Infect Chemother. 2020 Jun;52(2):165-182
https://doi.org/10.3947/ic.2020.52.2.165
pISSN 2093-2340·eISSN 2092-6448

Infection & Chemotherapy

Review Article

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Personal Protective Equipment for Healthcare Workers during the COVID-19 Pandemic

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OPEN ACCESS

Received: Jun 11, 2020
Accepted: Jun 14, 2020

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Conflict of Interest
No conflicts of interest.

ABSTRACT

The coronavirus disease (COVID-19) pandemic has posed a challenge for healthcare systems, and healthcare workers (HCWs) are at high risk of exposure. Protecting HCWs is of paramount importance to maintain continuous patient care and keep healthcare systems functioning. Used alongside administrative and engineering control measures, personal protective equipment (PPE) is the last line of defense and the core component of protection. Current data suggest that severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is mainly transmitted through respiratory droplets and close contact. Airborne transmission may occur during aerosol-generating procedures. However, the modes of transmission still remain uncertain, especially regarding the possibility of airborne transmission when aerosol-generating procedures are not performed. Thus, there are some inconsistencies in the respiratory protective equipment recommended by international and national organizations. In Korea, there have been several modifications to PPE recommendations offering options in choosing PPE for respiratory and body protection, which confuses HCWs; they are often unsure what to wear and when to wear it. The choice of PPE is based on the risk of exposure and possible modes of transmission. The level of protection provided by PPE differs based on standards and test methods. Thus, understanding them is the key in selecting the proper PPE. This article reviews evidence on the mode of SARS-CoV-2 transmission, compares the current PPE recommendations of the World Health Organization with those in Korea, and discusses standard requirements and the proper selection of PPE.

Keywords: Personal protective equipment; Healthcare workers; Coronavirus disease (COVID-19); Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)

INTRODUCTION

Coronavirus disease (COVID-19), which is caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has spread to 216 countries in just a few months. The numbers of cases and deaths have been on the rise since the first case was identified in Wuhan, China in early December 2019 [1]. The COVID-19 pandemic has posed a great challenge for healthcare systems, as the disease has spread explosively, exceeding hospital capacities and placing healthcare workers (HCWs) at high risk of exposure. The proportion of infected

HCWs among confirmed cases was reported to be 10% in Italy and 20% in Spain [2]. In the United States (US), approximately 3% of confirmed cases are HCWs, and 55% of these reported exposure to COVID-19 patients only in healthcare settings [3]. Infected HCWs could also be a source of infection for patients and other HCWs. Protecting HCWs is of paramount importance to maintain continuous patient care and keep healthcare systems functioning.

Measures to prevent transmission of SARS-CoV-2 to HCWs include all levels of hazard control: administrative controls, engineering controls, and personal protective equipment (PPE). Administrative controls include implementing triage, early recognition of suspected patients, source control, providing adequate training for HCWs, monitoring adherence to infection control policies and procedures, and implementing measures to minimize contact with COVID-19 patients (*i.e.*, using telemedicine to initially evaluate suspected patients or designating dedicated HCWs to care only for COVID-19 patients). Engineering controls include placing suspected or confirmed patients in an airborne-infection isolation room, maintaining adequate ventilation, and using physical barriers to prevent transmission between patients and HCWs [4-6]. Along with these control measures, the use of PPE is the last line of defense and a critical component. The choice of PPE is based on the nature of interactions with patients and the modes of transmission [7].

Current data suggest SARS-CoV-2 is transmitted mainly through respiratory droplets and close contact; airborne transmission may be possible during aerosol-generating procedures (AGPs) [8-11]. However, there is still uncertainty surrounding the modes of SARS-CoV-2 transmission, which caused differences in the PPE recommendations of the World Health Organization (WHO) and those of individual countries [12]. In Korea, the first case of COVID-19 was identified on January 20, 2020, and it spread throughout the country. During the initial phase of the pandemic, the government issued guidelines for infection prevention and control in healthcare settings. Selection of appropriate PPE was based on previous guidelines for the Middle East respiratory syndrome (MERS) outbreak in 2015; inconsistencies among these guidelines were also noted. After several updates, the PPE recommendations offered options when choosing PPE for respiratory and body protection. However, selection of optimal PPE is often misinterpreted and misunderstood.

This review discusses the previous and recent evidence on the mode of transmission of respiratory transmissible viruses in conjunction with SARS-CoV-2, the current PPE recommendations in Korea in comparison with those of the WHO and other organizations, and the standard requirements and proper selection of PPE for respiratory and body protection.

MODE OF TRANSMISSION

1. Potential modes of respiratory virus transmission

In general, respiratory viruses can spread through multiple modes of transmission: contact, respiratory droplets, or aerosols [13]. Contact transmission can occur through direct physical contact with virus-laden respiratory secretions from infected individuals or indirectly through contact with inanimate objects or environments contaminated with the virus [13]. Conventionally, respiratory transmission is classified as either droplet or airborne transmission [4, 7]. It is generally accepted that droplet transmission occurs through deposition of large droplets (>5 μm in diameter) on the mucous membranes (eyes, nose, or mouth) of susceptible people. It occurs when a person is in close proximity to an infected

https://doi.org/10.3947/ic.2020.52.2.165

person, as large droplets travel only short distances (<1 m). Airborne transmission occurs through inhalation of aerosols (≤5 μm in diameter) generated from the respiratory tract of an infected person. Aerosols remain suspended in the air for a prolonged period, allowing them to be transmitted over a long distance [4].

