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State of the Science Review

Use of powered air-purifying respirator (PAPR) as part of protective equipment against SARS-CoV-2—a narrative review and critical appraisal of evidence

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Severe Acute Respiratory Syndrome Coronavirus (SARS)
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A B S T R A C T

Background: The last 2 decades have seen an increasing frequency of zoonotic origin viral diseases leaping from animal to human hosts including Severe Acute Respiratory Syndrome Coronaviruses (SARS-CoV-2). Respiratory component of the infectious disease program against SARS-CoV-2 incorporates use of protective airborne respiratory equipment.

Methods: In this narrative review, we explore the features of Powered Air Purifying Respirators (PAPR) as well as logistical and evidence-based advantages and disadvantages.

Results: Simulation study findings support increased heat tolerance and wearer comfort with a PAPR, versus decreased communication ability, mobility, and dexterity. Although PAPRs have been recommended for high-risk procedures on suspected or confirmed COVID-19 patients, this recommendation remains controversial due to lack of evidence. Guidelines for appropriate use of PAPR during the current pandemic are sparse. International regulatory bodies do not mandate the use of PAPR for high-risk aerosol generating procedures in patients with SARS-CoV-2. Current reports of the choice of protective respiratory technology during the SARS-CoV-2 pandemic are disparate. Patterns of use appear to be related to geographical locations.

Discussion: Field observational studies do not indicate a difference in healthcare worker infection utilizing PAPR devices versus other compliant respiratory equipment in healthcare workers performing AGPs in patients with SARS-CoV-2. Whether a higher PAPR filtration factor translates to decreased infection rates of HCWs remains to be elucidated. Utilization of PAPR with high filtration efficiency may represent an example of “precautionary principle” wherein action taken to reduce risk is guided by logistical advantages of PAPR system.

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Abbreviations: HCW, Healthcare worker; MERS-CoV, Middle East respiratory syndrome coronavirus; SARS, Severe Acute Respiratory Syndrome; PPE, Personal protective equipment; WHO, World Health Organization; PAPR, Powered air-purifying respirator

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Advent of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) has resulted in a dynamic pandemic with a novel organism. SARS-CoV-2 has a far lower case fatality rate (CFR) than Ebola fever, Middle Eastern Respiratory Syndrome (MERS-CoV) or Severe Acute Respiratory Syndrome Coronavirus 1 (SARS-CoV-1).¹ SARS-CoV-2 has therefore been reclassified away from a high consequence infectious disease. SARS-CoV-2 causes mild or asymptomatic disease in most cases; severe to critical illness occurs in a small proportion of infected individuals, with the highest rate seen in people older than 70 years. Known CFR of SARS-CoV-2 differs between countries ranging from 1.5% in Australia to 9.3% in Italy.² Regional differences in CFR may occur due to testing strategies and stratification of the standard of health care provided. The basic reproductive rate (R0) for SARS-

CoV-2 is estimated to be 2•5 (range 1•8–3•6) compared with 2•0–3•0 for SARS-CoV-1 and the 1918 Influenza pandemic, 0•9 for MERS-CoV, and 1•5 for the 2009 Influenza pandemic.¹ The main modes of transmission of SARS-CoV-2 include direct, droplet and fomite routes.³ At present, minimal infective dose for SARS-CoV-2 pathogen is unknown for any of the transmission modes.⁴ Limited evidence so far suggests that the minimum infective dose of COVID-19 in humans, may be lower than 1,000 particles, slightly higher than hundreds of particles estimated for SARS-CoV-1.⁵ Higher viral load shedding may be more readily associated with greater disease severity.⁶

World Health Organization (WHO) have recently altered their position on the possibility of airborne transmission of SARS-CoV-2.³ Airborne route has been recognized as a possible mode during routine activities such as coughing and talking. Experimental data support the possibility that SARS-CoV-2 may be transmitted by airborne aerosols even in the absence of aerosol-generating procedures.⁷ SARS-CoV-2 can remain suspended in the air for hours.⁸ SARS-CoV-2 ribonucleic acid (RNA) can be recovered from air samples in hospitals.^{9–11} Transmissibility and infectivity of persisting viral RNA titer have been questioned particularly in the light of the unknown minimum infective dose.¹² New findings of potential airborne transmission have implications for protecting health care workers (HCWs) in close contact with SARS-CoV-2 patients during routine activities. Ventilation is considered to be an important determinant in the transmission of airborne infections.¹³ In prior analysis of mitigating SARS-CoV-2 transmission, authors have stressed the role of increasing ventilation rate using natural ventilation, avoiding air recirculation, avoiding staying in another person's direct air flow, and reducing the number of people sharing the same room.¹⁴ In addition to these overall measures, consideration should be given to the use of airborne level protection in circumstances of close and prolonged patient contact. This expanded consideration of airborne disease protection would increase the demand on the respiratory equipment of personal protective equipment.

