AMERICAN ACADEMY OF OTOLARYNGOLOGY–HEAD AND NECK SURGERY®

Guidance for Return to Practice for Otolaryngology-Head and Neck Surgery

Part One

INTRODUCTION

While this document will address many important concerns, the environment is rapidly evolving, and new information and evidence may have become available since this version was completed. ***The intent is to consider this a living document and update it on a regular basis as new information becomes available and thusly the information contained herein is subject to change on an ongoing basis.***

Many concerns raised may be theoretical in nature or based on expert opinion rather than on scientific evidence. This guidance is not intended to be construed as the "standard of care," and may be superseded, supplemented, or enhanced by guidance from local, state, and federal government agencies, local/regional hospital systems, and/or other medical societies. These recommendations are not intended to define clinical indications for diagnostic and surgical procedures across the breadth of our specialty. These have been already determined over many years and are updated regularly.

We recognize that there may be local conditions related to the extent of COVID-19 infections within a community, the type of practice/hospital system, the availability of effective personal protective equipment (PPE) and other supplies, the physical configuration of workspaces, practice economics, local rules and regulations, and other constraints that may affect the ability to follow every aspect of this guidance.

RATIONALE AND SCOPE

As we transition back toward more widespread delivery of healthcare, otolaryngologists and their patients are seeking consistent guidance and principles to reinstitute diagnostic and therapeutic interventions.
There have been a number of publications describing the potential for increased risk faced by otolaryngologists due to the high concentration of viral particles in the nasal cavity, nasopharynx, oral cavity, oropharynx, and lower respiratory tract. A formal study demonstrating increased incidence of COVID-19 infections in otolaryngologist-head and neck surgeons through work exposure has not been documented. The concern is heightened by the potential of certain diagnostic and surgical procedures to theoretically cause aerosolization of viral particles that are considerably smaller and more difficult to defend against than the droplets that typically spread the disease. The correlation between potential aerosolization by a specific otolaryngic procedure and actual transmission of COVID-19 has not been established. This theoretical risk of transmission (TRT) affects not only the otolaryngologist treating the patient, but all staff in the room and potentially affects subsequent facility availability.

During this unprecedented time and with an abundance of caution, we recognize that physicians need guidance and that the absence of evidence may not recognize the potential risks in the current environment. Patient, staff, and personal safety must receive the highest prioritization along with strategies to provide the highest quality care. The purpose of these documents is to provide guidance to healthcare professionals during this time of crisis.

There are two main documents that will be released. This first document contains general considerations for practice that apply across the specialty. A second forthcoming document will contain subspecialty specific recommendations. These documents were prepared by the Future of Otolaryngology Task Force of the American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS) with input from the AAO-HNS Board of Directors, the Infectious Disease Committee, and Patient Safety and Quality Improvement Committee. The AAO-HNS approached the specialty societies within otolaryngology to set up a collaborative process to produce guidance for otolaryngologists

that would be consistent, practical, and implementable at the appropriate time, based on local conditions and regulatory guidance. The American Academy of Facial Plastic and Reconstructive Surgery (AAFPRS), American Academy of Otolaryngic Allergy (AAOA), American Broncho-Esophagological Association (ABEA), American Laryngological Association (ALA), American Neurotology Society (ANS), American Otological Society (AOS), American Rhinologic Society (ARS), American Head and Neck Society (AHNS), and American Society of Pediatric Otolaryngology (ASPO) worked with the corresponding AAO-HNS Committee to submit recommendations from their respective areas of expertise. We are extremely grateful for the quick response and true collaborative spirit exhibited during this process.

GENERAL CONSIDERATIONS

Aerosolization of Viral Particles

Aerosols are suspended particles which may contain pathogens and are categorized by droplet size. The smallest droplets have the potential to desiccate, forming droplet nuclei that may dissipate through diffusion and remain airborne for several hours.

In general, procedures are considered aerosol-generating if (1) they create and disperse aerosols and/or (2) they cause the patient to cough or sneeze. The U.S. Centers for Disease Control and Prevention (CDC) outlines several medical procedures, relevant to otolaryngologists, considered to be aerosol generating procedures (AGPs): open suctioning of airways, endotracheal intubation and extubation, non-invasive, ventilation (e.g., BiPAP, CPAP), bronchoscopy, manual ventilation, and nebulizer administration. The CDC list is not inclusive of all otolaryngology procedures.

