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High-Risk Aerosol Generating Procedures in COVID-19: Respiratory Protective Equipment Considerations

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Abstract

The correct selection and utilization of respiratory personal protective equipment is of the utmost importance in the current COVID-19 pandemic. This is especially true for healthcare workers exposed to high-risk aerosol generating procedures including otolaryngologists, ophthalmologists, neurosurgeons, maxillofacial surgeons, and laparoscopic surgeons.

This communication provides a review of approved forms of respiratory protection and compares their characteristics including surgical masks, N95 masks, elastomeric respirators, powered air-purifying respirators, and controlled air-purifying respirators. For standard airborne precautions, N95 masks are appropriate for respiratory protection. However, high-risk aerosol generating procedures may create aerosolization of high viral loads that represent increased risk to healthcare workers. In these situations, enhanced respiratory protection with filters certified as 99, 100, or HEPA may be appropriate.

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Introduction

There are many different forms of respiratory protective equipment. The importance of using appropriate protection is of utmost importance in the current COVID-19 pandemic due to SARS CoV2. However, healthcare workers often have narrow views of potential forms of respiratory protection given the historic limited utilization of enhanced respiratory protective options. Understanding approved forms, differences in respiratory personal protective equipment (PPE), and its role in protection from aerosols allows healthcare workers to choose the right type of protection for their situation. Finally, factors creating elevated risk to healthcare workers during aerosol generating procedures (AGP) are identified for categorization of "high-risk aerosol generating procedures". During high-risk AGPs increased level of personal protective equipment may be warranted.

OVERVIEW OF APPROVED RESPIRATORY PPE IN THE HEALTHCARE SETTING:

Common types of respiratory PPE (Table 1):

Respiratory protective equipment recognized by the Center for Disease Control and Prevention (CDC) in the healthcare setting include surgical masks, disposable masks/respirators (including N95 masks), elastomeric respirators, powered air-purifying respirators (PAPR), and controlled air-purifying respirators (CAPR). However, healthcare providers may not familiar with these options as not all have historically played a large role in hospital PPE. Each has unique characteristics that protect the wearer to varying levels. These are reviewed below and in Table 1.

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Surgical masks sit on the face and are loose fitting. Their intent is to block large particle droplets from reaching the nose and mouth. They are protective from droplets, splashes, sprays, and splatter. They are appropriate for modified droplet precautions but not for airborne precautions during AGPs. In addition to protecting the wearer, they filter exhaled air and protect sterile fields from contamination by the proceduralist.

Disposable masks/respirators come in a variety of filter options including N, R, or P types ranging from filtration level of 95 to 100. N95 masks (Figure 2) are the most common of these and are tight fitting masks sometimes called respirators. If correctly fitted, they form an airtight seal on the face around the mouth and nose. They are intended to protect the wearer from aerosolized particles and, unless specially designated as Food and Drug Administration (FDA) approved, they are not appropriate for use over a sterile field without additional coverage by a surgical mask.[1]

Elastomeric Respirator (Figure 1) are either half or full-face masks made of soft rubber that allows them to be repeatedly cleaned, disinfected, and reused by multiple providers. Their filtration capacity is determined by the filter attached; it ranges from N95 to P100 level particle capacity. Particulate filters used in the hospital setting will last 6 months to 1 year commonly. Elastomeric respirators are not appropriate for use over a sterile field without the addition of an FDA approved surgical mask over the exhalation valve.

Powered Air Purifying Respirator (PAPR) are composed of a face mask or hood and separate motor/fan/filter unit. It creates highly filtered air flow through the hood to protect the wearer

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from aerosolized particles. The motor/fan/filter unit is separate from the hood and typically located on a belt or pack. Due to the expulsion of airflow away from the wearer, these are not appropriate over sterile fields without modification.

Controlled Air-Purifying Respirator (CAPR) is similar to a PAPR in that it uses active filtered air flow within a hood or face mask to protect the wearer. For a CAPR, the motor, fan, and filter are moved into the headpiece itself and it doesn't have a separate unit on a belt or pack. Similar to a PAPR, it is not appropriate for use with a sterile field without modification due to the active airflow away from the wearer.

