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An Analysis of Registered Clinical Trials in Otolaryngology from 2007 to 2010: ClinicalTrials.gov

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Abstract

Objective—To describe the conditions studied, interventions used, study characteristics, and funding sources of otolaryngology clinical trials from the ClinicalTrials.gov database; compare this otolaryngology cohort of interventional studies to clinical visits in a health care system; and assess agreement between clinical trials and clinical activity.

Study Design—Database analysis.

Setting—Trial registration data downloaded from Clinical Trials.gov and administrative data from the Duke University Medical Center from October 1, 2007 to September 27, 2010.

Methods—Data extraction from ClinicalTrials.gov was done using MeSH and non-MeSH disease condition terms. Studies were subcategorized to create the following groupings for descriptive analysis: *ear, nose, allergy, voice, sleep, head and neck cancer, thyroid, and throat*. Duke Health System visits were queried by using selected ICD-9 codes for otolaryngology and non-otolaryngology providers. Visits were grouped similarly to ClinicalTrials.gov for further analysis. Chi-square tests were used to explore differences between groups.

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Author Contributions

David L. Witsell, design, interpretation of data, drafting manuscript, approval; Kristine A. Schulz, design, analysis of data, drafting manuscript, approval; Walter T. Lee, interpretation of data, drafting and review of manuscript, approval; Karen Chiswell, acquisition of data, analysis, drafting of manuscript and approval.

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Supplemental Material

Additional supporting information may be found at <http://oto.sagepub.com/content/by/supplemental-data>

Results—A total of 1115 of 40,970 registered interventional trials were assigned to otolaryngology. Head and neck cancer trials predominated. Study models most frequently incorporated parallel design (54.6%), 2 study groups (46.6%), and randomization (69.1%). Phase 2 or 3 studies constituted 46.4% of the cohort. Comparison of the ClinicalTrials.gov database with administrative health system visit data by disease condition showed discordance between national research activity and clinical visit volume for patients with otolaryngology complaints.

Conclusions—Analysis of otolaryngology-related clinical research as listed in ClinicalTrials.gov can inform patients, physicians, and policy makers about research focus areas. The relative burden of otolaryngology-associated conditions in our tertiary health system exceeds research activity within the field.

Keywords

otolaryngology; clinical trials; evidence-based medicine; database

Background

Practice guidelines that inform clinical decision making depend on the quality of the research supporting them¹; however, previous investigations suggest that many rely on inadequate evidence.² An analysis of data from the ClinicalTrials.gov registry showed that approximately 50% of interventional trials registered from 2007 to 2010 enrolled <70 participants and found substantial variation in use of randomization and blinding.³ Other studies examining this data set by clinical specialty have found misalignment between funding and disease prevalence.^{4,5}

Similar issues affect otolaryngology–head and neck surgery (OHNS). Despite expanding research activity, concerns linger about research quality and evidence supporting therapeutic decision making.^{6,7} However, recent reviews demonstrate improvements in study design, methodological reporting, and statistical analysis descriptions^{8,9} similar to those seen in other specialties.¹ An exploration of the alignment of research and disease prevalence across OHNS studies may help identify evidence gaps and inform strategies for improving them.

In this study, we examine data from ClinicalTrials.gov in order to classify and describe OHNS clinical trial activity and compare it with disease prevalence as reflected by clinic visit volume for OHNS-related conditions in a single large tertiary-care center. Since 2004, trial registration has been a condition of publication for many peer-reviewed journals,¹⁰ and federal trial registration requirements, first implemented in 1997¹¹ and expanded in 2007¹² make ClinicalTrials.gov a comprehensive and accessible resource for characterizing interventional studies. We hypothesized that OHNS would show (1) a trend toward device trials, nonrandomized studies, and no blinding compared with non-OHNS trials, all of which result from OHNS' status as a surgical specialty with a greater interest in these avenues of research, and (2) that research activity across OHNS sub-specialties would reflect relative disease burden as indicated by clinical volume.