However, mode of transmission cannot be simply dichotomized. There is no clear cut-off to differentiate small and large droplets. Different cutoffs have been suggested based on the area of the respiratory tract where particles deposit (respirable particles <10 μm in diameter penetrating the lower respiratory tract or inspirable particles 10 – 100 μm in diameter depositing in the upper respiratory tract) [14] or based on how they behave (particles <10 μm in diameter suspended in the air or particles >20 μm in diameter that settle fast by gravity) [15]. Particle size is dynamic; it depends on the initial size and composition, the force and pressure at emission, environmental conditions (*e.g.* temperature, relative humidity and airflow), and the time spent airborne [4]. The distance traveled and the length of time particles remain suspended in the air is also determined by particle size, settling velocity, relative humidity, and airflow [16]. Large droplets settle faster due to gravity, contaminating the near vicinity; some of them can rapidly evaporate to form aerosol particles termed "droplet nuclei," which behave as other aerosols. Settled droplets may facilitate fomite transmission and can be re-suspended in the air by diverse human activities. Large droplets can also move horizontally for more than 2 meters from the source during coughing or up to 8 meters during sneezing [17]. They can remain suspended for prolonged periods in certain environments, especially where turbulent airflow is abundant, such as in hospital settings where doors open constantly [15]. Particles of varying sizes (0.01 – 500 μm) are produced not only by medical procedures but also by respiratory activities such breathing, speaking, singing, coughing, or sneezing [18-21]. The proportion of aerosol-size particles differs according to the respiratory activities and individuals [21]. As such, it is important to understand that the size of the particles and the resulting behavior follows a continuum; it may overlap either side of this cut-off [21].

However, being airborne does not in itself guarantee effective transmission through aerosols. The virus in aerosols must remain viable in a sufficient quantity to be inhaled by a susceptible host. The virus contained in droplets is subject to biological decay over time, which is affected by the initial metabolic state of the virus, genetic characteristics, and the environment [22, 23]. In this context, the relative contribution of different modes of transmission should be considered, albeit the possibility of airborne transmission does exist. Airborne transmission can be classified as obligate, preferential, or opportunistic. In obligate airborne transmission, transmission occurs only via inhalation of aerosols (*e.g.*, in tuberculosis). Though transmission occurs through multiple routes in preferential airborne transmission, it predominately occurs through aerosols (*e.g.*, in measles, varicella). In opportunistic airborne transmission, the virus is transmitted predominantly through other routes; however, the virus may be transmitted through aerosols under favorable circumstances where aerosols are generated by performing AGPs (*e.g.*, in influenza, SARS-CoV-1 infection) [7, 22, 24].

2. Modes of SARS-CoV-2 transmission

The current consensus regarding the transmission of SARS-CoV-2 is that it is transmitted mainly through respiratory droplets and contact and that airborne transmission is possible during AGPs [9-11, 25]. Although no study has conclusively linked SARS-CoV-2 transmission to contaminated environmental surfaces, indirect contact with fomites is considered a possible route based on the evidence of heavy environmental contamination in healthcare

https://doi.org/10.3947/ic.2020.52.2.165

settings, objects used by COVID-19 patients [26, 27], and the finding that the virus remains viable on plastic surfaces for as long as 3 days [28].

However, there has been controversy whether SARS-CoV-2 can become airborne when AGPs are not performed. Some studies have suggested the potential of airborne SARS-CoV-2 transmission. In one experimental study, viable SARS-CoV-2 was detected in the air for 3 hours when an aerosolized environment was created using a three-jet Collison nebulizer and a Goldberg drum [28]. However, though this experimental condition may simulate circumstances when AGPs are performed, it does not reflect real-life clinical settings. A study in Nebraska detected viral RNA in air samples collected in COVID-19 patient rooms more than 6 feet way from the source patient and in the hallway outside patient rooms, but failed to detect viable virus in air samples [29]. Guo et al. detected SARS-CoV-2 RNA in air samples collected in intensive care units and general wards at a hospital in Wuhan, but the viral RNA was not detected on face shields, in buffer rooms, or in doffing rooms [30]. Liu et al. also found a high concentration of viral RNA in air samples from patients' toilet areas and staff PPE removal areas in two hospitals in Wuhan, suggesting re-suspension of the virus from contaminated surfaces [31]. However, both studies in Wuhan did not investigate the infectivity of the virus in those air samples. The presence of viral RNA in the air does not necessarily indicate viable virus in sufficient amounts to cause infection, nor does it mean that the virus can effectively be transmitted through this route [11, 32]. Further studies are needed to determine whether it is possible to detect viable SARS-CoV-2 in air samples from patient rooms in which no AGPs are performed and what role it may play in transmission. More importantly, in the study by Liu et al., viral RNA was reduced to undetectable levels in staff PPE removal areas after implementation of rigorous disinfection procedures, which emphasizes the importance of environmental disinfection to prevent the spread of the virus in the perspectives of infection prevention and control. In contrast, other studies have shown that viral RNA was not detected in air samples collected from COVID-19 patient rooms [26], 10 cm away from the patient's chin [27], or 2-5 meters away from the patient [33]. Transmission did not occur among HCWs wearing surgical masks when they were exposed to a COVID-19 patient, even during endotracheal intubation [34, 35]. No instances of transmission were observed among HCWs caring for COVID-19 patients when they used surgical masks as part of PPE routine care [36].

