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

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 may be possible during aerosol-generating procedures (e.g., manual ventilation before intubation, cardiopulmonary resuscitation) (1,2).
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. Minimize the number of individuals who need to use respiratory protection through the use of engineering and administrative controls (4).

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

1. Use appropriate precautions when caring for known or suspected COVID-19 patients.
 1. WHO recommends that HCP follow droplet and contact precautions during routine care of COVID-19 patients (1).
 1. HCP should use a facemask, eye protection (i.e., goggles, face shield), isolation gown, and gloves as personal protective equipment (PPE) (2).
 2. WHO recommends that HCP follow contact and airborne precautions during aerosol-generating procedures (AGPs) (1). CDC adds that respirators should be prioritized for situations in which respiratory protection is most important and the care of patients with pathogens requiring airborne precautions (e.g., tuberculosis, measles, varicella) (2).
 1. HCP should use a N95 FFR, eye protection, isolation gown, and gloves as PPE (2).

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

1. Use the CDC's [Personal Protective Equipment \(PPE\) Burn Rate Calculator](#) to determine when your facility's inventory of respirators will be depleted (5).
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 do the following:

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](#)
3. For non-NIOSH-approved respirators, ECRI recommends that you check FDA's Establishment Registration & Device Listing to verify that a vendor is registered with the FDA as a respirator manufacturer (6).

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

1. Follow the CDC's Conventional Capacity Strategies for optimizing the supply of N95 respirators, which include (7):
 1. Perform AGPs on known or suspected COVID-19 patients in airborne infection isolation rooms (AIIRs). Exclude visitors to these patients.
 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 N95 FFRs and have changed routine care practices, ECRI recommends that frontline HCP do the following:

1. Refer to the CDC's Conventional and Contingency Capacity Strategies for optimizing the supply of N95 respirators (7). Contingency capacity strategies include (7):
 1. Decrease the length of hospital stay for medically stable COVID-19 patients.

2. Temporarily suspend annual N95 FFR fit testing. For additional information, see OSHA's temporary enforcement guidance Healthcare Respiratory Protection Annual Fit-Testing for N95 Filtering Facepieces During the COVID-19 Outbreak (8).
3. Use expired N95 FFRs for HCP training, if needed.
4. 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 (4).
 2. For extended N95 FFR use, NIOSH recommends the following (4):
 1. Follow the manufacturer's instructions for use, including conducting a user seal check.
 2. Discard N95 respirators following use during aerosol generating procedures.
 3. Discard N95 respirators contaminated with blood, respiratory or nasal secretions, or other bodily fluids from patients.
 4. Discard N95 respirators after close contact with, or exit from, the care area of any patient co-infected with an infectious disease requiring contact precautions (e.g., norovirus, *Clostridioides difficile*). Discard any respirator that is obviously damaged or becomes hard to breathe through.
 5. Consider the use of a cleanable face shield over an N95 respirator and/or other steps (e.g., masking patients, use of engineering controls) to reduce surface contamination.
 6. 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).

For facilities that have a low supply of N95 FFRs, ECRI recommends that frontline HCP do the following:

1. Refer to the CDC's Conventional, Contingency, and Crisis Capacity Strategies for optimizing the supply of N95 respirators (7). Crisis capacity strategies include (7) the following:
 1. Use expired N95 FFRs for healthcare delivery. FDA approved the use of expired FFRs on March 28, 2020 (3).
 2. Use imported, non NIOSH-approved FFRs that are similar to NIOSH-approved FFRs:

Country	Performance Standard	Acceptable Product Classification	Substitute for NIOSH-approved products classified as
Australia	AS/NZS 1716:2012	P2	N95
		P3	N99 or lower
Brazil	ABNT/NBR 13698:2011	PFF2	N95
		PFF3	N99 or lower
People's Republic of China	GB 2626-2006 GB 2626-2019	KN/KP95	N95
		KN/KP100	N95
Europe	EN 149-2001	P2	N95
		P3	N99 or lower
Japan	JMHLW-2000	DS/DL2	N95
		DS/DL3	N99 or lower
Korea	KMOEL-2017-64	Special 1st	N95
Mexico	NOM-116-2009	N95	N95
		R95	R95 or lower
		P95	P95 or lower
		N99	N99 or lower
		R99	R99 or lower
		P99	P99 or lower
		N100	N100 or lower
		R100	R100 or lower
		P100	P100 or lower

