Title	Features N95 Surgical Masks as Personal Protection Equipment (PPE) – Based on CDC recommendations
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INTRODUCTION:

The Personal Protection Equipment includes protection clothing, gloves, facial protector, googles, surgical masks, breathers or other equipment developed to protect the user from lesions or illnesses or infections spreading.

The surgical masks are protection garments, which are liquid resistant, disposable, and loose-fitting that create a physical barrier between the user's mouth and nose and the immediate environment. In opposition to breathers, the surgical masks do not hermetically seal to the user's face and, therefore, do not proportionate a trustworthy level of protection against the inhalation of infectious sprays.

An N95 surgical breather is an approved breather by the FDA (United States Food and Drug Administration) and NIOSH (National Institute for Occupational Safety and Health), which is an American Government Agency responsible for the approval of breathing protection devices for the occupational use. The standpoint for the approval is that anyone can manufacture and sell any kind of breathing protection device, but only such that accomplish or exceed all stablished requirements in norms 42 CFR part 84 are recognized by NIOSH (1,2)

In general, the useful time of all filters and breathers approved by NIOSH **is limited by hygiene, damage and respiratory resistance considerations. All filters must be replaced always when they are damaged, dirty or causing a major notably respiratory resistance.**

Nevertheless, for dirty work places that might result in a heavy load for the filter, i.e. 200 mg, the time for service for N series filters only should be used further than eight hours of use (continuous or intermittent) doing an evaluation of work environment that specifically show:

(a) that the extended use do not corrode the filter efficiency bellow the efficiency level specified in the 42 CFR 84 or
(b) That the load of total mass of filters is lower than 200 mg. A key consideration for a safe lengthened use is that the breather must maintain adjust and function.

The medical attention installations of must develop procedures clearly written to council that the personnel follows in general terms the next steps to reduce the contact transmission like thus (3):

- *Cast aside the N95 breathers after the use during the aerosol generation procedures.*

- *Cast aside N95 breathers contaminated with blood, respiratory or nasal secretions or with other patients' body fluids.*
- *Cast aside N95 breathers after a close contact or exit of attention area of any infected patient with an infectious disease that requires contact precautions*.
- *Consider the use of a facial protector that can be cleaned over an N95 breathers and / or other steps (for instance, masking patients, Engineering controls) to reduce the surface contamination*.
- *Perform hands hygiene with water and soap or a hands' sanitizer based on alcohol before and after touching or adjusting the breather (if necessary for comfort or keep in shape)*

It is unlikely that the lengthened use only degrade the respiratory protection. However, the health centers must develop procedures clearly written to council that the personnel cast aside any breather that is obviously damaged or difficult in use to breathe (3)

Likewise the FDA indicate several procedures due to scarcity of tools of protection, which propone other different standards (4)

Risks of breather's lengthened use and reuse

Although the lengthened use and reuse of breathers have a potential benefit to keep limited supplies of disposable N95 breathers, concerns have been laid out about such practice. Some devices have not been approved by the FDA for reuse. The User Instructions of some manufacturers recommend they should be casted aside after each use (i. e. "one use only"), while others allow its reuse if the installation infection control policy allows it.

The most significant risk **is the transmission by contact when touching the contaminated breather's surface.** The N95 breathers certified by NIOSH and approved by the FDA as medical devices for the use of medical attention personnel are named "N95 surgical breathers". Likewise all N95 breathers certified by NIOSH, these products have been evaluated by the certification process of NIOSH and have shown that can filter a minimal of 95% of air particles in the worst test conditions. The FDA also has evaluated that these products have shown an acceptable level of resistance to fluid and flames, which may be important in Medical occupational surroundings, as surgical areas.

