Awake Rhinology Surgery in Response to the COVID-19 Pandemic in Europe

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Keywords
Awake rhinology surgery · Ear · Nose and throat surgery · Nasal surgery · Local anaesthesia · COVID-19 · Recommendations

Abstract
Background: European health-care systems are faced with a backlog of surgical procedures following the suspension of routine surgery during the COVID-19 crisis. Routine rhinology surgery under general anaesthetic (GA) is now faced with significant challenges which include limited theatre capacity, the negative ramifications of surgical prioritization, reduced patient throughput in secondary care, and additional personal protective equipment requirements. Delayed surgery in rhinology, particularly with regards to chronic rhinosinusitis, has previously been shown to have poorer surgical outcomes, a detrimental effect on quality of life and long-term negative health socio-economic effects. Awake rhinology surgery under local anaesthetic (LA) provides an ideal alternative to GA. It provides a means of operating on patients in a setting alternative to currently over-subscribed main theatres, by utilizing satellite facilities, while ensuring identical surgical outcomes for patients who may otherwise have been forced to wait a long time for their procedure. It also confers additional benefits in terms of shorter recovery time and hospital stay for patients. Objectives: We have developed a set of recommendations that are intended to help support clinicians and managers to better adopt LA rhinology protocols and minimize the risk to the patient and health-care professionals involved. Methodology: International roundtable forums were conducted and supplemented by individual interviews. The international board consisted of 12 rhinologists experienced in awake rhinology surgery. Feedback was analysed and shared to develop a consensus of best practice. Recommendations: Local and national guidelines need to be adhered to with specific focus on patient and clinician safety. When performing awake rhinology procedures in the COVID-19 recovery process, consider implementing specific safety measures and
workflow practices to safeguard patients and staff and minimize the risk of infection. **Conclusion:** Awake surgery potentially provides quicker access to routine rhinology surgery in the post-COVID-19 recovery phase, ensuring patients are treated in a timely matter, thereby avoiding higher downstream costs, and improving outcomes.

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**Introduction**

In response to the global COVID-19 pandemic, elective surgical procedures were cancelled or postponed across most European countries, in order to divert healthcare resources to treating infected patients and minimize the spread of the infection [1]. Guidelines published at the start of the outbreak recommended all rhinology procedures be postponed until infection rates stabilized and stipulated that enhanced personal protective equipment (PPE) should be worn to perform urgent or emergency rhinology procedures [2–5]. A similar response may be used in any future pandemic situation to concentrate the healthcare workforce to alleviate the acute situation.

With the number of new COVID-19 cases in decline, many European healthcare services are beginning to restart elective surgical procedures, while implementing safeguarding measures to mitigate against the risk of further COVID-19 infections [6–8]. An emerging challenge to healthcare managers is how to prioritize a backlog of postponed elective surgical procedures across many disciplines within the constraints of limited capacity in surgical theatres. Elective, non-cancer related rhinology procedures are likely to be amongst the last to restart as more critical procedures are prioritized. However, a long delay to elective rhinology procedures has the potential to impose a substantial financial burden to patients and healthcare providers. Nasal conditions, such as chronic rhinosinusitis have a severe and detrimental impact on patients’ quality of life [9] and delayed surgery is associated with higher costs and poorer outcomes [10–12].

Performing rhinology procedures as awake surgery, using local anaesthetic (LA), may provide a solution to recommencing activity within the current conventional theatre capacity constraints. Facilitated by new techniques and developments in technology, awake surgery is already an established method applicable to many rhinology procedures and it has been widely adopted in the USA [13] and in some European countries. Where similar outcomes can be achieved, awake surgery offers many advantages over general anaesthetic (GA), requiring fewer staff and typically resulting in a shorter hospital stay and faster recovery [14–16]. Furthermore, awake surgery can be performed safely and efficiently outside of traditional surgical theatres, presenting an opportunity to leverage unused capacity in alternate sites, often outside of major hospitals. This would allow elective rhinology procedures to be restarted without competing for theatre space with procedures that can only be performed in theatre. A further potential advantage to offering rhinology procedures outside of the main hospital is that this may reduce infection risk and patient anxiety. Furthermore, awake surgery, under LA, has the potential to allow patients with comorbidities, who might otherwise have been deemed unsuitable for GA, to undergo their required procedure more safely.