Recommendations on the exact level of the respiratory component for aerosol generating procedures (AGPs) in patients suspected or confirmed to have COVID-19 are heterogeneous across international governing bodies.^{15,16} In general, these recommendations include a range of disposable respirators including N95 face masks and face filtering pieces level 2 or 3 (FFP2/FFP3). FFP2 respirators have a similar filtration efficacy to N95 face masks whereby each have a minimum filtration capacity of 94% or 95%, respectively, for particles greater than 0.3 μm . FFP3 respirators have greater efficacy whereby they filter more than 99 percent of equivalent particles.¹⁷ There is a paucity of consideration of re-usable respirators including air-purifying respirators (APRs) or powered air-purifying respirators (PAPRs). PAPRs can be described as respirators that protect the user by filtering out contaminants in the air and use a battery-operated blower to provide the user with clean air through a tight-fitting respirator, a loose-fitting hood, or a helmet.¹⁸ This process creates an air flow providing a higher assigned protection factor (APF) than the reusable elastomeric nonpowered air-purifying half facepiece (half mask) or N95 FFRs.¹⁶ The APF of a respirator denotes the level of protection that the respirator is expected to provide to users who are properly fitted and trained. The APF is the ratio of pollutant outside the device (environment) to that inside the device (inhaled component). For example, an APF of 10 "means that a user could expect to inhale no more than one tenth of the airborne contaminant present."¹⁷ A PAPR may have a tight-fitting half or full facepiece or a loose-fitting facepiece, hood, or helmet. It has an Occupational Health and Safety Administration (OSHA) APF of at least 25 for loose-fitting hoods and helmets, 50 for tight-fitting half masks, and 1,000 for full facepiece types.¹⁶ PAPRs use high-efficiency particulate air (HEPA) filters. HEPA filters have a similar filtration as P100 (ie, they filter at least 99.97% of particles 0.3 μm in diameter and are oil proof).⁹ PAPRs are considered

Table 1

Powered air-purifying respirator (PAPR) classification according to NIOSH/EN (National Institute for Occupational Safety and Health (NIOSH) and European Norms (EN) with stated assigned protection factor (APF)

Respirator type	NIOSH/EN nomenclature	Minimum filtration capacity for particles > 0.3 μm	OSHA/EN standard APF
Powered Air-purifying Respirator (PAPR)	PAPR Half Facepiece	99.97%	50
	PAPR Full Facepiece	99.97%	1,000
	PAPR Helmet/Hood	99.97%	25–1,000
	Loose fitting Facepiece	99.97%	25

Explanation: Please note: "Minimum filtration capacity tends to be a unified measure for any and all particles whether biological or particulate." OSHA = Occupational Health and Safety Administration.

more protective in terms of the level of respiratory protection due to the higher efficiency of their filtration pieces as well as the maintenance of outward positive pressure. The hoods of PAPRs can provide splash protection and some degree of eye protection^{19, 20}. The most commonly used models of PAPRs available for respiratory protection are manufactured by 3M (USA) and Bullard (USA).²¹ Reports in literature include the use of 3M Airmate, Jupiter or Proflow.^{21,22} There is a great diversity in available PAPR devices. A full list of NIOSH-approved respirators can be obtained online at www.cdc.gov/niosh/nppt/respusers.html. Following the Ebola outbreak in 2014, the WHO and USA Center for Diseases Control (CDC) put out a call for lightweight, highly protective PAPRs specifically designed for HCWs. Cleanspace Halo is a new PAPR designed and manufactured specifically for health care users without a belt or hoses.²³

Advantages of PAPR devices include higher APF of at least 25 (Table 1). PAPRs with loose-fitting headgear can be worn with a limited amount of facial hair. Logistical disadvantages of PAPR include challenges in communication and mobility. Proper maintenance of PAPR requires disinfection, cleaning, safe storage and battery maintenance. There is a risk of battery failure and inadvertent exposure. PAPR systems are more expensive than individual N95 respirator (although they achieve more wears per piece of equipment with PAPR). In addition, there is a requirement for education of significant proportion of HCW workforce.²² Limited information exists for use of one type of facial protection (eg, FFP3) over another (eg, FFP2/N95). High filtration pieces appear to have a protective advantage in laboratory settings.²⁴ However, this does not translate to firm findings of greater HCWs protection in field studies.²⁵ Increased layers and technical challenges of PAPR use can lead to increased complexity of patient care.²⁶ The objective of this review is to critically appraise international recommendations and geographical patterns of use of PAPRs during the management of patients in the current pandemic with SARS-CoV-2 virus. We appraised the caveats required to provide benefit to the practitioner in this environment by utilizing this device. We aimed to review the evidence base for use of PAPR devices in protecting HCWs during the SARS-CoV-2. We considered the principles which may be used to justify deployment of this device. As this is a narrative review, we did not perform any systematic or meta-analysis of the current literature. Not all available studies were discussed; we focused on current societal recommendations and pertinent international review papers. As no randomized studies were available on this topic, we focused on available field and cohort studies.