Based on these findings, it is believed that SARS-CoV-2 is mainly transmitted through droplets and contact, and that airborne transmission is possible under certain circumstances when aerosols are generated during AGPs or support treatment [9, 11]. At the same time, the possibility of airborne transmission should carefully be considered as new evidence emerges.

CURRENT RECOMMENDATIONS FOR PPE

In this context, the WHO currently recommends droplet and contact precautions for HCWs caring for COVID-19 patients and airborne precautions for settings where AGPs or support treatment are performed [25]. For droplet precaution, use of medical masks (also referred to as surgical masks) and eye protection (goggles or face shields) is recommended. For contact precaution, long-sleeved water-resistant gowns and gloves are recommended; when AGPs are performed, use of N95, filtering facepiece (FFP)2, FFP3, or equivalent respirators is recommended instead of surgical masks, and additional use of aprons is suggested if gowns are not fluid-resistant [37] (**Table 1**). However, there are inconsistences in the

https://doi.org/10.3947/ic.2020.52.2.165

recommendations of organizations and countries. PPE recommendations in Canada [38], Australia [39], and the United Kingdom [40] are consistent with those put forth by the WHO. The US Centers for Disease Control and Prevention (CDC) and the European Center for Disease Control and Prevention (ECDC) initially recommended airborne precautions for any situations involving contact with COVID-19 patients; however, they have modified their recommendations to specify that surgical masks are acceptable alternatives if respirators are not available [9, 10]. Despite this difference, airborne precautions are commonly recommended when AGPs are performed (**Table 1**). Although the transmission risk for HCWs may differ based on procedure being performed [41], AGPs listed in the guidelines generally include endotracheal intubation, bronchoscopy, tracheostomy, cardiopulmonary resuscitation, sputum induction, non-invasive ventilation, manual ventilation, airway suctioning, and nebulizer therapy. In the ECDC guidelines, prone positioning of the patient and disconnecting the patient from a ventilator are also considered AGPs [10, 42]. Surgery or procedures in which high-speed devices are used can also generate aerosols [43]. Although it remains uncertain whether SARS-CoV-2 is transmitted through this route, such procedures may impose substantial transmission risk in dental-clinic settings [44]. Collecting nasopharyngeal/oropharyngeal swabs for SARS-CoV-2 tests can provoke coughing and sneezing, possibly leading to the production of aerosols [9, 10]. However, this procedure requires less time and may pose a less significant risk than other AGPs. For this reason, the recommended respiratory protective equipment for collecting swabs differs

Table 1. Comparisons of personal protective equipment recommendations from the World Health Organization, the US Centers for Disease Prevention and Control (CDC), the European CDC, and Korea CDC [9, 10, 37, 47]

Settings	KCDC (March 2020)	WHO (April 2020)	CDC (May 2020)	ECDC (May 2020)
Triage: patient examination with direct contact	· KF94 mask or equivalent respirator · Eye protection[a] · Gown[b] or coveralls with foot covers · Gloves	· Medical mask · Eye protection[a] · Gown[b] · Gloves	· N95 respirator (or facemask if a respirator is not available) · Eye protection[a] · Gloves	· Surgical mask or, if available, FFP2 respirator · Eye protection[a] · Gown[b] or apron · Gloves
Usual inpatient care	· KF94 mask or equivalent respirator · Eye protection[a] · Gown[b] or coveralls with foot covers · Gloves	· Medical mask · Eye protection[a] · Gown[b] · Gloves	· N95 respirator (or higher-level respirator) or facemask (if a respirator is not available) · Eye protection[a] · Gown · Gloves	· Surgical mask or, if available, FFP2 respirator · Eye protection[a] · Gown[b] or apron · Gloves
Aerosol-generating procedures[c]	· KF94 mask, equivalent respirator, or PAPR · Eye protection[a] · Gown[b] or coveralls with foot covers · Gloves	· N95, FFP2, or FFP3 respirator · Eye protection · Gown[b] · Gloves · Apron (if gowns are not fluid-resistant)	· N95 or higher-level respirator · Eye protection[a] · Gown[b] · Gloves	· FFP3 respirator · Eye protection[a] · Gown[b] · Gloves
Collecting specimens (not involving aerosol-generating procedures)	· KF94 mask, equivalent respirator, or PAPR · Eye protection[a] · Gown[b] or coveralls with foot covers · Gloves	· Medical mask · Eye protection[a] · Gown[b] · Gloves	· N95 or higher-level respirator (or facemask if a respirator is not available) · Eye protection[a] · Gown[b] · Gloves	Enclosed spaces: · Surgical mask or, if available. FFP respirator · Eye protection[a] · Gown[b], gloves Drive-through or outdoor facilities: · Surgical mask

WHO, World Health Organization; CDC, Centers for Disease Prevention and Control; ECDC, European Centers for Disease Prevention and Control; KCDC, Korea Centers for Disease Prevention and Control; PAPR, powered air-purifying respirator; FFP, filtering facepiece.
[a]Eye protection includes goggles or a face shield.
[b]Gown refers to a long-sleeved, fluid-resistant gown.
[c]Aerosol-generating procedures include endotracheal intubation, non-invasive ventilation, tracheostomy, cardiopulmonary resuscitation, manual ventilation, bronchoscopy, open suctioning, sputum induction, nebulizer therapy, etc.

https://doi.org/10.3947/ic.2020.52.2.165

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among guidelines (**Table 1**). The Australian and Canadian guidelines emphasize the need for a point-of-care risk assessment to determine the likelihood of exposure based on a patient's symptoms, tasks, and specific environments [38, 45].

