



# Difficult clinical decisions in sleep apnea surgery: identifying priorities for future clinical trials

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**Background:** A fundamental ethical principle for randomized clinical trials is to test clinical questions where equipoise (i.e., uncertainty) exists surrounding the correct treatment. We aimed to measure perceived importance, individual and collective community equipoise, and willingness to enroll patients in five potential trial targets (4 of which relate to pediatric patients) among otolaryngologists.

**Methods:** Sixty otolaryngologists attending the 5<sup>th</sup> South Pacific Otorhinolaryngology Forum Meeting in Fiji 2023 were surveyed using an electronic questionnaire. Equipoise was measured for all scenarios using three metrics. Metric 1: degree of importance measured using an ordinal scale. Metric 2: degree of clinical uncertainty measured using a bidirectional ordinal scale comparing two treatments. Responses were plotted in histograms and then categorized into three groups: (A) preferred treatment 1, (B) completely undecided, and (C) preferred treatment 2. The resulting proportions provide equipoise ratios: A:B:C. Metric 3: willingness to enroll patients in a randomized trial.

**Results:** Forty-eight otolaryngologists were eligible and completed the questionnaire. Three of the five potential trial scenarios exhibited high importance, community equipoise and willingness to enroll in a randomized controlled trial (RCT).

**Conclusions:** We identified three viable trial targets (2 pediatric, 1 adult) with perceived importance, equipoise and willingness to enroll patients in a RCT. Pediatric targets included multilevel upper airway surgery compared to device therapy post adenotonsillectomy with persistent symptomatic obstructive sleep apnea (OSA) [C = mild apnea-hypopnea index (AHI)  $\leq 5$ , D = moderate-severe AHI  $\geq 5$ ]. The adult target compared addition of drug-induced sleep endoscopy (DISE) to clinical examination alone in assessment of persistent symptomatic OSA (E = AHI  $\geq 5$ ) post adenotonsillectomy.

**Keywords:** Clinical equipoise; sleep apnea; snoring; tonsillotomy; tonsillectomy

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## Introduction

Obstructive sleep apnea (OSA) is a chronic condition causing marked morbidity and mortality, and is treated differently in children and adults (1-4). Pediatric OSA has a reported incidence of up to 5.7%, and may lead to behavioral and cognitive abnormalities, growth failure, systemic hypertension and cardiovascular effects such as cor-pulmonale, right and left ventricular dysfunction (5-8).

In Adults, partial or complete upper airway occlusion is temporized using conventional treatments such as: continuous positive airway pressure (CPAP); or dental appliance treatments including mandibular advancement splints (MAS) (9,10). However, in the pediatric population concerns of poor treatment adherence are magnified, raising the potential for targeted effective surgical treatments (11). The important considerations when initiating surgical intervention to treat pediatric OSA include integrating: age; symptom severity; underlying medical co-morbidities; with patient anatomy and polysomnographic findings.

The American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) and American Academy of Pediatrics (AAP) recommend adenotonsillectomy as first-line treatment for OSA in healthy children over two years of age with moderate-severe OSA and adenotonsillar hypertrophy (12,13). Several randomized systematic reviews have concluded that adenotonsillectomy is associated with less postoperative morbidity than adenotonsillectomy, but with a similar effect on pediatric OSA symptoms (14-18). However, there is a lack of prospective long-term randomized controlled trials (RCTs) to determine the risk of regrowth and reoperation rates.

Drug-induced sleep endoscopy (DISE) is increasingly being used to evaluate anatomical sites of collapse prior to surgical intervention both in children with multilevel collapse or with persistent OSA following adenotonsillectomy (19-21). Multilevel upper airway surgical procedures are sometimes considered to treat persistent pediatric OSA following adenotonsillectomy after careful flexible fiberoptic nasolaryngoscopic evaluation (22,23).

Randomized clinical trials are the gold standard for testing treatment effectiveness. Fifteen years ago, both the funding and effectiveness of upper airway surgery for snoring and sleep apnea came into question due to a lack of high-quality RCTs (24,25). This incentivized the field into developing and conducting RCTs (26-29). Despite these well executed trials, additional high-quality studies in the medium to long term are required to justify funding and strengthen the indication for surgery in specified situations.

Clinical trials in surgery are difficult to successfully undertake and pose particular practical and methodological challenges that have been examined in the literature (30-32). A number of barriers accounting for a relative lack of surgical RCTs have been described including: selecting appropriate control group; blinding; standardizing surgical technique between individual surgeon and centers over time (33,34). However, the inherent value of a well-conducted RCT should not be overlooked. Collaboration between research and surgical communities is essential to enable the conduct of well-designed and appropriate trials (35).

Barriers to recruiting individual surgeons and participants for clinical trials include time constraints; risk to therapeutic doctor-patient relationship; and perceived importance of research questions (36). The dual-role of the surgeon-researcher is the main source of ethical conflict in surgical RCTs. Even if the surgical community is in equipoise about a clinical scenario, individual surgeons may have strong treatment preferences which may dissuade their enrollment of patients. To conduct a clinical trial a genuine state of clinical uncertainty or equipoise should exist within the surgical community when less than 70% of clinicians agree that a particular treatment option is superior (37).