GENERAL CONSIDERATIONS

Within international guidelines there are variable practices with regards to the choice of the respiratory component of protective equipment during the current SARS-CoV-2 pandemic (Table 2).

Table 2
International recommendations for respiratory component of personal protective equipment during airborne procedures

European Centre for Disease (ECD) ²⁷ ;	<ul style="list-style-type: none"> • FFP2/3 respirator in addition to standard PPE at all times when performing aerosol-generating procedures in suspected or confirmed COVID-19 patients²⁷ (https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html); 	
Public Health England ¹⁵ ;	<ul style="list-style-type: none"> • FFP3 level respiratory protection in addition to standard PPE for health care providers in the context of Aerosol Generating Procedures in patients with suspected or confirmed COVID-19¹⁵; 	
Centre for Disease Control (CDC) USA ²⁸ ;	<ul style="list-style-type: none"> • Health workers should wear at least an N95 mask in addition to contact precaution PPE, when performing aerosol generating procedures; 	
Canadian Standards Association (CSA) ²⁹ ;	<ul style="list-style-type: none"> • Recommend that the choice of respiratory protection for any encounter with a patient with SARS-CoV-2 is at least a face filtering respirator; 	<ul style="list-style-type: none"> • According to the control banding approach for SARS-CoV-2, a biosafety Risk Group 3 organism, at least a PAPR is required for an aerosol generating procedure;
The Communicable Disease Network Australia (CDNA) ³⁰ ;	<ul style="list-style-type: none"> • Use contact and airborne precautions routinely for aerosol generating procedures. PPE for aerosol generating procedures includes long-sleeved gown, FFP2/N95 mask, face shield or goggles and disposable nonsterile gloves; 	<ul style="list-style-type: none"> • CDNA recommends that if a health care worker is required to remain in the room for longer periods of time (greater than one hour), the use of PAPR may be considered for additional comfort and visibility³⁰;

SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; PAPR = powered air-purifying respirator; PPE = personal protective equipment; FFP2 = face filtering piece 2; FFP3 = face filtering piece 3.

CDNA, unlike CDC, EDC, or Public Health of England, do not recommend routine use of a face filtering respirator with a higher level of protection—such as an FFP3—for exposures to patients with serious symptoms or undergoing aerosol-generating procedures. However, only CDNA describe the use of PAPR for suspected or confirmed SARS-CoV-2 patients under some circumstances.

When PAPRs are used to reduce inhalation exposures, OSHA requires a written respiratory protection program in compliance with OSHA 29CFR1910.134 standard.¹⁶ The OSHA Respiratory Protection standard 29 CFR 1910.134 requires that employers establish and maintain a respiratory protection program for workplaces in which workers may be exposed to respiratory hazards. There is no commitment to utilizing one type of a respirator over another in this OSHA-standard. In addition, the PAPR devices in health care use must be NIOSH approved. Current PAPR certification standards have been developed primarily for industrial applications¹⁸. In March 2020, in response to the SARS-CoV-2 pandemic, FDA issued an emergency authorization for use in health care of other PAPRs approved by NIOSH, in accordance with 42 CFR Part 84, and those that are listed on the NIOSH CEL for PAPRs with particulate protection.³¹ The CDC does not commit to recommending the use of FFP versus a PAPR for airborne precautions in patients with SARS-CoV-2. Prior to the current pandemic, some USA territories proactively instituted their own health care-related OSHA-specific standards. In August 2009, during the peak of novel influenza A (H1N1) pandemic, California-OSHA enacted the first occupational standard for aerosol transmissible diseases in the USA.³² An overall airborne diseases plan is presented including requirements for airborne diseases management and engineering controls. With some exceptions, California-OSHA mandate the use of PAPR for high hazard procedures (aerosol-generating procedures) on suspected or confirmed airborne infectious diseases cases, and on cadavers known or suspected to be infected with these. California's Aerosol Transmissible Diseases Standard (California Code of Regulations title 8 section 5199) requires California hospitals to provide PAPRs and other personal protective equipment for aerosol-generating procedures involving patients who are suspected or confirmed cases of COVID-19. AGPs must be performed in an airborne infection isolation room.³³ Another factor featuring in the more ready availability of PAPR devices in the USA was institutional preparedness for management of Ebola Hemorrhagic Fever (Ebola virus) in 2014.³⁴ The CDC recommends the use of a PAPR or a disposable NIOSH-

approved N95 FFR with a face shield for EVD patient care to protect eyes, mouth, and nose from contact and aerosol exposure. Many hospitals chose to use PAPRs as part of HCW PPE ensembles. This shift to PAPR use in hospitals may have affected the prevalence of PAPR types available to HCWs in the USA.³⁴