Some authors indicate the possibility of reuse of these surgical breathers with decontamination without its performance or protection might be affected, and the FDA recently sent out a guide that will allow the certified institutions can do the reprocessing of these N95 medical devices considered initially for a one use only (5, 6, 19)

Having said that, Prevention and Diseases Control Center –CDC lays out three strategic plans of lengthened use of N95 breathers according to the capacity and supply in different moments like this:

I. CONVENTIONAL CAPACITY STRATEGIES

In patient's attention without any change of daily practices. This set or controls must be implemented in general plans of prevention and control of infections in medical attention surroundings. (7)

A. Engineering Controls: Controls that can be effective beside the protection, because they reduce the exposure to the Hospital Health Personnel (HCP) when a barrier is set up between the dancer and the HCP. These might be:

1. *Airborne infection isolation room*: patients with COVID-19 known or suspicious must be collocated in an airborne infection isolation room (AIIR) that has been built and maintained according to nowadays standards (8).
2. *Physical Barriers Use:* the barriers as window or plastic can be one effective solution to reduce the exposure of sanitary professionals to potentially infectious patients.
3. *Adequate maintenance of ventilation systems*: other keystone of engineering controls are the ventilation systems, which proportionate air flow from a clean station (HCP workstation or area) towards the contaminated flow (ill patient) (beside adequate filters, change rate), that are installed and maintained adequately.

B. Administrative Controls: administrative controls are laboral and practices and policies told by the employer that reduce or avoid dangerous exposure. Its effectiveness dependes on the commitment of the employer and the acceptance of the HCP and the conscious use of the strategies. The training, monitor and regular reinforcement are necessary to guarantee that the policies and procedures are followed consciously. Many of these strategies must already be incorporated to the existent policies of prevention and infections control in medical attention environments.

1. *Limit of number of patients that go to the Hospital or ambulatory patients:* Consider develop mechanisms to evaluate patients in search of acute respiratory diseases before of its non-urgent attention or visits or elective procedures, like the system of appointments reminder. Postpone or reprogram such with signs or symptoms that are presented to these non-acute visits.
2. *Exclude all health professionals that are not directly involved in the patients' attention:* the nowadays guide of the DSD (9) recommends that, for COVID-19, only the essential personnel enters in the patient attention area, and the installations consider to attend these patients with an indicated HCP
3. *Limit encounters face to face with the patient*: Measures can be exploited to limit encounters of contact face to face between the PS and the COVID-19 patients confirmed or suspicious. Alternative mechanisms for interaction between the PS and the patient include phones, video monitor, and videophone calls in cell phones or in tablets.
4. *Exclude visitors to patients with known or suspicious COVID – 19:* Restrict visitors entering to patients' rooms with known COVID- 19 or suspicious COVID-19.
5. *Control Source:* Identify and evaluate patients that might be ill or that have been exposed to a COVID – 19 known person. Patients with suspicious symptoms of COVID-19 or other respiratory infection (e. g. fever, cough) that are presented to the attention must use facial masks.
6. *Cohort Patients*: The cohort is the practice of grouping infected patients with the same organism to limit its attention to an area and avoid contact with other patients. The cohorts are created according to the clinic diagnosis, the microbiological confirmation when available, the epidiomology and the mode of the infectious agent. When there are no available individual rooms, patients with confirmed COVID-19 can be placed on one single room. The cohort of patents might minimize the use of breather when lengthened breather use.

