




PRACTICE GUIDELINES**AHNS endocrine surgery section consensus statement on nasopharyngolaryngoscopy and clinic reopening during COVID-19: How to get back to optimal safe care**

Benjamin Bleier MD¹ | Alan Workman MD MTR¹ | Ciersten Burks MD¹  | Alice Maxfield MD² | Brendan C. Stack Jr MD³  | Cherie-Ann Nathan MD⁴  | Susan McCammon MD⁵ | Mark Varvares MD¹  | Cecelia Schmalbach MD⁶ | Steven Wang MD⁷ | Joseph Califano MD⁸ | Yelizaveta Shnayder MD⁹ | Marion B. Gillespie MD¹⁰ | Danny Enepekides MD, MPH¹¹ | Ian Witterick MD¹² | Ivan El-Sayed MD¹³  | Derrick Lin MD¹ | Urjeet Patel MD¹³ | Dennis Kraus MD¹⁴ | Gregory Randolph MD¹

¹Massachusetts Eye and Ear, Divisions of Rhinology, Head and Neck Surgery and Thyroid and Parathyroid Endocrine Surgery, Department of Otolaryngology Head and Neck Surgery, Harvard Medical School, Boston, MA

²Department Otolaryngology Head and Neck Surgery, Brigham and Women's Hospital, Harvard Medical School, Boston, MA

³Department of Otolaryngology-Head and Neck Surgery, Southern Illinois University School of Medicine, Illinois, IL

⁴Department of Otolaryngology-Head and Neck Surgery, LSUHSC, Louisiana New Orleans

⁵Department of Otolaryngology-Head and Neck Surgery, University of Alabama at Birmingham, Birmingham, AL

⁶Department of Otolaryngology-HNS Lewis Katz School of Medicine at Temple University, Philadelphia, PA

⁷Department of Otolaryngology-Head and Neck Surgery, University of Arizona College of Medicine, Tucson, Tucson, AZ

⁸Division of Otolaryngology Head and Neck Surgery, Department of Surgery, University of California San Diego, San Diego, California

⁹Department of Otolaryngology - Head and Neck Surgery, University of Kansas School of Medicine, Kansas City, Kansas

¹⁰UTHSC Department of Otolaryngology- Head and Neck Surgery, Memphis, TN

¹¹Sunnybrook Health Sciences Centre, Department of Otolaryngology-Head & Neck Surgery, University of Toronto, Toronto, CA

¹²Department of Otolaryngology- Head and Neck Surgery, University of Toronto, Toronto, CA

¹³Department of Otolaryngology, Northwestern University, Evanston, IL

¹⁴Department of Otolaryngology - Head & Neck Surgery Lenox Hill Hospital, Zucker School of Medicine at Hofstra/Northwell, New York

Correspondence

Gregory Randolph, Department of Otolaryngology-Head and Neck Surgery, Harvard Medical School, Massachusetts Eye & Ear, 243 Charles Street, Boston, MA 02114.

Email: gregory_randolph@meei.harvard.edu

Abstract

This article provides best practice guidelines regarding nasopharyngolaryngoscopy and OHNS clinic reopening during the COVID-19 pandemic. The aim is to provide evidence-based recommendations defining the risks of COVID-19 in clinic, the importance of pre-visit screening in addition to testing, along with ways to adhere to CDC guidelines for environmental, source, and engineering controls.

KEYWORDS

clinic reopening, consensus statement, COVID-19, nasopharyngolaryngoscopy, Otolaryngology-Head and Neck Surgery

1 | INTRODUCTION

The following document represents a series of best practice guidance for Otolaryngology-Head and Neck Surgery (HNS) clinic reopening in the COVID-19 era. In this environment of unprecedented data evolution including rapidly changing disease rates, new and varying testing modalities as well as shifting patient attitudes to the more normal resumption of their clinic care, these guidelines may be subject to change as we continue to learn more about viral transmission characteristics, pathophysiology, treatments, and mitigation strategies. The italicized sections represent the most up-to-date, evidence-based recommendations for clinic reopening recognizing evidence is limited in this space. The bulleted sections reflect a practical distillation of these recommendations based on the consensus opinion of the expert author panel as seen through the lens of several of the AHNS disease sections. We appreciate that due to COVID-19's changing prevalence and the overall dynamic clinical landscape of its testing and treatment, these recommendations will change over time. These are the best of our thoughts now.