Nasal endoscopy and flexible nasal laryngoscopy in and of itself are presumably not AGPs. However, they may potentially increase the likelihood of cough, gag, and sneeze, with possible subsequent aerosolization, and therefore appropriate precautions should be considered based on individual clinical circumstances.

There are theoretical concerns of increased risk of transmission of COVID-19 infection when interventions involving the pharyngeal mucosa and the respiratory tract potentially cause aerosol generation in an actively infected individual. To date, there is no definitive evidence of transmission associated with specific otolaryngologic procedures. Although there is a published anecdotal report that suggested the theory that a high-speed drill may have caused transmission to healthcare workers during a pituitary surgery, this report was subsequently refuted by the primary surgical team who attributed all healthcare worker COVID-19 transmission to non-surgical care provided by staff who were not wearing appropriate PPE.

Information about PPE

PPE is critical to protect individuals from exposure to and transmission of COVID-19. Every patient interaction has differing levels of theoretical risk of transmission based on anatomy/pathophysiology, the presumed likelihood of aerosolization caused by an intervention, and the extent of exposure. For a specific patient, COVID-19 status and the assumed risk of aerosolization caused by a specific intervention can be helpful in determining the appropriate level of PPE required for the particular situation.

For patients that are known to be actively infected with and shedding COVID-19, maximal available and appropriate PPE should be used during all levels of interaction.

Given the variable false negative rate of current testing and the presence of asymptomatic COVID-19 positive carriers, it is incumbent on the clinicians to take a conservative approach when determining the appropriate PPE for themselves, staff, and patients based on the potential risk of the activity being performed.

Procedures that manipulate the mucous membranes of the pharynx and respiratory tract that may have a higher risk of aerosol transmission should be performed with great caution, and staff should utilize appropriate respiratory protection such as N95 masks and eye wear/face shields based on the availability of these resources and the clinical situation.

Physicians should consider performing a "PPE timeout" as part of the standard preoperative and intraoperative checklist in the operating room and before embarking on potential AGPs in the office. Considerations include patient COVID-19 testing status, risk of possible transmission (e.g., droplets), and availability of appropriate PPE equipment for staff. A "PPE timeout" may help to ensure that the entire team is coordinated regarding possible transmission risks and necessary precautions.

The use of PPE is paramount in keeping providers and staff safe from transmission of COVID-19. The adequacy and specific type of PPE to be used depends on the intervention being performed, health system and governmental recommendations, resource availability, and practicality of PPE. Currently, there is wide variability of PPE resources nationally and there are reports of substandard equipment from foreign manufacturers entering the market that are not U.S. Food and Drug Administration (FDA)/ National Institute for Occupational Safety and Health (NIOSH) approved.

Consider wearing dedicated scrubs or other easily washed clothing for the clinic and changing prior to leaving the facility. In the case of COVID-19 positive patients, providers and associated staff should wear an N95 or higher-rated mask, face shield, gown, and gloves. Hair and shoe covers may be considered based on risk of splashing and droplet formation. Occlusive goggles should be considered if face shields are incompatible with use of the microscope or other surgical tools. Powered air purifying respirator (PAPR) may also be considered if the provider has an inadequate N95/FFP2 fit and there is a concern about aerosolization risk during a procedure.

A Centers for Disease Control and Prevention (CDC) PPE calculator may be helpful to determine so-called PPE burn rate to determine supply needs:
https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/burn-calculator.html

Personal Protective Equipment (PPE)

Term	Definition
Personal Protective Equipment (PPE)	General term to describe equipment worn to minimize transmission of infectious particles
Surgical mask	• Used in the operating room and clinic • Loosely covers the nose and mouth • May protect against droplet transmission • Does not prevent aerosol transmission • Not generally reusable
Respirator	• Tight fitting masks that provide a facial seal • Fit testing necessary to guarantee appropriate sizing among available respirators • Generally designed to prevent two-way transmission – filtering both inflow and outflow of air • Protects against both droplets and aerosols • Classified by the federal government based on their percentage of filtration and air leakage • For COVID-19, the most commonly used respirators are N95 and filtering facepiece 2 (FFP 2). (Differences in name come from regulatory agencies in the United States and Europe) • Generally, N95 and filtering facepiece (FFP) 2 masks filter at least 94% of particulate • Respirators are generally reusable with a small degradation in efficacy, if sanitized appropriately • N95 masks with exhalation valves should not be used if possible. The exhalation valve allows unfiltered exhaled air to escape into the environment which can expose others and could contaminate a sterile field
Powered air purifying respirator (PAPR)	• Specific type of respirator that actively circulates and filters air around an individual's face • PAPR styles vary and may include a simple hood, a full head and shoulder cover or a body suit • The most widely available PAPR hoods have variable protection for the neck and attach loosely beneath the chin, possibly requiring a secondary surgical mask / N95 respirator beneath the hood • PAPR hood is generally reusable but must be carefully cleaned between uses • PAPR is indicated if available N95/FFP2 respirators do not provide complete seal during individual fit testing