7. *HCP Cohort*: The assignment of designed HCP teams to give attention to all COVID-19 patients confirmed or suspicious might minimize the use of breather when lengthened RPD use is implemented.
8. *Telemedicine:* The nursing advice lines and telemedicine can detect and control patients with suspicious COVID-19 without the need that the PS use respiratory protection. Promote the use of those technologies and nets of reference can help to classify people to an adequate attention level, which can reduce the attendance of patients that seek evaluation to the medical attention center.
9. *Training about the Instructions for the use of N95 breathers*: It is important that the HCP is trained in the instructions for the use of N95 breathers, Respiratory protection standard by OSHA (11), requires that the employers give training about breathers before demanding to an employee use a breather at his/ her workplace.
10. *Training about the use of N95 breathers:* Training employees about the adequate use of breathers, including when wearing or wearing off, the use limitations, and the maintenance is essential for the effective use of the respiratory protection. The health professional must be completely trained before being subdued to an adjustment test to guarantee that they feel comfortable with the breather and that they know how to do a verification of user's seal.
11. *Adjust Test just in time:* Adjust Tests just in time are referred to the capacity of installations of medical attention to do evaluations, training, and adjustment tests to big scale of employees when necessary during the pandemic.
12. *Limited breathers during training:* in order to keep the supply of N95 breathers, the medical attention installations must understand which of its HCP must be and do not have to be in a respiratory protection program, and, therefore, medically evaluated, trained and tested. If the training and the adjustment tests are carried out during two separate steps, it is possible to permit a limited reuse of N95 breathers used by the individual PS during both steps.
13. *Qualitative Adjustment Test:* the method of breather adjustment test are classified ad qualitative or quantitative, and there are multiple protocols of each classification recommended by NIOSH or that accomplish with the requirements of the Respiratory Protection Standard by OSHA (12). A qualitative adjustment test is a test of approved or disapproved to evaluate the adaptation of the breather adjustment based in the individual sensory detection of a test agent (13). A quantitative adjustment test numerically measures the effectiveness of the breather to seal with the users' face without depending the voluntary or involuntary response of the user to a test agent (14).

C. Personal Protection Equipment and Respiratory Protectors

If it seems good to you, the administrative and engineering controls must be considered first when selecting controls; the use of Personal Protection Equipment (EPP) must also be part of a set of strategies used to protect the personal. The adequate use of the respiratory protection by the HCP requires an integral program that includes medical authorization, training and adjustment tests. The program must also include dispositions for cleanliness, disinfection, inspection, repair and storage of breathers used by the workers at work. The adequate storage conditions can maximize the lifetime of breathers. The next strategies in this section are used traditionally by some health systems. If not yet being implemented, these strategies can be considered by the medical attention environments before a possible scarce of N95 breathers before implementing contingency strategies numbered later.

1. *N95 Surgical Breathers:* N95 Surgical breathers are recommended only to be used by health professionals that need protection against risk as well in the air or fluids (for instance, splatters, aerosols) (15). In scarce times, only the health professionals working in sterile field or that might be exposed to splatters, aerosols, blood splatters, or high-speed body fluids at must receive such breathers. Other health professionals may use N95 standard breathers. If N95 surgical breathers are not available, and there is risk that the worker is exposed to splatters, aerosols, blood splatters or high-speed body fluids, then a facial protector must be used over the N95 standard breather.
2. *Alternative uses to N95 surgical breathers:* Use alternatives to N95 surgical breathers when it is feasible (16). This includes other types of breathers with filter mask, air purifier breathers of half elastomer mask and full mask. Motorized Purified Air Breathers (PAPR) when feasible. All these alternatives will proportionate equivalent or higher than the N95 breathers when used adequately. NIOSH maintains and on-line search version of the list of certified equipment that identifies all breathers approved by NIOSH. NIOSH approves other breathers with filter mask that are at least as good protectors as the N95. These include the N99, N100, P95, P99, R95, R99 and R 100. The elastomer breathers are breathers adjusted at half mask that are made of synthetic material or rubber that are allowed to be repeatedly sanitized, cleaned, and reused. They are equipped with interchangeably filters cartridges. As the N95 breathers, the elastomer breathers require annual adjustment tests. The elastomer breathers should not ne uses in surgical environments due to the concern that the air that is released from the exhalation valve may pollute the sterile field. The PAPR are reuse breathers that can be hoods or loose-fitting helmets. These breathers work with batteries with a blower that pulls out the air trough filters or connected cartridges. The filter is typically an High Efficiency Particle Air filter (HEPA). The PAPR of loose fitting do not require adjustment tests and can be used by people with face hair. Nevertheless, the PAPR must not be used in surgical surroundings due to concern that the blower escape and the exhaled air may pollute the sterile field. The installations that use elastomer breathers and PAPR must have updated cleaning and sanitized procedures that are an essential part of the use for the protection against infectious agents.