Filter Types and Nomenclature

The filtering capacity of masks, respirators, and respirator cartridges is denoted by a letter and numeric value. Filters are marked as either N, R, or P. The filters marked N are not resistant to oil, R are somewhat resistant to oil, and P are strongly resistant to oil. The number associated with each filter denotes its filtering capacity for particles 0.3 microns in size. A respirator designated "95" filters at least 95% of particles 0.3 microns in size. A mask designated "99" filters at least 99% of particles 0.3 microns in size. A mask designated "100" filters at least 99.97% of particles 0.3 microns in size.

Thus, respirators or masks with N95 filtering capacity are non-resistant to oil and are able to filter out 95% of 0.3 micron particles. These are considered the lowest level of approved respiratory protection for airborne SARS viruses by the Centers Disease Control and Prevention (CDC).[2]

In comparison, P100 filters are oil proof and filter 99.97% of 0.3 micron particles. They are considered the highest level of protection against SARS viruses by the CDC.

The filters used within PAPRs and CAPRs are designated as High-Efficiency Particulate Air (HEPA) filter. They filter out 99.97% of 0.3 micron particles and are considered equivalent to P100 level filters.

AEROSOL GENERATING PROCEDURES:

The SARS-CoV2 is predominantly transmitted by droplets (5-10 microns); however, it can become aerosolized during certain conditions termed "aerosol generating procedures".[3] When aerosolized, viral particles become airborne in droplet nuclei that are less than 5 microns in size, can travel greater than 1 meter, and remain airborne for up to 3 hrs.[4] During those events, virus droplet nuclei can pass through the pores of surgical masks. Thus, in situations that may be aerosol generating, healthcare workers should wear respiratory PPE to N95 protection level or higher. Additionally, goggles or faceshields cover the front and lateral portions of the head are required.

HIGH-RISK AEROSOL GENERATING PROCEDURES

Not all AGPs are equivalent; consider the differences in an isolated coughing event verses an 8 hour endoscopic skull base surgery with powered instrumentation. A N95 mask is the minimum approved level of respiratory protection for airborne isolation for SARS viruses and is generally

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sufficient for routine situations. However, use of higher level of respiratory PPE should be considered for high-risk AGPs.[2,5-7]

The definition of High-risk AGPs has not been well characterized to date but review of literature suggests consideration of these factors. High-risk AGPs are those events that have potential to create aerosols with high viral loads and may represent elevated risk to healthcare workers for infection by SARS CoV2.[5,8] Factors that may increase the risk of transmission during AGPs include duration of exposure, proximity of provider to aerosol, manipulation of high viral load tissue (nasopharynx/oropharynx), and aerosolization through the use of energy devices (laser, cautery, drills, microdebriders, saws, and ultrasonic devices).[5,9-12] AGPs with these additional factors should be considered "High-Risk Aerosol Generating Procedures." Surgical inventions meeting criteria for classification as high-risk AGPs are performed most commonly by otolaryngologists, maxillofacial surgeons, neurosurgeons, and laparoscopic surgeons.[10,13] This is consistent with reports of elevated rates of nosocomial COVID infections in these provider groups.[5]

Regarding duration and proximity to the aerosol exposure, the best data comes from the SARS outbreak of 2003. A systematic review of reports of nosocomial infection during the 2003 SARS outbreak showed the most association across studies for increased risk of disease transmission was endotracheal intubation. There was a statistically significant increased risk of transmission of SARS for healthcare workers that performed or were involved with endotracheal intubation with an odds ratio was 8.8% (95% CI 5.3,14.4) and no statistical heterogeneity (I^2=0%).[9] This would suggest that aerosol exposure that is equal or greater in duration and/or proximity to that

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of staff during endotracheal intubation is potentially high-risk. The average time for standard oral intubation under normal conditions is approximately 16 minutes from the time of entering an OR.[14] Thus, any exposure equivalent or beyond this average intubation time, may be considered as a high-risk factor. Similarly, equivalent or greater proximity to the aerosol source compared to the positions of anesthesiologist and nursing staff during an intubation event may represent a high-risk factor for transmission based on this data.

