Balancing the Risk – Strategies for Respiratory Protection During a Pandemic

By Christina M. Baxter (Emergency Response TIPS) and Jeffrey O. Stull (International Personnel Protection)

Responders can be exposed to the SARS-CoV-2 virus responsible for COVID-19 by inhaling aerosolized droplets from an infected individualized persons' coughs and sneezes as well as contact with contaminated surfaces with subsequent hand transfer to the mouth, nose, or eyes. First responders may be at increased risk for exposure with potentially sick patients from increased aerosol and fluid volumes and close proximity. For this reason, extra caution in the selection, handling, and cleaning of PPE used by first responders must be exercised. This document discusses a proposed approach for balancing risk while maintaining the highest level of protective posture as the pandemic continues.

Finally, there is considerable confusion in the community regarding the need for fit testing, especially as it relates to filter facepiece respirators. NIOSH released a blog post on this topic and it is worth a quick review by all (https://blogs.cdc.gov/niosh-science-blog/2020/04/01/fit-testing-during-outbreaks/).

PHASE 1 (WHILE RESPIRATOR SUPPLIES ARE AVAILABLE)

To reduce the risk from inhalation exposure, responders should conduct initial patient assessment from 6 feet away, or the doorway if possible. If an infectious disease is suspected, donning a respirator effective against COVID-19 is paramount. Consider minimizing the number of responders involved with specific patients to extend respirator supplies.

Filtering Facepiece Respirators (FFRs)

- The minimum level of respiratory protection is an N95 filtering facepiece respirator that is certified and approved by the National Institute for Occupational Safety and Health (NIOSH) per specific filtration efficiency and other requirements.
    - These respirators offer a better faceseal through the use of two straps and are rated to block 95% of the particulates that have an average size of 0.3 microns. In comparison, cough aerosols can have a diameter of 0.35 to 10 microns in size [1]. Measured average droplet sizes for sneezes are generally larger but can involve larger volumes of expelled aerosol [2].
- Improved respiratory protection is offered by wearing NIOSH-approved P100 filtering facepiece respirators, which offer a better faceseal on the wearer's face compared to N95 respirators by incorporating adjustable straps and are rated to provide a filtration efficiency of 99.97% against sodium chloride particulates with an average size of 0.3 microns. Tests of these respirators against viral surrogates (of much smaller size) have shown this same level of effectiveness or better [3].

Reusable Air Purifying Respirators (APRs) and Powered Air Purifying Respirators (PAPRs)

- P100 level protection can also be provided by reusable elastomeric facepieces (air-purifying respirators or APRs) that use P100 filters, cartridges, or canisters. These types of respirators provide a higher protection factor because they allow better sealing of the respirators to the individual wearer's face. The P100 filters or cartridges also provide the same level of filtration performance described above for P100 filtering facepiece respirators but allow for replacement of the filters and cartridges as needed.

  - During standard operations, APR and PAPR canisters must be used in their NIOSH-approved configuration. This means that you can not interchange one manufacturer's filters with another's masks.
  - There is no defined service life for P100 filters or cartridges. The length of time these filters or cartridges can remain effective is dependent on the level of exposure, levels of other ambient particles that may be present, and their design (open versus housed filters). Typically, particulate filtering media is changed when there is a noticeable increase in breathing resistance.
    - The filters or cartridges should be stored according to manufacturers' directions when not in use.
  - There are many types of cartridges that incorporate P100 filtering capabilities but are combined with chemical adsorption capabilities. A common form of this type is a combined organic vapor/acid gas cartridge that is coupled or integrated with a P100 pre-filter. Similarly, a Cap-1 canister used for CBRN respirators provides P100 capabilities. However, both types of products are relatively expensive, much heavier than P100 filters alone, and can adsorb humidity or environmental non-hazardous contaminants leading to short service life.
    - The filters or cartridges should be stored according to manufacturers' directions and in a humidity-free container when not in use.
- PAPRs are another option that use the same types of canisters and cartridges and may either be connected to a reusable elastomeric facepiece or combined with a hood. In either case, a blower pulls air through the cartridges or canisters to provide filtered air. Hoods used with PAPRs are generally constructed of disposable materials that need to be replaced.
  - Do not use a PAPR that requires multiple canisters with a canister missing. This will blow unfiltered air into the user's face and increase the risk of inhalation exposure to the wearer.
- Do not interchange canisters between APRs and PAPRs.
  - When using a PAPR canister on an APR, air flow may be restricted which could result in increased breathing resistance.
  - When using an APR canister on a PAPR, the service life of the canister would be reduced and the flow rate could exceed the canisters capacity creating tunneling through the adsorbant material.
- Reusable respirators require specific cleaning and sanitization when reused or shared among different first responders.
  - The plastic casings on the filters should be wiped, not sprayed, with an EPA-registered disinfectant. EPA-registered disinfectants can be found at: https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2.

PHASE 2 (WHEN RESPIRATOR SUPPLIES ARE LOW)

The ability to reuse or extend the life of these respirators must be balanced carefully with the risks. Therefore, a written plan should be utilized to ensure compliance and to demonstrate that the risks have been properly evaluated and minimized.