2 | DEFINING THE RISKS IN THE OTOLARYNGOLOGY-HNS CLINIC

Recommendation 1: The infectious transmission risk of SARS-CoV-2 in the outpatient clinic depends on a number of incompletely understood and variable factors including geotemporal prevalence, testing type and reliability, personal protective equipment (PPE) availability and efficacy, clinic procedural airborne and droplet aerosolization, and their associated clinical significance as it relates to infectivity/replicativity. Providers should remain aware of the evolving literature and adhere to local, regional, and national guidance with respect to infection control.

On December 30, 2019, bronchoalveolar lavage samples of a patient in Wuhan, China, with idiopathic pneumonia were positive for pan-Betacoronavirus. Bioinformatic analysis demonstrated that it had a 96% similarity to the bat SARS-like coronavirus strain BatCov RaTG13. This novel zoonotic virus was named SARS-CoV-2 and the resultant disease, COVID-19, has rapidly progressed into a global pandemic.¹ The transmission characteristics of COVID-19 are not fully characterized and thus evidence-based protocols regarding health care worker (HCW) protection have been extrapolated from prior experience with the SARS-CoV and Influenza A/H1N1 outbreaks in 2003 and 2009, respectively. Coronaviruses are approximately 0.125 μm in size and are currently thought to spread primarily via direct contact and respiratory droplets.² Airborne aerosol transmission

has been increasingly recognized as a potential mode of infection both in the healthcare³ setting as well as in the community.⁴⁻⁶ These risks are particularly germane to the Otolaryngology-HNS provider in light of evidence of viral loads within the upper aerodigestive tract among both symptomatic and asymptomatic patients.⁷ Fortunately, several studies evaluating health care worker (HCW) infection, some of which have included classically defined aerosol generating procedures (eg, intubation, extubation, and non-invasive ventilation) have suggested that the period of infectivity is limited and that a significant inoculum is required to cause infection.⁷⁻⁹

3 | PRE-VISIT SCREENING AND TESTING

Recommendation 2: Pre-visit symptom and contact screening is a useful method of routing potential COVID-19 positive patients toward telemedicine visits. The interpretation of RT-PCR-based testing remains dependent on multiple factors including false negative rate and varying community prevalence. While positive tests may be used to exclude patients from a clinic visit, negative test results should be viewed with caution and within the context of local negative predictive value rates.

- All patients should undergo pre-visit symptom and contact screening within 72 h of their visit. Confirmation screening should occur on the day of the visit.
- Physicians and provider team members should be screened daily for symptoms.
- Physicians must be aware of their patient population specific data as it relates to disease prevalence.
- Pre-procedural COVID-19 RT-PCR testing can be considered as an adjunct to symptom screening for patients undergoing diagnostic/surveillance nasopharyngolaryngoscopy (NPL) or rigid nasal endoscopy (RNE).
- In regions of high or rapidly increasing prevalence, negative RT-PCR test results should be interpreted with caution.

The most prevalent method for SARS-CoV-2 testing is based on reverse transcriptase polymerase chain reaction (RT-PCR) for the presence of viral RNA. With more established testing protocols, evidence has emerged that accurate results are predicated on the three principle concepts of proper timing, proper site, and proper sample acquisition. There are multiple factors that impact test interpretation and account for geotemporal differences in prevalence such as the negative predictive value and false omission rate. However, within the health care setting

and against the background of a virus with no reliable treatment or vaccine, the false negative rate represents one of the most important metrics. This stems from the fact that failure to identify a COVID-19 positive patient could result in inadvertent spread to both the health care team as well as other vulnerable patients.¹⁰ From the perspective of proper timing, a recent meta-analysis¹¹ confirmed that the highest risk of a false negative result occurs in the pre-symptomatic period up to 4 days prior to symptom onset. With regard to proper site, several studies, including one of 353 patients, confirmed that the nasopharynx is the optimal sampling location although the nasal cavity is also clinically acceptable.^{12,13} Finally, with respect to proper sample, adequate viral material must be obtained in order to be amplified and subsequently detected by RT-PCR. Consequently, the CDC recommends the use of flocked swabs over calcium alginate swabs as, among other advantages, they improve sample yield through increased surface area within the multi-length (eg, “flocked”) swab fibers. Common otolaryngologic diseases, particularly those that impact the sinonasal cavity and skull base, may complicate optimal testing with respect to all three tenets of timing, site, and sample acquisition. At the current time, nasopharyngeal RT-PCR testing for SARS-CoV-2 may be helpful to exclude positive patients however a negative result should be viewed with caution when making decisions to supplant source/environmental controls and provider PPE. While asymptomatic rates remain poorly defined, screening questions for symptoms¹⁴ and infectious contacts remain a simple adjunct to identifying potential COVID-19 positive patients. This facilitates routing to a telemedicine visit or having the ability to plan appropriately to protect members of the health care team and vulnerable patients.