A single surgeon may have “individual equipoise”, whereby they are genuinely uncertain of which treatment holds superior therapeutic merit. The surgical community can also demonstrate “community equipoise” by one of two outcomes: majority are uncertain; or equal proportions favoring each alternative treatment (37).

There is a need to identify appropriate and well-designed clinical trials in sleep surgery that are ethical, viable and broadly supported by the surgical community for addressing clinical questions in which community equipoise exists. Our previous study identified two potential RCT targets in adults with OSA. This study identified multiple potential RCT targets in paediatric OSA. We present five common, but untested, clinical scenarios for practicing otolaryngologists to gauge perceived clinical importance, community and individual equipoise and willingness to enroll patients in either a RCT or non-randomized follow up study. We present this article in accordance with the SURGE reporting checklist (available at <https://www.theajo.com/article/view/10.21037/ajo-24-16/rc>).

## Methods

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). This study was approved

by the Illawarra Shoalhaven Local Health District Research Review Board, Low and Negligible Risk (ISLHD LNR/QA205, 26/07/23) Review. Informed consent was taken from all individual participants. All participants were attendees of the 5<sup>th</sup> South Pacific ORL Forum Meeting in Fiji 2023 who were surveyed to quantify their attitudes toward five clinical scenarios. Surgeons were given a QR code link attachment to an online questionnaire. Most surgeons completed the questionnaire at the time of the meeting, however one month allowed to submit before the data collection phase was closed. Respondents who indicated they were not involved in sleep surgery were excluded from analysis.

We presented five clinical scenarios (A to D pediatrics, E adults) each with two treatment options. The questionnaire [see Supplementary file ([Appendix 1](#))] methodology was developed by the Surgical Outcomes Research Centre in Sydney (REFS), modified from our previous study, published in *Otolaryngology-Head & Neck Surgery*, “Clinical Equipoise in Sleep Surgery” [2011] (32).

- ❖ Scenario A: intracapsular tonsillectomy compared to tonsillectomy in pediatric patients (aged 2–18 years) with sleep breathing disorder (no prior surgery or history of recurrent tonsillitis).
- ❖ Scenario B: is the addition of DISE to clinical examination better than clinical examination alone in pediatric patients (aged 2–18 years) post adenotonsillectomy with persistent symptomatic OSA with an apnea-hypopnea index (AHI)  $\geq 2$  on polysomnogram?
- ❖ Scenario C: multilevel stepwise upper airway reconstruction (any identifiable target can be addressed; revision (adeno)tonsillectomy, inferior turbinoplasty, lingual tonsil reduction, supraglottoplasty, other—performed at clinician discretion) compared to medical &/or device therapy (orthodontic procedures, MAS, CPAP) in pediatric patients (aged 2–18 years) post adenotonsillectomy with persistent symptomatic mild OSA (AHI  $\leq 5$ ) on polysomnogram.
- ❖ Scenario D: multilevel stepwise upper airway reconstruction (any identifiable target can be addressed; revision (adeno)tonsillectomy, inferior turbinoplasty, lingual tonsil reduction, supraglottoplasty, other—performed at clinician discretion) compared to medical &/or device therapy (orthodontic procedures, MAS, CPAP) in pediatric patients (aged 2–18 years) post adenotonsillectomy with persistent symptomatic moderate to severe OSA

(AHI  $\geq 5$ ) on polysomnogram.

- ❖ Scenario E: is the addition of DISE to clinical examination better than clinical examination alone in adult patients post adenotonsillectomy with persistent symptomatic OSA (AHI  $\geq 5$  on polysomnogram)?

Participants were initially asked to quantify the importance of each clinical scenario (extremely important, very important, somewhat important, not at all important). We subsequently calculated an importance ratio (yes:no) by reducing these four options into two groups. The “Yes, it is important” option combined the responses of extremely important or very important. The “No, it is not important” option combined somewhat important or not at all important.

To quantify community equipoise, an 11-point bidirectional ordinal scale with a treatment option anchored at either end was used. The scale is centered on 0 to indicate “completely undecided” and numbered from 1 to 5 toward each end to represent increasing certainty of the preferred treatment option (refer to *x*-axes of *Figures 1–5*).