II. EVENTUALITY CAPACITY STRATEGIES

In the continuity of attention, the next steps can be classified as eventuality capacity, which can change everyday practice, but cannot have a significant impact in the attention given to the patient or to the security to sanitary professionals. The next steps can be considered in the context of a possible upcoming scarce of N95 breathers. The decision of implementing such practices must be taken case by case taking into account the known features of the SARS-CoV-2 and local conditions (17).

A. Administrative Controls:

1. Diminishing the hospital stay time for medically stable patients with COVID-19: Nowadays the CDC recommend the discharge of patients with confirmed COVID-19 when they aare medically stable and have a home environment suitable to return. If patients cannot be discharged due more to social reasons than medical. Public Health Workers can need to identify an alternative dwelling non hospital where patients can convalesce.

2. Use of N95 breathers beyond useful lifetime designed by the manufacturer for training and adjustment tests: In scarce times, the use of N95 breathers beyond useful lifetime designed by manufacturer can be considered. However, the expired breathers may not accomplish with the requirements they were certified. With time, components as the strap and the material can affect adjustment quality and the seal. Due to this, the use of expired breathers could prioritize for situations when the PS are not exposed to pathogens, as the training and adjustment test. As the expired breathers can still accomplish with an important purpose, the installations of medical attention must retain all N95 breathers during the first phases of the outbreak.

3. Extended use of N95 breathers: Moreover, the practice that allow the lengthened use of N95 breathers can be considered when it would be acceptable. The decision of implementing policies that permit the extended use of N95 breathers must be taken by professionals that administer the program of institutional breathing protection, consulted with its departments of occupational health and infection controls with contribution of state / local health departments (18). The CDC recommends the extended use as an option to keep breathers during outbreaks and pandemics of former respiratory pathogens. The extended use is referred to the practice of using the same N95 breather for repeated encounters of close contact with different patients, without taking off the breather among encounters. The extended use (18) is well adapted in situations in which various patients with the same diagnostics of an infectious disease, which their attention requires the use of a breather can be grouped (for instance can be accommodated in the same hospital unit).

B. <u>N95 Breathers Limited Reuse</u>

The reuse refers to the practice of using the same N95 breather by a health professional for multiple encounters with different patients, but eliminating it (i. e. taking it off) after each encounter (18). This practice often is known as “limited reuse” because there are restrictions to limit the quantity of times that the same breather is used. Consulting with the breather´s manufacturer about the maximum number of uses recommended for the model N95 is important. If there is not available a manufacturer guide, data suggest limiting the number of reuses at not more than five uses by device to guarantee an adequate security level. N95 and other disposable breathers must not be shared by multiple HCP. The CDC has recommended orientations about the implementation of the limited reuse of N95 breathers in sanitary environments. To maintain the breather integrity, it is important that the HCP hang the used breathers in the designed storage area or keep in a breathable and clean container, as a paper bag, among uses. Modifying the N95 breather by putting any material inside or over the breather is not recommended. Modifying may affect negatively the performance of the breather and may null the NIOSH approval. In this sense the FDA has sent out a Guide for establishments that wish to be certified to do the reprocessing and reusing of N95 breathers (19), and FDA has certified the Batelle’s decontamination system using Hidrogen Peroxide steam and are using it in several centers of USA, allowing a decontamination up to 20 time of breathers (20).

III. ALTERNATIVE STRATEGIES IN CRISIS:

These crisis capacities or alternative strategies accompany and are based on strategies of conventional capacity and contingency. The following measures are not according to the USA attention nowadays standards. Nevertheless, the individual measures or a combination of such measures can be needed to be considered during scarce times of N95 breathers expected or known (21).