4 | ENVIRONMENTAL CONTROLS

Recommendations: Clinics should adhere to CDC guidelines with regards to signage, social distancing, and routine cleaning of all clinic surfaces using hospital grade disinfectants.

- CDC or institutional approved signage should be posted outside of all major entrances regarding hand hygiene, respiratory hygiene, and cough etiquette.
- Source control masks should be provided to all patients upon entry to the facility. Alcohol-based hand rub (ABHR) should be applied both before and after donning of the mask.
- Social distancing guidelines should be enforced in the clinic setting. This includes scheduling patients to

avoid crowding, blocking and/or arranging waiting room at 6 ft intervals, maintaining unidirectional clinic flow whenever possible, and protection of front-desk staff using barriers and/or distancing measures.

- All high-touch surfaces should be routinely cleaned using EPA-registered disinfectants after each patient use both in the waiting room and clinic room.
- Clinic room surfaces should be decluttered to facilitate cleaning.

Infection control should begin prior to the moment the patient enters the facility. As recommended by the CDC,¹⁵ visual alerts should be placed in strategic areas, including the entrance, providing information regarding hand hygiene, respiratory hygiene, and cough etiquette. Upon entrance, source control should be implemented by providing a face covering along with instruction on performing hand hygiene (eg, using an ABHR) both before and after donning the covering. While the CDC advocates for a cloth covering if a facemask is not available, in the setting of an outpatient otolaryngology visit we advocate for the provision of source control masks if endoscopic instrumentation of the nose and/or throat is planned. The check-in/reception and waiting room areas should provide ABHR, tissues, no-touch receptacles for disposal and modify layouts in order to remain in accordance with CDC guidelines regarding social distancing.¹⁶ Routine cleaning and disinfection of equipment and frequently touched surfaces using EPA-registered, hospital grade disinfectants, are required both in the waiting and exam rooms to reduce the risk of contact transmission. One must keep in mind the physician can also be considered a source and so physicians should wear masks at all times in the health care facility. If they remove their mask as with eating or drinking, they must stay 6 ft from others. Physicians must attest daily to not having COVID-19 symptoms and stay home if sick.

5 | PROCEDURAL RISK AND SOURCE CONTROL

Recommendations: Airborne aerosol generation may occur during certain endonasal procedures. Source control masks may be used to mitigate the risk of environmental aerosol contamination but have differential efficacy with respect to droplet vs airborne aerosol protection. Providers can additionally consider high level PPE use including face shields and N95 respirators when performing endonasal endoscopic procedures where airborne aerosol generation is expected.

- In the setting of unknown COVID-19 status, NPL and RNE should be performed with the provider wearing

- an N95 respirator, gown, gloves, and face shield/eye protection.
- Patients can maintain some form of mask source control to prevent respiratory droplet dispersion during NPL/RNE.
 - Topical anesthesia and decongestants should be directly applied to the nasal mucosa, nebulizing and/or atomizing devices should be avoided.
 - A well-tolerated NPL/RNE exam using source control and without significant reflexive behavior (eg, severe coughing, gagging, vomiting and/or sneezing) may be considered a non-aerosolizing procedure with regards to room turnover precautions.

Recent studies among healthy controls have demonstrated significant airborne aerosol production may occur during nasal endoscopy, talking, and sneezing. Data vary between studies depending on the experimental setup and equipment used and not all studies show laryngoscopy interventions generate aerosols above that produced by breathing or phonation.¹⁷ The most common method used to reduce sneezing, namely topical nasal anesthesia and decongestion spray, also produced a significant number of aerosols.¹⁸ Studies employing episodic stresses such as sneeze have shown that surgical masks are vulnerable to leakage from dynamic changes in both pressure and air velocity.¹⁹⁻²¹ These findings are of particular concern to the otolaryngologic provider as sneeze behaviors have been shown to produce a spectrum of particles subtending both the airborne and droplet range at high velocity.²² However, N95 respirators were found to successfully contain sneeze-associated aerosols¹⁸ even when used with a VENT modification to enable endoscopy.²³ These findings suggest that in the presence of appropriate source control, endoscopic endonasal exams including NPL and RNE may be performed safely with limited risk of aerosol contamination of the environment. However, in the absence of adequate source control, these aerosolization risks suggest the provider should adopt high level PPE when possible.