OSHA's 3 lines of defense against bioaerosol threats, including SARS-CoV-2 consist of: engineering controls, administrative controls, and personal protective equipment.³⁵ Once effective engineering and administrative controls have been instituted, appropriate respirators should be introduced. In this case the bioaerosol threat has been classified away from a high consequence infectious diseases. However, due to the high transmissibility of SARS-COV-2 with inducement of critical illness in 15% of population, high level of respiratory protection is required for at risk activities.³⁶ In order to appropriately assign the respirator standard required, evaluation of the exposure level of the airborne concentration needs to occur. Selection of an appropriate respirator against SARS-CoV-2 can be a complex task due to the lack of comprehensive evidence with regards to aerosol dispersion, infective content, minimum infective dose, degree of airborne spread, and longevity of the particular FFP in use. During prior pandemics recommended level of respiratory protection was identified as a critical knowledge gap.³⁷ There have been no clear international guidelines produced on appropriate choice of a respirator for an appropriate situation. Canadian Institute for Health had developed a control banding method for selecting respiratory protection against bioaerosols.^{38,39} The model consists of a matrix of tabulation of 4 risk groups of organisms, 5 exposure levels, and ventilation control level. Each category is given a number of points according to predetermined risk. The desired APF is determined according to the total number of points and the final band category. According to this risk-storing system, an APF required care of patients with SARS-CoV-2 in circumstances of procedural aerosol generation is 25.³⁸ This APF is higher than a generic recommended N95 and at the level of a full face piece respirator or a PAPR.

Some manufacturer's guidelines state that PAPR use is contraindicated during surgery and/or presence of a sterile field.⁴⁰ This is likely due to the absence of filtration of the expired air. With some PAPR models, the exhaled air exits underneath the hood, with proximity to the sterile field. An observational study has examined the particulate count in the sterile surgical field with the use of a PAPR hood under laminar conditions.⁴¹ Results demonstrated that the

hooded PAPR does not increase particulate transfer to the surgical field. A separate study examined the aerosolized droplet contamination of a surgical field. Surgical masks reduced contamination by 98.48%, and both PAPRs reduced contamination by 100%, compared with the usage of no facial covering.⁴² A study aimed to compare environmental contamination from 3 different PAPR models to N95 masks by examining the number of Colony Forming Units (CFU) from the environment.⁴³ All respirators tested generated a lower mean CFU than the surgical mask, and all the PAPRs tested showed less CFU than the surgical N95. Many international institutions use PAPR's as a part of the peri-operative personnel protection protocol. A number of otolaryngologic societies recommend the use of a PAPR for ultra-high-risk AGPs such as prolonged endoscopic bone drilling.⁴⁴⁻⁴⁶ With these manufacturer's guidelines juxtaposed against personnel protection, perioperative risk management protocols need to be devised by individual institutions. Use of PAPR devices in health care is complicated by unclear internal and external PAPR decontamination standards. A recent study demonstrated growth of in culture of bacteria and fungi despite application of appropriate manufacturer recommended cleaning protocols for PAPR devices.⁴⁷ Viruses, including SARS-CoV-2 were not grown from the swabbed internal hoods.

Regional and global critical shortages can occur in the supply chain of personal protective equipment during a significant time of requirement.⁴⁸ Global Preparedness Monitoring Board issued a report in September 2019 which warned that the risk of a global pandemic was growing. Fewer equipment shortages have been reported for PAPR technology than single use FFP.⁴⁰ Ready availability of PAPRs in designated treatment institutions can form a part of the risk mitigation strategy of equipment shortages during acute epidemic stages. A fully assembled PAPR eliminates the need for emergency procurement of disposable respiratory and eye protective equipment. A comparative cost of stockpiling various respiratory equipment was calculated in an influenza pandemic model.⁴⁹ The authors modelled estimates of the cost of an emergency stockpile calculated on the basis of purchasing, storing, managing, and rotating the inventory. Elastomeric negative pressure respirators were calculated to be the most cost-effective pandemic preparedness measure.⁴⁹ Stockpiling PAPRs was the most expensive strategy. This expense was driven in large part by the cost and maintenance of batteries, which are required for PAPR operation. In this costs analysis, the authors did not include the time required or equipment needed for regular fit testing of N95 masks, which by law (in the USA) needs to be repeated every year. This inclusion would significantly compound the cost of N95 availability for pandemics. Health care facilities need to have multiple systems for ready availability of elastomeric APRs, PAPRs, and N95s as they have different features which make them desirable in variable settings.⁴⁰ Different health care institutions have incorporated the use of PAPR into their pandemic preparedness operations. University of Maryland Medical Centre developed a mixed protection strategy that emphasized the use of stockpiled reusable elastomeric air purifying respirators, a handful of N95 respirators, and approximately 400 PAPRs.⁴⁰ Selective deployment of PAPRs in their facilities made respiratory protection available to all staff and helped minimize the need to potentially fit test all staff. In other health care units PAPR's are predeployed to high-risk units.