A. When N95 supplies are used up:

1. *Personal Protection and respiratory protection Equipment:* **Breathers use beyond lifetime designed by the manufacturer for the delivery of medical attention.** Using breathers beyond the lifetime designed by the manufacturer for the care of patients with COVID-19 can be considered. However, the breathers use beyond designed lifetime by the manufacturer may not accomplish the requirements what have been certified. Eventually, components as straps and nasal bridge materials can be corroded, what can affect the adjustment quality and seal (22). Using these breathers is optimal in the context of a respiratory protection program that includes medical attention, training and adjustment tests. If these are used in the medical attention provided, it is particularly important that the PS make a verification of expected seal before entering to a patient's attention area. The CDC do not recommend using the N95 beyond the lifetime designed by the manufacturer in surgical environments.
2. ***Use of approved breathers according to standards used in other countries, which are similar to the N95 breathers approved by NIOSH***: Other countries approve the breathers for occupational use and approve the breathers according to such norms. These products are evaluated using some similar methods used by NIOSH, and **some methods that are different, but protecting the PS is expected.** Such with equivalent protection or similar to NIOSH approved breathers can be available to proportionate respiratory protection to workers exposed to damaging particles in the air. For instance (23):

Country	Performance Standard	Aceptable products' classification	Norms / orientation documents	Protection factor ≥ 10
Australia	AS /NZS 1716:2012	P3 P2	AS / NZS 1715: 2009	Yes
Brazil	ABNT / NBR 13698:2011	PFF3 PFF2	CDU Fundacentro 614.894	Yes
China	GB 2626 -2006	KN 100 KP 100 KN95 KP95	GB / T 18664-2002	Yes
Europe	EN 149-2001	FFP3 FFP2	EN 529:2005	Yes
Japan	JMHLW-2000	DS/ DL3 DS/ DL2	JIS T8150:2006	Yes
Korea	KMOEL- 2017-64	SPECIAL FIRST	KOSHA GUIDE H-82-2015	Yes
Mexico	NOM – 116 - 2009	N100, P100, R100 N99, P 99, R 99 N 95, P95, R95	NOM 116	Yes

Country	Performance Standard	Aceptable products' classification	Norms / orientation documents	Protection factor ≥ 10
NIOSH requirements in USA	**NIOSH approved 42 CFR 84**	**N 100, P100, R 100 N99, P99, R99 N 95, P95, R95**	**OSHA 29CFR1910.134**	**Yes**

3. *N95 breathers limited reuse for COVID- 19 patients:* **The limited reuse of N95 breathers when attending COVID – 19 patients could be necessary.** However, it is unknown, which is the potential contribution in the transmission by contact for the SARS-CoV-2, and caution must be taken into account.
4. ***Prioritizing the use of N95 breathers and masks by activity type:*** the number of infectious particles needed to cause an infection (infectious doses) often is uncertain or unknown for the respiratory pathogens. Besides, there is often uncertainty about the influence of factors as the length to exposition and the nature of clinic symptoms about the probability of infection transmission person to person. When health professionals mus use facial masks when entering attention patients area, source control (that is, the symptomatic patients masking), and the distance maintaining from patient are particularly important to reduce the transmission risk.

This prioritizing approach for the conservation is destined to be used when the N95 breathers are limited since it is not possible to practice as routine manner the attention standards for all HCP who use breathers N95 when attending a COVID – 19 patient. N95 breathers beyond lifetime designed by the manufacturer; when available, it is preferable the use of facial masks. **The N95, or the elastomer breathers, or PAPR must be prioritized for health professionals with the expositions of higher potential, including the presence in the room during procedures of aerosol generation done in symptomatic people.**
Suggested use of mask and breather, based on the distance of a patient with COVID-19 suspicious or known and use of source control *.