The viral presence of tissue has been studied from several tissue sources but a comprehensive comparison of viral load from various body sites has not been completed. Currently, there is evidence of elevated viral presence in all upper airway tissue with highest levels present in nasal tissue compared to oropharyngeal sampling.[11] Comparing saliva to throat washes, viral RNA was present in both samples and not statistically significantly different.[15] Conversely SARS-CoV2 has also been rarely isolated from tears or from conjunctival swabs of actively infected patients, and no virus has been cultured from any conjunctiva samples; this suggests lower viral loads relative to the rest of upper airway mucosa.[16-17] There is evidence of significant viral presence in the gastrointestinal system. Viral nucleocapsid protein has been detected in gastric, duodenal, and rectal glandular epithelial samples (but not esophageal tissue). Viral detection is also present in stool samples; interestingly, the presence of virus in stool samples persists even after nasopharyngeal tests are no longer positive.[18] The liver is another site that virus has been isolated. But the viral load in this tissue is thought to be lower due to lack of viral inclusions.[19]

Prior research into the viral particle aerosolization with the use of energy instruments has confirmed creation of viral aerosols containing viable infectious virus particles. Powered drills,

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microdebriders, and saws are known to aerosolize infectious HIV particles from patient blood during use.[20-21] Additionally, use of lasers in patients with HPV virus in the oropharynx and larynx creates viral plumes with viable infectious material known to cause disease transmission to healthcare workers.[22-24] Electrocautery will similarly create an aerosolized plume from which viable cells can be cultured including viruses and neoplastic cells.[21,25] Thus, use of energy instruments creates viable aerosolized viral particles that are high-risk and there is prior evidence of viral disease transmission to healthcare workers by this method.

Enhanced Respiratory Protection during High-Risk Aerosol Generating Procedures

During high-risk AGPs, use of enhanced respiratory PPE greater than an N95 level should be considered for all healthcare workers present.[5-6] This is supported by the CDC whose recommendations for respiratory protection include "use of a higher level of respiratory protection may be considered for certain aerosol-generating procedures".[2] For high-risk AGPs, respiratory protection above N95 should be considered. Options for this include N-P 99 masks, N-P 100 masks, elastomeric respirators with filters type N-P 99-100 level, PAPR, or CAPR. Additionally, fitted goggles should be worn for eye protection; face shields are not adequate eye protection during high-risk AGPs.[2,6]

The exact risk to health care workers for nosocomial infection by SARS CoV2 during high-risk AGPs cannot be quantified due lack of data; a problem that is universal in discussion of the management and approach to SARS CoV2. Even before SARS CoV2, there was a lack of data on risks regarding AGPs with no quantitative study having been performed.[26] However, there are anecdotal reports providing support for the importance of enhanced respiratory protection above

that provided by an N95 during high-risk AGPs from the current SARS CoV2 pandemic and the 2003 SARS outbreak literature. Early evidence that N95 masks may be insufficient protection came from a report out of Wuhan that 14 healthcare workers involved in a transnasal pituitary surgery on a SARS CoV positive patient contracted SARS CoV2 despite wearing fit tested N95 respirators and all other appropriate PPE during the case.[27] A second similar event was reported from a separate hospital in Wuhan when a transnasal pituitary surgery was performed for pituitary apoplexy on a SARS CoV2 positive patient and the surgeon and all OR nurses subsequently developed clinical illness despite use of PPE and N95 masks. Importantly, the only individual that did not contract the disease was the anesthesiologist who wore a PAPR throughout the surgery.[28] During the SARS outbreak of 2003, similar evidence existed of nosocomial infection despite use of an N95 during difficult, prolonged intubation resulting in transnasal endoscopic intubation.[29] A separate event of cardiopulmonary resuscitation in a SARS CoV1 positive patient resulted in 3 out of 9 participating healthcare workers developing clinical evidence of nosocomial infection. All healthcare workers that fell ill following this event had been wearing N95 masks; in comparison, no healthcare workers wearing PAPRs that participated in the event (n=3) contracted SARS.[30] Furthermore, zero infections occurred in operating room staff during the 2003 SARS outbreak at the national hospital caring for SARS patients in Singapore where PAPRs were used by all staff for all high-risk procedures.[6] Thus, use of enhanced respiratory PPE should be considered for all providers present during high-risk AGPs and is supported by evidence from the current SARS-CoV2 pandemic and the 2003 SARS outbreak.

