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[COVID-19] Strategies for Addressing Expected or Known N95 Respirator Shortages [ECRI Exclusive Hazard Report] [Update]		

Summary

Update Reason: ECRI updates recommendations.

Problem

1. The coronavirus disease (COVID-19) patient surge has contributed to a worldwide shortage of N95 respirators.
2. WHO and CDC report that airborne transmission of SARS-CoV-2 virus is possible during aerosol-generating procedures (e.g., manual ventilation before intubation, cardiopulmonary resuscitation) (1) and when a COVID-19 patient coughs, sneezes, talks, or breathes (2).
3. Respirators are used to protect healthcare personnel (HCP) from airborne pathogen exposure; single-use N95 filtering facepiece respirators (FFRs) are the most common type of respirator used in healthcare.
4. Increased N95 FFR use during the COVID-19 patient surge will likely exceed the available supply, resulting in shortages at many healthcare facilities.
5. A respirator shortage may lead to HCP exposure to SARS-CoV-2 virus during the COVID-19 pandemic.

ECRI Recommendations:

ECRI recommends that facilities immediately:

1. Inventory the following products if they are available in your facility. Keep a separate inventory for products that have expired (i.e., NIOSH-approved products that have exceeded the manufacturer-specified shelf life, are not damaged, and have been held in accordance with manufacturers' storage conditions) (3).
 1. N95 FFRs
 2. Other FFRs, such as N99, N100, R95, R99, R100, P95, P99, and P100
 3. Cartridges for elastomeric respirators (e.g., N95, N99, N100)
 4. Surgical N95 respirators
2. Inventory all elastomeric half-mask respirators, elastomeric full facepiece respirators, and powered air-purifying respirators (PAPRs) that are present in your facility and have passed visual inspection.
3. Place all respirators in secure, monitored sites that are accessible in case of emergent clinician need (e.g., rooms with keypad or badge entry).
4. Minimize the number of individuals who need to use respiratory protection through the use of engineering and administrative controls (4,5).
5. As needed, provide HCP with education, hands-on training, and competency assessment of:
 1. Isolation precautions and personal protective equipment (PPE) requirements for their job responsibilities
 2. PPE donning and doffing

For facilities that have N95 FFRs, ECRI recommends the following:

1. Follow Standard Precautions during routine care of known or suspected COVID-19 patients (6,7).
 1. HCP should use a respirator (i.e., N95 FFR, N95-equivalent respirator, or higher-level respirator), eye protection (i.e., goggles or a face shield), isolation gown and gloves as PPE (6).
 1. CDC adds that respirators should be prioritized for situations in which respiratory protection is most important, such as during aerosol-generating procedures (AGPs).
 2. When a respirator is not available, HCP should use a facemask, eye protection, isolation gown and gloves as PPE (6).
 3. FFRs, facemasks, and other disposable PPE should not be shared by multiple HCP.

For facilities that have N95 FFRs, ECRI recommends that Infection Prevention and Control staff:

1. Use the CDC's [Personal Protective Equipment \(PPE\) Burn Rate Calculator](#) to determine when your facility's inventory of respirators will be depleted (8).
2. Share the calculator findings with local, state, or federal public health officials, appropriate state agencies that are managing the overall COVID-19 emergency response, state crisis standards of care committees, or other relevant public health organizations.
3. Inquire about respirator resupply via local, state, or federal stockpiles.

For facilities that have N95 FFRs, ECRI recommends that Procurement staff:

1. Continue attempts to source respirators, including FFRs, surgical N95 respirators, elastomeric respirators, and PAPRs.
2. Links to NIOSH-approved respirators that include vendor website and contact information are provided below.

1. FFRs:
 1. [N95 FFRs](#)
 2. [N99 FFRs](#)
 3. [N100 FFRs](#)
 4. [R95 FFRs](#)
 5. [P95 FFRs](#)
 6. [P99 FFRs](#)
 7. [P100 FFRs](#)
2. [Surgical N95 Respirators](#)
3. Elastomeric respirators:
 1. [N95 Elastomeric Half-Mask Respirators](#)
 2. [N99 Elastomeric Half-Mask Respirators](#)
 3. [N100 Elastomeric Half-Mask Respirators](#)
 4. [R95 Elastomeric Half-Mask Respirators](#)
 5. [R99 Elastomeric Half-Mask Respirators](#)
 6. [P95 Elastomeric Half-Mask Respirators](#)
 7. [P100 Elastomeric Half-Mask Respirators](#)
 8. [N95 Elastomeric Full Facepiece Respirators](#)
 9. [N99 Elastomeric Full Facepiece Respirators](#)
 10. [R95 Elastomeric Full Facepiece Respirators](#)
 11. [P95 Elastomeric Full Facepiece Respirators](#)
 12. [P100 Elastomeric Full Facepiece Respirators](#)
4. PAPRs:
 1. [HEPA PAPR with Full Facepiece](#)
 2. [HEPA PAPR with Half-Mask Facepiece](#)
 3. [HEPA PAPR with Helmet](#)
 4. [HEPA PAPR with Hood](#)