- On April 6, 2020, FDA authorized the use of the following non NIOSH-approved respirators manufactured in China (9):

Manufacturer	Respirator Model(s)	Country of Manufacture
Bei Bei Safety Co Ltd.	B702, B702V, B704, B704V	China
BYD Precision Manufacture Co. Ltd.	BYD KN95 Particulate Respirator (Model Number: DG3101)	China
Fujian Kang Chen Daily Necessities Co, Ltd.	K0450, 57793	China
Weini Technology Development Co., Ltd	FFP2 NR E-300, FFP2 NR E-680, FFP2 NR 952, FFP2 NR F-820	China

- On March 28, 2020, FDA approved the use of disposable FFRs that have marketing authorization in the following regulatory jurisdictions (10):
 1. European CE Mark
 2. Australian Register of Therapeutic Goods (ARTG) Certificate of Inclusion
 3. Health Canada Licence
 4. Japan Pharmaceuticals and Medical Device (PMDA)/Ministry of Health Labour and Welfare (MHLW)

- Use imported, non NIOSH-approved respirator cartridges that are similar to NIOSH-approved elastomeric respirator cartridges:

Country	Performance Standard	Acceptable Product Classification	Substitute for NIOSH-approved products classified as
Australia	AS/NZS 1716:2012	P2	N95
		P3	N99 or lower
Brazil	ABNT/NBR 13694:1996; ABNT/NBR 13697:1996	P2	N95
		P3	N99 or lower
People's Republic of China	GB 2626-2006; GB 2626-2019	KN/KP95	N95
		KN/KP100	N95
Europe	EN140-1999; EN 143-2000	P2	N95
		P3	N99 or lower
Japan	JMHLW-2000	RS/RL2	N95
		RS/RL3	N99 or lower
Korea	KMOEL-2014-46	Special 1st	N95
Mexico	NOM-116-2009	N95	N95
		R95	R95 or lower
		P95	P95 or lower
		N99	N99 or lower
		R99	R99 or lower
		P99	P99 or lower
		N100	N100 or lower

	R100	R100 or lower
	P100	P100 or lower

• Re-use 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. The respirator is stored in between encounters to be put on again before the next encounter with a patient (4).
2. For N95 FFR re-use without decontamination between uses, NIOSH recommends the following (4):
 1. Follow previous recommendations for extended use of N95 FFRs.
 2. If possible, issue HCP who are expected to perform AGPs on suspected or known COVID-19 patients a minimum of five respirators (7).
 3. Follow the employer's maximum number of donnings (or up to five if the manufacturer does not provide a recommendation) and recommended inspection procedures (4).
 4. 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.
 5. Store used respirators in a clean, breathable 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 ensure that the person using the respirator is clearly identified. The amount of time in between uses should exceed the 72 hour expected survival time of the SARS-CoV2 virus (7). Paper bag storage containers should be disposed of after use.
 6. Use a pair of clean (non-sterile) 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 that the respirator is sitting comfortably on your face with a good seal.
3. For N95 FFR re-use with decontamination between uses, consider the following (11):
 1. If information from the FFR manufacturer or a third-party distributor is available showing that FFRs can be successfully decontaminated without affecting respirator performance, then FFRs that are decontaminated following the recommended procedure can be worn for any patient care activities.
 2. If information is not available or shows that a respirator cannot be decontaminated without negatively affecting the performance, respirators may still be decontaminated. However, given the uncertainties regarding the impact of decontamination on respirator performance, these FFRs should not be worn by HCPs when performing or present for an AGP.
 3. CDC provides a table that summarizes the FFR decontamination recommendations applicable to crisis capacity standards of care (11):