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For non-sterile procedures, enhanced respiratory protection options include a variety of disposable masks, elastomeric respirators, or powered air-purifying systems. Disposable mask types above an N95 include: N99, R99, P99, N100, R100, or P100. Benefits to these masks are that they are similar to N95s and thus more familiar to healthcare workers. However, these masks may not be readily accessible within the healthcare setting, require fit testing, and are intended for single use. Alternatively, a reusable elastomeric respirator with filters type N99, R99, P99, N100, R100, or P100 is an option. An elastomeric respirator has the advantage of being reusable and able to be disinfected between uses. Although the filter cartridges are ultimately disposable, they are meant to be reused until they no longer can be breathed through or become visibly soiled which typically provides protection for 6 to 12 months. Elastomeric respirators additionally can be used with goggles, surgical glasses, headlights, and microscopes. The downside to these respirators is that they are unfamiliar to many in healthcare, still require fit testing, and may not be readily accessible within the healthcare setting. Lastly, both PAPRs and CAPRs can be used for enhanced respiratory protection when working with non-sterile fields. A significant positive for PAPRs and CAPRs is there lack of need for fit testing. The downside to their use in OR includes difficulty using with surgical glasses, a headlight, and a microscope. Additionally, there is a potential limited supply of these devices and they are more expensive per unit.

For enhanced respiratory protection, all of the above respirators can be used during high-risk AGPs with sterile fields; however, modification is required to ensure protection of the sterile field from the wearer. When using NIOSH approved N99, R99, P99, N100, R100, or P100 masks during sterile procedures, they need to be covered by FDA approved surgical mask.

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Similarly, when a NIOSH approved elastomeric respirator is used during sterile procedures, the exhale valve needs to be covered by FDA approved surgical mask to maintain sterility. A PAPR can also be used during sterile procedures safely, but modifications are recommended reduce risk of contamination of the sterile field.[31] Recommended configurations include use of a hood with the PAPR that extends below the clavicles so that the edges can be covered and tucked within a surgical gown. This modification plus positioning the motor units exhaust away from the field can help protect the field from contamination. Comparatively, modifying the CAPR should be to the end goal of directing exhaled and exhausted air away from the surgical field.[32]

CONCLUSIONS:

The COVID-19 pandemic caused by SARS CoV2 has created a heightened need for knowledge regarding respiratory protective equipment. N95 masks/respirators are appropriate for most airborne precaution situations. However, high-risk AGPs including those with extended duration of exposure, proximity to the airway, manipulation of high viral load tissue (nasopharynx/oropharynx), and aerosolization through the use of energy devices (drills, microdebriders, saws, and ultrasonic devices) may require heightened levels of respiratory PPE. Selection of enhanced respiratory PPE is partially guided by procedural situation but can include masks/respirators with 99 to 100 level filters (elastomeric or disposable), PAPRs, and CAPRs. Knowledge of conservation strategies for respiratory PPE by healthcare workers will help them choose appropriate equipment and help mitigate supply shortages.

List of Abbreviations: AGP = aerosol generating procedure, PPE = personal protective equipment, Food and Drug Administration = FDA, CDC = centers for disease control and

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prevention, Powered Air Purifying Respirator = PAPR, Controlled Air Purifying Respirator = CAPR, National Institute for Occupational Safety and Health = NIOSH, High-Efficiency Particulate Air = HEPA,

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367 Table 1: Comparison of Respiratory PPE

Type of PPE	Regulatory Group	Filtration Capacity	Duration of Use	Fit Testing Required	Primary Intent	Protection from Aerosols
Surgical Mask	FDA	3 micron particles	Single Use	NO	Blocks large particle droplets, splashes, sprays, and splatter	NO
N95 Mask	NIOSH	95% of 0.3 micron particles	Single Use	YES	Efficient filtration of airborne particles down to 0.3 microns	YES
Elastomeric Respirator	NIOSH	Up to 99.97% of 0.3 micron particles*	Reusable	YES	Efficient filtration of airborne particles with reusable equipment with exchangeable filter cartridges	YES
PAPR	NIOSH	99.97% of 0.3 micron particles	Reusable	NO	Filter air and create powered positive outflow of air from within a hood or mask	YES
CAPR	NIOSH	99.97% of 0.3 micron	Reusable	NO	Filter air and create powered positive outflow of air from	YES

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		particles			within a hood or mask	

*filtration capacity of elastomeric respirators is determined by the filters used with the device. The most common ones used in healthcare setting are p100 particle filters providing 99.97% filtration of 0.3 micron particles.