The aim of this study was to set out recommendations from an international panel of rhinologists drawn from many countries who are all experienced in safety measures and good practice in undertaking awake surgery. These recommendations are intended to support European rhinologists and hospital managers to better utilize awake surgery capacity for rhinology during the recovery phase and are also relevant beyond the COVID-19 pandemic.

A series of five virtual international round-table forums, supplemented by interviews and email correspondence, were conducted with a panel of rhinologists aiming to address gaps in current European guidelines for treating patients during the global COVID-19 pandemic. The panel included 10 European rhinologists, based in Germany, Italy, Ireland, Portugal, Spain, Switzerland, and England, and 2 from the USA. Awake surgery was identified as a key area of need and a topic guide was used to capture panel insights on the following:

1. Advantages (both to patients and health care) of awake surgery during the COVID-19 recovery process
2. a. Ideal patient and surgical procedure selection
   b. Patient consent with COVID-19
   c. Procedural room and standard operating procedures for awake surgery
   d. COVID-19 infection prevention control measures, aerosol-generating procedure risk, and PPE
   e. Best practice workflow management and
   f. Teaching and training

The panel also considered local rhinology COVID-19 and procedure guidance and available industry equipment. The recommendations presented below reflect the panel’s consensus on best practice and should be read in conjunction with supporting local and national COVID-19 guidelines and guidelines for elective rhinology surgery.
Recommendations

Patient, Procedure Selection, and Consent

Patient selection for awake surgery is a key and should not differ from pre-COVID-19 selection criteria. If the surgical capability is severely limited during the pandemic, medical conditions that do not result in permanent morbidity and mortality should be postponed. To avoid long-lasting negative effects associated with prolonged delay, alternative treatment strategies including awake surgery are necessary. The authors strongly recommend against the general avoidance of rhinologic surgical procedures during the pandemic: nasal blockage, the key symptom of surgically treated rhinologic disease, may result in increased mouth breathing, bypassing the clearance function of the nose and thereby increasing the individual risk of suffering from acute infections, including COVID-19 [17].

Patients need to be fully aware of the benefits and limitations of awake surgery. As with any surgical intervention, informed consent should be attained, once the patient has had adequate time to assimilate all information provided to them regarding the procedure in question. Recognition of the similarities between awake rhinology surgery and usual awake dental surgery may provide a point of reference to the patient who is still unsure of what kind of experience they are likely to have.

During the COVID-19 recovery process, ensure patients are consented both for the procedure and the risks of surgery during COVID-19, in keeping with local and national guidelines (refer to section Patient Safety, Communication, and Testing for communication protocols). Before recommending awake surgery, consider the safety and practicalities of performing the procedure under LA, including:

- Ensuring local and national COVID-19 guidelines are followed to ensure the safety of the patient and healthcare professionals
- The overall procedure time and the patient’s ability to remain comfortable throughout
• The level of discomfort the procedure will generate and whether this is appropriate for LA
• The level of vascular control required and the risk of bleeding
• The possible need for judicious use of electrocautery and the suitability of this for awake surgery
• The surgeon’s ability to effectively communicate with the patient throughout the procedure
• The surgeon’s confidence to effectively perform the procedure with the patient being awake

Patients’ suitability is individually specific and should only be judged after completing a full patient history and assessment and considering all risks. Risks specific to individuals should be recorded and evaluated. Good candidates for awake surgery include patients
• with a good understanding and willingness to have awake surgery,
• who require a procedure suitable for awake surgery (refer to Table 1), and
• with a mild or moderate disease.

Caution should be taken when recommending awake surgery in patients
• under 16,
• with pregnancy or suspected pregnancy,
• with an inability to participate in an informed consent process,
• with an inability to communicate clearly,
• where there is advanced disease,
• with a history of sensitivity or allergy to LA medication,
• with unsuitable anatomical features, such as severely deviated septum, and
• with current or a recent COVID-19 positive result or symptoms.

Special care should be taken when considering patients with high-risk of bleeding (such as anticoagulation) or comorbidities. Awake rhinology surgery is sometimes a safer option where patients are at a higher risk of bleeding or at a higher risk of complications from a GA, such as, for example, obstructive sleep apnoea, chronic obstructive pulmonary disease, and obesity.

Where patients have had a recent positive test or symptoms consistent with COVID-19, elective surgery should be postponed until the patient no longer tests positive and the symptoms have been resolved. Local protocols should guide clinicians in terms of timing for surgery.