Methods

To compare clinical trial activity to disease-visit prevalence, we accessed data on clinical visit volumes using an administrative database of patients at Duke University Medical Center (DUMC). The study was approved by the Duke University Health System Institutional Review Board (Pro00036741); informed consent was not required.

Creation of the OHNS Data Set from ClinicalTrials.gov

A data set of 96,346 clinical studies registered in ClinicalTrials.gov was downloaded in XML format on September 27, 2010, and organized in a relational database (Oracle RDBMS v11.1g) to facilitate aggregate analysis.¹³ A detailed description of the Aggregate Analysis of ClinicalTrials.gov (AACT) database has been published.¹⁴ Briefly, analysis was restricted to interventional studies registered from October 1, 2007, to September 27, 2010. We focused on this 3-year period when expanded federal reporting requirements took effect^{12,15} with the aim of reducing selection bias in our data set and taking advantage of improved reporting during this interval. Interventional trials were defined as those in which subjects are assigned by an investigator based on a protocol to receive specific interventions. Studies were identified as interventional by data submitters (study sponsor or investigator). Disease condition terms (Medical Subject Heading [MeSH] and non-MeSH) provided by registrants and MeSH terms generated by a National Library of Medicine algorithm were evaluated by Duke OHNS authors (D.L.W., K.A.S., W.T.L.) and annotated for relevance to OHNS. Figure 1 presents the evaluation process for including studies in the final OHNS data set (n = 1115).

Studies were assigned to condition groups using manual review and electronic search of condition terms submitted by registrants for specific text term excerpts. Table 1 presents the logic used to map term excerpts to condition groups. Because studies may have multiple submitted conditions, a study could fall into more than 1 class. Studies not flagged in any condition group (n = 46) were reviewed manually and assigned to a condition group.

A method for flagging surgical interventions of particular interest was applied to the data set. Data set fields (including brief title, conditions, keywords, intervention names, and intervention MeSH terms) were searched for term excerpts listed in Table 1. A study was flagged with a particular intervention if the excerpt was found in the search fields; a given study could be flagged with more than 1 intervention.

Studies were classified according to reported age eligibility criteria to examine inclusion of pediatric populations. Studies that did not explicitly exclude children (did not report minimum age ≥ 18 years) and studies that restricted enrollment to children (reported maximum age ≤ 18 years) were enumerated.

The AACT database also records lead sponsor, that is, the primary organization overseeing study implementation and responsible for data analysis, and collaborators, other organizations that provide support, including funding. We used the following algorithm to derive probable funding source: if the lead sponsor was from industry or the study had industry collaborators without National Institutes of Health (NIH) involvement, the study

was categorized as industry funded; if the NIH was involved as a sponsor or collaborator and the lead sponsor was not from industry, the study was classed as NIH funded; all other studies were classed as funded by nonindustry, non-NIH sources.

Duke Visits and Patients

DUMC is a large regional academic medical center including community-based and regional practitioners. An administrative database containing DUMC outpatient clinic visits spanning the study interval was analyzed. Unique visits were classified using patient identifier, clinic identifier, physician identifier, and visit date. Investigators reviewed the physicians associated with clinics labeled as ear, nose, and throat (ENT), identifying those working in OHNS. Investigators then generated a list of International Classification of Disease (ICD) codes (version 9)¹⁶ related to otolaryngology (Table 2) and grouped in similar fashion to condition classifications.

Patients were considered OHNS patients if they had at least 1 OHNS visit during the study interval. Visits were classified as “Duke OHNS” if the clinic was noted as ENT and the physician was identified as working at OHNS. Visits were classified as Duke non-OHNS visits if they were not OHNS visits and had an otolaryngology-related ICD-9 code. Patients were considered Duke non-OHNS patients if they had ≥ 1 Duke non-OHNS visit. Visits were counted in a particular condition group (eg, allergy) if they (or any visits with the same patient identifier, clinic, physician, and date) had ≥ 1 diagnosis code assigned to that grouping. Patients were counted in a condition grouping if they had any visits during the study interval classified in that grouping. Visits and patients without ≥ 1 valid ICD-9 code were excluded from the denominator when calculating percentages of visits or patients in each condition group.

