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Respiratory protection for health care professionals. A perspective to COVID-19

Protección respiratoria para profesionales de cuidados de la salud. Una perspectiva ante el COVID-19

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ABSTRACT

The pandemic generated by the new SARS-CoV-2 virus has required the immediate response of health care professionals in a dizzying manner, responding to the exponential increase in the number of patients requiring hospitalization. This situation has required health care professionals to respond immediately to the pandemic situation, including shortages of patient care supplies, including personal protective equipment. This article is intended to explain the differences between surgical masks and respirators, the principles of operation of N95 respirators, their worldwide equivalents (including the Mexican Official Standard NOM-116-STPS-2009), the correct ways to use these devices, and the strategies that exist to optimize the use of these devices during the SARS-CoV-2 health emergency.

RESUMEN

La pandemia generada por el nuevo virus SARS-CoV-2 ha requerido la respuesta inmediata de los profesionales de cuidados para la salud de manera vertiginosa, respondiendo al aumento de pacientes que requieren hospitalización de forma exponencial. Esta situación ha necesitado que los profesionales de la salud atiendan de forma inmediata la situación generada por la pandemia, incluso con el desabasto de insumos necesarios para la atención de pacientes, incluidos los equipos de protección personal. El presente artículo tiene la intención de explicar las diferencias entre mascarillas quirúrgicas y respiradores, los principios de funcionamiento de los respiradores N95, sus equivalentes a nivel mundial (incluyendo la Norma Oficial Mexicana NOM-116-STPS-2009), las formas correctas de utilización de este tipo de dispositivos y las estrategias que existen para optimizar el uso de estos dispositivos durante la emergencia sanitaria por SARS-CoV-2.

Surgery masks and respiratory protective equipment (also known as respirators) have been widely used by healthcare professionals as methods of infection control.

SURGICAL MASKS

A surgical mask is defined as a disposable device that provides no fit and is intended to create a physical barrier between the user's mouth and nose and potential contaminants in the immediate environment.[1] These devices are intended to protect the wearer against splashes of body fluids, which are generated during health care procedures, and do not provide any respiratory protection because they do not create a seal on the wearer's face.

Such devices are regulated by the Food and Drug Administration (FDA) in the United States and require performance evaluations of the following parameters:

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- Fluid resistance
- Bacterial filtration efficiency
- Flammability
- Biocompatibility

Bacterial filtration efficiency is performed on the materials used to manufacture surgical masks, looking for the protection they provide against biological aerosols. According to the ASTM-2100 standard of the United States of America, there are three levels of bacterial filtration efficiency *(Table 1)*.[2]

Bacterial filtration efficiency is performed with a test aerosol of approximately 3.0 ± 0.3 μm and is commonly confused with the particulate filtration efficiency at which respiratory protective equipment is approved.

As mentioned above, surgical masks provide protection for users against splashes of body fluids, including saliva droplets to which healthcare professionals may be exposed during medical procedures. However, it is important to note that this type of device does not provide respiratory protection.

RESPIRATORY PROTECTION EQUIPMENT (RESPIRATORS)

According to NOM-116-STPS-2009 "Personal protective equipment – Negative pressure air purifying respirators against harmful particles – Specifications and test methods", a respirator can be defined as: a positive or negative pressure personal protective equipment that purifies or supplies air to protect the user's respiratory tract against contaminants found in the work environment *(Table 2)*.[3]

Table 1: Bacterial filtration efficiency levels.[2]

	Type 1	Type 2	Type 3
BFE% ASTM F2101	≥ 95	≥ 98	≥ 98
PFE% ASTM F2299	≥ 95	≥ 98	≥ 98

These devices are designed to provide protection against any contaminant dispersed in the environment, provided that they have been selected according to the hazard present in the environment, and that the user uses it correctly and consistently throughout the time spent in the workplace.

Health authorities worldwide suggest the use of N95 respirators or their equivalents for healthcare professionals who are in contact with persons confirmed with SARS-CoV-2 virus (COVID-19), especially in those procedures where aerosol generation is likely. In general, they also recommend the use of filtering face pieces or disposable respirators (FFR), because of their ease of implementation and the possibility of disposing of the respirators at the end of their lifetime (generally, one working day).