The extent to which additional filtration efficiency of PAPR translates to true protectiveness is currently unclear. Despite the theoretical advantages of PAPR, there have to date been no controlled clinical trials on the efficacy of this technology during the SARS-Cov-1, SARS-Cov-2, EBOLA, or MERS pandemics in comparison with other high-level respiratory protection.⁵⁰ When there is limited robust evidence, our decision making may be guided by precautionary principles. Precautionary principle is a powerful risk mitigation strategy during threats to human lives. PAPR use during AGPs, or in particular prolonged AGPs with sustained aerosol release, can be considered a risk

mitigation strategy. There is no available clear evidence-base from randomized controlled trials on the ability of use of PAPR to truly mitigate the risk of cross-infection during AGPs. We therefore need to be guided by subjective measures of decision-making theory by considering the cause and effect.⁵¹ It can be considered scientifically plausible that with their higher HEPA filter and greater APF, PAPR may be more protective during high-risk AGP. Precautionary principles can be tied to utility of preventing potential catastrophic outcomes in HCWs. As the threat of the health care provider infection in these circumstances can be considered severe, their use may be considered legitimate. With the level of risk posed, proof of causation may not be required under all circumstances.

PAPR USE DURING SIMULATION STUDIES

Simulation studies allow for exploration of utility and reliability of personal protective equipment during modelled care tasks. They are performed in a safe setting without true haste resulting in a potential performance bias.⁵² A recent systematic review of simulation studies in the field of personal protective equipment identified moderate quality of evidence toward improved health care worker comfort with regards to heat tolerance with PAPR technology compared to alternative respirators.¹⁷ PAPRs eliminate the heat build-up by convection through positive pressure airflow.⁵³ Participants in a simulation studies rated the ease of breathing with the PAPR system significantly better than with the APR.^{54,55} These participant self-reports are in line with the perceived logistical advantage of ease of breathing with positive pressure APRs.²⁸ A randomized controlled study which compared simulated airway management with the use of PAPR to the use of APR, demonstrated improved visibility with PAPR devices in comparison with APR.⁵⁶

Multiple observational studies have indicated greater self-reported wearer comfort among users of PAPR technology.^{23,57,58} A single cohort observational study found that all participants using N95 reported discomfort compared to 30 percent of wearers utilizing PAPR devices.⁵⁷ If HCWs are provided with sufficient comfortable and well-fitting respiratory protection, it is likely that compliance with preventive programs will be increased.⁵⁹ Prior reports have outlined potential for claustrophobia in health care providers with field use of PAPR.⁶⁰ During the tuberculosis outbreaks, use of PAPR's had a low institutional uptake. This occurred due to a number of factors, including concerns that doctors would appear frightening to their patients and that the motor's hissing noise would interfere with patient communication.⁶¹ Greater acceptance of PAPR by HCWS during both the SARS-Cov-1 pandemic and Ebola may be influenced by HCW perception of relative risk. Khoo et al published a survey illustrating that PAPR as opposed to N95 were more comfortable for HCWs during an Ebola outbreak in Singapore.⁶² These findings are in-line with surveys assessing the experience of users in established respiratory compliance program.⁶³ Despite somewhat less favorable ratings on communication, experienced PAPR users prefer reusable respirators over N95s in increased threat scenarios.⁶³ A study used transcranial doppler monitoring of middle cerebral artery to evaluate mean flow velocity and pulsatility index (PI) in users wearing N95 masks.⁶⁴ There was a significant increase in mean flow velocity and decrease in PI, with a concomitant increase in EtCO₂. These adverse physiological events were mitigated by the use of additional PAPR.

Despite the reports of greater wearer comfort and improved physiological parameters, PAPR users tend to score the technology lower on the measures of mobility, dexterity, audibility, and communication.¹⁷ This finding is consistent across studies.^{54,56,65,66} Radonovich et al reported health care worker noncompliance across all respirator models, including N95, APR, and PAPR.⁶⁷ PAPRs in particular were not tolerated due to communication difficulties. A study performed by AlGhamri et al identified no cognitive impairment in individuals

using PAPRs while performing predetermined tasks but found a negative effect in cognitive function when using negative pressure, full-face respirators.⁶⁸ PAPR use does require regular training preferably in simulation settings. A single study which compared use of PAPR versus the use of APR identified that overall statistically slower total performance times were observed with use of the PAPR when compared to the control arm and use of the negative pressure elastomeric respirators.⁵⁸