In Korea, airborne and contact precautions continue to be recommended in any situations involving any contact with suspected or confirmed patients, with some modifications. Initially, the Korea Center for Disease Control and Prevention (KCDC) guidelines recommended coveralls with shoe covers for contact precautions, goggles/face shields for eye protection, N95 or equivalent respirators for respiratory protection, and powered air-purifying respirators (PAPRs) when AGPs are performed [46]. In the March 2020 revision of these guidelines, long-sleeved water-resistant gowns and KF94 masks were recommended [47]. These modifications may have caused confusion and misunderstanding among HCWs [48]. To select appropriate PPE, it is important to know the differences among respiratory protective equipment (respirators, surgical masks, PAPRs) and protective clothing (coveralls, gowns) and their benefits and drawbacks.

RESPIRATORY PROTECTION: SURGICAL MASK, FILTERING FACEPIECE RESPIRATOR, AND POWERED AIR-PURIFYING RESPIRATOR

The main difference between medical masks and respirators is their purpose. Medical masks, also known as surgical masks, are designed to reduce spread of infections from the wearer to others and to protect the wearer's mucous membranes in the nose and mouth from exposure to large respiratory droplets and splashes or sprays of blood or bodily fluids. They are loose-fitting devices not designed to filter small airborne particles [49]. In contrast, respirators are designed to protect the wearers from inhaling hazardous airborne particles by filtering airborne particles (an air-purifying respirator) or supplying clean air to the wearer (an atmosphere-supplying respirator). Air-purifying respirators are further divided into three categories: filtering facepiece respirators (FFRs), elastomeric facepiece respirators, and PAPRs [49]. FFRs, generally known as respirators, are disposable particulate respirators classified in accordance with their filtering efficiency. In healthcare settings, FFRs with at least 95% filtering efficacy, also known as N95 respirators, are commonly used for airborne precautions and need to tightly fit the face to provide proper protection. Other types of air-purifying respirators can be used as alternatives to N95 respirators [49-51].

The WHO has released the Disease Commodity Package (DCP) for COVID-19, a datasheet that lists critical commodities and technical specifications [52]. According to this DCP, surgical masks worn by HCWs should meet the standards of EN 14683 type II, IR, IIR or American Society for Testing and Materials (ASTM) F2100 minimum level 1, or the equivalent, while surgical masks won by patients (for source control) should meet type I, level 1, or equivalent standards. The following are recommended for FFRs: 1) the minimum N95 respirator according to the Food and Drug Administration (FDA) Class II under 21 CFR 878.4040 and the CDC National Institute for Occupational Safety and Health (NIOSH), 2) the minimum FFP2 respirator according to the EN149, EU PPE regulation 2016/425 Category III, or 3) the equivalent [52]. To choose the proper equipment, it is necessary to understand the standards and requirements to which surgical masks or respirators must conform.

https://doi.org/10.3947/ic.2020.52.2.165

1. Surgical mask

Most surgical masks are composed of three-layers: an outer fluid-repelling layer, a middle layer serving as a high filter, and an inner moisture-absorbing layer. Surgical masks without this three-layer feature cannot provide adequate protection [53]. In the US and Europe, surgical masks are classified as medical devices and regulated accordingly. In the US, five elements are tested to standardize their quality: fluid resistance to synthetic blood, particulate and bacterial filtration efficiency, breathing resistance (pressure drop), flammability, and biocompatibility [54, 55]. In Europe, similar standard requirements have been adopted [56]. Surgical masks are categorized into levels 1, 2, or 3 in the US and I, II, or IIR in Europe (**Table 2**).

In Korea, however, there are no minimum standards or standardized testing methods to determine the filtering efficiency of surgical masks, and the efficiency of the filters in available surgical masks may vary widely. Fluid resistance to water is the only performance test required for surgical masks in Korea [57]. Fluid resistance reflects only one of the surgical mask's purposes: to minimize the amount of fluid that could transfer from the outer layers through to the inner layer in cases of splash or spray. However, the surface tension of water is greater than that of blood, and blood can penetrate through fabrics more readily than water [58,59]. The lack of equivalent Korean standards makes it difficult for HCWs to choose appropriate surgical masks as recommended by the WHO. Also, it is difficult to uniformly recommend the use of any surgical mask during care for patients with COVID-19 in Korea unless reliable Korean standards for surgical masks are established. Healthcare facilities should cautiously check whether products meet the standard requirements when procuring surgical masks for HCWs.