Statistical Methods

Frequencies and percentages are provided for categorical trial characteristics; medians and interquartile ranges are provided for continuous characteristics. Unless otherwise indicated, missing values are excluded from calculations. Trial characteristics are compared between otolaryngology studies and studies with other disease conditions. For OHNS trials, the conditions studied and pediatric eligibility were derived by funding source. Chi-square tests were used to compare groups. Two-sided alternative hypotheses were tested, and a *P* value <.01 was interpreted as statistically significant. No adjustment was made for multiple comparisons. Definitions for variables collected in the ClinicalTrials.gov database are available at <http://prsinfo.clinicaltrials.gov/definitions.html>.

Results

A total of 40,970 interventional trials were registered with ClinicalTrials.gov from October 1, 2007, to September 27, 2010; 1115 (2.7%) were identified as OHNS studies. Of these, 161 began prior to 2006.

OHNS studies were classified by condition groups (Table 1) and could belong to ≥ 1 group. A total of 225 studies (20.2%) were classified under “head and neck cancer only,” followed by “sleep only” (10.9%, *n* = 122) and “ear conditions only” (10.8%, *n* = 120). Allergy and

nose conditions were common, with 6.9% (n = 77) of studies classed as “allergy only,” 7.4% (n = 82) “nose only,” and 20.8% (n = 232) “allergy and nose.” Supplemental Table S1 (available at otojournal.org) displays OHNS studies by condition group and funding source. A minority of studies (25.6%; n = 285) included children, and 11.0% (n = 123) restricted enrollment to those aged ≥ 18 years (Table 3).

Detailed characteristics for otolaryngology versus non-otolaryngology trials are provided in Supplemental Table S2. In OHNS trials, we did not observe an imbalance in sex-based eligibility restrictions with regard to recruitment goals, with 96.8% of trials enrolling both male and female participants. The most common study purpose was treatment evaluation (877/1063 [82.5%]); the least common was health services research (10/1063 [0.9%]).

The most common interventional model was parallel design (575/1053 [54.6%]). Of studies reporting number of arms, 496 of 1065 (46.6%) had 2 arms, and 114 of 1065 (10.7%) had 3 arms. Among studies with ≥ 2 arms, 348 of 710 (49.0%) reported a placebo arm and 667 of 704 (94.7%) were randomized. Among those using randomization, 149 of 660 (22.6%) were not blinded/masked, and 426 of 660 (64.5%) were double-blinded. Phase 2 and 3 trials together accounted for 517 studies (46.4%); 289 recorded the phase as “not applicable.” A total of 28.6% (282/987) reported ≥ 1 site.

The most frequently observed intervention was drug (n = 668 [59.9%]), followed by device and/or procedure (n = 268 [24.0%]). Interventions were described by free text reported by data submitters. Although coding and quantification of the exact frequencies of interventions was beyond the scope of this analysis, we observed the following trends when reviewing the 20 most frequent intervention names for each intervention type: among studies with a drug intervention, chemotherapeutic and allergy (steroid or oral antihistamine) agents were most common. Among studies noting device interventions, continuous positive airway pressure (CPAP)/CPAP-related devices were common, as was repetitive transcranial magnetic stimulation for tinnitus. Among studies listing procedural interventions, quality-of-life assessment, therapeutic conventional surgery, and biopsy were most common. Behavioral interventions were rare.

Querying specific surgery terms showed 100 studies with ≥ 1 of these terms, the most common being tonsillectomy (n = 19), thyroidectomy (n = 19), sinus surgery (n = 15), biopsy procedures (n = 13), and tympanostomy (n = 7).

Categorization and comparison of reported primary outcomes were not practicable due to the very high prevalence of free-text descriptions in the data set.

