EMORY UNIVERSITY

OtoSurg 1

A Prospective Evaluation of Worldwide Tonsillectomy Indications, Techniques, and Outcomes

Internal Protocol v3.2
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ABSTRACT

Background:

Tonsillectomy is the most common pediatric surgery performed globally, yet little is known about how tonsillectomy outcomes vary worldwide.

Preliminary Data:

Although generally considered a safe surgery, tonsillectomy carries significant risks. Approximately 3% of US children require hospital readmission within 30 days due to life-threatening complications. While mortality rates in high-income countries (HICs) are relatively low (~0.0005%), mortality rates in low- and middle-income countries (LMICs) are not well characterized, with some reports suggesting rates many times higher (~3%).

Research Gap:

Despite the frequency and significance of tonsillectomy, it remains unclear how surgical indications, techniques, and settings may impact outcomes worldwide. In addition, there is currently no mechanism to perform a prospective investigation of global tonsillectomy outcomes.

Hypotheses and Specific Aims:

We hypothesize that the morbidity and mortality of routine tonsil surgery vary significantly according to geographic region and healthcare setting, as well as surgical indications and techniques. We aim to 1) describe surgical indications and operative techniques used for

pediatric tonsillectomy across global World Health Organization (WHO) regions and 2) quantify 30-day post-tonsillectomy complication and mortality rates globally.

Design:

OtoSurg 1 will be an international, multi-site, prospective cohort study. The central IRB is approved and hosted by Emory University (IRB ID: STUDY00009113). All healthcare facilities globally that perform pediatric tonsillectomy will be invited to participate. Participating investigators will be trained to collect data on patients undergoing tonsillectomy over a 60-day period at their respective institutions. Site-based teams will record demographic data, surgical indication(s), surgical technique(s), postoperative complications, and mortality directly into a global de-identified tonsillectomy outcomes data registry. We will leverage existing relationships and professional networks to recruit participants from 30 sites in each of the six WHO regions for a target of 180 partner sites.

Potential Impact:

This study will highlight potential opportunities for intervention to standardize and improve outcomes for the world's most common pediatric surgery, focusing on LMICs. Beyond its primary objectives, this project will also seek to 1) recruit and train a collaborative research network of otolaryngology surgeons from around the world and 2) build the digital infrastructure necessary to support this network sustainably. This collaborative research network will serve as the foundation for future large-scale research initiatives and for the development and implementation of novel, data-driven interventions.

INTRODUCTION

The Global Otolaryngology-Head and Neck Surgery (OHNS) Initiative is a 501(c)(3) nonprofit organization that aims to perform global, collaborative public health research with the aim of better understanding and expanding access to otolaryngology care worldwide [1]. The Global OHNS Initiative has published expert consensus-based studies that identified priority global OHNS conditions and procedures in both adult and pediatric populations [2,3]. Examples of the procedures identified as global priorities were tonsillectomy, thyroidectomy, and tracheostomy. The significant and disparate global burden of otolaryngology conditions underscores the need to conduct robust international studies to identify opportunities for intervention and improve health outcomes [4–6].

Conducting meaningful global outcomes research in otolaryngology requires coordinated, large-scale collaboration across diverse healthcare settings. The GlobalSurg Collaborative (GlobalSurg) serves as a model for the design of this study. GlobalSurg, the product of the UK National Institute of Health Care Research's Global Health Research Unit on Global Surgery, is a robust international community that produces high-impact, prospective, multi-site research studies to advance surgical care [7–9]. In 2016, GlobalSurg published a landmark article assessing worldwide emergency abdominal surgery outcomes, establishing a precedent for the design of collaborative global international surgical outcomes research [7]. This study builds on the successful GlobalSurg model and will help quantify potential disparities in global pediatric tonsillectomy outcomes.

Study Topic Selection

Candidate procedures for OtoSurg 1 were first identified by the study authors using the Global OHNS Initiative's consensus priority procedures, which are widely performed across global settings, delivered by OHNS providers, and easily measurable [2]. Candidate procedures were discussed at two separate open forum Global OHNS Initiative meetings, and there was a collective agreement supporting the selection of pediatric tonsillectomy. Although tonsillectomy is the most common pediatric surgery worldwide, there is limited understanding of how its indications, techniques, and outcomes vary across diverse healthcare settings [10]. Findings from the Global OHNS Initiative studies highlight its importance: tonsillectomy and control of post-tonsillectomy hemorrhage were ranked among the top consensus procedures for pediatric otolaryngology [3]. At the same time, tonsillar hypertrophy and obstructive sleep apnea were identified as the 3rd and 6th most critical pediatric conditions, respectively [3].

Although generally considered a safe surgery, tonsillectomy carries significant risks for children. Approximately 3% of children in the United States (US) require hospital readmission within 30 days due to life-threatening complications [11,12]. While mortality rates in high-income countries (HICs) are low (~0.0005%), mortality rates in low- and middle-income countries (LMICs) are not well characterized, with some reports suggesting rates that are orders of magnitude higher (~3%) [13–15]. New techniques such as intracapsular tonsillectomy and radiofrequency plasma ablation (e.g., Coblator or COBLATION Technology (Trademark of Smith & Nephew PLC, Watford, England)) tonsillectomy may reduce the incidence of complications [16–20]. However, it is

unclear how these techniques are utilized across different settings and whether they are associated with specific postoperative outcomes.