For facilities that have N95 FFRs and have not altered routine care practices, ECRI recommends that frontline HCP:

1. Follow the CDC's Conventional Capacity Strategies for Optimizing the Supply of N95 Respirators, which include (4):
 1. Perform AGPs on known or suspected COVID-19 patients in airborne infection isolation rooms (AIIRs), if possible. Limit visitors to those that are essential for patients' physical or emotional care (e.g., parent).
 2. Cohort patients. Group patients together who are infected with the same organism to confine their care to one area.
 3. Cohort HCPs. Designate HCPs to provide care for all patients with suspected or confirmed COVID-19 (e.g., physicians, nurses, Environmental Services staff).
 4. Use alternatives to N95 FFRs such as other FFRs, elastomeric half-mask respirators, elastomeric full facepiece respirators, and PAPRs.

For facilities that have an expected shortage of N95 FFRs, ECRI recommends that frontline HCP:

1. Refer to the CDC's Conventional and Contingency Capacity Strategies for Optimizing the Supply of N95 Respirators (4,10). Contingency capacity strategies include (10):
 1. Discharge suspected or confirmed COVID-19 patients when they are medically stable and have an appropriate home environment in which to return.
 2. Use N95 FFRs that are expired for training and fit testing, if needed. For additional information, see OSHA's temporary enforcement guidance Respiratory Protection Annual Fit-Testing for N95 Filtering Facepieces in All Industries During the COVID-19 Outbreak (11).
 3. Extended use of N95 FFRs:
 1. Extended use is the practice of wearing the same N95 FFR for repeated close contact encounters with several cohorted patients, without removing the respirator between patient encounters (5).
 2. For extended N95 FFR use, NIOSH recommends (5):
 1. Perform hand hygiene with soap and water or an alcohol-based hand sanitizer before and after touching or adjusting the respirator (if necessary for comfort or to maintain fit).
 2. Follow the manufacturer's instructions for use, including conducting a user seal check.
 3. Discard N95 respirators following use during aerosol generating procedures.
 4. Discard N95 respirators contaminated with blood, respiratory or nasal secretions, or other bodily fluids from patients.
 5. Discard any respirator that is obviously damaged or becomes hard to breathe through.
 6. Consider the use of a facemask or cleanable face shield over an N95 respirator and/or other steps (e.g., masking patients, use of engineering controls) to reduce surface contamination.

For facilities that have a known shortage of N95 FFRs, ECRI recommends that frontline HCP:

1. Refer to CDC's Flowchart to Determine if an N95 FFR Crisis Capacity Strategy Is Needed (12):
 1. If the answer to any scenario is "yes," crisis capacity strategies are not needed. Refer to the above strategies.
 2. If the answer to any scenario is "no," refer to the CDC's Conventional, Contingency, and Crisis/Alternate Capacity Strategies for Optimizing the Supply of N95 Respirators (4,10,13). Crisis capacity strategies include (13):
 1. Use expired N95 FFRs for healthcare delivery. FDA authorized the use of expired FFRs on March 28, 2020 (3).
 2. Use imported, non NIOSH-approved FFRs that are similar to NIOSH-approved FFRs.
 1. For sourcing non-NIOSH-approved FFRs, see NIOSH's guidance to help identify counterfeit respirators (9) and ECRI's report [Use of Imported N95-Style Masks, without NIOSH Certification or Independent Lab Validation, May Put Healthcare Workers and Patients at Risk during the COVID-19 Pandemic](#).
 2. FDA authorized the use of non-NIOSH approved FFRs manufactured according to the standards in Chart 1 below (14).
 1. [List of authorized imported, non-NIOSH approved FFRs that meet the above standards](#) (15).
 3. FDA authorized the use of some non-NIOSH approved FFRs manufactured in China (16):
 1. [List of authorized imported, non-NIOSH approved FFRs manufactured in China](#) (17)
 2. [List of unauthorized Chinese FFRs](#) (18)
 3. Limited re-use of N95 FFRs.
 1. Re-use refers to the practice of using the same N95 respirator for multiple encounters with patients, but removing it after each encounter.
 1. The respirator is stored in between encounters to be put on again before the next encounter with a patient (5).