Abbreviations: Powered Air Purifying Respirator = PAPR, Controlled Air Purifying Respirator = CAPR, FDA = Food and Drug Administration, NIOSH = National Institute for Occupational Safety and Health

375 Figure 1: N95 mask

376 Figure 2: Half-face elastomeric respirator with P100 filters

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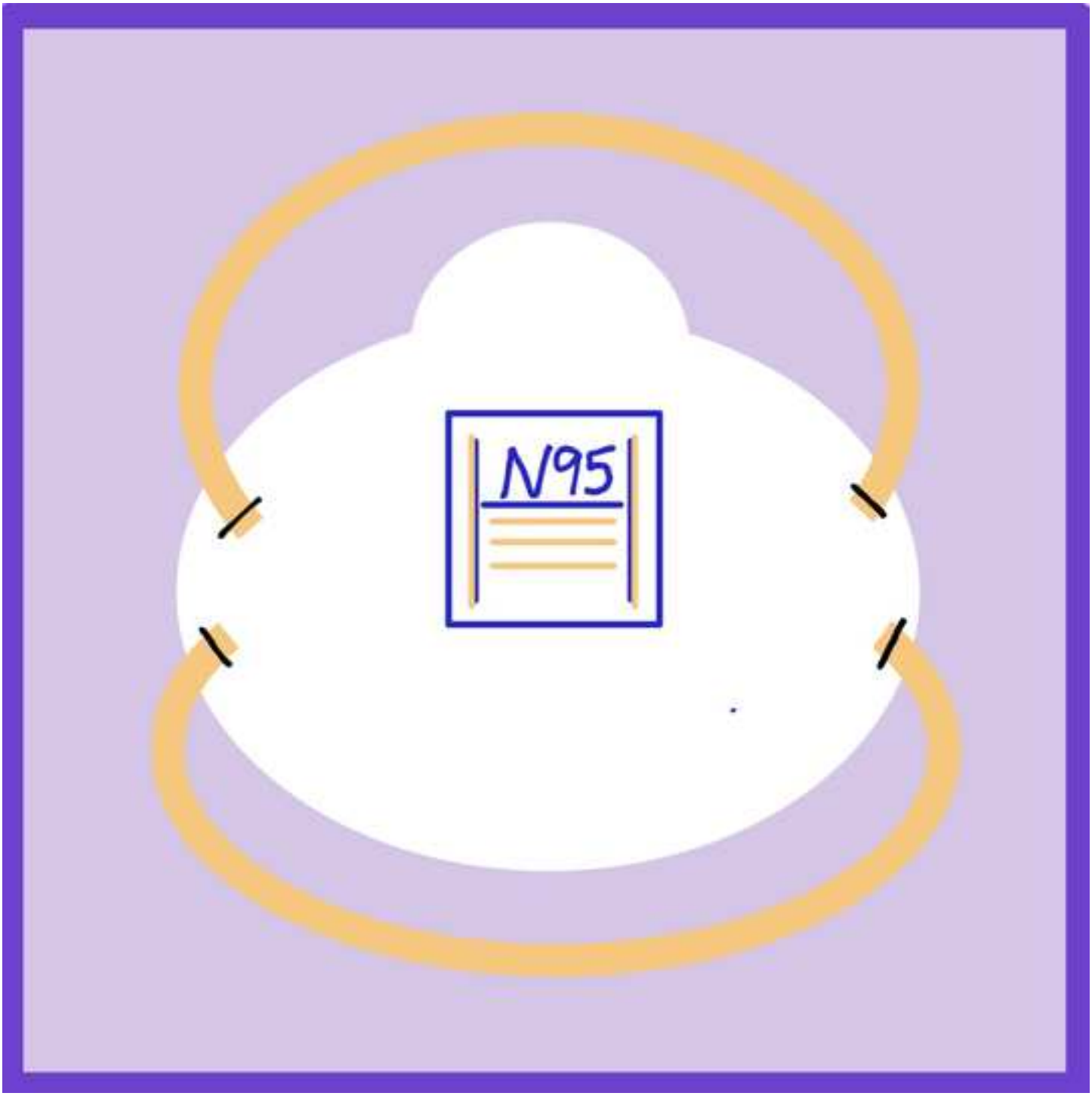