The indications, techniques, and postoperative outcomes for pediatric tonsillectomy are well documented in the US, as evidenced by the updated clinical practice guideline from the American Academy of Otolaryngology – Head and Neck Surgery, published in 2019 [12]. A 2015 systematic review and meta-analysis of adenotonsillectomy complications identified respiratory compromise and secondary hemorrhage as the most common early complications globally [13]. However, country-specific clinical practice guidelines and investigations of postoperative complications remain limited in many settings. Several reports in the literature provide insight into current practices in LMICs. For example, Muninnobpamasa et al. described the prevalence of post-tonsillectomy complications at a single institution in Thailand, Kligerman et al. found that tonsillectomy (with or without adenoidectomy) was the most frequently performed OHNS surgery at a single institution in Haiti, and Onotai et al. reported that preoperative blood grouping and cross-matching before adenoid and tonsil surgeries were often not cost-effective or relevant in most circumstances at a single institution in Nigeria [14,21,22]. Additional reports from HICs highlight knowledge gaps. For example, Murto et al. identified that rates of adverse post-adenotonsillectomy outcomes and associated factors were poorly described in Canada, indicating a need for standardized perioperative treatment algorithms [15].

Building on this background, OtoSurg 1 will be an international, multi-site, prospective cohort study that will describe global variations in indications, techniques, and outcomes for pediatric tonsillectomy. Additionally, this study will provide a framework for future multinational,

prospective collaborations to be replicated across the global OHNS research community. Ultimately, this research network is intended to improve access to high-quality otolaryngology care globally.

MATERIALS AND METHODS

Aims

The primary aims of this project are 1) to characterize pediatric tonsillectomy surgical indications and techniques across World Health Organization (WHO) regions and 2) to quantify global pediatric 30-day post-tonsillectomy complications and mortality. The secondary aims of this project are 1) to recruit and train a collaborative research network of otolaryngology surgeons and trainees from around the world who will be poised to carry out future research projects and 2) to build the digital infrastructure necessary to support this network sustainably.

Hypothesis

We hypothesize that the morbidity and mortality associated with routine tonsillectomy, as well as surgical indications and techniques, vary significantly across different geographic regions and healthcare facilities.

Study Design, Setting, and Site Eligibility

OtoSurg 1 will be an international, multi-site, prospective observational cohort study. This study will follow a methodology similar to that previously developed and implemented by GlobalSurg [23,24]. The OtoSurg Leadership Team will consist of three groups: Recruitment and Publicity, Research Support, and Data Management and Analytics (Figure 1). The Recruitment and

Publicity Team will oversee all WHO regional leads, individual country leads, and specific hospital teams. The Research Support Team will manage the onboarding process for new OtoSurg members, develop educational materials, and assist with IRB and REDCap use. The Data Management and Analytics Team will collect, validate, and analyze all study data. By working closely together, these three core teams will serve as the organizational framework of OtoSurg 1.

The broader OtoSurg network will be organized utilizing a hub-and-spoke model, with the Global OHNS Initiative and Emory University serving as the central hub, linking to regional representatives across the six WHO regions and individual researchers at country-specific partner sites (Figure 2). Any healthcare facilities worldwide where pediatric tonsillectomies are performed will be eligible to participate (except sites in the People's Republic of China (PRC) due to the Personal Information Protection Law (PIPL) of the People's Republic of China). The study will aim for balanced representation from each of the six WHO regions.

Each participating research site must have between two and four investigators, fulfilling the required roles of Data Recorder, Data Validator, and Team Lead. The Data Recorder and Data Validator must be two separate individuals. However, either of these individuals may also serve as the Team Lead. The Team Lead will act as the primary point of contact with the central coordinating hub. Whenever possible, each team is encouraged to include at least one attending physician from the participating site. The attending physician may serve as the Data Recorder, Data Validator, or Team Lead, or may instead participate in a more general advisory capacity to support the team. Participating sites must obtain IRB approval or exemption and have access to

the shared REDCap database. Aside from these requirements, there are no strict inclusion or exclusion criteria for sites. There is no minimum number of patients required to be recorded per facility or healthcare setting.

A team will capture data on all pediatric tonsillectomy cases performed at their site during the designated 60-day study period – even if not every case is performed by the specific attending physician listed on the project. The attending physician listed on the project will serve as the representative for the entire division or site. For example, at Emory University, the Division of Pediatric Otolaryngology includes seven faculty members. Even if only one faculty member is designated as the attending physician on the Emory OtoSurg 1 team during a 60-day data collection period, we encourage the inclusion of all tonsillectomy cases performed by any member of the division during that time frame. This approach will help ensure comprehensive data capture and avoid selection bias. However, the final decision regarding which cases to include will be at the discretion of each participating site and is subject to their local IRB/Ethics approval process. Every member of each research team will be listed as an author on the final manuscript, except those who do not meet the data validation criteria outlined below.

Timeline

The study will begin with recruiting and training participating sites. Recruitment, training, and individual site IRB approval will occur over 12 months from October 13, 2025, to October 13, 2026 (Fig 3). The six-month data collection period will be from October 13, 2026, to April 13, 2027. Individual sites will be able to select any 60-day interval during this data collection

window to record and submit their data. Data validation, cleaning, and preparation will occur over two months from April 13, 2027, to June 13, 2027. Data analysis will occur over two months, from June 13, 2027, to August 13, 2027. Results are expected to be complete by August 13, 2027. Manuscript writing, review, and author validations will occur over two months, from August 13, 2027, to October 13, 2027. We anticipate submitting the final manuscript in late 2027 or early 2028.

Study Population and Inclusion/Exclusion Criteria

The study population will comprise all consecutive patients under 18 years old undergoing tonsillectomy during the specified study period at the participating site. Tonsillectomy will be defined as the removal or ablation of any amount of palatine tonsil tissue using any surgical method. Both unilateral and bilateral tonsillectomy cases are eligible. Patients undergoing concurrent procedures, such as adenoidectomy or tympanostomy tube placement, will be included. Sites from any country worldwide are eligible to participate, excluding the PRC due to the PIPL.