In the United States of America, the National Institute for Occupational Safety and Health (NIOSH), through the 42 CFR 84 standard, established guidelines for the approval of respirators. Within this standard, NIOSH classifies particulate respirators into nine different classes, according to the type of filter media, and the filtration efficiency of respirators *(Table 3)*.[4]

The filter media used in the construction of particulate respirators are electrostatic filters, which act to easily attract very small particles to the filter surface. Atmospheres containing oils in their composition can damage this electrostatic charge and thus decrease the filtration efficiency of the respirator.

Likewise, particulate filters are tested with aerosols with an aerodynamic mass diameter of 0.3 µm. Because of its size, this aerosol is extremely difficult for a respirator to trap, so it was selected as the test aerosol.

Worldwide, there are other standards for certification and/or approval of respirators, among which those that have similarities with the characteristics expressed by NIOSH standard 42 CFR 84 stand out. *Table 4* shows some equivalent standards for N95 respirators.[5]

The various approvals shown in *Table 4* are equivalent to those established by NIOSH; consideration should be given to performing a

respirator fit test to ensure that the facepiece fits properly on the user's face.

It is also important to consider the respirator selection process according to the application within the healthcare facility. The selection processes are sometimes complicated and are likely to require the assistance of an occupational hygiene or occupational health specialist. There are some tools available that can provide clear guidance for proper respirator selection. To provide protection against SARS-CoV-2 (COVID-19), health authorities suggest the use of particulate respirators, especially an N95 respirator or its equivalent. This recommendation is since the main risk of exposure of health care personnel occurs in procedures where aerosols are generated, such as patient intubation processes or respiratory therapies, and these aerosols, in essence, are liquid particles that are easily trapped by the electrostatic filtering media of respirators.[6]

It is of utmost importance that health care professionals identify respiratory protective equipment suitable for use in areas where SARS-CoV-2 confirmed patients are treated. Disposable or maintenance-free respirators are a good option for protection, provided they are available; in cases where these are limited, professionals could opt for the use of reusable half-face or full-face respirators. Another interesting option is the use of forced air purifying respirators (PAPR's), especially when health professionals need to spend very long periods of time working inside facilities where people with SARS-CoV-2 are treated.

While it is true that most respirators provide protection based on test methods, it is important to consider some other factors that may influence the performance of respiratory protective equipment, such as:

- Ease of placement/removal of the face piece.
- Time of respirator use.
- Compatibility with other personal protective equipment.
- Ease of cleaning/decontamination.

At the industrial level, respirators are used under a written respiratory protection program. This program establishes the guidelines for managing the use of respirators to provide maximum protection to users. Within the Respiratory Protection program, fit testing is established. The purpose of these tests is to ensure that the respirator model used by a person generates an adequate fit (seal) on the face. These fit tests must be performed by all personnel whose activities require the use of respirators. This test can help identify those individuals who, due to their physical or anatomical characteristics, cannot achieve a good respirator seal, compromising safety when using these devices.

Fit testing is a routine practice in industry in general, but little seen in healthcare settings. It is recommended that all employees who use respirators as a measure of protection against

Table 2: Classification of respirators.[3]

	Negative pressure	Positive pressure
Air purifiers	Disposable respirators Reusable half-face respirators Reusable full-face respirators	Forced air purifiers (PAPR's)
Air supply	Pressure-demand air line systems	Air line systems Self-contained air systems

Table 3: National Institute for Occupational Safety and Health (NIOSH) classification of respirators.[4]

%	N Does not resist oil sprays	R Partially resists oil aerosols	P Aerosol and oil-proof
95.00	N95	R95	P95
99.00	N99	R99	P99
99.97	N100	R100	P100

Table 4: Equivalent respirator standards N95.[5]

Certification class (standard)	N95 NIOSH 42CFR84 USA:	N95 STPS NOM-116-STPS Mex.	FFP2 EN-149 2001 EU	KN95 GB2626 2006 China	P2 AS/NZ 1716:2012 Aus. N.Z.	1st Class Korea KMOEL-2017-64	DS Japan JMHLW, Notification 214, 2018
Performance of filter (%)	≥ 95	≥ 95	≥ 94	≥ 95	≥ 94	≥ 94	≥ 95
Testing agent	NaCl	NaCl	NaCl Kerosene oil	NaCl	NaCl	NaCl Kerosene oil	NaCl
Test flow (l/min)	85	85	95	85	95	95	85

SARS-CoV-2 virus be fit tested to ensure that the respirator model being used provides adequate protection.