Eye protection	• Corrective eyeglasses and surgical loupes may not provide adequate protection from droplets • Safety glasses with/without side protections may provide more droplet protection • Occlusive eyewear (e.g., swim goggles) may offer improved protection from droplets than safety glasses • Face shields may decrease contamination to masks and can be worn over eyewear • Surgical "orthopedic" hoods offer head covering but do not offer respiratory protection

Suggested Minimal PPE

COVID Testing Status	**Instrumentation**	**Intervention disrupting respiratory mucosa**	**Suggested Minimal PPE**
Positive	Any	Any	N95 or PAPR; eye protection, gloves, gown
Unknown	Any	Yes	N95 or PAPR; eye protection, gloves
Unknown	Potential aerosol generating instrumentation/thermal	No	N95 or PAPR; eye protection, gloves
Negative*	Any	Yes	* N95 or PAPR; eye protection, gloves
Negative*	Potential aerosol generating instrumentation/thermal	No	* N95 or PAPR; eye protection, gloves
Unknown/Negative	Non-potential aerosol generating instrumentation/Non-thermal	No	Surgical mask, eye protection. gloves

***** Given the current variability in testing, this is the best recommendation to maximize safety at the present time**.** Providers should be aware of the sensitivity/specificity of institutional COVID-19 testing as there are reports of high rates of false negative rates with certain testing modalities. These recommendations may be adjusted based on access to PPE and reliability of testing.

Role and types of COVID testing

In non-symptomatic patients, the goal in pre-operative COVID-19 testing is to minimize elective and non-urgent/emergent surgery in patients who carry the infection. In patients undergoing urgent/emergent surgery, COVID-19 testing is helpful for determining the appropriate peri-operative precautions necessary for the physician, staff, and facility.

Ideally, COVID-19 testing should be accurate with a high sensitivity and specificity, rapid, widely available, and cost-effective. In reality testing may vary by facility in terms of what type of testing is available, which equipment is used, how long it takes to get results, and the sensitivity and specificity of results. Additionally, institutions may have differing criteria for who can get tested and what preoperative testing is required. There is a wide range of resource availability nationally.

Swabbing the nasopharynx may be technically difficult and may be one of the causes of a high false negative rate at some locations. It also may be difficult to perform in pediatric patients. Many of the antibody tests that are currently being used have not been thoroughly evaluated by the FDA. Clinicians should seek to understand the limitations, capabilities, and requirements of their local practice environment when determining the role and reliability of testing.

It is important to remember that asymptomatic patients who carry COVID-19 may be contagious and that there may be asymptomatic patients with false negative test results. Testing is particularly problematic in pediatric settings where most children will be asymptomatic or have mild disease.

We recommend that patients should be screened at least once with COVID-19 PCR testing (swab) prior to the surgical date unless delay caused by testing will result in harm to the patient, subject to local testing availability and stage of community disease penetrance. Currently, the value of COVID-19 antibody testing (IgM, IgG) is unknown as the accuracy of the testing and significance of the results are still being validated. However, a positive IgM for COVID 19 should raise caution for the surgeon and local institution and justifies further evaluation.

The timing of the testing prior to a procedure should be dependent on how long it takes to obtain the results of the test. After the patient is tested for COVID-19, the patient should remain self-isolated until the procedure date.

We recommend non-emergent procedures not be performed until the results of the test are available if one has been obtained. For life-threatening emergencies for which pre-operative COVID-19 testing is not an option, the patient should be presumed to be positive for purposes of PPE utilization and post-operative management.

Testing Resources:

Infectious Diseases Society of America Guidelines on the Diagnosis of COVID-19

Access the full guidelines here: https://www.idsociety.org/COVID19guidelines/dx#

Content specific to testing from IDSA can be found in the following locations of the guidelines:

- The **Executive Summary** includes an algorithm based on 15 recommendations for SARS-CoV-2 nucleic acid testing based on systematic reviews of the diagnostic literature. (Figure 1). https://www.idsociety.org/globalassets/idsa/practice-guidelines/covid-19/diagnostics/figure-1.pdf
- **Recommendation 15:** The IDSA panel suggests SARS-CoV-2 RNA testing in asymptomatic individuals without a known exposure to COVID-19 who are undergoing a time-sensitive aerosol generating procedure (e.g., bronchoscopy) when PPE is limited, and testing is available (conditional recommendation, very low certainty of evidence).