Outcome Measures

The primary outcome measures will include the distribution of pediatric tonsillectomy surgical indications and techniques across WHO regions and the rate of complications and mortality within 30 days of tonsillectomy. Complications will be defined as hospital readmission, unplanned surgical intervention, or postoperative hemorrhage. Postoperative hemorrhage will be

defined as any amount of postoperative bleeding that prompts the patient to return to the hospital, seek additional medical care, require further medical intervention, or delay hospital discharge. [12,25,26]

Data Abstraction and Recording

Each participating site will prospectively collect and record data over a consecutive 60-day period of its choosing within the overall 6-month data collection window. Participating teams will implement site-specific strategies to ensure the identification and inclusion of all eligible patients. These strategies may include daily review of operating room logbooks, multidisciplinary team meetings, and review of surgical admission or handover lists. Patient-level data will be obtained through a review of medical records, discussions with clinical team members, or, where appropriate, communication with patients and their families during routine clinical care. Data on postoperative complications will be collected based on return visits to the clinic, emergency room, and/or hospital within 30 days following surgery. Teams will not be required to contact patients and families individually to inquire about postoperative complications. The following patient data will be collected: age, sex, anesthesia preoperative risk class, tonsillectomy indication, tonsillectomy technique (intracapsular vs extracapsular; Bovie/monopolar diathermy vs bipolar diathermy vs radiofrequency plasma ablation vs microdebrider vs cold steel vs other), 30-day postoperative major complications, and 30-day postoperative mortality. In addition, data on participating sites will be collected, including WHO region, country, WHO health care facility level, and country World Bank income group [27]. The data variables and specific survey questions were developed using iterative feedback from

representatives of each of the six WHO regions. Further information pertaining to anesthesia preoperative risk class, indications for surgery, and surgical instrumentation may be found in Appendix A. A complete list of captured data elements and parameters may be found in Appendix B.

The OtoSurg team will offer two options for data recording: either a hard copy or an electronic form. Sites can use either method or a combination of both, depending on their local workflows. All data must be recorded in a de-identified format using a unique study identifier (ID). Each site is responsible for maintaining a secure local linkage file that connects study IDs to individual patient identifiers. This file will remain confidential and will not be shared with the OtoSurg team.

Data Submission

Data submission will be completed using a secure, password-protected REDCap survey link provided by the OtoSurg team. This link will only be accessible to sites that have received IRB approval or exemption to participate. Data for each patient must be submitted no earlier than 30 days after their surgery date to ensure complete 30-day outcome reporting. Sites can choose to submit data continuously, in batches, or all at once, but all data must be submitted within three months of the site's initial data collection start date. Once a REDCap survey response is submitted, it cannot be edited or revised, so sites must ensure completeness and accuracy before submission.

Data Validation

Each participating site will designate one team member as the Data Validator. This person will independently record the total number of tonsillectomy cases that meet the inclusion criteria during the specified data collection period at their site. This total will be referred to as the total case ascertainment. Data Validators can gather this information either prospectively or retrospectively, depending on what is most practical for their site's workflow and record-keeping systems. Sites missing data for more than 20% of patients included during their 60-day collection period will be excluded from the final analysis and will be ineligible for authorship.

The Data Validator will be randomly assigned five cases from their team to review. The Data Management and Analytics team will randomly assign these cases and provide the Data Validator with the submitted data. If fewer than five cases are available, all eligible cases will be reviewed. To perform the review, the Data Validator will obtain the de-identified study data and the local linkage file from the Data Recorder, which will be in the form of a Microsoft Excel file or a hard copy paper file. Using this information, the Data Validator will conduct a retrospective chart review for these cases to evaluate the accuracy and completeness of the recorded data. The Data Validator will submit a separate, password-protected REDCap survey link provided by the OtoSurg team. This survey will ask the Data Validator to assess the accuracy and completeness of the recorded data and determine if patients had postoperative follow-up.

Recruitment and Training

An open invitation to participate in OtoSurg 1 will be broadly shared through personal contacts, professional email listservs, and existing national and international networks. Regional and country leads will be recruited who can provide a detailed site-specific understanding to support recruitment and training. The Recruitment and Publicity Team will partner directly with the Global OHNS Initiative's extensive network of LMIC and HIC providers in addition to collaborating with otolaryngology professional society leaders worldwide to promote balanced representation from all WHO regions.

The OtoSurg team will provide research training and access to a shared REDCap database. They will also assist with participant recruitment and IRB processes. Training resources will include live webinars, PDF documents (including a dedicated IRB support guide), and pre-recorded videos developed for this study. Training materials will be offered in English, with translations into partner site languages as resources permit. Training materials will be hosted on a central website to facilitate access by participants globally.

Power Analysis and Statistical Analysis Plan

Aim 1 (to characterize pediatric tonsillectomy surgical indications and techniques across WHO regions) will be purely descriptive and does not require a power analysis. We aim to recruit 30 individual sites from each of the six WHO regions (a target of 180 total sites) to ensure the data is globally diverse and representative of each WHO region.

Aim 2 (to quantify global pediatric 30-day post-tonsillectomy complications and mortality) is more specific and does require a detailed power analysis and statistical plan. To achieve this aim, we will compare the differences in rates of both major complications and mortality between HICs and LMICs. The rate of postoperative complications is estimated to be approximately 5% greater in LMICs than in HICs [13,16,23,24]. We anticipate an unbalanced sampling ratio of 70% HIC and 30% LMIC participants. To achieve 80% power and 95% confidence with the above effect size and sampling ratio, we will need to recruit data from a total of 5,770 individual patients. Regarding the secondary outcome of mortality, our literature review suggests a maximum mortality rate of 3% in LMICs, compared to a maximum rate of 0.01% in HICs [10,21]. Assuming the same parameters as above, we must recruit data from at least 4,260 participants to detect a difference between HIC and LMIC populations.