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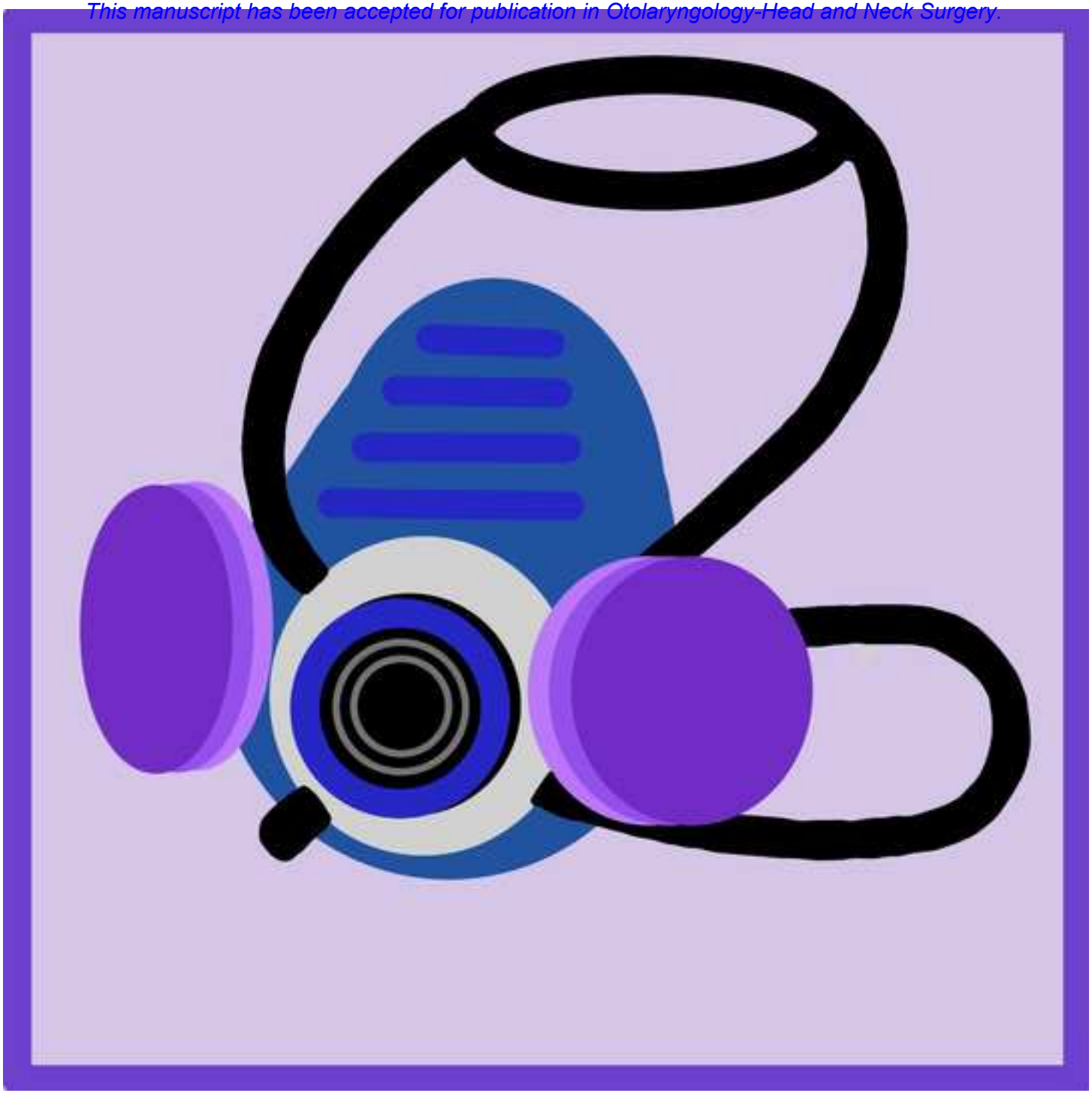
Figure 2



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