The SARS-CoV-2 health emergency has caused healthcare facilities around the world to experience shortages of supplies, including ventilators and surgical masks. This has prompted health authorities to establish recommendations to extend the life span of ventilators. The US Centers for Disease Control and Prevention (CDC) published strategies for optimizing the supply of personal protective equipment (PPE) on its website on March 18, 2020.[7] These strategies include assessing PPE overdemand capacity, which refers to the ability to handle a sudden and unexpected increase in patient volume that would otherwise severely challenge or exceed a facility's current capacity. The use of three general strata is suggested to describe overdemand capacity, which can be used to prioritize measures to conserve PPE supplies across the continuum of care:

- **Conventional capability:** measures consisting of engineering, administrative and PPE controls that should already be implemented in overall infection prevention and control plans in healthcare settings.
- **Contingency capacity:** measures that can be used temporarily during periods of expected PPE shortages.
- **Crisis capability:** strategies that are not commensurate with US standards of care but should be considered during periods of known PPE shortages.

This health emergency places these strategies in a state of crisis capacity, where PPE shortages are a constant in healthcare settings. Given this situation, CDC guidelines in the United States of America suggest healthcare sites consider crisis capacity scenarios, which should be carefully planned for prior to implementation. CDC suggests that some crisis capacity strategies are uncertain and may present a risk of transmission among healthcare personnel and patients. Among these crisis capacity strategies, CDC suggests:

- Consider using intact PPE that is beyond the manufacturer's designated service life for patient care activities.
- Carefully prioritize the use of PPE for selected care activities.
- If commercial PPE is not available, carefully consider whether alternative approaches will reduce the risk of exposure to health care professionals, and whether these methods are safe for patient care.

On February 4, 2020, the U.S. Federal Government stated that circumstances exist to warrant the authorization of additional

respiratory protective devices in healthcare settings during the SARS-CoV-2 outbreak.

On February 29, the U.S. Food and Drug Administration (FDA) issued a series of updates to manufacturers, facilities, and state and local jurisdictions on emergency use authorizations for respirators and other personal protective equipment.

These emergency use authorizations strengthen the protection of public health institutions in the United States of America against CBRN risks (i.e.: chemical, biological, radiological, and nuclear) by facilitating the availability and use of the necessary supplies to deal with emergencies; in this case, the emergency generated by the SARS-CoV-2 virus. In the case of respiratory protection equipment, the emergency use authorizations establish protocols for respirator decontamination processes, by means of certain methods established and approved by the FDA. It is important to note that these decontamination protocols are only valid during the declaration of a sanitary emergency by the Federal Government of the United States of America.

Respirator decontamination processes are not recommended by any disposable respirator manufacturer since the original conception of these devices is to discard them after use. However, global supply problems of disposable respirators have forced health authorities to seek methods of decontamination of these supplies to keep health care professionals protected.

For a decontamination method to be considered by the FDA, it is required to meet the following conditions:

- Effectively inactivate the SARS-CoV-2 virus.
- Do not damage the filtering media or any element of the respirator (nose clip, adjustment straps).
- Do not damage the fit provided by a disposable respirator.
- That the selected method does not represent a risk for the respirator user.

For respirator decontamination protocols and methods, please refer to the following link:[8] https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covidppe.

Currently, manufacturers of respirators and decontamination methods are collaborating with the FDA, universities, and research institutes to evaluate methods of decontaminating disposable respirators in a safe manner.

Finally, a controversial issue for healthcare professionals is whether the respirators being used are approved or certified under the above guidelines. It is important for health care professionals to verify that the respirators comply with the regulations under which they are designed. It is suggested that respirator test reports or certificates be reviewed prior to use to ensure their reliability.

While it is important to verify that respirators are approved under some international standard and remember that these devices provide protection if they fit properly on the user's face, so a pre-use test at the health care facility is recommended.

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