Office and Clinic Considerations

The following is a list of considerations for the patient encounter itself.

- Pre-screening should be considered at the time of booking the appointment, prior to entry into the clinic, as well as at the start of the visit. Important screening questions include exposure to contacts with COVID-19 infection, cough, shortness of breath, fever, chills with/without shaking, muscle pain, headache, and new loss of taste or smell (i.e., less than 14 days). Patients who fail screening should be considered for more detailed screening or be evaluated via a telemedicine visit. If there is concern about current COVID-19 infection, these patients should also be considered for testing and/or referred to their primary care physician or an appropriate COVID-19 testing facility.
- Consider taking a history prior to the visit via phone, web portal, or telehealth in order to minimize the time the patient spends in the office and appropriately triage the patient.

- Consider informing patients at the time of scheduling to self-quarantine as much as possible prior to the appointment and to cancel in-office appointments if patients develop fever, cough, shortness of breath or difficulty breathing, chills, repeated shaking with chills, muscle pain, headache, sore throat, or new loss of smell/taste.
- Consider a patient check-in process during which patients are screened for COVID-19 symptoms and temperatures and/or pulse oximetry are obtained.
- Consider limiting individuals accompanying the patient to only those needed to directly support the patient (e.g., caregiver, parent of a minor, case manager, interpreter if telephone services are not available).
- All patients, including children, should wear a mask that covers the nose and mouth and be informed that it is to be worn at all times.
- All patients should maintain appropriate social distancing requirements in the waiting area after patient check-in. Consider removing and blocking off furniture in waiting areas to allow for appropriate spacing. Offices should space out seats according to recommended distances.
- Establish an appropriate number of patients scheduled per hour to allow for the increased time of check-in, patient encounter, room cleaning, and turn over.
- For those offices with small waiting rooms or difficulty maintaining social distancing practices in common areas, consider alternative patient flow processes. For example, this may involve allowing patients to wait in their cars and be called directly into the clinic room, with check-in performed in the clinic rooms.
- Consider moving patients along designated paths to minimize contact among patients.

Staff Responsibilities

- It is recommended that all staff should be screened for COVID-19 symptoms and undergo temperature checks on a routine basis.
- It is recommended that all staff should practice social distancing and wear a mask at all times while in the work environment.
- All staff should adhere to recommended hand hygiene protocols (e.g., washing with soap and water for 20 seconds and using hand sanitizer).
- All staff keep personal workspaces cleaned according to approved disinfectant protocols and store personal effects.
- Staff should wear appropriate PPE during patient interactions.
- Providers should wear appropriate PPE during patient encounters.
- It is recommended that all staff should be proactively informed that they should not come to work prior to contacting their supervisor if they have any fever, new cough, new muscle aches, new shortness of breath, or new loss of sense of smell or taste.

Clinical Space Considerations

- It is recommended that the number of patients in the waiting room be monitored to ensure that social distancing can be practiced.
- It is recommended that exam room and nursing station counters are cleared of excess paper products, supplies, and equipment. The number of items on counters should be a bare minimum.
- Consider covering office equipment such as video towers when not in use.
- Monitor PPE and cleaning supply inventory and have a procurement plan.
- Consider adding an inline filter for suction devices.
- Maximize hand sanitizer visibility and access if available. If hand sanitizer is not available, encourage hand washing for staff and patients.
- Minimize and/or consider eliminating magazines, brochures, pens, clipboards, and other loose materials and shared-use items from the waiting and exam rooms. All materials used during a patient encounter should be thoroughly sanitized using approved procedures prior to additional patient exposure.

Exam Room Considerations

- Staff should be trained and monitored to ensure the rooms are being cleaned and properly sanitized.
- Develop and follow equipment and room cleaning protocols.
- Consider individual treatment trays to avoid opening drawers.
- Dedicated medical equipment should be used when caring for patients with known or suspected COVID-19.
- As much as possible, limit staff and non-essential personnel from being in the exam room during all office procedures.
- If a confirmed COVID-19 positive patient is seen in the office and has an aerosol generating event, the exam room should be rested for a period of time determined by air exchange and other local factors.