Univariate and multivariate logistic regression will be performed to calculate the odds of major complications and mortality based on the location of surgery (i.e., LMICs vs. HICs). Confounders will be accounted for using regression modeling and controlling for surgical technique, anesthesia preoperative risk class, and patient factors (e.g., age). In addition, descriptive analysis will be performed to highlight differences in surgical techniques and demonstrate possible trends between techniques, indications, and outcomes. The study's secondary aims do not require a specific power analysis or statistical plan.

Ethical Concerns

There are no specific ethical concerns regarding this project. All data will be observational, de-identified, and will not impact patient clinical care. Individual IRB approval or exemption will be required for each participating site. All collaborators will be appropriately trained and supported with guidance on how to seek local IRB approval or exemption. All members of research teams at participating sites will receive authorship credit on any manuscripts produced in accordance with the previously defined authorship criteria and the Global OHNS Initiative Research Equity Guidelines [28].

Consent Process

The authorship team believes a waiver of informed consent is valid for this study, and a waiver has been granted by the central hub IRB/ethics committee at Emory University. Informed consent was waived on the basis that the proposed data collection involves no increased risk to study subjects. Like most chart review studies, this project involves a review of medical records, which, by nature, contain protected health information; however, no direct interventions, treatments, or interactions with participants will occur. The medical record will be reviewed, and de-identified data will be recorded directly into REDCap, ensuring that there is no potential for physical, psychological, or social harm to participants. However, each individual participating site needs to make its own determination in accordance with local IRB/ethics committee requirements.

In anticipation of partner sites whose IRB/ethics committees may deny a waiver of informed consent and require written consent, we have provided a standardized, plain-language patient

information sheet and written participant consent form, both of which are available on the OtoSurg website. All study participants will be children <18 years old. As such, for partner sites that require written consent, consent will be obtained from the child's parent or legal guardian. Consent forms will be completed by either the principal investigator, a partner site research team member, or a member of hospital staff whose regular clinical responsibilities and privileges include obtaining consent from patients and their families. Three copies of each consent form will be made, one for the patient and their family, one for the research team's records, and one for the hospital's records.

DISCUSSION

Our study aims to assess postoperative complications and mortality in pediatric tonsillectomy cases globally, identifying gaps and highlighting targetable areas for improving outcomes across varying settings. Additionally, this study will foster the development of a collaborative international OHNS research network and build the digital infrastructure to support this network sustainably.

Potential Difficulties and Limitations

Similar methodological studies have been successfully conducted in the general surgery literature [7–9,29–44]. A potential challenge will be recruitment and participation in LMICs. We have accounted for this by utilizing an unbalanced sampling ratio of 70% HICs to 30% LMICs and allocating 12 months for site recruitment. Additionally, we have selected the Global OHNS Initiative as a central hub to facilitate outreach to and relationships with LMIC partners.

Another challenge will be ensuring data accuracy. For this reason, we are devoting significant time and effort to training collaborators. We have developed research training that follows well-established principles, encouraging participating sites to implement data extraction methods that are contextually appropriate for their institutions [9]. Additionally, we will require each site to have a designated Data Validator who will audit results to ensure data completion and accuracy.

A small portion of complications and/or mortalities may be missed if patients do not return to the same hospital where they had their initial surgery. This is an inherent limitation of the study. When reviewing cases, the Data Validator will assess the number of postoperative patients who had direct follow-up, regardless of their complication status. Additionally, velopharyngeal insufficiency and velopharyngeal and/or oropharyngeal stenosis are important major complications that are more likely to occur with poor surgical technique and which may be underreported in some regions. However, these complications typically take more than 30 days to become clinically evident in the postoperative period. As such, patients who develop these complications may be missed, an inherent limitation of the study design.