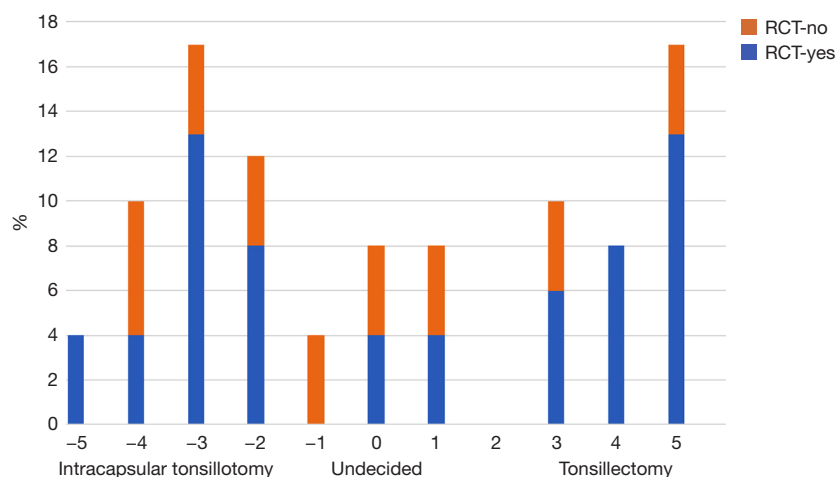
Surgeon willingness to participate in each suggested trial was analysed by way of a willingness to enroll ratio (W:X & Y:Z) incorporating the following: would take part in a randomized clinical trial (W); would not take part in a randomized clinical trial (X); would take part in a non-randomized follow-up study (Y), and would not take part in a non-randomized follow-up study (Z).

Surgeons were subsequently asked a range clinical practice-related question including age, gender, location of practice, and type of appointment. This demographic information was obtained only for descriptive purposes.

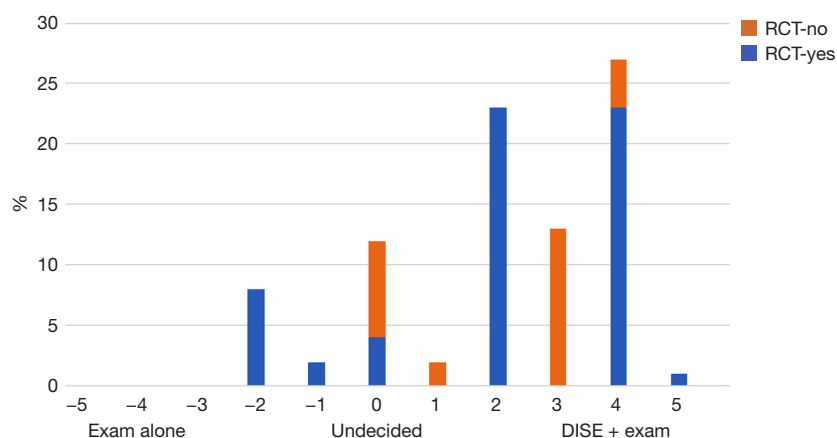
### Statistical analysis

Community equipoise was investigated by classifying the surgeon’s response using a bidirectional ordinal scale. Responses were plotted in a histogram and also classified into one of three groups to calculate the equipoise ratio: (A) preferred treatment 1, left-hand side; (B) completely undecided, and (C) preferred treatment 2, right-hand side). The equipoise ratios are calculated as percentages out of 100 and presented in proportions (A:B:C). For example, an equipoise ratio of 10:7:83 illustrates that 83% of surgeons selected preferred treatment 2. In this clinical scenario since more than 70% of surgeons perceive treatment 2 to be superior, no equipoise exists (37).

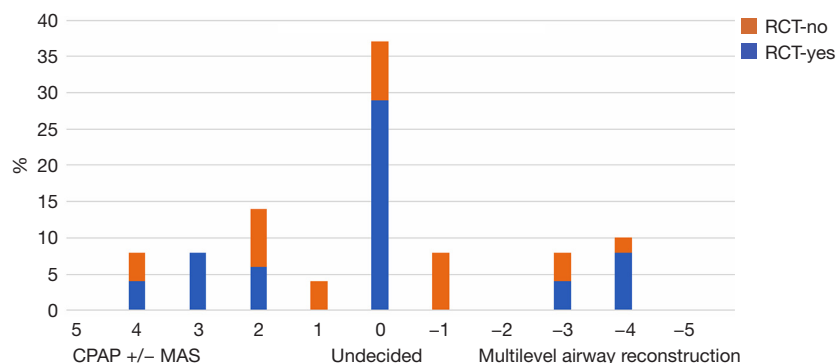
An example of community equipoise would be 50:5:45, where there is nearly equal preference to alternative



