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Background

The field of Otolaryngology is rapidly evolving and thus requires trustworthy clinical evidence to support the most current medical technologies and techniques. One way to ensure the publication of methodologically sound research is the use of reporting guidelines and clinical trial registration. Here we aim to evaluate the editorial policies of the top Otolaryngology journals and determine their adherence to reporting guidelines and clinical trial registration. Additionally we aim to evaluate whether RCTs published in journals requiring these guidelines are more compliant with trial registration and reporting guidelines compared to their counterparts not requiring such guidelines.

Methods

This study used a cross-sectional design to select RCTs published in the top 20 Otolaryngology journals from June 8th 2017 to June 8th 2021. Individual studies were evaluated for adherence to clinical trial registration as well as the CONSORT guideline for clinical trials by the presence or absence of a CONSORT flow diagram and clinical trial registration number in the published text. Additionally the top 20 journal’s “instructions for authors” section was evaluated to determine if a journal “required”, “recommended”, or “did not require” the 20 most commonly used study guidelines.

Table 1. Otolaryngology Journal Statistics

Journal	H-5 index	H-5 median	Geographic Region
The Laryngoscope	53	67	USA
Head & Neck	50	60	USA
Hearing Research	47	57	Netherlands
Otolaryngology–Head and Neck Surgery	44	61	USA
Ear and Hearing	42	57	USA
JAMA Otolaryngology–Head & Neck Surgery	41	58	USA
European Archives of Oto-Rhino-Laryngology	41	54	Germany
Otology & Neurotology	40	58	USA
International Forum of Allergy & Rhinology	34	47	USA
International Journal of Pediatric Otorhinolaryngology	34	44	Ireland
Clinical Otolaryngology	31	45	UK
American Journal of Rhinology & Allergy	27	39	USA
Brazilian Journal of Otorhinolaryngology	27	38	Brazil
Annals of Otology, Rhinology & Laryngology	26	35	USA
Auris Nasus Larynx	26	35	Ireland
The Journal of Laryngology & Otology	26	34	UK
Audiology and Neurotology	25	33	Switzerland
Journal of Otolaryngology-Head & Neck Surgery	25	33	UK
Otolaryngologic Clinics of North America	25	33	UK
Acta Oto-Laryngologica	25	28	UK

Table 2. Comparison of Reporting Guideline Policies Among Otolaryngology Journals

Reporting Guidelines	Otolaryngology Journals (N= 20) Requiring or Recommending Each Reporting Guideline
CONSORT	12
MOOSE	2
QUOROM	0
PRISMA	12
STARD	4
STROBE	5
ARRIVE	8
CARE	2
CHEERS	3
SRQR	2
SQUIRE	3
SPIRIT	3
COREQ	3
TRIPOD	3
PRISMA-P	2
Total	64

*CONSORT = Consolidated Standards of Reporting Trials, MOOSE = Meta-Analysis of Observational Studies in Epidemiology, QUOROM = Quality of Reporting of Meta-Analyses, PRISMA = Preferred Reporting Items for Systematic Reviews and Meta-Analyses, STARD = Standards for Reporting of Diagnostic Accuracy, STROBE = Strengthening the Reporting of Observational Studies in Epidemiology, ARRIVE = Animal Research: Reporting of In Vivo Experiments, CARE = case report guidelines, CHEERS = Consolidated Health Economic Evaluation Reporting Standards, SRQR = Standards for Reporting Qualitative Research, SQUIRE = Standards for Quality Improvement Reporting Excellence, SPIRIT = Standard Protocol Items: Recommendations for Interventional Trials, COREQ = consolidated criteria for reporting qualitative research, TRIPOD = transparent reporting of a multivariable prediction model for individual prognosis or diagnosis, and PRISMA-P = Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols.

Results

Of the 20 top Otolaryngology journals, 5 (25%) did not “require” nor “recommend” the use of a single guideline within their “Instructions to Authors” section. Of the remaining journals, 8 (40%) “required” the use of at least one guideline. The remaining 7 journals “recommended”, but did not “require” at least one guideline. Additionally, 9 (45%) of the journals did not require clinical trial registration prior to publication among RCTs. Among the journals requiring CONSORT guidelines 119 (59%) of the 199 RCTs included a CONSORT flow diagram within the study. Among the journals recommending CONSORT guidelines, only 92 (39%) of the 235 RCTs included a CONSORT flow diagram within the study. Journals requiring CONSORT guidelines were more likely to include flow diagrams compared to journals recommending CONSORT (odds ratio [OR] = 2.31, 95% confidence interval [CI] = 1.57-3.40)

Table 3. Comparisons of Reporting Guidelines According to Journal Policies

Reporting Guidelines	Flow Diagram	No Flow Diagram	Total
Requires CONSORT*	119	80	199
Recommends CONSORT	92	143	235
CONSORT not mentioned	102	131	233
Total	313	354	667

*CONSORT= Consolidated Standards of Reporting Trials

Table 4. Comparisons of Trial Registration According to Journal Policies

Trial Registration	Reported Trial Registration	Did Not Report Trial Registration	Total
Requires trial registration	143	256	399
No registration requirement	91	177	268
Total	234	433	667

Summary

Our results indicate that there is subpar utilization of reporting guidelines as well as enforcement of these guidelines among the top Otolaryngology journals. Of equal concern is the similar lack of utilization and enforcement of clinical trial registration. Based on the findings of our study this is a problem which can be solved at the journal level as requirement of these editorial policies leads to a 2.3x increased likelihood of adherence. As such we encourage Otolaryngology journals to adapt their policies to require incorporation of reporting guidelines and clinical trial registration in their published RCTs.