2. FFR performance will decrease as the number of hours and number of donnings and doffings increase (12).
2. For N95 FFR re-use without FFR decontamination between uses, NIOSH recommends the following (5):
 1. Follow previous recommendations for extended use of N95 FFRs.
 2. Follow the manufacturer's maximum number of donnings (or up to five times if the manufacturer does not provide a recommendation) and recommended inspection procedures.
 3. Avoid touching the inside of the respirator. If inadvertent contact is made with the inside of the respirator, discard the respirator and perform hand hygiene.
 4. Hang used respirators in a designated storage area or keep them in a clean, breathable container such as a paper bag between uses so that they do not become damaged or deformed. To minimize potential cross-contamination, store respirators so that they do not touch each other and the person using the respirator is clearly identified. Paper bag storage containers should be disposed of after use.
 5. If available, use a pair of clean (nonsterile) gloves when donning a used N95 respirator and performing a user seal check. Discard gloves after the N95 FFR is donned and any adjustments are made to ensure the respirator is sitting comfortably on your face with a good seal.
 3. For N95 FFR re-use with FFR decontamination between uses, consider the following (12):
 1. Decontamination should be performed only on NIOSH-approved FFRs without exhalation valves.
 2. Decontamination will not increase the number of times (up to five) that an FFR can be worn.
 3. Ultraviolet (UV) light, hydrogen peroxide vapor, and moist heat have shown the most promise as potential methods of FFR decontamination:
 1. FDA has authorized several [Decontamination Systems for Personal Protective Equipment](#) during the COVID-19 public health emergency.
 2. For information on UV light decontamination, see ECRI's report: [Decontamination of N95 Respirators: UV Light May Be Considered for Limited Re-use Situation](#).
 4. Plan to follow the decontamination system manufacturer's instructions for FFR decontamination
 5. Establish methods for:
 1. Tracking decontamination cycles of each FFR
 2. Monitoring potential adverse effects of FFR decontamination (e.g., skin irritation, headaches, respiratory distress)
 4. Use expired N95 FFRs that have not been evaluated by NIOSH for healthcare delivery (13).
 5. Prioritize the use of N95 FFRs and facemasks by activity type. CDC provides a table of suggested facemask or respirator use, based upon distance from a patient with suspected or known COVID-19 (13). See Chart 2 below.
 6. As soon as new supplies can meet the projected demand, all crisis capacity strategies, including FFR re-use and decontamination, should be discontinued (12).

For facilities that have zero N95 FFRs, ECRI recommends that frontline HCP:

1. Exclude HCP at a higher risk for severe illness (i.e., those of older age, those with chronic medical conditions, those who may be pregnant) from contact with known or suspected COVID-19 patients (13).
2. Use an expedient patient isolation room for risk-reduction. For additional information, see NIOSH's report "Expedient Methods for Surge Airborne Isolation within Healthcare Settings during Response to a Natural or Manmade Epidemic" (19).
3. Use a ventilated headboard to decrease the risk of HCP exposure to patient-generated aerosols (19).
4. When no respirators or facemasks are available, use clean, dry cloth masks (20).
 1. Cloth masks should be used with a faceshield that covers the entire front (that extends to the chin or below) and sides of the face.
 2. Cloth masks are not considered PPE because their ability to protect HCP is unknown.

Country	Performance Standard	Acceptable product classifications	Standards/Guidance Documents	Assigned Protection Factor ≥ 10
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 T8150: 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
US NIOSH Requirements	NIOSH approved 42 CFR 84	N100, P100, R100, N99, P99, R99, N95, P95, R95	OSHA 29CFR1910.134	Yes

Chart 1

HCP planned proximity to the patient during encounter	Facemask or respirator needed?	
	Patient is wearing a facemask for the entire encounter	Patient is not wearing a facemask or their mask needs to be removed for any period of time during the encounter

HCP will remain at greater than 6 feet from a symptomatic patient	Facemask required if HCP must enter the patient care area	Facemask required if HCP must enter the patient care area
HCP will be within 6 feet of a symptomatic patient, including providing direct patient care	Facemask required	N95 FFR/elastomeric respirator/PAPR, based on availability
HCP will be present in the room during aerosol generating procedures	N95 FFR/elastomeric respirator/PAPR, based on availability	N95 FFR/elastomeric respirator/PAPR, based on availability
Note: Based on availability, organizations may require and/or individuals may voluntarily choose to utilize higher levels of protection.		