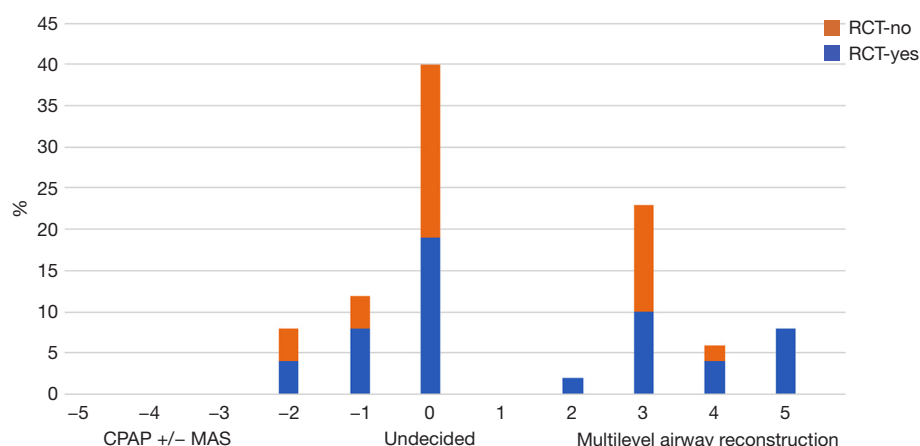
**Figure 1** Scenario A: intracapsular tonsillotomy versus tonsillectomy in pediatric patients (aged 2–18 years) with sleep breathing disorder (no surgery or recurrent tonsillitis). Most surgeons willing to enroll in a RCT irrespective of treatment uncertainty. RCT, randomized controlled trial.



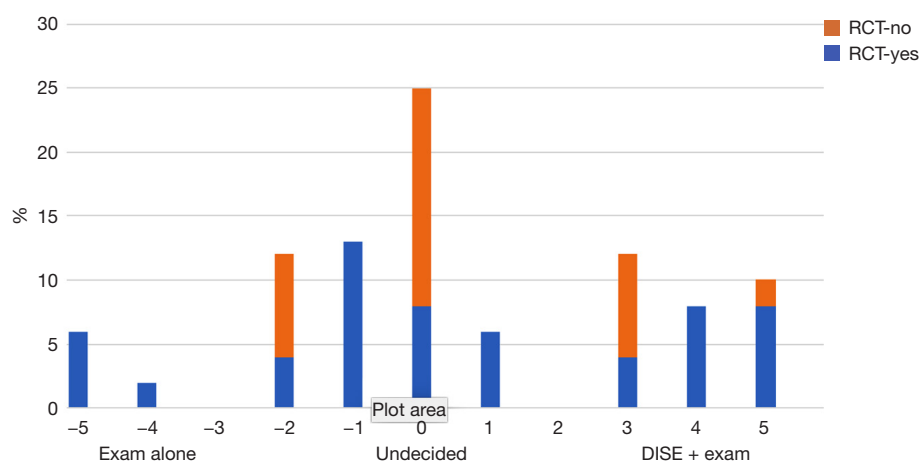
**Figure 2** Scenario B: is addition of DISE to clinical examination better than clinical examination alone in pediatric patients (aged 2–18 years) post adenotonsillectomy with persistent symptomatic OSA and AHI  $\geq 2$  (polysomnogram)? RCT, randomized controlled trial; DISE, drug-induced sleep endoscopy; OSA, obstructive sleep apnea; AHI, apnea-hypopnea index.



**Figure 3** Scenario C: multilevel stepwise upper airway reconstruction compared to medical +/- device therapy in pediatric patients (aged 2– $\leq 18$  years) post adenotonsillectomy with persistent symptomatic mild OSA (AHI  $\leq 5$ , polysomnogram). RCT, randomized controlled trial; CPAP, continuous positive airway pressure; MAS, mandibular advancement splints; OSA, obstructive sleep apnea; AHI, apnea-hypopnea index.



**Figure 4** Scenario D: multilevel stepwise upper airway reconstruction compared to medical +/- device therapy in pediatric patients (aged 2–≤18 years) post adenotonsillectomy with persistent symptomatic moderate to severe OSA (AHI ≥5, polysomnogram). RCT, randomized controlled trial; CPAP, continuous positive airway pressure; MAS, mandibular advancement splints; OSA, obstructive sleep apnea; AHI, apnea-hypopnea index.



**Figure 5** Scenario E: is addition of DISE to clinical examination better than clinical examination alone in adult patients post adenotonsillectomy with persistent symptomatic OSA (AHI ≥5, polysomnogram)? RCT, randomized controlled trial; DISE, drug-induced sleep endoscopy; OSA, obstructive sleep apnea; AHI, apnea-hypopnea index.

treatments. An example of individual equipoise would be 10:75:15, where the majority are undecided not knowing which option is superior.

For each of the five clinical scenarios we have plotted the clinical equipoise in a histogram with a bidirectional ordinal scale ranging from +5 to -5 centered on zero (personal equipoise). Willingness to enroll their patients in a RCT is plotted with each bar of a clinical equipoise plot as a percentage of the total participants. Each Figures 1–5 demonstrates surgeons' willingness to enroll patients in a RCT weighted to the clinical uncertainty of the respective

scenarios A–E.