2. Filtering facepiece respirators

FFRs are labeled according to their filtering efficiency and the national regulations defining the standard conditions. In the US, there are nine classes of FFRs according to filtration efficacy (95%, 99%, and 99.97%) and the filter's oil resistance (N, R, and P). N95 respirators filter 95% of airborne particles 0.3 microns in size and are not resistant to oil. They are regulated under NIOSH CFR Part 84 [60]. The European standard (EN149:2001) places FFRs into three classes: FFP1, FFP2, and FFP3 according to their filtering efficiency (80%, 94%, and 99%, respectively) [61, 62]. As the Korean standards follow the European standards, FFRs manufactured in Korea are classified similarly: KF80, KF94, and KF99 (**Table 3**) [62, 63]. FFP2/3 and KF94/99 respirators are used for HCWs. In addition to a filtering efficiency test, a breathing resistance test (pressure drop) is required. Pressure drop is an objective measure of breathability; a high pressure drop indicates more difficulty in breathing. KF94 and FFP2 respirators require ≤70 Pa at an airflow rate of 30 L/min, whereas N95 respirators

Table 2. Comparison of the standard requirements for surgical masks in the US and Europe [55]

Test	The US ASTM F2100-19			Europe EN 14683:2019		
	Level 1	Level 2	Level 3	Type I	Type II	Type IIR
Bacterial filtration efficiency (%)	≥95	≥98	≥98	≥95	≥98	≥98
Particulate filtration efficiency (%)	≥95	≥98	≥98	Not required	Not required	Not required
Fluid resistance to synthetic blood	Pass at 80 mmHg	Pass at 120 mmHg	Pass at 160 mmHg	Not required	Not required	Pass at ≥16.0 kPa (>120 mmHg)
Differential Pressure	<5.0 mmH_2O/cm^2	<6.0 mmH_2O/cm^2	<6.0 mmH_2O/cm^2	<40 Pa/cm^2	<40 Pa/cm^2	<60 Pa/cm^2
Microbial Cleanliness	Not required				≤30 CFU/g	
Flammability	Class 1				Not required	
Biocompatibility	510 K Guidance recommends testing to ISO 10993			Complete an evaluation according to ISO 10993		

US, United States; CFU, colony-forming unit; ASTM, American Society for Testing and Materials; ISO, international organization for standardization.

https://doi.org/10.3947/ic.2020.52.2.165

Table 3. Comparison of respirator approval standards for KF masks and FFP respirators [62, 63]

	Filtering efficiency (%)	Test agent	Inhalation resistance- pressure drop (flow rate)	Total inward leakage[a] (%)
Korea				
KF80	80	NaCl	≤60 (at 30 L/min)	25
KF94	94	NaCl & paraffin oil	≤70 (at 30 L/min)	11
KF99	99	NaCl & paraffin oil	≤100 (at 30 L/min)	5
Europe				
FFP1	80	NaCl & paraffin oil	≤60 (at 30 L/min), ≤210 (at 95 L/min)	22[b]
FFP2	94	NaCl & paraffin oil	≤70 (at 30 L/min), ≤240 (at 95 L/min)	8[b]
FFP3	99	NaCl & paraffin oil	≤100 (at 30 L/min), ≤300 (at 95 L/min)	2[b]

FPP, filtering facepiece.
[a]At least 46 of the 50 individual exercise results (10 subjects x 5 exercises) for total inward leakage shall not be greater than the requirements.
[b]For European standards, at least 8 out of 10 individual wearers' arithmetic means for total inward leakage shall not be greater than the requirements as well.

require ≤343 Pa at 85 L/min. Since pressure drop increases with the flow rate, standard pressure drop requirements are similar, even though they appear different [64, 65]. In Korea and Europe, total inward leakage (TIL) is also tested on human subjects (**Table 3**) [62]. In the US, the TIL test is not performed. Instead, fit testing must be performed prior to working in the environment where wearing a respirator is required and be repeated annually under the Occupational Safety and Health Administration (OSHA) regulation 1910.134 [66]. Despite differences in test methods, it is generally considered that US N95, EU FFP2, and KF94 respirators are equivalent for filtering non-oil based airborne particles [64, 65, 67].

However, concerns have been raised because the fit test is not regularly performed in many Korean hospitals, despite the Korea OSHA recommending a fit test for wearers every year [68, 69]. Respirators must fit the face tightly for effective filtering of airborne particles. Noti et al. demonstrated that a poorly-fitting N95 respirator was not as effective as a tightly fitting respirator at blocking infectious viruses (66.5% *vs.* 99.6% blocked, respectively) and performed no better than unsealed surgical masks (66.5% *vs.* 56.6% blocked, respectively) in a simulation experiment [70]. In Korea, the TIL test is performed on ten human subjects doing five types of exercise [63]. This TIL test can eliminate respirators that are inherently poorly-fitting and that do not comply with this requirement or identify that the tested respirator is generally well-fitting. However, fitting is affected by a wearer's face shape and size, age, and gender, as well as the respirator design [71, 72]. Fit testing helps to select a respirator model that fits an individual's face well enough to provide at least the assigned protection factor of 10 [73]. Fit performance was also found to vary by respirator model, ranging from fitting less than 5% to those fitting 95% of the test subjects [71]. In addition to the model type, ear-loop designs appear to be less effective in achieving a proper fit than head-band designs [67]. This is worrisome, since most KF94 masks have ear loops. As AGPs may put HCWs at an increased risk for virus exposure and infection, the design of KF94 masks limits their use during AGPs. KF94 masks of various shapes and sizes and with elastic head-band designs should be offered to HCWs to improve the fitting of the masks. A recent study on the current status of fit testing in Korea showed that 82% of 52 HCWs failed to meet the criteria of fit factor 100, even when using N95 respirators [68]. Considering these findings, HCWs should be fit-tested for FFRs, regardless of their labels (KF94, N95, or FFP2) to ensure respiratory protection. Though it is challenging and laborious for hospitals to implement fit testing practices for all HCWs in the midst of the COVID-19 pandemic, protecting HCWs is of paramount importance.