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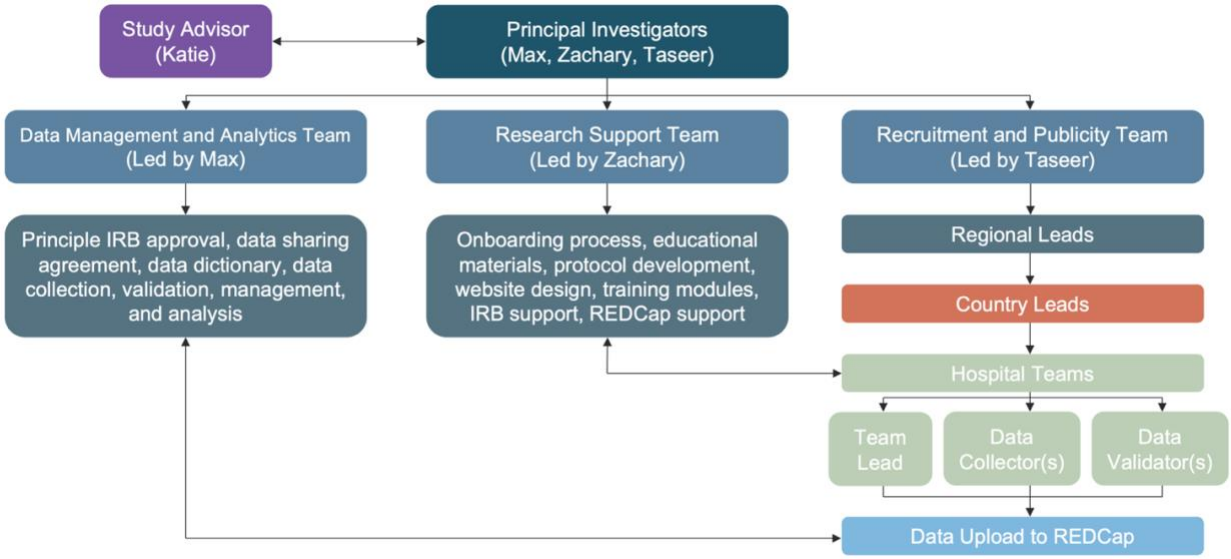
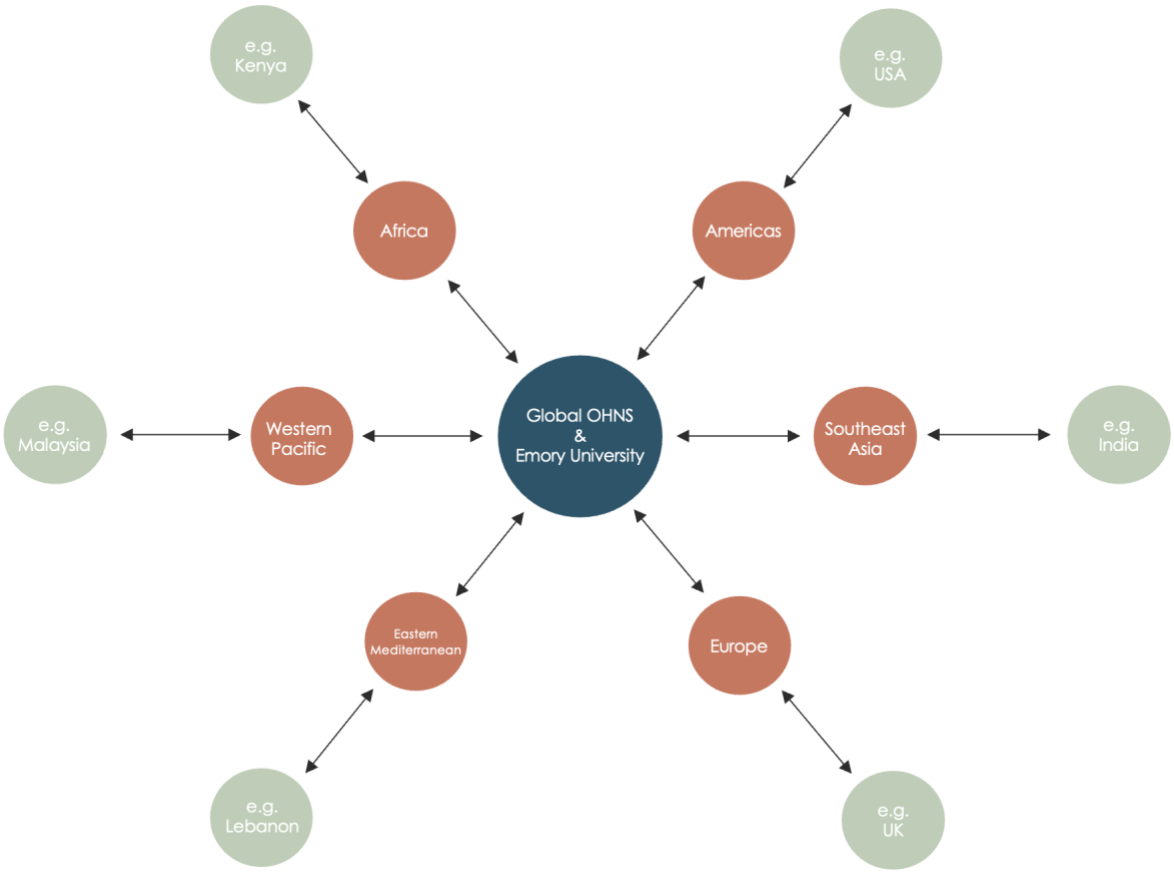
FIGURES