## Results

The questionnaire was first presented in-person to 60 attendees at the 5<sup>th</sup> South Pacific ORL forum meeting 2023. We then excluded the sample responses of those that indicated they were no longer practicing or had never undertaken surgery for the relief of snoring or sleep apnea because they were not part of our population description. This left 48 otolaryngologists. Demographic characteristics

**Table 1** Characteristics of respondents (N=48)

| Characteristics                     | n  |
|-------------------------------------|----|
| Age (years)                         |    |
| <35                                 | 6  |
| 35–44                               | 7  |
| 45–54                               | 26 |
| 55–64                               | 5  |
| ≥65                                 | 4  |
| Gender                              |    |
| Male                                | 24 |
| Female                              | 24 |
| Location of practice                |    |
| Capital city                        | 26 |
| Other major urban area              | 18 |
| Rural area                          | 4  |
| Other                               | 0  |
| Type of appointment                 |    |
| Conjoint/academic staff             | 6  |
| Visiting medical officer/consultant | 21 |
| Staff specialist                    | 4  |
| Salaried university academic        | 9  |
| Other                               | 8  |
| Hospital work                       |    |
| Tertiary referral teaching hospital | 35 |
| District general hospital           | 5  |
| Private hospital                    | 8  |
| Other                               | 0  |

are shown in *Table 1*. The importance, equipoise ratios, and willingness to enroll patients for a RCT are presented in *Table 2* together with our conclusions as to whether this is a viable clinical trial target. We have plotted the combined clinical equipoise data with willingness to enroll in each separate uncertainty score bar for all scenarios in *Figures 1–5*.

Scenario A demonstrated a moderate importance ratio, community equipoise and willingness to enroll patients in a RCT. Scenario B demonstrated a high importance ratio, no community equipoise and no willingness to enroll patients in an RCT. Scenario C demonstrated a high importance ratio, community and individual equipoise and a willingness to enroll in an RCT. Scenario D demonstrated a high importance ratio, community and individual equipoise and a willingness to enroll in an RCT. Scenario E demonstrated a moderate importance ratio, community equipoise and a willingness to enroll in an RCT. Scenarios A–E all demonstrated a willingness to enroll patients in a non-randomized follow up study.

## Discussion

Feasible clinical trials in surgery must be perceived as important, unanswered (community equipoise), and supported (high willingness to enroll patients). Three of the five sleep surgery trial targets (C–E) we presented to surgeons were regarded as important, unanswered (equipoise—*Figures 3–5*) and supported (willingness to enroll their patients in a RCT). All trial targets demonstrated a willingness to enroll in a non-randomized follow-up study. Our survey suggests that three clinical trial

**Table 2** Clinical importance, equipoise ratios, and willingness to enroll patients in clinical trials for 5 sleep surgery scenarios

| Clinical scenario                                        | Importance ratio<br>(yes:no, %) | Equipoise ratio<br>(A:B:C, %) | Willingness to enroll in<br>RCT ratio (W:X, %) | Willingness to enroll in<br>non-RCT ratio (Y:Z, %) | Viable clinical<br>trial target |
|----------------------------------------------------------|---------------------------------|-------------------------------|------------------------------------------------|----------------------------------------------------|---------------------------------|
| Tonsillotomy vs. tonsillectomy                           | 52:48                           | 48:4:44                       | 35:65                                          | 83:17                                              | No                              |
| Paediatrics: exam alone vs. DISE & exam                  | 81:19                           | 10:13:77                      | 77:23                                          | 79:21                                              | No                              |
| Mild OSA: multilevel airway recon vs. CPAP +/- MAS       | 81:19                           | 27:38:35                      | 60:40                                          | 83:17                                              | Yes                             |
| Mod/severe OSA: CPAP +/- MAS vs. multilevel airway recon | 92:8                            | 20:40:40                      | 56:44                                          | 87:13                                              | Yes                             |
| Adult: DISE & exam vs. exam alone                        | 54:46                           | 33:25:42                      | 65:35                                          | 75:25                                              | Yes                             |

DISE, drug-induced sleep endoscopy; OSA, obstructive sleep apnea; CPAP, continuous positive airway pressure; MAS, mandibular advancement splints; RCT, randomized controlled trial; A, preferred treatment 1; B, completely undecided; C, preferred treatment 2; W, would take part in a randomized clinical trial; X, would not take part in a randomized clinical trial; Y, would take part in a non-randomized follow-up study; Z, would not take part in a non-randomized follow-up study.

targets (C, D and E, 2 pediatric and 1 adult) are feasible for a randomized trial.

Scenario A demonstrated low importance and no willingness to enroll patients in a RCT despite the existence of community equipoise. This discrepancy between community equipoise and low importance and an unwillingness to enroll patients in a RCT seems counterintuitive. However, this may indicate that surgeons perceive either option of similar efficacy with minimal long-term morbidity. Despite there being a lack of prospective long-term RCTs on intracapsular tonsillectomy to determine the risk of regrowth and reoperation rates, there remains an unwillingness to enroll pediatric patients in a clinical trial. Scenario A does not look like a strong candidate for a clinical trial based on these data.

Scenario B demonstrated high importance and willingness to enroll patients in an RCT, but low community equipoise. This may be explained by DISE in the pediatric population being relatively well understood with low morbidity. At this stage scenario B seems a difficult clinical trial target to us because once the trial starts otolaryngologists may not accept the reality of their patients being randomized into the clinical examination alone arm and the trial may suffer from a problem with cross-overs.