Even so, fit testing alone does not guarantee respiratory protection [74]. Inappropriate donning and skipping the self-seal-check after donning an FFR were found to be frequent

https://doi.org/10.3947/ic.2020.52.2.165

causes of improper fit [68, 74]. Since training on the proper use of FFRs can improve fitting of the respirators among HCWs [74, 75], training programs should be implemented along with fit testing.

The risk of exposure to blood or bodily fluids should also be considered when selecting the proper FFRs, because most FFRs are not water-resistant. To protect HCWs against the splash/spray of blood or bodily fluids as well as airborne particles (*i.e.*, during an operation on a patient with COVID-19), surgical respirators with fluid resistance properties should be used [49]. A surgical N95 respirator, which is approved by the NIOSH as an FFR and the FDA as a surgical mask, is one example.

3. Powered air purifying respirator

PAPRs are increasingly used as an alternative to N95 respirators. PAPRs use a battery-powered fan to force air through a filter, cartridge, or canister to a tight-fitting facepiece or loose-fitting hood [49]. Loose-fitting PAPRs are commonly used in healthcare settings, as they have several advantages: higher respiratory protection with an assigned protection factor of 25 (as compared to 10 for N95 respirators), a barrier against splash, and less difficulty in breathing. They are also reusable, and do not require fit testing [50, 76].

However, there are disadvantages to PAPRs use: They are heavy, may impede HCWs' ability to care for patients, limit communication due to noise, require batteries to be recharged or replaced, and take up significant storage space [76]. Although a fit test is not required, they do need to be properly sized, as protection can decrease with oversized or stretched-out PAPRs [77]. Another disadvantage is that the wearer's exhaled air is unfiltered, which limits the use of PAPRs in close proximity to sterile fields [50, 76]. More importantly, risk of contamination during doffing procedures is high, requiring HCWs to receive special training and assistance in the doffing process. Cleaning and disinfection must be performed between uses. This process must be thorough and performed by trained individuals.

Loose-fitting PAPRs are suitable when AGPs are frequently performed (such as in intensive care unit settings), when HCWs are not able to wear tight-fitting FFRs, or when the fitting of a FFR may be compromised. For safe use, healthcare facilities should be aware of the advantages and disadvantages associated with PAPRs. They must also establish a robust maintenance program, including HCW training for proper PAPR use and the cleaning and disinfection process prior to the use of PAPRs [76, 78].

4. The comparative effectiveness of N95 respirators and surgical masks in preventing respiratory viral infections

Infectious aerosol particles are produced by diverse respiratory activities, including speaking and breathing [79, 80]. HCWs in close proximity to patients with COVID-19 are at risk of short-range airborne transmission as well as large-droplet transmission [81]. As such, there have been debates regarding the effectiveness of surgical masks against the virus in routine patient care, and use of N95 respirators or the equivalent is often advocated [82]. However, no clinical trial has compared the effectiveness of surgical masks and N95 respirators in preventing COVID-19 among HCWs. Based on the systematic review of five observational studies on HCWs, wearing any mask (surgical mask or N95 respirator) reduced the risk of developing respiratory infection (odds ratio [OR] for surgical masks, 0.13; 95% confidence interval [CI], 0.03 – 0.62 *vs.* OR for N95 respirators, 0.12; 95% CI, 0.05 – 0.26) [83]. A recent randomized clinical trial in the US demonstrated no significant difference in the incidence

https://doi.org/10.3947/ic.2020.52.2.165

of laboratory confirmed influenza between outpatient HCWs wearing surgical masks and those wearing N95 respirators [84]. Two meta-analyses, which were separately performed by different research groups, reached the same conclusion: Surgical masks and N95 respirators offer similar protection against respiratory viral infection among HCWs during non-aerosol-generating care [85, 86]. Based on these findings, the Infectious Disease Society of America recommends that HCWs caring for patients with suspected or confirmed COVID-19 use either a surgical mask or N95 (or N99 or PRPR) respirator and that HCWs involved in AGPs use N95 or higher-level respirators [83]. Chu et al. investigated the effectiveness of face masks in preventing transmission of SARS, MERS, or COVID-19 in healthcare and non-healthcare settings by analyzing 44 observational studies. They found that the use of face masks (12 – 16-layer cotton masks, surgical masks, N95, or similar respirators) resulted in a large reduction of infection risk in healthcare settings (relative risk [RR], 0.30; 95% CI, 0.22 – 0.41). N95 or similar respirators had a stronger protective association (RR, 0.04; 95% CI, 0.004 – 0.30) than surgical masks or 12 – 16-layer cotton masks (RR, 0.33; 95% CI, 0.17 – 0.61), and both N95 and surgical masks had a strong association with protection when compared to single-layer masks [87]. The review, however, included only four studies comparing N95 or similar respirators with no mask, and two of them involved situations in which AGPs were performed. Based on this review alone, it is difficult to generalize that the use of N95 or similar respirators provides more protection during routine care for patients with COVID-19. Therefore, the use of N95, FFP2, or higher-level respirators such as PAPRs should be prioritized when AGPs are performed. It is also necessary to vigilantly monitor situations or procedures that may increase the possibility of aerosol transmission, because many of the characteristics of SARS-CoV-2 remain unknown.