Industry funding accounted for 544 (48.8%) of OHNS studies, followed by 496 (44.5%) funded by non-industry, non-NIH sources. At least 154 (13.8% of OHNS) had university/academic lead sponsors, and 75 (6.7%) were funded by NIH. The most common industry lead sponsors were Schering-Plough (n = 41) and Alcon Research (n = 22). The 3 largest academic sponsors were University of Chicago (n = 22), Memorial Sloan-Kettering Cancer Center (n = 16), and M.D. Anderson Cancer Center (n = 11). Several non-US universities/academic medical centers were among the top 20 nonindustry/non-NIH lead sponsors. The Department of Veterans Affairs was lead sponsor of 13 trials, the National Cancer Institute

provided funding to 40, the National Institute on Deafness and Other Communication Disorders provided funding to 8, and the National Heart, Lung, and Blood Institute funded 4.

Comparison of the OHNS data set to non-OHNS trials showed that OHNS studies more often had a primary purpose of “treatment” evaluation compared with “prevention” (82.5% vs 74.7% and 5.2% vs 11.0% respectively; $P < .001$). OHNS and non-OHNS trials were similar regarding number of arms ($P = .40$); however, OHNS trials with 2 arms were more likely to use placebo comparators than non-OHNS trials (49.0% vs 32.6%; $P < .001$). Although randomization was common in both OHNS and non-OHNS trials with 2 arms (94.7% vs 92.1%; $P = .011$), randomized OHNS studies were more often double-blinded (64.5% vs 48.9%; $P < .001$) with an endpoint classification of “efficacy” (40.1% vs 34.0%; $P < .001$), and OHNS trials were less likely to be phase 1 (8.1% vs 15.4%; $P < .001$). OHNS studies were more likely to enroll both male and female participants (96.8% vs 85.1%; $P < .001$) and more often restricted enrollment to children (< 18 years, 11.0%; $P < .001$) compared with non-OHNS trials. The OHNS data set included a greater proportion of trials with device (14.8%; $P < .001$) and radiation (6.5%; $P < .001$) interventions and a smaller proportion of behavioral interventions (4.2%; $P < .001$). The proportion of trials examining drug interventions was similar (~60% for both OHNS and non-OHNS trials; $P = .73$).

Contextual Results

During the study interval, 7,269,430 clinical visits occurred for 787,546 unique patients at Duke outpatient clinics. Of these, 35.7% ($n = 280,985$) were seen by a non-otolaryngologist (non-OHNS) for an ENT-related diagnosis, while 3.1% ($n = 24,159$) were seen by OHNS. Both OHNS and non-OHNS patients with 1 ENT diagnosis had a median of 2 visits over the study period.

We then grouped patients categorically by disease condition and provider to describe the relative burden of ENT-related conditions within DUMC. Among non-OHNS providers, the most frequently encountered disease problem categories were listed as throat (34.9% of visits), ear (14.9%), and sleep (10.2%). For OHNS providers, the most frequently encountered categories were ear (35.9% of visits), throat (17.5%), and head and neck cancer (15.5%).

We also examined the proportion of studies by the ClinicalTrials.gov OHNS condition group for non-OHNS (Figure 2) and OHNS visits (Figure 3) and presented these results stratified by funding source (ie, industry or NIH; Figure 4 and 5). We then used the proportion of visits by condition group as a proxy for health care disease burden. An arbitrary threshold of >10% difference between the proportion of studies and proportion of visits was used to define an outlier. At both non-OHNS health system (Figure 2) and OHNS (Figure 3) levels, the nose, allergy, and head and neck cancer condition groups are outliers.

Research sponsor differences are examined in Figures 4 and 5. Industry funding tends to be skewed toward allergy and nose conditions, while NIH funding is skewed toward head and neck cancers. Outlier conditions with a health care system burden exceeding research focus (ie, visit volume > research focus) are throat (at non-OHNS health system level) and voice

and ear (at OHNS) level, regardless of funding source. Figures 4 and 5 display non-OHNS health system volume for ENT conditions compared with study volume in the OHNS data set of ClinicalTrials.gov and OHNS volume for ENT conditions as compared with study volume in the OHNS data set of ClinicalTrials.gov, respectively, stratified by industry or NIH funding. Industry funding tends to be skewed toward allergy and nose conditions, while NIH funding is skewed toward head and neck cancers. Throat conditions appear to receive a disproportionately small fraction of funding from either source, relative to prevalence of visits for throat conditions.