There is a trend toward lower level of cross-contamination in participants using PAPR technology compared to alternative respiratory protection in low quality simulation studies.^{57,69} These observations are counterintuitive toward an assumption that due to complexity of technology, cross-contamination during doffing with PAPR is more likely. Results of the prior systematic review of PAPR utility by HCWs, demonstrated a trend toward lower HCW contamination rates and decreased doffing violations while utilizing PAPR compared to standard respirators.¹⁷ Donning and doffing of PAPR equipment requires significant labor-intensive training. A single randomized trial evaluated the utility of training on donning and doffing of personal protective equipment including PAPR.⁷⁰ This study identified that structured training using a PAPR decreased the likelihood of self-contamination from 100% to 86%.⁷⁰ In a study of compliance with the use of personal protective equipment, use of “gatekeeper/spotter” improve compliance with PAPR use from 81% to 100%.⁷¹

PAPR USE DURING THE SARS-COV-2 GLOBAL PANDEMIC

Health care worker protection must be optimized with supportive infrastructure, appropriate policies and procedures, robust infection control systems and personal protective equipment. PAPR has been recommended for high-risk procedures on suspected or confirmed COVID-19 patients.⁷² This recommendation is controversial due to lack of evidence.^{72,73} Historical origins of this recommendations can be traced to the outbreak among HCWs of SARS-CoV-1.^{74,75} The focus on AGPs as a risk for acquiring SARS among health care workers in Toronto led to recommendations that for exposures to high concentrations of infectious particles, HCWs should be wearing PAPRs.^{76,77} Peng et al recommended exclusive use of PAPR devices for intubation of suspected or confirmed SARS patients in all clinical areas including Emergency Department, Intensive Care and Operating Theater. Infection control procedures mandated the use of PAPR devices for management of emergency cases in Singapore General Hospital at the advent of the SARS-CoV-1 epidemic.⁷⁸ As more detailed epidemiologic data were published, risk factors for nosocomial transmission of SARS included exposure during aerosol-generating medical procedures, failure to isolate infectious patients, and the lack or uneven use of personal protective equipment.^{79,81} Lack of compliance and variable adherence to personal protective equipment emerged as primary risk factors for cross-infection of HCWs.²⁶ Use of more standardized PPE was implemented in a more stringent manner with consistent use and high compliance. It was identified that SARS-CoV-1 transmission was not supported once these measures were institute precautions.⁸² No definitive evidence has emerged that PAPR devices reduce the likelihood of airborne transmission of SARS to a greater degree than standardized appropriately used PPE embedded within an overarching strong infection control program and regular training.

Current reports of the choice of protective respiratory technology during the SARS-CoV-2 pandemic are disparate (Supplementary file 1). Reports from Singapore describe routine use of PAPR in anesthesia protocols for care of patients suspected or confirmed to have COVID-19.^{22,83,84} Due to the ready availability respiratory protective equipment, these hospitals had a greater likelihood of health worker protection at the start of the pandemic. Routine PAPR use is recommended by Ti et al during induction and reversal of anesthesia

for all personnel within 2 m of the patient, at all times during airway instrumentation and for transport of critically ill patients.⁸³ Chen et al described a rapid ramp up of PAPR training as part of their “just in time” response.⁸⁵ This involved resources for infection prevention and control measures against AGP, with a focus on PAPR training.⁸⁵ Singapore General Hospital initiated re-fresher training for the anesthesia staff using PAPR at the start of the pandemic.²² Institutional guidelines from Singapore General Health recommended use of PAPRs for all AGPs in patients suspected or confirmed to have COVID-19.⁸⁶ There have been no reports of designated PAPR use from under-resourced health systems. Availability of PAPR devices is likely limited to well-resourced health systems due to the cost, training, and maintenance burden.^{40,83,84} Availability of PAPR devices is further influenced by geographical patterns of use, with greater availability in the USA compared to the European counterpart health systems.^{15,40} Prior to the current pandemic, 85% of health care institutions in the USA reported the local availability of PAPR devices.