Scenarios C (mild OSA) and D (moderate-severe OSA) both demonstrated high importance ratios, similar community and individual equipoise ratios and moderate willingness to enroll pediatric patients in a RCT. These findings may indicate concerns surrounding pediatric OSA causing marked morbidity and mortality, and if left untreated may cause neurocognitive and cardiovascular abnormalities. Particularly in the pediatric population, poor adherence to non-surgical treatments severely limits disease alleviation, which may be better managed with surgical treatments.

Scenario E demonstrated low importance but reasonable community equipoise and moderate willingness to enroll in a RCT. These findings may suggest that some surgeons deem this to be a promising trial target, whilst others remain uncertain regarding the role of DISE in adults.

The limitations of the study include the relatively small sample size of 48 surgeons however this is partly explained by our methodology surveying participants of the 2023 South Pacific ORL Forum Meeting with a dominant interest in sleep surgery.

Our previous publication identified two suitable clinical trials in adult OSA comparing surgical *vs.* non-surgical interventions. This current study identified two potential

trial targets in pediatric OSA. We also identified a trial target in adults with persistent symptomatic OSA post adenotonsillectomy.

## Conclusions

We have identified three potential trial targets (scenarios C, D, E) and one less promising trial target (A). Multilevel stepwise upper-airway reconstruction versus medical therapy in pediatric patients post adenotonsillectomy with persistent symptomatic mild OSA (AHI <5), persistent symptomatic moderate-severe OSA (AHI ≥5), and DISE and clinical exam versus clinical exam alone to assess adult with persistent symptomatic OSA (AHI ≥5) post adenotonsillectomy. Significant equipoise exists surrounding the ideal treatment for these conditions.

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## Footnote

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*Ethical Statement:* The authors are accountable for all

aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). This study was approved by the Illawarra Shoalhaven Local Health District Research Review Board, Low and Negligible Risk (ISLHD LNR/QA205, 26/07/23) Review. Informed consent was taken from all individual participants.

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## Appendix 1 Equipose questionnaire

### *Difficult clinical decisions in sleep apnea surgery: identifying priorities for future research*

This survey aims to gather information about controversial areas of practice where further clinical research could be useful to resolve difficult clinical questions in sleep surgery. The information will be useful for future clinical trials, patient preference studies and quality of life research.

There are four sections, with five questions each. This form will take approximately 5 minutes to complete. Thank you for your time.

#### **Part I: difficult clinical topics in sleep surgery**

The following management scenarios have been suggested as difficult clinical topics, either because of lack of evidence for long-term patient-centered benefits or because of lack of comparison with other potential treatment pathways.

For each scenario, please rate how important you perceive the problem to be (in terms of future clinical research) by tick the appropriate box.

A: Intracapsular tonsillotomy compared to tonsillectomy in pediatric patients (aged  $\geq 2$ –18 years) with sleep breathing disorder without previous surgery or history of recurrent tonsillitis

This clinical question is....

|                                       |                                       |                                       |                                       |
|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|
| Extremely                             | Very                                  | Somewhat                              | Not at all                            |
| Important                             | Important                             | Important                             | Important                             |
| <input type="checkbox"/> <sub>1</sub> | <input type="checkbox"/> <sub>2</sub> | <input type="checkbox"/> <sub>3</sub> | <input type="checkbox"/> <sub>4</sub> |

B: Is the addition of drug-induced sleep endoscopy (DISE) to clinical examination better than clinical examination alone in pediatric patients (aged 2– $\leq 18$  years) post adenotonsillectomy with persistent symptomatic OSA with an AHI  $\geq 2$  on polysomnogram?

This clinical question is....

|                                       |                                       |                                       |                                       |
|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|
| Extremely                             | Very                                  | Somewhat                              | Not at all                            |
| Important                             | Important                             | Important                             | Important                             |
| <input type="checkbox"/> <sub>1</sub> | <input type="checkbox"/> <sub>2</sub> | <input type="checkbox"/> <sub>3</sub> | <input type="checkbox"/> <sub>4</sub> |

C: Multilevel stepwise upper airway reconstruction (any identifiable target can be addressed; revision (adeno)tonsillectomy, inferior turbinoplasty, lingual tonsil reduction, supraglottoplasty, other—performed at clinician discretion) compared to medical &/or device therapy (orthodontic procedures, mandibular advancement splint, CPAP) in pediatric patients (aged 2– $\leq 18$  years) post adenotonsillectomy with persistent symptomatic mild OSA (AHI  $\leq 5$ ) on polysomnogram?