Discussion

Our analysis of OHNS-related trials registered in the ClinicalTrials.gov database from 2007 to 2010 shows findings similar to previous reports from the OHNS field. The top disease conditions were head and neck oncology and sleep- and ear-related conditions; nose and allergy studies together were also prevalent. Voice-related trials were relatively rare, consistent with previous reports noting poor evidence levels for voice interventions—possibly due to lack of specific pharmacologic agents aimed at voice disorders or lack of clarity regarding outcomes measurement.⁷

Our data also agree with previous work showing that industry funds a substantial portion of clinical trials.^{3–5} Given mandated registration for interventional trials, it is unsurprising that we saw a higher proportion of trials using blinding and randomization than previously noted.

Despite concerns that otolaryngology is not keeping pace in building an adequate evidence base, we found that rates of blinding, randomization, enrollment, and study completion were comparable to those of the greater clinical registry cohort. As expected from a surgical subspecialty, device trials were more frequent in the OHNS registry cohort versus the non-OHNS cohort but still accounted for a low percentage of overall activity. The analysis of device and/or technical/procedural trials is complicated by the lexicon of otolaryngology and lack of registry data input specifications, as shown by the 100 studies (9.0%) with 1 or more OHNS surgical terms.

Most registered trials in otolaryngology evaluate drug efficacy—either chemotherapeutic agents for head and neck cancer or allergy-modifying medications. Industry led or collaborated on 49% of these trials. Consistent with other findings,^{17,18} the role of large academic centers and universities in this field is significant, underscoring their importance as sources of innovation, pilot funding, and ongoing research investment.

Our analysis found that trials in OHNS diseases/processes represent <3% of interventional clinical trials registered during the study interval. However, when we compared these findings to data from non-OHNS providers at DUMC, 35.7% of patients and 12.2% of clinic visits revealed diagnosis information relevant to OHNS. We offer 2 possible interpretations for this finding.

First, this disparity may reflect a need for increased research in otolaryngology-related illnesses to complement the relative prevalence of these conditions, at least in large academic health systems such as DUMC. Second, our specialty's heterogeneity and the

acute nature of many otolaryngology illnesses (vs diseases such as arthritis) could diffuse research efforts among disparate but anatomically related conditions. This hypothesis is supported by the disproportionate share of clinical trial activity in head and neck cancer relative to ear or throat problems, according to prevalence of these conditions. Of note, we neither weighed the relative morbidity and cost to society that each disease carries nor assessed ease of studying a condition's outcome. Allergy and nose-related conditions are heavily studied according to our analysis, likely due to an investment focus from pharmaceutical research.

These inferences highlight the role of ClinicalTrials.gov in enabling an effective national strategic initiative for conducting clinical trials. This and other analyses^{3-5,19} may focus attention on the registry's value while providing an impetus to address lingering challenges. In the future, the registry could be enhanced by better standardized data formats and definitions, thereby improving searches and aggregate field analyses. With current mandates for registering study data, the registry will likely prove an increasingly important source of information on clinical trials activity. Given the diversity of otolaryngology, agreement and education on common terminology will be accelerated by a collective focus on evidence-based guidelines and research initiatives currently under way. Future efforts in otolaryngology should focus on clinical effectiveness research performed through practice-based research networks such as the National Institute on Deafness and Other Communication Disorders-funded CHEER network (<https://www.cheerresearch.org/>).²⁰ An emphasis on participation in such networks may benefit the field by helping to ensure data integrity and generalizability of findings, as well as by fostering the study of conditions whose presentations are more frequently seen in daily clinical practice.

ClinicalTrials.gov, like other databases, is subject to design limitations. Our study required manual review to classify trials because of variability introduced by open formatting and free-text entry permitted by the registry. Our study categorizations were based on clinical knowledge, and condition groups were subjectively assigned but were independently reviewed and adjudicated. In addition, clinical data were extracted from a large tertiary referral center, and our analysis of patient volume with otolaryngology illnesses versus research activity may not be generalizable to other health care systems.