Figure 1: OtoSurg 1 Organizational Structure



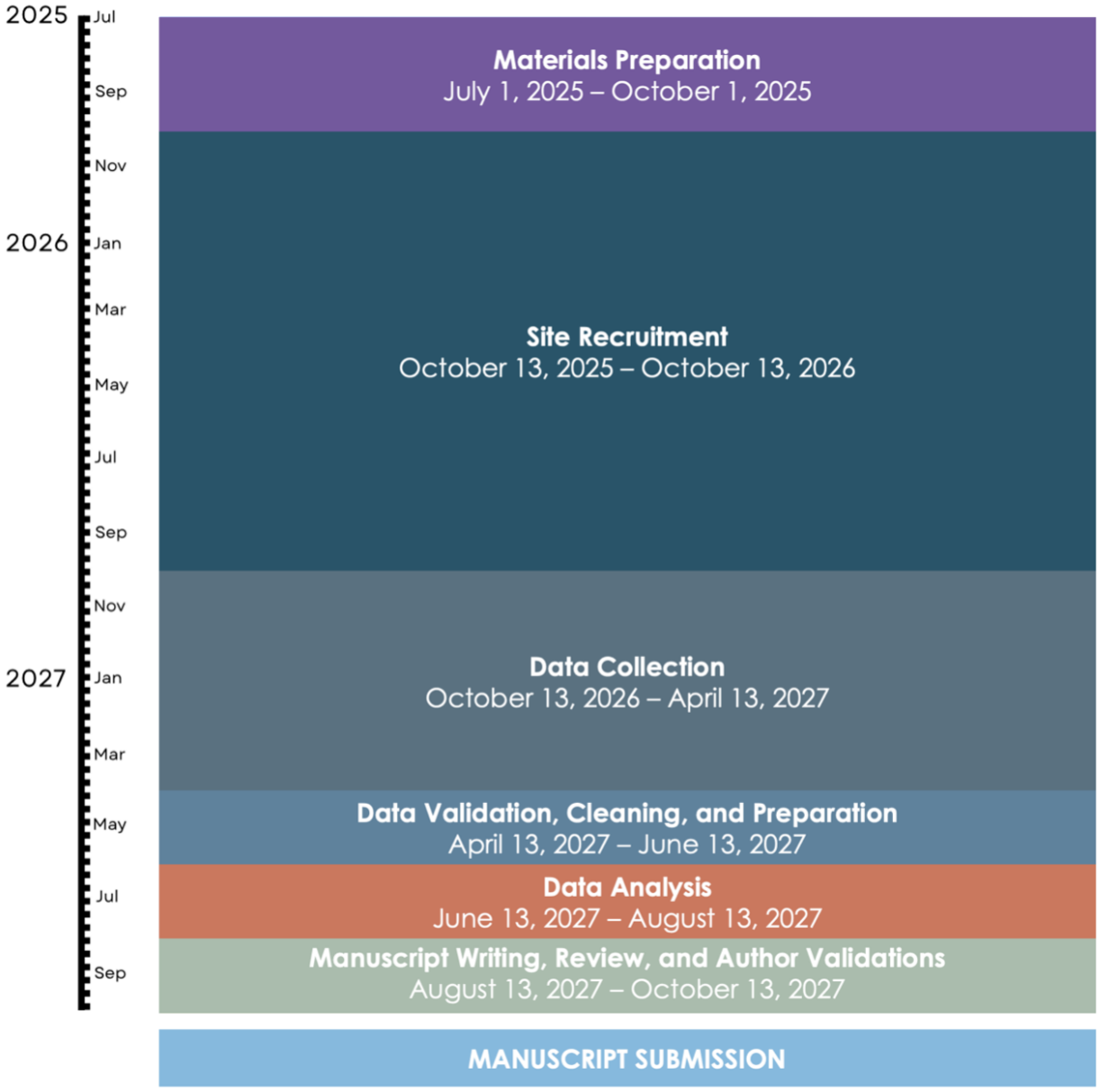
The OtoSurg Leadership Team will consist of three groups: Recruitment and Publicity, Research Support, and Data Management and Analytics. The Recruitment and Publicity Team will oversee all WHO regional leads, individual country leads, and specific hospital teams. The Research Support Team will manage the onboarding process for new OtoSurg members, develop educational materials, and provide IRB and REDCap assistance. The Data Management and Analytics Team will collect, validate, and analyze all study data. By working closely together, these three teams will serve as the organizational framework of OtoSurg 1.

Figure 2: OtoSurg 1 Hub-and-Spoke Model



The Global OHNS Initiative and Emory University will serve as the central hub (blue), and regional representatives in the six WHO regions (orange) will act as liaisons to individual partner sites (green).

Figure 3: OtoSurg 1 Timeline



Overview of the OtoSurg 1 project timeline.

Appendix A: Perioperative Classifications, Indications, and Instruments

American Society of Anesthesiologists (ASA) Classification: [45]

ASA Classification	Definition	Example
I	A normal healthy patient.	Healthy, non-smoking, no or minimal alcohol use.
II	A patient with mild systemic disease.	Mild diseases only without substantive functional limitations. Current smoker, social alcohol drinker, pregnancy, obesity (30<BMI<40), well-controlled DM/HTN, mild lung disease
III	A patient with severe systemic disease.	Substantive functional limitations; One or more moderate to severe diseases. Poorly controlled DM or HTN, COPD, morbid obesity (BMI ≥40), active hepatitis, alcohol dependence or abuse, implanted pacemaker, moderate reduction of ejection fraction, ESRD undergoing regularly scheduled dialysis,

		history (>3 months) of MI, CVA, TIA, or CAD/stents.
IV	A patient with severe systemic disease that is a constant threat to life.	Recent (<3 months) MI, CVA, TIA or CAD/stents, ongoing cardiac ischemia or severe valve dysfunction, severe reduction of ejection fraction, shock, sepsis, DIC, ARD or ESRD not undergoing regularly scheduled dialysis.
V	A moribund patient who is not expected to survive without the operation.	Ruptured abdominal/thoracic aneurysm, massive trauma, intracranial bleed with mass effect, ischemic bowel in the face of significant cardiac pathology or multiple organ/system dysfunction.

Abbreviations:

DM Diabetes Mellitus

HTN Hypertension

COPD Chronic Obstructive Pulmonary Disease

ESRD End-Stage Renal Disease

MI Myocardial Infarction

CVA Cardiovascular Accident

TIA Transient Ischemic Attack

CAD Coronary Artery Disease

DIC Disseminated Intravascular Coagulation

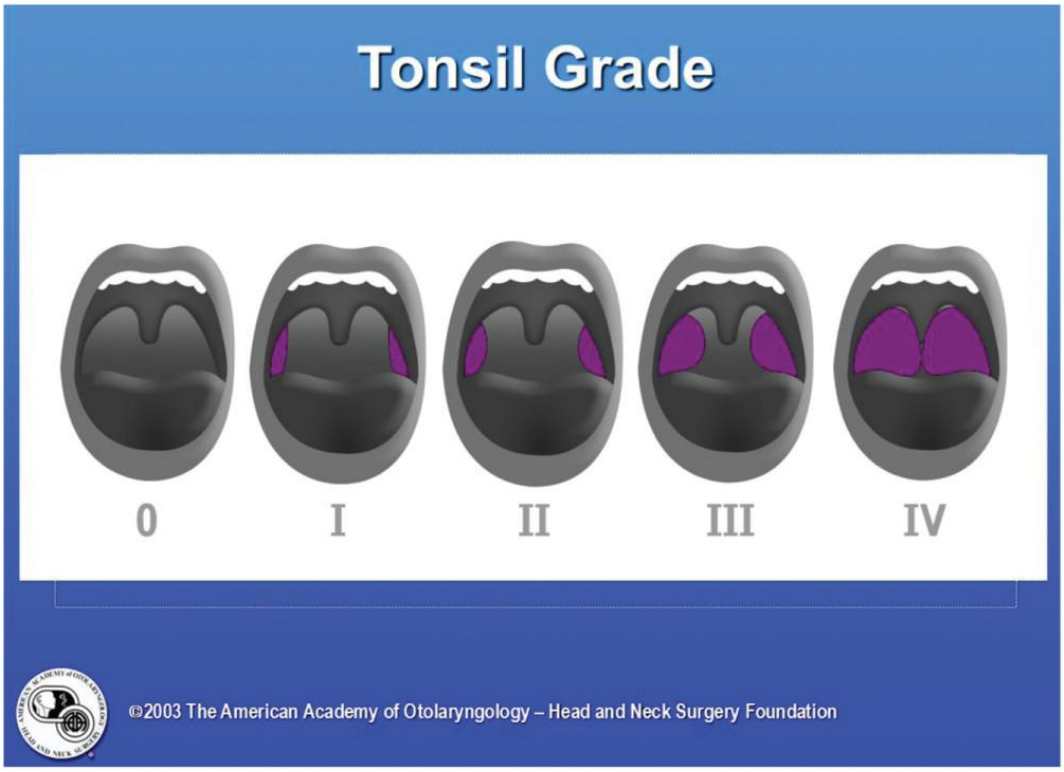
ARD Acute Respiratory Distress

Indications for Surgery: [12]

Indications	Definition
Recurrent throat infections	≥7 episodes in past year, ≥5 episodes per year for 2 years, or ≥3 episodes per year for 3 years; each episode should have clinical features (fever, cervical adenopathy, tonsillar exudate, or positive group A strep test). May also consider surgery with modifying factors (severe episodes, antibiotic allergies, significant school absences).
Obstructive sleep-disordered breathing (oSDB)	Clinical diagnosis: obstructive abnormalities of respiratory pattern or oxygenation/ventilation during sleep (snoring, mouth breathing, apneas). Includes spectrum from primary snoring to obstructive sleep apnea (OSA). Associated symptoms: inattention, poor concentration, hyperactivity, excessive sleepiness, growth failure, enuresis, behavioral problems.

Tonsil Grading: [12,46]

Brodsky Grading	Definitions
Grade I (Tonsils hidden within pillars)	Tonsils occupy <25% of airway
Grade II (Tonsils extend to pillars)	Tonsils occupy 25–50% of airway
Grade III (Tonsils extend beyond pillars)	Tonsils occupy 50–75% of airway
Grade IV (Tonsils extend to midline)	Tonsils occupy >75% of airway



Definitions of Postoperative Complications: [12]

Complications	Definitions
Primary bleeding	Bleeding occurring within 24 hours of surgery
Secondary bleeding	Bleeding occurring more than 24 hours after surgery
Respiratory compromise	Airway obstruction, laryngospasm, or hypoxemia requiring intervention
Pain	Significant throat pain postoperatively, often requiring analgesia
Dehydration	Inadequate oral intake leading to clinical dehydration, sometimes requiring IV fluids
Nausea and vomiting	Postoperative emesis, may delay oral intake and discharge
Trauma to adjacent structures	Injury to teeth, lips, tongue, pharyngeal wall, or soft palate during surgery
Velopharyngeal insufficiency	Hypernasal speech or nasal regurgitation due to palatal dysfunction
Post obstructive pulmonary edema	Pulmonary edema following relief of chronic upper airway obstruction
Referred otalgia	Ear pain due to shared nerve pathways with the oropharynx
Death	Rare, but may result from severe bleeding or airway compromise

Instruments:

Device	Image
Radiofrequency Plasma Ablation	
Snare	

Curette	
Microdebrider	

Bovie/mono- polar cautery	
Suction Bovie	
Scalpel	

Appendix B: Data Dictionary

Pediatric Tonsillectomy Case	Required Data (description/comment)
Study Site Information	
Site ID (Unique ID for your study location.) Note: Must star with 2 letters and end with 4 numbers.	Text, required
Email address for site study coordinator	Text (email), required
Subject Demographics	
Patient De-identified Study Number (Unique deidentified code for the specific study subject)	Text, required
Sex at birth	Male / Female / Non-binary / Not reported
Subject Age (age in years at time of procedure; please round to the nearest whole year)	Text (integer, Min: 0, Max: 120), Required
Body mass Index (BMI) (kg/m^2)	(number; record to 1 decimal point)
Subject Characteristics	
Major Medical Comorbidities (Health Conditions)	1) Autoimmune condition (e.g., rheumatoid arthritis, systemic lupus erythematous, vasculitis) 2) Bleeding disorder 3) Cardiac disease (e.g. congenital heart defect or valvular disease)

