final approval; Drew Locandro, draft writing, revisions for intellectual content, final approval; Gregory W. Randolph, draft writing, revisions for intellectual content, final approval; Jennifer J. Shin, draft writing, revisions for intellectual content, corresponding author, final approval.

Disclosures

Competing interests: Thomas Carroll is a recipient of a Brigham Care Redesign Incubator Program Award and is a consultant for Sofregen Medical and Pentax Medical. Stella Lee is an investigator in clinical trials with Sanofi Aventis and Allakos Inc for treatment of chronic rhinosinusitis with polyps. Jennifer J. Shin receives textbook royalties from Evidence-Based Otolaryngology (Springer) and from Otolaryngology Prep and Practice (Plural Publishing) and is a recipient of a Harvard Medical School Shore Foundation/Center for Faculty Development Grant, the Cotton-Fitton Endowed Lectureship, and a Brigham Care Redesign Incubator Program Award.

Sponsorships: None.

Funding source: None.

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