6 | ENGINEERING CONTROLS

Recommendations: Airborne aerosol generation during Otolaryngology-HNS procedures has the potential to contaminate enclosed clinic spaces. As infective virus may persist for prolonged periods, modifications of clinical rooms and room turnover to optimize ventilation, air exchange, airflow, and air filtration should be considered during higher risk procedures.

- Providers should be aware of their local room air exchange rates.
- Providers should be in contact with their local infection control experts regarding room turnover times based on air exchanges, filtration, and ventilation pathways.
- In the setting of a well-tolerated NPL/RNE exam using adequate source control, prolonged room closure may be at the discretion of the provider.
- In the setting of a poorly tolerated NPL/RNE exam with concern for airborne aerosol generation, room closure with adequate air exchange and filtration should be employed.

There have been several epidemiologic reports supporting the transmission of COVID-19 by airborne aerosolization within enclosed spaces.^{24,25} Furthermore, experimental evidence has suggested viruses may persist for several hours in air.²⁶ These studies, coupled with the risk of airborne aerosol generation during endoscopic endonasal procedures,¹⁸ indicate that the air supply within the enclosed clinic space should be considered when implementing infection control guidelines.

In some cases, architectural and engineering modifications can be made to air exchange to improve safety. Many reports and studies on aerosol transmission of airborne viruses are performed in a closed system with air stagnation. However, clinical patient interactions occur in the dynamic health care environment. Specific ventilation guidelines exist for various areas within health care facilities, such as the operating rooms and clinic rooms. One of the most important metrics is air changes per hour (ACH) and the time required for airborne-contaminant removal based on 99% and 99.9% efficiency. Importantly, the ACH is not linear. For instance, in a room with 10 ACH, the time to remove airborne contaminants with 99% and 99.9% efficiency is 28 and 41 min, respectively. Of note, these ACH guidelines typically assume that the room is empty and there is perfect air mixing, which is often not the case. The direction of airflow has also been found to be extremely important in airborne transmission of pathogens. The ventilation system and exhaust should direct airflow from clean to dirty, such as from the aerosol generating source toward the exhaust and cleared away. Increasing ACH is only helpful if there is an optimized ventilation design with a "path" established between the contaminant and the exhaust, to prevent interruption by air streams. Air filtration is another critical feature of air handling. High-efficiency particulate air (HEPA) filters use mechanical filtration to remove airborne particles and are standardized at a

minimum 99.97% efficiency rating for removing particles $\geq 0.3 \mu\text{m}$.²⁷ While there is no specific data on the use of HEPA filters in the clinical setting during the COVID-19 pandemic, previous data on HEPA filters for other known airborne pathogens suggest they should be considered to enhance air filtration and circulation to further decrease risk of airborne aerosol transmission SARS-CoV-2.

Recommendations in this space are varied and evolving. The Canadian Society of Otolaryngology-HNS set of recommendations are available at:

<https://www.entcanada.org/wp-content/uploads/Return-to-Clinic-Practice-in-Otolaryngology-May-23-2020-FINAL.pdf>

<https://www.entcanada.org/wp-content/uploads/KK-preamble-laryngoscopyV6-May112020REV2.pdf>

<https://www.entcanada.org/wp-content/uploads/Laryngo-scopy-in-OPD-006-June-3-2020.pdf>

<https://www.entcanada.org/wp-content/uploads/CSO-Position-Paper-on-Elective-Sinus-and-Skull-Base-Surgery-During-the-COVID-July-13-2020-FINAL.pdf>

The American Academy of Otolaryngology and Head and Neck Surgery set of recommendations are available at:

https://www.entnet.org/sites/default/files/uploads/guidance_for_return_to_practice_part_2_final_05122020.pdf

ORCID

Ciersten Burks  <https://orcid.org/0000-0002-9377-5715>

Brendan C. Stack Jr  <https://orcid.org/0000-0003-2896-1615>

Cherie-Ann Nathan  <https://orcid.org/0000-0001-7386-318X>

Mark Varvares  <https://orcid.org/0000-0002-6570-5672>

Ivan El-Sayed  <https://orcid.org/0000-0001-8121-3726>

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