HCP planned proximity to the case patient during the encounter	Determination of mask or breather	
	Masked patient during the whole encounter (that is. Source control)	The patient, or mask, without mask must be retired by any period of time during the encounter with the patient
The PS will stay further than 6 feet from the symptomatic patient.	The PS who stays at such distance from patient should not enter to the patient's attention area, if entrance is required: without mask or breather.	The PS who stays at such distance of the patient should not need enter in patient's attention area, if entrance is required: without mask or breather.
The PS is between 3 to 6 feet from the symptomatic patient.	The PS who stays at such distance from the patient should not enter to the patient's attention area; if entrance is required: mask	The PS who stays at such distance from the patient should not enter to the patient's attention area; if entrance is required: mask.
The PS will be at 3 feet from the symptomatic patient,	Facial mask	N95 breather / elastomer / PAPR according to availability.

HCP planned proximity to the case patient during the encounter	Determination of mask or breather	
	Masked patient during the whole encounter (that is. Source control)	The patient, or mask, without mask must be retired by any period of time during the encounter with the patient
including direct patient's attention.		
HCP will be present in the room during aerosol generation done to symptomatic people	N95 breather / elastomer / PAPR according to availability.	N95 breather / elastomer / PAPR according to availability.

* According to availability, organizations can demand and / or people can voluntary option of using higher levels of protection

B. When no breathers are left

Administrative Controls:

Excluding the health professional with higher risk of COVID-19 grave illness, because the contact with patients with known or suspicious COVID-19. During severe limitations of resources, consider excluding health professionals that can have major risk of grave COVID-19 illness, as older patients, such with chronical medical complaints or such that might be under pregnancy, when taking care with patients confirmed or suspicious. It is possible to design a health professional who has clinically recovered of COVID-19 to give preferable attention to additional COVID-19 patients. People who have recovered of COVID-19 disease may have developed certain protection immunity, but it is not confirmed yet.

Engineering controls:

1. *Isolation rooms of patients to reduce risks*: the portable ventilator devices with High Efficiency Particulate Air Filtration (HEPA) that are carefully placed may enlarge effective changes of air by hour of clean air to the patient room, reducing the risk that the people enter to the room without breathing protection. NIOSH has developed a guide to use portable HEPA filtration systems to create isolation rooms for patients. The advisable focus of the isolation room of patient implies the establishment of an internal isolation zone of high pressure of ventilation and negative pressure that can be found inside a bigger and cleaner ventilation zone. In absence of any left supply of N95 breathers, can be possible use this technology together with HCP with masks

2. *Ventilated headboards*: NIOSH has developed the ventilation headboard that extracts the air exhaled by the patient in bed towards a HEPA filter that diminishes the risk of exposition to a HCP to the aerosol generated by the patient. This technology consists in a light aluminum frame, resistant and adjustable to a retractile plastic cover. The ventilated headboard can be implemented in combination with ventilator units / HEPA filter to proportionate isolation capacity of overvoltages in a variety of surroundings, from rooms of

traditional patients to TRIAGE stations. In absence of any left supply of N95 breathers, this technology can be used together with the PS and / or patients that use masks.

Conclusion:

The N95 breathers are protection equipment that are used in major frequency to control expositions to transmitted infections through the air route and its effectivity depends in larger measure of care, adjustment, training, and adequate uses. The optimal form of preventing the transmission does not only depend of the use of this device or other protection equipment, but of combination of interventions of controls such as Engineering and Administrative controls that have been mentioned above. The application of a combination of such controls may proportionate and additional grade of protection, even if an intervention fails or it is not available. When these N95 are being scarce or there is not supply, it is recommended prioritize the use of breathers for the health personnel with higher risk, the use of alternative breathers with the same or similar filtration capacity, including in non surgical context, elastomer breathers and PAPR can be disinfected, cleaned, disinfected, and reused repeatedly. Likewise, it is recommended the use of N95 breathers beyond lifetime recommended by the manufacturer; the reuse of the same and even the reprocessing under validated conditions as long as the adjustment and its function are not damaged, dirty, or causing a higher respiratory resistance. In case of total absence of N95 breathers or homologue alternatives, the use of surgical masks can be evaluated for the care of patients with COVID-19 beside the engineering and administrative specific controls. However, considering this option should be considered with precaution.

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