This clinical question is....

|                                       |                                       |                                       |                                       |
|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|
| Extremely                             | Very                                  | Somewhat                              | Not at all                            |
| Important                             | Important                             | Important                             | Important                             |
| <input type="checkbox"/> <sub>1</sub> | <input type="checkbox"/> <sub>2</sub> | <input type="checkbox"/> <sub>3</sub> | <input type="checkbox"/> <sub>4</sub> |

D: Multilevel stepwise upper airway reconstruction (any identifiable target can be addressed; revision (adeno)tonsillectomy, inferior turbinoplasty, lingual tonsil reduction, supraglottoplasty, other—performed at clinician discretion) compared to medical &/or device therapy (orthodontic procedures, mandibular advancement splint, CPAP) in pediatric patients (aged 2– $\leq 18$  years) post adenotonsillectomy with persistent symptomatic moderate to severe OSA (AHI  $\geq 5$ ) on polysomnogram?

This clinical question is....

|                                       |                                       |                                       |                                       |
|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|
| Extremely                             | Very                                  | Somewhat                              | Not at all                            |
| Important                             | Important                             | Important                             | Important                             |
| <input type="checkbox"/> <sub>1</sub> | <input type="checkbox"/> <sub>2</sub> | <input type="checkbox"/> <sub>3</sub> | <input type="checkbox"/> <sub>4</sub> |

E: Is the addition of drug-induced sleep endoscopy (DISE) to clinical examination better than clinical examination alone in adult patients post adenotonsillectomy with persistent symptomatic OSA (AHI  $\geq 5$  on polysomnogram)?

This clinical question is....

|                                       |                                       |                                       |                                       |
|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|
| Extremely                             | Very                                  | Somewhat                              | Not at all                            |
| Important                             | Important                             | Important                             | Important                             |
| <input type="checkbox"/> <sub>1</sub> | <input type="checkbox"/> <sub>2</sub> | <input type="checkbox"/> <sub>3</sub> | <input type="checkbox"/> <sub>4</sub> |

## Part II: clinical uncertainty

For each scenario, we are interested in your current level of certainty about which treatment option is better. Please rate your level of certainty on the scale below by selecting the number that best reflects your view.

*If you are completely undecided between the two options, please select '5'*

If, however, you consider one treatment option to be superior, for whatever reason, please indicate how strongly you hold this view by selecting the appropriate number (towards your chosen option) on the scale.

A: Intracapsular tonsillotomy compared to tonsillectomy in pediatric patients (aged  $\geq 2$ –18 years) with sleep breathing disorder without previous surgery or history of recurrent tonsillitis.

Choose 5 if you are completely undecided between the two options.

0 1 2 3 4 5 6 7 8 9 10

Intracapsular Tonsillotomy

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

Tonsillectomy

B: Is the addition of drug-induced sleep endoscopy (DISE) to clinical examination better than clinical examination alone in pediatric patients (aged 2– $\leq 18$  years) post adenotonsillectomy with persistent symptomatic OSA with an AHI  $\geq 2$  on polysomnogram?

Choose 5 if you are completely undecided between the two options.

0 1 2 3 4 5 6 7 8 9 10

Clinical Examination  
Alone

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

Clinical Examination and  
DISE

C: Multilevel stepwise upper airway reconstruction (any identifiable target can be addressed; revision (adeno)tonsillectomy, inferior turbinoplasty, lingual tonsil reduction, supraglottoplasty, other—performed at clinician discretion) compared to medical &/or device therapy (orthodontic procedures, mandibular advancement splint, CPAP) in pediatric patients (aged 2– $\leq 18$  years) post adenotonsillectomy with persistent symptomatic mild OSA (AHI  $\leq 5$ ) on polysomnogram?

Choose 5 if you are completely undecided between the two options.

0 1 2 3 4 5 6 7 8 9 10

Medical &/or  
Device Therapy

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

Multilevel stepwise upper airway  
reconstruction

D: Multilevel stepwise upper airway reconstruction (any identifiable target can be addressed; revision (adeno)tonsillectomy, inferior turbinoplasty, lingual tonsil reduction, supraglottoplasty, other—performed at clinician discretion) compared to medical &/or device therapy (orthodontic procedures, mandibular advancement splint, CPAP) in pediatric patients (aged 2– $\leq 18$  years) post adenotonsillectomy with persistent symptomatic moderate to severe OSA (AHI  $\geq 5$ ) on polysomnogram?

Choose 5 if you are completely undecided between the two options.

0 1 2 3 4 5 6 7 8 9 10

Medical &/or  
Device Therapy

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

Multilevel stepwise upper airway  
reconstruction

E: Is the addition of drug-induced sleep endoscopy (DISE) to clinical examination better than clinical examination alone in adult patients post adenotonsillectomy with persistent symptomatic OSA (AHI  $\geq 5$  on polysomnogram)?

Choose 5 if you are completely undecided between the two options.

0 1 2 3 4 5 6 7 8 9 10

Clinical Examination  
Alone

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

DISE + Clinical  
Examination

### Part III: multicenter research

Imagine that funding and research support are available to evaluate patient outcomes in each of the clinical scenarios. We are interested in whether you would consider participating in such multicenter research.