(1) Utilize the emergency provision for canister interchangeability. This decision must be made by the Authority Having Jurisdiction (AHJ). The design of APRs enables the interchangeable exchange of like canisters by standardizing the design requirements for the mechanical connector external threads, canister internal threads, and connector gasket of the respirator.
   - Requires more frequent inspection of the connector gasket.
   - If threads are cut, dented, or fractured, dispose of the canister.
   - Section 3e from https://www.cdc.gov/niosh/npptl/guidancedocs/interapr070805.html.

(2) Consider reusing your approved respiratory protection (i.e., use in a non-approved manner). In order to do this, everyone should still have their own facemask of filter. It should be stored according to the manufacturer's instructions or in a labeled paper bag. Remember, many filters use electret filtration media which is not compatible with storage in plastic bags.
   - N95 respirators are designed for one-time use followed by disposal. During a pandemic, this may not be possible due to limited supply chain options.
     - The CDC provides guidance for extended use and limited reuse of N95 respirators at: https://www.cdc.gov/niosh/topics/hcwcontrols/recommendedguidanceextuse.html.

(3) Recognize that surgical or procedure masks, medical face masks, and many dust masks are not respirators and should not be relied on for protection from inhalation of contaminated aerosols; however, they can be used as a cover over certain types of respirators to extend their service time, but this practice comes at the expense of increased breathing resistance [4].

(4) Procure masks that are certified by the NIOSH-equivalent agencies in other countries.
   - NIOSH evaluations for representative models of USA and European facepieces using much smaller aerosol particles in the range of 30 to 60 nanometers (1/10 the size used in normal testing; more in line with viral particles) showed percentages of penetrating particles as <4.28%, for N95, <2.22% for FFP2, <0.009% for P100, and <0.164% for FFP3 respirator models [5].

Country	Performance Standard	Acceptable Product Classifications	Standards/ Guidance Documents	Protection Factor ≥ 10
USA	**NIOSH approved; 42 CFR 84**	**N100, P100, R100 N99, P99, R99 N95, P95, R95**	**OSHA 29CFR1910.134**	**Yes**
Australia	AS/NZS 1716:2012	P3 P2	AS/NZS 1715:2009	Yes
Brazil	ABNT/NBR 13698:2011	PFF3 PFF2	Fundacentro CDU 614.894	Yes
Europe	EN 149-2001	FFP3 FFP2	EN 529:2005	Yes
Japan	JMHLW-2000	DS/DL3 DS/DL2	JIS T8510:2006	Yes
Korea	KMOEL-2017-64	Special 1st	KOSHA Guide H-82-2015	Yes
Mexico	NOM-116-2009	N100, P100, R100 N99, P99, R99 N95, P95, R95	NOM-116	Yes

(5) Use masks beyond the "expiration date".

- The service life of filters is limited by hygiene, damage, and breathing resistance. All filters should be replaced when soiled, damaged, or when causing increased operator discomfort.
- Mask components such as straps and nose bridge material should be inspected for any signs of degradation which may affect the quality of fit and seal.
- NIOSH recently performed an evaluation of N95 filtering facepiece respirators that were outdated but stored within the PPE stockpile. During the study, they evaluated 3971 FFPs for inhalation/exhalation resistance and filtration performance according against the NIOSH standard test procedures. Of those FFPs tested, 86.5% still met the N95 protection levels [6].

(6) Prioritize protection by exposure risk.

Risk	Details	Minimum Respiratory Protection
Low	Greater than 6' from patient	No mask
Mid	3' – 6' from symptomatic patient	Surgical mask
High	Direct contact with patient, within 3' of patient, or in space where an activity that could release aerosol (intubation, suction, etc.) is occurring	N95 (high performing FFPs are also warranted)

PHASE 3 (WHEN RESPIRATOR SUPPLIES ARE DEPLETED)

When N95 respirators are so limited that routine practices are no longer possible, the following approaches can be utilized following an appropriate risk assessment performed by the authority having jurisdiction (AHJ):

(1) Surgical or procedure masks, medical face masks, and many dust masks are not respirators and should not be relied on for protection from inhalation of contaminated aerosols.
- If these types of products are the only type of face covering available, then priority should be given to those medical face masks that at least meet the Level 2 or Level 3 requirements of ASTM F2100 [7].
    - Priority order: ASTM F2100 Level 3 > ASTM F2100 Level 2 > ASTM F2100 Level 1 > Surgical molded utility mask > Utility mask. This is based upon the masks' resistance to synthetic blood, bacterial filtration efficiency (1 – 5 microns), and particulate filtration efficiency (0.1 – 10 microns).