PROTECTIVE CLOTHING: GOWNS *VS.* COVERALLS

The choice of protective clothing should be based on a thorough risk assessment of potential exposure to blood and body fluids and transmission modes. The risk of exposure may depend on the stage of the disease, the severity of symptoms, and the types of procedures conducted. Once the risks are assessed, selection can be guided by the type of barrier, design, critical properties such as seams/closures, and donning and doffing features of the clothing.

The WHO, CDC, and ECDC recommend the use of long-sleeved water-resistant gowns and gloves when caring for COVID-19 patients. In its recent publication on the rational use of PPE, the WHO also specifies situations in which gowns should be donned. According to the WHO DCP for COVID-19, EN 13975, any performance level gowns or Association for the Advancement of Medical Instrumentation (AAMI) PB70, all level or equivalent gowns are acceptable [52]. Regarding coveralls as PPE against COVID-19, the WHO stated they are neither required nor generally recommended, and the CDC recommends them as an alternative in contingency situations. On the other hand, in Korea, initial recommendations recommended only coveralls for body protection; the guidelines were subsequently changed to specify that either gowns or coveralls can be used. This may cause confusion among frontline HCWs regarding what kind of protective clothing should be chosen. Moreover, there is no national standard for HCW protective clothing in Korea. Therefore, it is necessary to understand the relevant international standards and test methods to select and procure the proper protective clothing.

In the US, surgical and isolation gowns are medical devices subjected to regulation. ANSI/AAMI PB70 classifies surgical gowns and isolation gowns into 4 levels (level 1 being the

https://doi.org/10.3947/ic.2020.52.2.165

lowest, level 4 being the highest) based on their liquid barrier performance [88]. Tests for level 1 – 3 gowns use water, but level 4 gowns are required to pass blood and viral penetration resistance tests at a pressure of 13.8 Pa, which is considered water-impermeable (**Table 4**) [59]. The designs of surgical and isolation gowns are based on the anticipated location (critical zones) and degree of liquid contact. For isolation gowns, the whole garment is anticipated to have direct contact with blood, bodily fluids, or pathogens, and the entire gown, including the seams, needs to achieve barrier performance. For surgical gowns, the front panel and lower sleeves of the gown are required to achieve barrier performance [88]. The European standard EN13759 classifies gowns as either high performance or standard performance based on their resistance to liquid and microbial penetration (**Table 4**) [59, 89]. For gowns to protect HCWs from infectious agents, the garments must meet the standard EN 14126 performance requirements, which include tests for penetration resistance to blood/bodily fluids (ISO 16603) or to blood-borne pathogens (ISO 16604) under different hydrostatic pressures ranging from class 1 (0 kPa) to class 6 (20 kPa) [59, 89]. This standard is usually also used to evaluate and classify coveralls for HCWs in Europe. In the US, the NFPA 1999 standard is used to classify clothing items, including coveralls for HCWs; the materials and seams are tested for viral penetration resistance using ASTM F1671, and the overall liquid integrity, strength, and physical hazard resistance are also tested [59].

As there are various performance levels of gowns and coveralls, it cannot be simply concluded that one is more protective than the other. The specific barrier properties should be thoroughly reviewed, and protective clothing appropriate for specific diseases should be selected accordingly. For example, for Ebola virus disease, which is mainly transmitted through contact with blood or bodily fluids, gowns and coveralls should be resistant to penetration by blood and any bodily fluids or by blood-borne pathogens and compliant with the corresponding standards. Fluid-resistant protective clothing includes ANSI/AAMI PB70 level 3 or EN 13795 high performance gowns and coveralls made of fabrics passing tests

Table 4. Comparison of barrier performance of surgical and isolation gowns according to ANSI/AMMI PB70 and EN 13795 standards [59, 89]

	ANSI/AAMI PB70		EN 13795	
	Classification	Testing	Classification	Testing
Low risk	Level 1 Minimal water resistance: some resistance to water spray	AATCC 42 - Water penetration ≤4.5 g	Low performance	EN 20811 - Hydrostatic pressure ≥10 cm (less critical areas) & ≥100 cm (critical areas)
	Level 2 Low water resistance: resistant to water spray and some resistance to water penetration under constant contact with increasing pressure	AATCC 42 - Water penetration ≤1.0 g AATCC 127 - Hydrostatic pressure ≥20 cm water column		EN ISO 22612 - EN ISO 22612 - Resistance to microbial penetration, dry ≤300 (less critical areas) EN ISO 22612 Resistance to microbial penetration, wet ≥2.8 I_B (critical areas)
High risk	Level 3 Moderate water resistance: resistant to water spray and some resistance to water penetration under constant contact with increasing pressure	AATCC 42 - Water penetration ≤1.0 g AATCC 127 - Hydrostatic pressure ≥50 cm water column	High performance	EN 20811 - Hydrostatic pressure ≥10 cm (less critical areas) & ≥100 cm (critical areas) EN ISO 22612 - Resistance to microbial penetration, dry ≤300 (less critical areas)
	Level 4 Blood and viral penetration resistance	ASTM F1670 (Blood) & ASTM F1671 (Viral): No penetration at 13.8 kPa		EN ISO 22612 Resistance to microbial penetration, wet ≥6.0 I_B (critical areas)