Awake surgery can be safely performed on a broad range of rhinology procedures including but not limited to endoscopic sinus surgery, maxillary sinus antrostomy, polypectomy, procedures for chronic rhinitis (e.g., cryotherapy), sinus balloon dilatation, eustachian tube balloon dilatation, reposition of fractured nasal bones, lacrimal duct procedures, rhinoplasty (cosmetic), alar surgery, septoplasty, limited septorhinoplasty, division of synechia, and turbinate reduction surgery or turbinoplasty.

When a surgeon is new to performing awake surgery, it may be prudent to first focus on minimally invasive procedures and select patients with less complex disease, expanding to more invasive procedures and more complex patients as the surgeon grows more comfortable. Irrespective of being performed under LA or GA, particular caution should be taken when performing procedures that involve endonasal drilling during the COVID-19 pandemic due to the higher risk of aerosol generation [18–20]. When using heat energy, including lasers, be mindful of the risk of aerosol generation and take appropriate precautions using suction [21]. In general, simultaneous, constant suction may reduce the risk posed by aerosols when applied correctly, for example, when in the nasopharynx via the contralateral nasal side.

Patient positioning is an important consideration as this differs from most standard rhinology procedures under GA. We recommend performing awake surgery with the patient lying in the supine position as this allows secretions to naturally collect in the nasopharynx where it can be easily be removed through judicious use of suction, making the procedure more comfortable for the patient, and importantly reducing the risk of the patient coughing or sneezing thereby generating aerosol. Table 1 lists select rhinology procedures, focussing on the procedures most suitable for awake surgery, summarizing their suitability for awake surgery, and the risk of aerosol generation.

**Timing of Surgery**

Surgery should be performed based on clinical priority. However, awake surgery may help minimize prolonged and unnecessary delays to treatment in the aftermath of the COVID-19 pandemic by utilizing alternative sites to perform surgery. This is preferable over a prolonged wait for procedures under GA as the health-related quality of life benefits are well-documented [12, 22]. It is important to ensure the decision to undertake awake surgery is made jointly with the patient.

**Patient Safety, Communication, and Testing**

Communication is paramount before and during awake surgery. There will undoubtedly be a level of patient anxiety about being awake during the procedure.
Should the clinician be unable to reassure the patient sufficiently, alternative options should be discussed, for example, GA. Patients should be adequately counselled about the risk of developing COVID-19 infection from attending hospital and the very low-risk during surgery and clinicians should proactively communicate all COVID-19 safety and PPE protocols in advance of surgery to the patient emphasizing that all measures are intended to limit risk. Some hospitals have taken to handing out patient information leaflets outlining the hospital’s COVID-19 service operating procedure. Where patients are in a higher risk group for COVID-19 morbidity or are particularly anxious regarding COVID-19 infection, consider ways to reduce the time they spend in the facility, for example, waiting in the car park rather than in waiting areas before surgery; or even deferring the surgery to a later date.

It is prudent that all local protocols are followed to ensure the safety of staff and patients alike from developing COVID-19. Various testing regimes have been adopted, some of which include the following:
- Assessing for symptoms and checking temperature on the day of surgery
- Questionnaire assessment of symptoms in advance of clinic
- Quarantine for 7 days before surgery [5].
- Testing for COVID-19 before surgery, asking patients to quarantine in between
- Performing the antibody test

If doubt exists with the reliability of testing, and if COVID-19 is still active in the local community, it may be prudent to assume that all patients could be COVID-19 positive. Patients should be made aware of all relevant social distancing protocols in advance of surgery and the relevant information leaflets/advice should be given to patients ahead of admission so that they can familiarize themselves with the local policies. Due to limited specificity and sensitivity associated with rapid testing, polymerase chain reaction testing is regarded as the clinical gold standard for elective surgery, such as awake rhinologic operations. Delaying rhinologic procedures until immunization may be an option to minimize infection risk. However, as immunization may fail, the need for safety measures will persist.

PPE for Surgeon, Staff, and Patient

Health-care professionals should follow local, regional or national guidelines with respect to PPE to reduce the risk of COVID-19 infection during the procedure. For awake surgery, it is important that the patient and surgeon can communicate with each other throughout the procedure; therefore, PPE should be positioned to allow this. All surgical clothing should be disposable or sterilized afterwards. For patients that test negative, N95 masks are typically accepted as clinical standard. Filtering facepiece code 2 masks and protective glasses may be recommended by local authorities at times where there is a higher risk of infection. Where patients test COVID-19 positive, consider performing the procedure under GA to decrease the risk of infection. In the rare case that awake surgery has to be performed in a COVID-19 positive patient, use of filtering facepiece code 3 masks, double gloves, and protective glasses are strongly recommended [23]. This equipment should be changed between procedure to avoid cross-contamination between cases. This is particularly important given current awareness of subtypes of COVID-19 mutations.