(2) The NIOSH respirator certification process does not currently include provisions for decontamination and reuse of FFPs. On 04 April 2020, the CDC released guidance on the *Decontamination and Reuse of Filtering Facepiece Respirators using Contingency and Crisis Capability Strategies* [10]. This document is available at: https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/decontamination-reuse-respirators.html. The below table is an excerpt from the CDC/guidance:

Method	Treatment level	FFR filtration performance	FFR fit performance	Other observations
Vaporous hydrogen peroxide (VHP)	**Battelle**: Bioquell Clarus C HPV generator. The HPV cycle included a 10 min conditioning phase, 20 min gassing phase at 2 g/min, 150 min dwell phase at 0.5 g/min, and 300 min of aeration. *[NOTE: FDA approved on 28 March 2020]*	Passed	FFR fit was shown to be unaffected for up to 20 VHP treatment	Degradation of straps after 30 cycles

	Bergman et al.: Room Bio-Decontamination Services (RBDS, Bioquell UK Ltd) which utilizes four portable modules: the Clarus R HPV generator (utilizing 30% H2O2), the Clarus R20 aeration unit, an instrumentation module, and control computer. Room concentration = 8 g/m^3, 15 min dwell time, 125 min total cycle time.		cycles using a head form	
Ultraviolet germicidal irradiation (UGVI)	0.5-950 J/cm^2	Passed	90-100% passing rate after 3 cycles depending on model	n/a
Microwave generated steam	100-1250W microwave models (range from 40 sec to 2 min)	All models passed filtration evaluation for 1 or 20 treatment cycles as per test	95-100% passing rate after 3 and 20 cycles for all models tested	n/a

Please remember that this guidance is for when N95 respirators are no longer available and should not be used as standard care. Any breathing discomfort by the wearer, noticeable material degradation, or inability to pass a user seal check should be considered as the indicator for end of service life for the respective mask.

(3) When all other methods fail, and there are no forms of protection remaining, then the use of homemade products can be considered but should be carefully monitored through the careful inspection of "cleaned" FFPs to ensure no damage is present.

- Research has demonstrated that common fabric materials may provide marginal protection against virus-size particles in exhaled breath (e.g., T-shirt, bandana materials). The tested materials allowed 40 – 90% instantaneous penetration levels when challenged at the NIOSH N95 challenge levels, whereas the N95 filter media control allowed 0.12% [5].
- While the protection factors derived from common fabric materials are similar to those found in surgical masks, the fabrics are not tested for protection against droplets and liquid splashes [9]. Therefore, any use of common fabric materials should be combined with the use of a reusable (and cleanable) faceshield to minimize any direct spray of droplets to the filter material and, hopefully, minimize overall viral load to which the wearer is exposed.

REFERENCES

[1] Lindsley, W. G., Pearce, T. A., Hudnall, J. B., Davis, K. A., Davis, S. M., Fisher, M. A., ... & Coffey, C. C. (2012). Quantity and size distribution of cough-generated aerosol particles produced by influenza patients during and after illness. *Journal of occupational and environmental hygiene*, 9(7), 443-449.
[2] Han, Z. Y., Weng, W. G., & Huang, Q. Y. (2013). Characterizations of particle size distribution of the droplets exhaled by sneeze. *Journal of the Royal Society Interface*, 10(88), 20130560.

[3] Eninger, R. M., Honda, T., Adhikari, A., Heinonen-Tanski, H., Reponen, T., & Grinshpun, S. A. (2008). Filter performance of N99 and N95 facepiece respirators against viruses and ultrafine particles. *Ann. Occup. Hyg*., 52(5), 385-396.
[4] Roberge, R. J. (2008). Effect of surgical masks worn concurrently over N95 filtering facepiece respirators: extended service life versus increased user burden. *Journal of Public Health Management and Practice*, 14(2), E19-E26.
[5] Rengasamy, S., Eimer, B. C., & Shaffer, R. E. (2009). Comparison of nanoparticle filtration performance of NIOSH-approved and CE-marked particulate filtering facepiece respirators. *Ann. Occup. Hyg., 53*(2), 117-128.
[6] Greenawald, L., Moore, S.M., Yorio, P.L., & Wizner, K. (2020). PPE CASE Personal Protective Equipment Conformity Assessment Studies and Evaluations Performance of Stockpiled Air-Purifying Respirators, Facility One of Ten: Inhalation and Exhalation Resistance and Filtration Efficiency Performance. Report. Technical Report, Centers for Disease Control and Prevention.
[7] ASTM International, ASTM Subcommittee F23.40. (2019). Standard Specification for Performance of Materials Used in Medical Face Masks (ASTM F2100-19).
[8] Viscusi, D. J., Bergman, M., Sinkule, E., & Shaffer, R. E. (2009). Evaluation of the filtration performance of 21 N95 filtering face piece respirators after prolonged storage. *American journal of infection control*, 37(5), 381-38.
[9] Rengasamy, S., Eimer, B., and Shaffer, R. (2010) Simple Respiratory Protection – Evaluation of the Filtration Performance of Cloth Masks and Common Fabric Materials Against 20-1000 nm Size Particles. Ann. Occup. Hyg., 54(7), 789-798.
[10] Decontamination and Reuse of Filtering Facepiece Respirators using Contingency and Crisis Capacity Strategies. https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/decontamination-reuse-respirators.html. Accessed 4/1/2020.