There have been 2 on-field observational studies reporting the rates of assumed cross-infection with SARS-CoV-2 of airway proceduralists. Yao et al retrospectively assessed the rates of cross infection in anesthesiologists in Wuhan at the beginning of the calendar year. In both groups, HCWs utilized droplet precautions with either PAPR (n = 50); goggles, FFP2/N95 mask with a face shield (n = 22) or goggles, FFP/N95 with a full hood without positive pressure (n = 130).⁸⁷ A key feature of this infection control program was robust governance of personal protection programs. This was reflected in the comprehensive approach to the personal protective equipment, staff specialization in the care of COVID-19 patients and segregation of this health-worker cohort from the community. Authors reported an impressive zero cross-infection of airway proceduralists. Intubate-COVID, a large prospective international database studying COVID-19 outcomes in HCWs, recently reported their first set of results. In this prospective observational study, primary endpoint was defined as incidence of laboratory-confirmed COVID-19 diagnosis or new symptoms requiring self-isolation or hospitalization after a tracheal intubation episode. The overall incidence of the primary endpoint was 10.7% over a median follow-up of 32 days. Most participants were diagnosed through reported symptomatic self-isolation 144 (8.4%). The risk of the primary endpoint varied by country and was higher in females. The risk of COVID-19 outcome was not associated with respiratory protection program or use of PAPR.⁸⁸ The investigators reported that PAPRs (43.4%) were used more commonly in the United States of America (USA) than the United Kingdom (UK). In the UK participants more frequently used FFP3/N100 respirator masks (89.3%). The investigators did not report a significant difference in the primary endpoint rates in these 2 countries.⁸⁸ Investigators did not report the exact number of users protected by PAPR devices internationally. In this study, comprehensive description of individual country personal protective equipment and infection prevention governance strategies were not provided. This study had only 28.8% of laboratory confirmed infections. In addition, in the absence of phylogenetic analysis it is not possible to conclude the source of infection, be it patient contact or community acquired. In these 2 observational studies, differences in the airway proceduralist’s COVID outcomes appear distinct: 10.7% in the El-Boghdadly et al’ study versus 0% reported in Yao et al.^{87,88} This finding of absolute difference between the studies may be indicative of the overarching infection control processes: such as infection control governance and training in the use and availability of all aspects of personal protective equipment. In addition, this observed difference may be confounded by particularly robust contact protective systems in the Yao et al study. Comparison of infection rates with HCWs not wearing the PAPR technology may be biased by other PPE protection factors such as the utility of system-related compliance measures.⁸⁹ In contrast to the intubate COVID study, other evidence from the UK describes

exceedingly low cross-infection rates among anesthetists and intensivists.³⁶ A plausible explanation for the exceedingly low cross-infection rates may be familiarity among this cohort with infection control and preparedness practices. It is very unlikely that PAPR use in the UK has played a role in infection prevention of COVID-19.⁸⁸

Meng et al have recently described the mandatory level of personal protective equipment required for care of critically ill patients amid the COVID outbreak in Wuhan.⁹⁰ While these precautions consisted of disposable hair cover, fluid-resistant gown, 2 layers of gloves, goggle and face shield, fluid-resistant shoe covers, they did not extend to mandating a PAPR. Rather, the requirement was for a fit-tested N95 respirator or equivalent. Congruent with this, Institutional Recommendations from the Joint Task Force of the Chinese Society of Anesthesiology and the Chinese Association of Anesthesiologists center on N95 use for airway proceduralists.⁹¹

It is considered that not all AGPs are equivalent. Some, such as endoscopic sinus surgery, are considered higher risk due to the shear forces of drilling with consequent particulate dispersion. Prior literature reviews have considered high-risk AGPs as those that have the potential to create aerosols with high viral loads and that may represent an increased risk to HCWs.²¹ Procedures with the potential for longer aerosol generation through virtue of duration are considered to increase the risk of transmissibility.⁴⁴ Use of FFP for high-risk AGPs of longer duration may be of concern due to a potential time limit on the efficacy of a FFP.⁹² Factors that are thought to increase the viral load include manipulation of susceptible tissues such as oropharynx and larynx. Another risk factor for transmissibility is proximity of the provider to aerosol.⁴⁴ Patients with a more severe illness are likely to carry a higher viral load.⁹³ Liu et al published their results in *Lancet Infect Diseases*, March 2020, that the mean viral load of severe cases was around 60 times higher than that of mild cases.⁹³ A laboratory study has explored the efficacy of N95 in filtering the targeted particle sizes ranging from 10 to 600 nm.⁹⁴ Standard certification tests are performed with particles of approximately 300 nm (0.3 μm), which is assumed to be the most penetrating size. The results indicate that the nanoparticle penetration through a face-sealed N95 respirator may be in excess of the 5% threshold, particularly at high respiratory flow rates. With reports that SARS-CoV-2 may be transported through airborne droplet nuclei as small as 0.3 μm , N95 use may not be an ideal option for situations with high sustained aerosol dispersion.

It is thought that the reasons why infections in staff occurred at the start of the pandemic may have been due to factors such as: little initial knowledge of COVID-19 and insufficient overarching infection protection measures.⁹⁵ Givi et al and the Canadian Society of Otolaryngology-Head and Neck Surgery also suggest the use of PAPR for HCWs when performing AGPs on patients with probable or confirmed COVID-19.⁹⁶ Vukkadala et al recommend exclusive use of PAPR for all personnel involved in high-risk AGPs in patients who are COVID-19 positive.⁴⁵ Several authors and otolaryngologic societies have recommended the use of PAPR during the high-risk AGPs such as drilling during middle ear surgery. In confirmed positive COVID-19 patients during urgent endoscopic sino-nasal and skull base surgery, it is recommended that due to frequent suction, irrigation, and drilling which potentially aerosolize infectious vapor, all personnel in the operation room wear PAPR.⁹⁷ Authors from a British public institution have reported that enhanced level of PPE, including the use of PAPR should be mandatory during the performance of tracheostomy.⁴⁶ New York Head and Neck Society recommend the use of a PAPR for personnel performing a tracheostomy.⁹⁸ In-line with geographical patterns of practice, ENT UK Society recommend use of FFP3 or a PAPR for all personnel involved in performance of a tracheostomy for a COVID-19 patient.¹⁵ Selected case reports have described exclusive use of PAPR for all staff involved in a COVID-19 patient undergoing a tracheostomy.⁹⁹ In contrast a recent observational study described 30-day outcomes of the first 100 cases from a