Decontamination method	Available FFR manufacturer or third-party guidance for decontamination procedure	Recommended use after decontamination	Decontaminated FFR user requirements
Ultraviolet (UV) disinfection	Yes	Can be worn for any patient care activities	<ol style="list-style-type: none"> 1. Clean hands with soap and water or an alcohol-based hand sanitizer before and after touching or adjusting the FFR. 2. Avoid touching the inside of the FFR. 3. Use a pair of clean (non-sterile) gloves when donning and performing a user seal check. 4. Visually inspect the FFR to determine if its integrity has been compromised. 5. Check that components such as the straps, nose bridge, and nose foam material did not degrade, which can affect the quality of the fit, and seal.
Vaporized hydrogen peroxide			
Moist heat			

UV disinfection	No	Can be worn for patient care activities except when performing or present for an AGP	<p>6. If the integrity of any part of the FFR is compromised, or if a successful user seal check cannot be performed, discard the FFR and try another FFR.</p> <p>7. Users should perform a user seal check immediately after they don each FFR and should not use a FFR on which they cannot perform a successful user seal check.</p>
Vaporized hydrogen peroxide			
Moist heat			

1. Use expired N95 FFRs identified by CDC as NOT performing adequately for healthcare delivery (12,13).
2. Prioritize the use of N95 FFRs and facemasks by activity type. CDC provides a table of suggested facemask or respirator use, based on distance from a patient with suspected or known COVID-19 (7):

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	No facemask or respirator required	No facemask or respirator required
HCP will be within 3 to 6 feet of a symptomatic patient	Facemask required	Facemask required
HCP will be within 3 feet of 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 AGPs performed on symptomatic persons	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.		

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

1. Exclude HCP at 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 (7,12).
2. Designate convalescent HCP (i.e., those who have clinically recovered from COVID-19 and may have some protective immunity) to preferentially provide care to known or suspected COVID-19 patients (7,12).
3. 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" (14).
4. Use a ventilated headboard to decrease the risk of HCP exposure to patient-generated aerosols (14).
5. As a last resort, use homemade masks (15).

1. Homemade masks should be used with faceshields that cover the entire front (that extends to the chin or below) and sides of the face.

2. Homemade masks are not considered PPE because their ability to protect HCP is unknown (15).

Background:

1. FDA's March 11, 2020, EUA Clarification Letter on Respirators states: "As a result of the Public Health Emergency associated with COVID-19, there is shortage of FFRs intended for use by healthcare workers and others to mitigate further transmission of COVID-19" (16).
2. WHO and CDC guidance details possible airborne transmission of SARS-CoV-2 virus:
 1. WHO guidance states that airborne transmission (of SARS-CoV-2) may be possible in specific circumstances and settings in which procedures that generate aerosols are performed (i.e. endotracheal intubation, bronchoscopy, open suctioning, administration of nebulized treatment, manual ventilation before intubation, turning the patient to the prone position, disconnecting the patient from the ventilator, non-invasive positive-pressure ventilation, tracheostomy, cardiopulmonary resuscitation) (1).
 2. CDC's guidance states that some procedures performed on known or suspected COVID-19 patients could generate infectious aerosols. In particular, procedures that are likely to induce coughing (e.g., sputum induction, open suctioning of airways) should be performed cautiously and avoided if possible (2).
 3. If performed, the following should occur (2):
 1. HCP in the room should wear an N95 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 ideally take place in an AIIR.
 4. Clean and disinfect procedure room surfaces promptly.
3. A March 27, 2020, survey of US infection preventionists conducted by APIC revealed that (17):
 1. 48.3% of respondent's facilities are almost out of or have zero respirators.
 2. 31.7% of respondent's facilities are almost out of or have zero facemasks.
 3. 49.2% of respondent's facilities are almost out of or have zero faceshields.
 4. 24.5% of respondent's facilities are almost out of or have zero isolation gowns.
4. A recent JAMA article details several approaches for sourcing PPE that may be useful to facilities with dwindling PPE supply (18).

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UMDNS Term(s)

Respirators, Air-Purifying, Particulate [20359]

Geographic Region(s)

Worldwide

Suggested Distribution

Anesthesia, Cardiology/Cardiac Catheterization Laboratory, Clinical/Biomedical Engineering, 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.