ANSI, American National Standards Institute; AAMI, Association for the Advancement of Medical Instrumentation; AATCC, American Association of Textile Chemists and Colorists; ISO, International Organization for Standardization; ASTM, American Society for Testing and Materials.
AATCC 42 Water resistance: impact penetration test determines the ability of a material to resist water penetration under spray impact; AATCC 127 Water resistance: hydrostatic pressure test determines the ability of a material to resist water penetration under constant contact with increasing pressure; ASTM F1670 Synthetic blood penetration tests determine the ability of a material to resist the penetration of synthetic blood under constant contact; ASTM F1671 Viral penetration tests determine the ability of a material to resist the penetration of a microorganism under constant contact. EN 20811 evaluates a fabric's resistance to water penetration under constantly increasing hydrostatic pressure. The EN ISO 22612 test evaluates a dry fabric's ability to resist penetration of particles carrying microorganisms. The EN ISO 22610 test evaluates a fabric's resistance to microbial penetration under conditions of liquid pooling on the fabric and mechanical rubbing. Test results are expressed in I "Barrier Index." I=6.0 indicates no penetration.

https://doi.org/10.3947/ic.2020.52.2.165

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using ASTM 1670 (13.8 kPa), ISO 16603 class 3, or higher pressure (≥3.5 kPa). Protective clothing resistant to blood-borne pathogen penetration includes ANSI/AAMI level 4 gowns or coveralls made of fabric passing tests using ASTM F1671 (13.8 kPa), ISO 16604 class 2, or higher pressure (≥1.75 kPa) [90]. For COVID-19, any water-resistant level gowns are acceptable [52]. Thus, the proper level of gown protection should be chosen based on the risk assessment of exposure, the pressure and type of contact, as well as the duration and type of procedure [91].

No study has compared the effectiveness of gowns and coveralls in reducing transmission of the virus to HCWs, and gowns and coveralls are generally considered acceptable and effective [59, 92]. One of the major differences is the design. Coveralls are designed to cover the whole body, including the back and lower legs, while gowns do not provide continuous whole body protection. When wearing gowns, protection of the back area can be compromised depending on the activities of HCWs, such as squatting or sitting down, so sufficient overlap of fabric is necessary to cover the back. On the other hand, barrier protection can be compromised when using coveralls with a front zipper closure not covered with a flap of barrier material because seam barrier properties are essential for protection [59]. Gowns are easier to don and doff, and they are more likely to be used correctly as HCWs are relatively more familiar with gowns than with coveralls. In contrast, coveralls are difficult to doff, and the risk of self-contamination can be higher during the doffing process [59, 93-97]. HCWs should be trained properly and should practice the use of coveralls before using them during patient care. Moreover, coveralls generate more heat stress than do gowns, which leads to discomfort, fatigue, and dehydration. Considering these differences, the decision of which of the two to use should be based on availability, HCW activities, and the physical characteristics of the work environment [59].

In summary, current data suggest that SARS-CoV-2 is primarily transmitted through respiratory droplets and close contact. Airborne transmission may occur during AGPs in healthcare settings. PPE for droplet and contact precautions, such as surgical masks with eye protection, gowns, and gloves, are recommended for HCWs in contact with suspected or confirmed COVID-19 patients, and N95 or equivalent respirators should to be worn by HCWs whenever AGPs are performed. Although droplets and close contact are the main modes of SARS-CoV-2 transmission, selection of the proper PPE should be based on a through risk assessment of the extent and duration of exposure and the properties of the PPE required for protection. Degrees of respiratory protection and barrier properties differ according to various standards and test methods. Therefore, it is important to understand the national or international standards for respiratory protective equipment and protective clothing, and PPE certified to provide effective protection against SARS-CoV-2 should be chosen. Healthcare facilities must check the specifications of products thoroughly before procuring them. It is also important to ensure that HCWs are well trained for the proper use of PPE, because appropriate donning and doffing is essential for proper protection. The overuse of PPE can lead to supply shortages when high levels of protection must be used, potentially exposing HCWs to greater risk of infection. Therefore, PPE should be appropriately selected and rationally used. It should bear in mind that PPE is the last line of protection and its use alone does not effectively reduce transmission risk. Effective administrative and engineering controls, including early identification of suspected patients and source control, must be implemented simultaneously. Furthermore, basic infection prevention measures, such as frequent hand washing and rigorous environmental cleaning and disinfection, must be

https://doi.org/10.3947/ic.2020.52.2.165

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emphasized. As the occurrence of airborne transmission when AGPs are not performed remains uncertain, PPE recommendations are subject to change in accordance with future study results. Healthcare facilities and HCWs should be vigilantly aware of such changes in recommended PPE and prepare for the future.

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