Office Procedure Considerations

- Due to known limitations of available PPE, clinicians may consider use of reusable N95 masks or periodic decontamination of PPE based on local policies, resources, and equipment.
- Designate a single room, microscope, and audiology booth for COVID-19 positive patients and persons under investigation and use an approved cleaning protocol after each use.
- Limit atomizer and nebulizer use as much as possible and consider nasal pledgets or cotton soaked in decongestant or local anesthesia instead.
- Recommend patients wear masks, if possible, during office endoscopy.
- Laryngoscopy, nasopharyngoscopy, nasal endoscopy, manipulation of the external auditory canal, and other instrumentation of the upper airway should be carefully considered, as these are potentially AGPs if they result in a patient sneezing or coughing.
- If diagnostic endoscopy is necessary in a non-Covid-19 positive patient, PPE including exam gloves, a surgical mask or a N95 respirator if preferred and available, with a face shield or goggles is appropriate. This recommendation can be adjusted based on availability and quality of COVID-19 testing and/or current local incidence of COVID-19.
- If available, a video system rather than direct visualization through the endoscope can be considered to keep the examiners face further away from the patient.
- Ear canal and mastoid instrumentation can elicit coughing due to stimulation of Arnold's nerve cough reflex with resultant aerosolization. It is also theoretically possible that aerosolization could occur through instrumentation of infected tissue, including suction of middle ear effusions.
- Suction systems should be evaluated, and inline filtration should be considered when feasible.
- Suction tubing should be changed or sanitized per appropriate protocols after any encounter with a high-risk patient.
- Office procedures should be performed with as few staff present as possible.
- Proper protocols and precautions should be used for handling and cleaning instrumentation after the procedure.

Telemedicine

- Consider the use of telemedicine for patients in whom a physical exam is not necessary or possible for medical management. Including but not limited to:
    - Vulnerable/at-risk patients with significant comorbidities
    - Follow-up for selected surgical patients
    - Follow-up for review of test results
    - Established patients with mild exacerbations of chronic disorders
    - Medication refills or adjustments
    - Preoperative counseling
    - New patients seeking consultation
    - Patients whose screening raises concern forCOVID-19 symptoms
    - Non-urgent in hospital consultations

ASC, Hospital OR Considerations

The urgency of a specific surgical intervention is determined by the clinical presentation, potential morbidity, independent surgical judgement. and the availability of appropriate resources. Procedures should be prioritized taking into account institutional policies, regional COVID-19 prevalence, facility capacity issues, PPE availability, COVID-19 testing availability, and test sensitivity/specificity, local resource consumption, and relevant potential EMTALA considerations.

- If possible and appropriate, the operating rooms should be designated for COVID-19 positive and COVID-19 negative patients.
- Intubation and AGPs should be performed in a negative pressure room with the door closed, if possible.
- All providers not essential for intubation should remain outside the operating room during endotracheal intubation and extubation to minimize exposure.
- In high-risk patients, procedures may be carried out by the most experienced surgeons to mitigate risk to staff and ensure minimal OR time. Trainees participation should be guided by local policies. Videotaping procedures with appropriate permissions may be used for teaching purposes outside the operating room.
- Proper PPE for the level of risk should be worn.
- When possible, attempts should be made to reduce particle distribution radius with surgical field coverage (e.g., draping), air evacuation (e.g., suction), and limiting the use of technology that theoretically may cause aerosolization.
- Modification of visualization techniques (e.g. surgical loupes, endoscopes in lieu of microscopes, etc.) may be necessary to accommodate different types of PPE.
- A barrier/drape may be placed between the surgical field and anesthesia.
- Given the possibility that aerosolization of viable pathogens (including virus) may also occur during electrocautery and generation of surgical smoke, consideration should be given to using additional local vasoconstriction and cold techniques during soft tissue dissection.

Specific Medication Concerns

Corticosteroid medications are frequently used in the treatment of various otolaryngologic disorders. Current recommendations advocate for continued use of inhaled steroids and nasal steroid sprays to maintain a healthy airway and avoid need for emergency care. Systemic corticosteroids have special consideration in the era of COVID-19 infection. The use of systemic corticosteroids in patients with active COVID-19 infections have been shown to worsen infection in the early phases and should be avoided except in cases of ARDS. Corticosteroids are helpful for severe exacerbations of allergic diseases and asthma, often precluding the need for emergency care and can still be used in the COVID-19 era. The decision for use of short bursts of systemic corticosteroids should be made with a shared-decision model, informing patients of the risks of potential worsening COVID-19 infection while helping them avoid emergent care where there could be exposure to COVID-19 positive providers and patients.

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