OHNS-related clinical trials recorded in the ClinicalTrials.gov database from 2007 to 2010 shows findings similar to previous reports, with head and neck oncology, sleep-, and ear-related conditions and the combination of nose and allergy interventional studies accounting for the largest proportion of trials activity and voice-related clinical trials remaining relatively rare. The largest proportion of OHNS trials were funded by industry, and use of blinding and randomization were more prevalent than previously reported. The relatively small proportion of OHNS trials compared with OHNS disease prevalence suggests that realignment of research efforts and funding may be appropriate to advance therapeutic development.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1.
Methodology used to derive the otolaryngology study data set.

Figure 2.

Non-OHNS health system volume for ENT conditions compared with study volume in the OHNS data set of ClinicalTrials.gov. ENT, ear, nose, and throat; OHNS, otolaryngology–head and neck surgery.

Figure 3. OHNS volume for ENT conditions as compared with study volume in OHNS data set of ClinicalTrials.gov. ENT, ear, nose, and throat; OHNS, otolaryngology–head and neck surgery.

Figure 4.

Non-OHNS health system volume for ENT conditions compared with study volume in the OHNS data set of ClinicalTrials.gov stratified by industry (solid dots) (A) or NIH funding (open dots) (B). ENT, ear, nose, and throat; NIH, National Institutes of Health; OHNS, otolaryngology–head and neck surgery.

Figure 5.

OHNS volume for ENT conditions as compared with study volume in the OHNS data set of ClinicalTrials.gov stratified by industry (solid dots) (A) or NIH funding (open dots) (B).

ENT, ear, nose, and throat; NIH, National Institutes of Health; OHNS, otolaryngology–head and neck surgery.

Table 1

Excerpts used to search and group submitted condition terms.

Text Term Excerpt	Condition Group
Hearing, ear, tinnitus, otitis, dizziness, tympan, balance	Ear
Nose, sinusitis, rhinitis, rhino	Nose
Allerg	Allergy
Voice, dysphagia	Voice
Sleep	Sleep
Cancer, head, neck	Head and neck cancer
Throat, tonsil, pharyn, airway, trach	Throat
Thyroid	Thyroid
Fac, nasolabial	Facial
Mouth, oral	Mouth

Table 2

Coding of ICD-9 diagnosis codes used to classify Duke University Medical Center diagnoses.