Surgeon and Staff Training

Surgeons new to awake rhinology surgery should familiarize themselves with a LA protocol. Participation in some form of training is highly recommended before performing awake surgery. Some surgeons have found it beneficial to initially perform awake procedures in a general theatre and move to an ambulatory or office setting when more comfortable with this method.

Where staff are not experienced in awake surgery, additional training may be required on techniques and norms associated with treating patients that are awake. Where staff have been on leave or working from home during the peak of the COVID-19 outbreak, consider additional training to familiarize staff with changes in work practices.

Facility Set-Up and Patient Flow

Awake surgery can be performed in traditional theatres, outpatient theatres, ambulatory procedure rooms, or surgeons’ offices. When setting up a new procedure room for awake rhinology surgery, ensure all standard equipment required is available. Endoscopic rooms may easily be adapted because they typically already contain most of this equipment. In addition to a standard procedure set-up, consider the list of key tools for awake rhinology surgery detailed in Table 2, with commentary on additional considerations to mitigate against the risk of infection. The list excludes procedure-specific consumables, for example, balloon dilation tool, cryotherapy tool, and implants.
Follow local COVID-19 protocols for managing patient flows within the facility. It is important to consider the communal areas such as the waiting room and the bathroom facilities as these may become potential sites of transmission. It is advisable to minimize the number of people in these areas at any one time and if possible, patients should be advised to attend on their own and to have their companion waiting outside the facility. Signposting should be clearly displayed, aligned with local social distancing guidelines.

**Procedure Room**

When setting up a new awake rhinology surgery clinic, it is important to consider the air ventilation in the procedure room. Efficient air ventilation minimizes aerosol exposure and, therefore, reduces infection risk. Air scrubbers are the gold standard and are used in surgical theatres with newer models providing in excess of 20 air exchanges per hour. Where air scrubbers are not available, high-quality suction devices, such as safe air suction devices or aspirators, are good alternatives. Pursuant to local guidance, all windows should be open to maximize air ventilation in a surgeon’s office. The time allotted to allow sufficient air exchange between procedures should be proportionate to the risk of aerosol generation with each procedure (refer to Table 1) and the type of air ventilation in the procedure room. Additional measures such as UV light cleaning and portable in-room HEPA high filtration should also be considered. It is important to follow local or national COVID-19 guidance with regards to cleaning procedure rooms between patients. Advice from infection control experts is valuable.

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**Table 2. Key tools for awake ENT surgery (list may be augmented to surgeon preference and technique)**

<table>
<thead>
<tr>
<th>Equipment</th>
<th>Considerations for awake surgery and reducing the risk of infection</th>
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</thead>
<tbody>
<tr>
<td>Rigid endoscope(s) and light cord(s)</td>
<td>High-level scope disinfectant, additional endoscopes may be needed to facilitate turn over and/or procedure type</td>
</tr>
<tr>
<td>Endoscopic camera</td>
<td>Disposable cable sheath covers</td>
</tr>
<tr>
<td>Sterilization system</td>
<td>High temperature table top sterilizer or low temperature sterilization</td>
</tr>
<tr>
<td>ENT video stack system</td>
<td>Monitor, light source, endoscopic camera, and camera control unit</td>
</tr>
<tr>
<td>Light source (head)</td>
<td>Integrated into helmet or on top of PPE</td>
</tr>
<tr>
<td>Anaesthetic set-up – local protocols</td>
<td>Refer to Table 3. Where possible, avoid sprays</td>
</tr>
<tr>
<td>Steel instruments (limited)</td>
<td>Basic FESS instrumentation set including: nasal speculum, sinus seekers, freer elevator, bayonet forceps, alligator forceps, blakesley forceps, blakesley forceps 45°, blakesley forceps 90°, Takahashi, blakesley thru cut straight, blakesley thru cut 45, sickle knife, suction tips, and sucker dissectors</td>
</tr>
<tr>
<td>Microdebrider/shaver</td>
<td>Microdebrider hand piece, blades, and suction; consider supplementing with a respiratory droplet filtration system, commonly referred to as a surgical particle aspirator</td>
</tr>
<tr>
<td>Patient monitoring equipment, that is, pulse ox and BP monitor</td>
<td>Follow local/regional/national guidelines</td>
</tr>
<tr>
<td>Micro suction</td>
<td>With filters where possible</td>
</tr>
<tr>
<td>ENT navigation unit</td>
<td>Antiviral cleanser</td>
</tr>
<tr>
<td>Air scrubber</td>
<td>Depending on the ventilation in the procedure room, consider air scrubbers (ref to section Procedure Room)</td>
</tr>
<tr>
<td>UV light/HEPA high filtration</td>
<td>Depending on the ventilation in the procedure room, consider UV light cleaning device or HEPA high filtration devices (ref to section Procedure Room)</td>
</tr>
<tr>
<td>Surgeon and staff PPE</td>
<td>Follow local/regional/national guidelines</td>
</tr>
<tr>
<td>Patient PPE</td>
<td>Follow local/regional/national guidelines</td>
</tr>
</tbody>
</table>