single tertiary UK hospital.¹⁰⁰ All procedures were performed in Personal Protective Equipment for AGPs, as defined by Public Health of England FFP3 masks with fluid repellent gowns, gloves, and eye protection). No powered respirators were worn by the tracheostomy team and negative pressure rooms were not used in ICU or the operating theatres.

There are no available studies on the efficacy of FFP versus PAPR devices for SARS-CoV-2 infective droplets and particles. A study randomized participants to an N95 respirator mask against a PAPR in a human exposure model to live attenuated influenza vaccine strains.¹⁰¹ Participants wearing N95 respirators encountered breakthrough events to LAIV in 3 of 29 cases (10%). This matches the 90% blocking of biohazards indicated by the APF of 10. The PAPR completely blocked transmission of LAIV. These findings represented the protective efficacy of the devices. Ten percent failure rate of commercially available qualitatively fit-tested N95 compared to the complete protection provided by a PAPR raises the question of acceptable limits for virus exposure especially to resistant or novel pathogens including SARS-CoV-2.

Some authors who make recommendations for the use of PAPR for critical care of Covid-19 patients, acknowledge that there is no conclusive evidence to show that this advanced respiratory technology decreases the likelihood of viral airborne transmission.⁷³ Whether a higher PAPR filtration factor translates to decreased infection rates of HCWs remains to be elucidated. True randomized controlled studies may not be ethically feasible due to higher filtration factor of PAPR. Pragmatic observational studies, as published recently in well-resourced areas may be both more ethical and feasible.⁸⁷ Utilization of PAPR with high filtration efficiency may represent an example of “precautionary principle” wherein action taken to reduce risk is guided by logistical advantages of PAPR system.

CONCLUSIONS

Despite numerous calls from international stake holders for increased preparedness, limited national and international resources were dedicated toward pandemic planning over the last decade. SARS-CoV-2 has brought to the fore this lack of pandemic preparedness including lack of planning, availability, and policies and procedures for use of respiratory protective equipment. Recommendations on the exact level of the respiratory component for AGPs in patients suspected or confirmed to have COVID-19 are heterogeneous across international governing bodies. There is a focus on recommending a range of disposable respirators including N95 face masks and FFP level 2 or 3 (FFP2/FFP3). There is a paucity of consideration of reusable respirators including APRs or PAPRs. PAPR availability can be considered as part of a tiered approach to pandemic preparedness. In well-resourced and well-prepared countries such as Singapore, PAPR availability and deployment have formed a cornerstone of pandemic preparedness and “just-in-time-response” to a pandemic. Their use on their own is unlikely to be the determinant of success or failure of infection control programs. Studies have demonstrated that PAPR storage and use are the most economically unfavorable mostly due to the cost of the re-chargeable batteries. PAPR have been developed and certified mainly for industrial use—as such health care regulatory and certification standards are lagging internationally. There are still significant barriers to use of PAPR in health care settings, such as approval and conditions for use in sterile surgical procedures. Simulation studies of task performance under modelled conditions, have reported that users rate higher the heat tolerance, visibility, breathability and wearer comfort with PAPR devices compared to alternative respiratory protection. Audibility, ease of communication, mobility and dexterity are generally scored lower by users of PAPR devices in simulation studies. Despite somewhat less favorable

ratings on communication, experienced PAPR users prefer reusable respirators over N95s in increased threat scenarios.

Anesthesiology societies do not focus on the exclusive use of PAPR devices for the respiratory component of AGP protection. Rather, the requirements are for a fit-tested N95 respirator or equivalent. Equivalent rates of health care provider infection have been demonstrated in cohorts utilizing PAPR versus other appropriate respiratory protection during the current pandemic. During high-risk prolonged AGPs, such as tracheostomy and endoscopic drilling, use of PAPR should be considered for exposures to emerging diseases with the potential for infection via the aerosol route. Respiratory protection of HCWs should not wait for definitive scientific evidence in circumstances of emerging lethal diseases, but rather be centered around optimal situationally tailored prevention.

SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found in the online version at <https://doi.org/10.1016/j.ajic.2020.11.009>.

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