*For each scenario, please indicate whether you would participate in either:*

1) A randomized controlled trial (in which patients would be randomly allocated to either treatment option)

OR

2) A non-randomized follow-up study (in which patients receive treatment in the usual way, but data are collected prospectively)

| Randomized controlled trial                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Would take part          | Would NOT take part      |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------------|
| A. Intracapsular tonsillotomy compared to tonsillectomy in pediatric patients (aged $\geq 2$ –18 years) with sleep breathing disorder without previous surgery or history of recurrent tonsillitis                                                                                                                                                                                                                                                                                                               | <input type="checkbox"/> | <input type="checkbox"/> |
| B. Is the addition of drug-induced sleep endoscopy (DISE) to clinical examination better than clinical examination alone in pediatric patients (aged 2– $\leq 18$ years) post adenotonsillectomy with persistent symptomatic OSA with an $AHI \geq 2$ on polysomnogram?                                                                                                                                                                                                                                          | <input type="checkbox"/> | <input type="checkbox"/> |
| C. Multilevel stepwise upper airway reconstruction (any identifiable target can be addressed; revision (adeno)tonsillectomy, inferior turbinoplasty, lingual tonsil reduction, supraglottoplasty, other—performed at clinician discretion) compared to medical &/or device therapy (orthodontic procedures, mandibular advancement splint, CPAP) in pediatric patients (aged 2– $\leq 18$ years) post adenotonsillectomy with persistent symptomatic mild OSA ( $AHI \leq 5$ ) on polysomnogram?                 | <input type="checkbox"/> | <input type="checkbox"/> |
| D. Multilevel stepwise upper airway reconstruction (any identifiable target can be addressed; revision (adeno)tonsillectomy, inferior turbinoplasty, lingual tonsil reduction, supraglottoplasty, other – performed at clinician discretion) compared to medical &/or device therapy (orthodontic procedures, mandibular advancement splint, CPAP) in pediatric patients (aged 2– $\leq 18$ years) post adenotonsillectomy with persistent symptomatic moderate to severe OSA ( $AHI \geq 5$ ) on polysomnogram? | <input type="checkbox"/> | <input type="checkbox"/> |
| E. Is the addition of drug-induced sleep endoscopy (DISE) to clinical examination better than clinical examination alone in adult patients post adenotonsillectomy with persistent symptomatic OSA ( $AHI \geq 5$ on polysomnogram)?                                                                                                                                                                                                                                                                             | <input type="checkbox"/> | <input type="checkbox"/> |

| Non-randomized follow up study                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Would take part          | Would NOT take part      |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------------|
| A. Intracapsular tonsillotomy compared to tonsillectomy in pediatric patients (age $\geq 2$ –18 years) with sleep breathing disorder without previous surgery or history of recurrent tonsillitis                                                                                                                                                                                                                                                                                                              | <input type="checkbox"/> | <input type="checkbox"/> |
| B. Is the addition of drug-induced sleep endoscopy (DISE) to clinical examination better than clinical examination alone in pediatric patients (aged 2– $\leq 18$ years) post adenotonsillectomy with persistent symptomatic OSA with an $AHI \geq 2$ on polysomnogram?                                                                                                                                                                                                                                        | <input type="checkbox"/> | <input type="checkbox"/> |
| C. Multilevel stepwise upper airway reconstruction (any identifiable target can be addressed; revision (adeno)tonsillectomy, inferior turbinoplasty, lingual tonsil reduction, supraglottoplasty, other – performed at clinician discretion) compared to medical &/or device therapy (orthodontic procedures, mandibular advancement splint, CPAP) in pediatric patients (aged 2– $\leq 18$ years) post adenotonsillectomy with persistent symptomatic mild OSA ( $AHI \leq 5$ ) on polysomnogram?             | <input type="checkbox"/> | <input type="checkbox"/> |
| D. Multilevel stepwise upper airway reconstruction (any identifiable target can be addressed; revision (adeno)tonsillectomy, inferior turbinoplasty, lingual tonsil reduction, supraglottoplasty, other—performed at clinician discretion) compared to medical &/or device therapy (orthodontic procedures, mandibular advancement splint, CPAP) in pediatric patients (aged 2– $\leq 18$ years) post adenotonsillectomy with persistent symptomatic moderate to severe OSA ( $AHI \geq 5$ ) on polysomnogram? | <input type="checkbox"/> | <input type="checkbox"/> |
| E. Is the addition of drug-induced sleep endoscopy (DISE) to clinical examination better than clinical examination alone in adult patients post adenotonsillectomy with persistent symptomatic OSA ( $AHI \geq 5$ on polysomnogram)?                                                                                                                                                                                                                                                                           | <input type="checkbox"/> | <input type="checkbox"/> |

Finally, a few questions about you and your practice so that we can determine whether we have a representative sample.

Are you            Male                                  □<sub>1</sub>  
                     Female                                 □<sub>2</sub>

*Please tick one box only*

Please tick one box that represents your **major** appointment.

*Please tick one box only.*

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