PPE, personal protective equipment.
Procedure and Anaesthetic Protocol

Health-care professionals should continue to maintain good practice whilst performing awake rhinology surgery. Patients’ oxygen levels should always be monitored using finger pulse oximetry. The surgeon should confirm all equipment required is ready for use before the procedure begins and it is important to communicate each step of the procedure clearly to the staff and patient throughout the procedure.

Surgeons new to awake rhinology surgery should follow an established LA protocol. Table 3 provides a suggested protocol which has been adapted from a widely used protocol in the USA, modified to be applicable for use in European settings [24]. This protocol should also be adapted as relevant for specific procedures. Variations of this and other local protocols are used across Europe, with surgeons modifying elements consistent with practice and personal preferences when they gain confidence and experience. Pre-procedure protocols including the administration of decongestant should be administered prior to the patient entering the clinic.

We recommend adapting LA protocols while the COVID-19 pandemic is ongoing. Examples of risk mitigation strategies are listed below:

- Avoid the use of topical intranasal sprays to minimize aerosols in the room
- Be mindful when soaking pledgets, oversaturation may cause medication to drip down the throat stimulating patients to cough unnecessarily
- Modify surgical masks to create VENT masks described by Workman et al. [18] to facilitate performing endoscopy
- Wash the mouth and nose out with betadine (0.5%) before starting the procedure to minimize the risk of infection
- With regard to the instrumentalation set-up, rotating devices such as shavers or drills will generate more aerosols resulting in a higher infectious risk for all persons present during surgery [25]. Therefore, we recommend the use of parallel suction whenever applicable to decrease the aerosol-generating potential. In some cases, traditional cutting instruments may be preferable. However, the change of instruments (e.g., drill to chisel) should not be accepted if it is associated with a possible increase of the likelihood of iatrogenic injuries than the local current infectious risk.

Post-Operative Follow-Up

Post-operative follow-up is typically the same as equivalent rhinology procedures under GA. Consider modifying standard post-operative follow-up care while the COVID-19 pandemic is ongoing by

- shortening the time to patient follow-up to identify any signs of infection earlier, and
- replacing in person follow-up appointments with telephone or teleconference appointments to minimize patient contact time if appropriate.

Conclusion and Key Recommendations

The recommendations presented here are intended to aid clinicians and hospital managers to consider awake surgery under LA as a safe and efficient method of delivering care to patients that may otherwise be delayed. It provides recommendations of how alternative venues can be safely adapted to perform awake rhinology procedures safely and efficiently in the wake of COVID-19. These recommendations are also relevant beyond the COVID-19 pandemic as the experience in the USA shows us.

A summary of the key recommendations for awake rhinology surgery are listed below:

- Ensure appropriate patient and procedure selection
- Engage patients in the procedure selection process, ensuring they understand all risks, benefits, and processes associated with the procedure selected
- Risks specific to individuals should be recorded and mitigated against the risk of infection
- Ensure surgeons and staff are appropriately trained in awake surgery
- Ensure new facilities have all required equipment in advance of surgery and confirm all equipment is available before starting a procedure
- Adhere to good practice guidance from governing bodies with regards to the procedure and follow an established anaesthetic protocol
- Proactively communicate with patients and staff throughout the procedure, being mindful that the patient is awake

A summary of key recommendations to minimize infection risks and patient anxiety include:

- Consider the risk of aerosol generation when selecting procedures
- Proactively communicate safety and PPE protocols with patients in advance of surgery
- In advance of surgery and in line with local and national guidelines, assess for COVID-19 infection
- Follow local or national PPE guidelines for staff and patients
- Source or adapt equipment and consumables to mitigate against the risk of infection
- Ensure the facility has appropriate air ventilation
Table 3. Suggested LA protocols, adapted from Gould et al. [24] for Europe*

<table>
<thead>
<tr>
<th>Protocol</th>
<th>Detail</th>
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<tbody>
<tr>
<td>1. Pre-procedure</td>
<td>• Oral anxiolytics** (administer 1 h before procedure): Diazeepam – 10 mg or Lorazepam – 1–2 mg • Oral analgesics** (administer 1 h before procedure) Codeine 30–60 mg and/or Paracetamol 500–1,000 mg • Decongestant (administer before coming to clinic) Oxymetazoline or Phenylephrine hydrochloride spray (0.5%)</td>
</tr>
<tr>
<td>2. Topical protocol</td>
<td>• Take caution when administering Avoid over saturation of pledgets • Step 1: Make a mixture of topical anaesthetic and nasal decongestant 50/50 premixed solution of ▪ Decongestant: 0.3–0.5 mL per side oxymetazoline (0.1%) or phenylephrine hydrochloride (0.5%) ▪ Topical anaesthetic: 0.3–0.5 mL per side 4% lidocaine Soak all pledgets, including cotton ball. Caution should be taken not to over-soak pledgets • Step 2: Place the first pledget or cotton ball inside of nose Place as posterior as possible to begin the anaesthetic and decongestant process Wait 5–10 min • Step 3: Place the remaining pledgets Begin after confirming anaesthesia Position pledgets meticulously 1.5″ pledget placement ▪ A. Deep in middle meatus; note: if necessary, position anterior, then reposition deeper in meatus 2–3 min later ▪ B. Superior along nasal septum and medial surface of middle turbinate ▪ C. Inferior surface of middle turbinate 3″ pledget placement ▪ D. Positioned along septum from sphenoid rostrum to nasal vestibule Wait 5–10 min</td>
</tr>
<tr>
<td>3. Infiltration protocol</td>
<td>• Take caution when administering Confirm patient is decongested Infiltrate slowly, 20 s per injection site • Typical anaesthetic Begin after confirming anaesthesia 1% lidocaine with 1:200,000 epinephrine Inject 0.5 mL per injection site • Injection locations – typical sites Superior to the root of the middle turbinate Anterior face of the middle turbinate Inferior turbinate Posterior septum Sphenopalatine region Sphenoid rostrum • Additional – as required Infraorbital nerve block (for difficult/narrow nasal anatomy) Septal spur or deflection • Confirm anaesthesia before beginning procedure</td>
</tr>
</tbody>
</table>
Awake Rhinology Surgery in Response to COVID-19 Pandemic

Ensuring the time allotted for air exchange between procedures is proportionate to the risk of aerosol generation and the ventilation system

Adapt cleaning protocols to minimize the risk of infection

Adapt post-operative follow-up appointments to avoid unnecessary patient contact

Complications with awake rhinology surgical procedures are very rare when performed by an experienced, trained clinician, in appropriately selected patients, in suitable facilities and following best practice protocols. Where these conditions are met, awake rhinology surgery provides an opportunity to recommence rhinology procedures much sooner than would have otherwise been delayed in the wake of COVID-19. By leveraging unused capacity in off-site facilities, awake rhinology surgery could help expedite care, ensure patients are treated in a timely manner, avoid higher downstream costs, and improve outcomes.

Acknowledgment

Deirdre Blissett, MedTech Economics Ltd., provided administrative and editorial support to consolidate ideas generated by the panel and edit the manuscript.

Conflict of Interest Statement

Dr. Andrews is a consultant physician for STRYKER ENT. He has not received any financial compensation for his contribution to this manuscript. Dr. Perkins reports personal fees from STRYKER ENT, outside the submitted work. All other authors have nothing to disclose.

Funding Sources

No authors received funding for their participation in this research. Deirdre Blissett is an independent medical writer, funded by STRYKER ENT.

Author Contributions

All authors made substantial contributions to the development of the recommendations, reviewed the first draft critically, and reviewed the final version of this manuscript. P.A., D.F., R.S.F., and A.B. provided an equal leading role in writing and editing the manuscript (shared responsible authorship).

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