Otolaryngology Class	ICD-9 Diagnosis Code
Allergy	472, 472.0, 472.00, 477, 477.0, 477.9
Ear	380.1, 380.10, 380.21, 380.22, 380.23, 380.4, 381, 381.00, 381.01, 381.1, 381.10, 381.2, 381.3, 381.4, 381.81, 382, 382.00, 382.1, 382.2, 382.3, 382.9, 383.0, 383.1, 383.30, 383.89, 384.2, 384.20, 384.21, 384.23, 385.19, 385.30, 385.32, 386, 386.00, 386.01, 386.1, 386.11, 386.19, 386.30, 386.9, 387.9, 388.3, 388.30, 388.31, 388.60, 388.7, 388.70, 389.00, 389.03, 389.1, 389.10, 389.11, 389.18, 389.2, 389.20, 389.9, 780.4, 780.41, 781.2, 781.3, 931, 993, 993.3, 993.8
Facial plastics	351.9, 738, 738.0, 744, 749, 754, 802, 802.0, 802.1, 802.20, 802.30, 802.4, 802.6, 802.8
Head and neck cancer diagnosis	140, 141, 142, 143, 144, 145, 146, 147, 148, 149, 160, 161, 172.0, 172.1, 172.2, 172.3, 172.4, 173.0, 173.1, 173.2, 173.3, 173.4, 195.0, 210.2, 210.4, 210.6, 216.3, 226, 229, 229.0, 229.8, 239.01, 239.02, 239.2, 241.9, 702.2, 784.2, 785.6
Mouth	112, 112.0, 524.6, 524.60, 524.62, 524.69, 527, 527.2, 527.5, 528, 528.0 528.2, 528.5, 529, 830.0
Nose	349.81, 446.4, 460, 460.0, 461, 461.0, 461.2, 461.6, 461.7, 461.8, 461.9, 470, 470.0, 470.00, 471.0, 471.1, 471.8, 471.9, 472.2, 473, 473.0, 473.2, 473.3, 473.7, 473.8, 473.9, 478, 478.0, 478.1, 780.54, 781.1, 784.7, 784.9
Sleep	327.2, 780.5, 780.53, 780.57, 786.09
Throat	306.4, 462, 463, 465.9, 472.1, 474, 474.0, 474.10, 474.11, 474.12, 474.9, 475, 530.1, 530.11, 530.3, 530.50, 530.6, 530.81, 530.9, 723.1, 784.1, 784.8, 786.2, 787.2, 933, 998.6
Thyroid	193, 240, 240.9
Unspecified	337.0, 350.2, 351, 351.0, 351.8, 446.5 464.1, 490, 493.9, 519.1, 549, 682, 682.0, 682.1, 784, 784.0, 784.01, 786.3, 831, 959, 959.0, 998.5
Voice	212.1, 239.11, 464.0, 476, 476.0, 478.3, 478.30, 478.32, 478.34, 478.4, 478.5, 478.6, 478.7, 478.74, 478.79, 519, 519.0, 519.8, 784.3, 784.4, 784.40, 784.49, 784.5, 786.1

Summary of conditions studied in pediatric trials by funding: otolaryngology interventional studies registered at ClinicalTrials.gov from October 2007 to September 2010.^a

Table 3

Conditions Studied	Industry (n = 61)	NIH (n = 6)	Other (n = 56)	All Pediatric (n = 123)	P Value
Study has 1 condition classed as ^b , n (%)					
Nose	28 (45.9)	1 (16.7)	8 (14.3)	37 (30.1)	<.001
Allergy	33 (54.1)	0 (0.0)	7 (12.5)	40 (32.5)	<.001
Head and neck cancer	0 (0.0)	0 (0.0)	1 (1.8)	1 (0.8)	.504
Throat	4 (6.6)	1 (16.7)	15 (26.8)	20 (16.3)	.012
Sleep	2 (3.3)	1 (16.7)	11 (19.6)	14 (11.4)	.019
Ear	14 (23.0)	3 (50.0)	15 (26.8)	32 (26.0)	.332
Thyroid	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	
Mouth	2 (3.3)	0 (0.0)	5 (8.9)	7 (5.7)	.481
Facial	0 (0.0)	1 (16.7)	2 (3.6)	3 (2.4)	.036
Voice	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	
None of the above	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	
Condition combinations, n (%)					
Allergy only	11 (18.0)	0 (0.0)	3 (5.4)	14 (11.4)	
Ear only	14 (23.0)	3 (50.0)	15 (26.8)	32 (26.0)	
Facial only	0 (0.0)	1 (16.7)	1 (1.8)	2 (1.6)	
Mouth only	2 (3.3)	0 (0.0)	5 (8.9)	7 (5.7)	
Nose only	6 (9.8)	0 (0.0)	4 (7.1)	10 (8.1)	
Sleep only	2 (3.3)	1 (16.7)	8 (14.3)	11 (8.9)	
Throat only	4 (6.6)	0 (0.0)	12 (21.4)	16 (13.0)	
Allergy/nose	22 (36.1)	0 (0.0)	4 (7.1)	26 (21.1)	
Facial/head and neck	0 (0.0)	0 (0.0)	1 (1.8)	1 (0.8)	
Nose/throat	0 (0.0)	1 (16.7)	0 (0.0)	1 (0.8)	
Sleep/throat	0 (0.0)	0 (0.0)	3 (5.4)	3 (2.4)	

^aFunding derived from lead sponsor and collaborator fields.

^bCategories are not mutually exclusive, so numbers may exceed 100.