Chart 2

Background:

1. To help address PPE shortages during the COVID-19 pandemic, FDA has issued Emergency Use Authorization (EUA) for certain PPE products, including FFRs (21).
2. Airborne transmission of SARS-CoV-2 virus is possible.
 1. It is possible that COVID-19 may spread through the droplet and airborne aerosols that are formed when a person who has COVID-19 coughs, sneezes, sings, talks, or breathes. There is growing evidence that droplets and airborne particles can remain suspended in the air and be breathed in by others, and travel distances beyond six feet (2).
 2. Some procedures performed on known or suspected COVID-19 patients could generate infectious aerosols, such as sputum induction, open suctioning of airways, and manual ventilation (22). AGPs should be performed cautiously and avoided if possible (6).
 3. If AGPs are performed, the following should occur (6):
 1. HCP in the room should wear an N95 FFR, N95-equivalent respirator, or higher-level respirator, eye protection, gloves, and a gown.
 2. The number of HCP present during the procedure should be limited to only those essential for patient care and procedure support.
 3. AGPs should take place in an AIIR if possible.
 4. Clean and disinfect procedure room surfaces promptly.
3. An October 22 through November 5, 2020, APIC survey with 1,083 U.S. infection preventionists responding about implementing PPE crisis standards of care (i.e., decontamination, extended use, or re-use) at any time during the COVID-19 pandemic revealed the following (23):
 1. 73% of respondent's facilities implemented crisis standards of care for respirators.
 2. 68.7% of respondent's facilities implemented crisis standards of care for facemasks.
 3. 75.8% of respondent's facilities implemented crisis standards of care for eye protection.
 4. 43.8% of respondent's facilities implemented crisis standards of care for isolation gowns.
 5. 10.1% of respondent's facilities implemented crisis standards of care for gloves.
4. ECRI has provided guidance for optimizing available PPE supplies, addressing PPE shortages, and implementing temporary airborne isolation methods:
 1. [Strategies to Conserve Existing Supplies of Personal Protective Equipment](#)
 2. [Guidance for Temporary Airborne Isolation of COVID-19 Patients Undergoing Aerosol-Generating Procedures](#)
 3. [Strategies for Addressing Expected or Known Facemask Shortages](#)
 4. [Strategies for Addressing Expected or Known Eye Protection Shortages](#)
 5. [Strategies to Combat Inadequate Supplies of Isolation Gowns](#)
 6. [Strategies for Addressing Expected or Known Shortages of Powered Air-Purifying Respirators and Accessories](#)
 7. [Strategies for Addressing Expected Glove Shortages](#)

8. [Strategies for the Use of Homemade Facemasks](#)

UMDNS Term(s)

Respirators, Air-Purifying, Particulate [20359]

Geographic Region(s)

Worldwide

Suggested Distribution

Anesthesia, Cardiology/Cardiac Catheterization Laboratory, Clinical/Biomedical Engineering, Clinical Laboratory/Pathology, Critical Care, Dialysis/Nephrology, Emergency/Outpatient Services, Infection Control, Nursery, Nursing, Obstetrics/Gynecology/Labor and Delivery, Oncology, OR/Surgery, Orthopedics, Pediatrics, Pulmonology/Respiratory Therapy, Diagnostic Imaging, Risk Management/Continuous Quality Improvement, Facilities/Building Management, Home Care, Gastroenterology, Dentistry/Oral Surgery, Ophthalmology, Phlebotomy, Physical Therapy/Rehabilitation, Internal Medicine, Dermatology, Otolaryngology, Point-of-Care Coordination, Sleep Laboratory, Vascular Laboratory, Pain Clinic, Staff Education, NICU, EMS/Transport, Perfusion, Pharmacy, IV Therapy, Central Sterilization Reprocessing, Materials Management

Comment

- This alert is a living document and may be updated when ECRI receives additional information.

Miscellaneous

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