	4) Cerebral palsy 5) Chronic kidney disease 6) Craniofacial abnormalities (i.e. Cleft palate or cleft lip, Pierre Robin, craniosynostosis, hemifacial microsomia, etc.) 7) Developmental delay 8) Down Syndrome 9) Diabetes (Type 1 or 2) 10) Severe asthma/ hyperactive airway disease 11) Sickle cell disease 12) Other neurological disorder 99) Other 0) None 999) Data unavailable
If other major medical comorbidity was noted, please specify:	Text
Anesthesia preoperative risk class (ASA physical status classification) (For additional information, please visit this link: ASA physical status classification): ASA I: an otherwise healthy child.	ASA I / ASA II / ASA III / ASA IV / ASA V

ASA II: patient with mild systemic disease. - For example, a child with mild asthma, mild obstructive sleep apnea or a well-managed abnormal heart rhythm. ASA III: patient with severe systemic disease. - For example, a child with severe asthma, a heart abnormality, epilepsy, or severe obstructive sleep apnea. ASA IV: patient with severe systemic disease that is a constant threat to life. - For example, a child with heart failure or dependent on a ventilator. ASA V: moribund patient who is not expected to survive without surgery. - For example, a child with a brain bleed or severe liver disease.	
Tonsillectomy indication	1) Recurrent acute tonsillitis / 2) Sleep disordered breathing and/or obstructive sleep apnea (either diagnosed clinically or via pre-operative testing)

	3) Peritonsillar abscess (either acute or history of peritonsillar abscess) / 4) Halitosis or tonsilliths 5) Tonsillar hypertrophy interfering with eating, speaking, or breathing 6) Tonsillar asymmetry/ Concern for neoplasm 9) Other indication
If other indication, please specify.	Text
Were either a pre-operative overnight polysomnogram, pulse oximetry, or other similar testing performed?	No / Yes- Polysomnogram/ Yes- Pulse oximetry/ Yes- Other preoperative overnight sleep testing/ Data unavailable
On pre-operative polysomnogram, what OSA severity was determined?	Mild (1-4) /Moderate (5-9) / Severe (10 or greater) / Not applicable (NA)/ Data unavailable
From pre-operative overnight oximetry, please record value for oxygenic desaturation index (ODI):	Text
From pre-operative overnight oximetry, please record value for O2 nadir, if available:	Text

If other pre-operative sleep testing was performed, please record available test results:	Text
Please select grade of pre-operative palatine tonsillar hypertrophy:	Grade I (Tonsils hidden within pillars) / Grade II (Tonsils extend to pillars) / Grade III (Tonsils extend beyond pillars) / Grade IV (Tonsils extend to midline)/ Data unavailable
Operative procedure	
Was an additional procedure (e.g., adenoidectomy, turbinate reduction, or other) performed at the time of tonsil surgery?	Yes/No
If yes, what additional procedure was performed?	Adenoidectomy/ Turbinate reduction/ Myringotomy with or without ear tube placement/ Other (open response)
If other procedure was performed at time of tonsillectomy, please indicate:	Text
Dissection Type	Intracapsular (partial/tonsillotomy) / Extracapsular (total)
What was the primary technique used for tonsillectomy/tonsillotomy?	Primary cold steel device (i.e. Snare or Scalpel or Microdebrider) /

(Please select the single answer that best describes the procedure)	Thermal powered device (i.e. Bovie/electrocautery or Radiofrequency plasma ablation)
If thermal powered device, what was the primary device used for procedure? (Note: If multiple devices were used, select only the one that you feel represents the primary device.)	Bovie (unipolar)/ Suction Bovie / Radiofrequency plasma ablation / Bipolar / Other (open response)
If cold steel device, what was the primary device used? (Note: If multiple devices were used, select only the one that you feel represents the primary device.)	Snare / Scalpel / Microdebrider / Fisher Tonsil Blade/ Hurd Dissector/ Other (open response)
What tools were used for hemostasis? (Please select all that apply)	Bovie (monopolar)/ Suction Bovie / Radiofrequency plasma ablation / Bipolar / Suture ligation/ Other (open response)
If other, please indicate what device was used for hemostasis:	Text
If other, please indicate what thermal powered device was used:	Text
If other, please indicate what cold steel device was used:	Text

What was the intraoperative estimated blood loss (EBL) for the procedure (in mL)?	Text (integer)
What was the patient's post-operative discharge status?	Same-day discharge to home/ Admitted to hospital overnight following surgery/ Other (please specify)
If patient was admitted postoperatively, please indicate level of care (floor, ICU) for admission:	Hospital floor bed/ Intensive care unit (ICU)
If postoperative discharge status is not listed above, please elaborate:	Text
Was an additional procedure (e.g., adenoidectomy, turbinate reduction, or other) performed at the time of tonsillectomy?	Yes / No
Postoperative complications and 30-day course	
30-day postoperative major complication (Select all that apply)	1) Hospital re-admission / 2) Need for unplanned surgical intervention / 3) Post-operative hemorrhage (greater than 15 mL) / 9) Other
If you believe another major postoperative complication occurred that is not reflected in the above choices, please specify:	Text

If postoperative complication was hospital readmission, reason for re-admission: (Please select all that apply)	1) Poor oral intake (including dehydration or vomiting) / 2) Pain control / 3) Tonsil bleeding / 4) Post-operative infection (e.g. lower respiratory tract infection)/ 5) Need for unplanned laryngo-tracheal intubation (distinct from intubation that may have been required for revision surgery) 9) Other
Management strategy for postoperative hemorrhage:	No intervention (observation) / Conservative measures (e.g. IV hydration, medication, or direct pressure) / Surgical control of bleeding Other
Timing of postoperative hemorrhage	Primary (less than 24 hours from completion of surgery)/ Secondary (greater than 24 hours from completion of surgery)
If other intervention for postoperative hemorrhage, please specify:	Text
Postoperative 30-day mortality/ death	Yes / No

Please describe postoperative cause of death (as best as possible):	Text

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