[Critical Priority] - H0609 : [COVID-19] Strategies for Addressing Expected or Known Shortages of Powered Air-Purifying Respirators and Accessories [ECRI Exclusive Hazard Report]

Medical Device Hazard Report

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UMDNS Terms:

- Respirators, Air-Purifying, Particulate/Gas/Vapor [20361]
- Filters, Air, Gas/Vapor, Chemical Agent, Mask/Respirator Cartridge [20722]
- Filters, Air, Particulate, Mask/Respirator Cartridge [20717]
- Respirators, Air-Purifying, Particulate [20359]

Geographic Regions: Worldwide

Suggested Distribution: Critical Care, Dialysis/Nephrology, Emergency/Outpatient Services, Infection Control, Nursery, Nursing, Obstetrics/Gynecology/Labor and Delivery, Oncology, Orthopedics, Pediatrics, Pulmonology/Respiratory Therapy, Diagnostic Imaging, Risk Management/Continuous Quality Improvement, Facilities/Building Management, Ophthalmology, Internal Medicine, Otolaryngology, Point-of-Care Coordination, Staff Education, NICU, EMS/Transport, IV Therapy, Central Sterilization Reprocessing, Materials Management

Problem:

1. The COVID-19 patient surge has contributed to a worldwide shortage of powered air-purifying respirators (PAPRs) and PAPR accessories (e.g., filters, breathing tubes, facepieces/helmets/hoods).
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.
4. Increased use of PAPRs and PAPR accessories during the COVID-19 patient surge will likely exceed the available supply, resulting in shortages at many healthcare facilities.
5. The potential consequence of this problem is HCP exposure to SARS-CoV-2 virus during the COVID-19 pandemic.

ECRI Recommendations:

ECRI recommends that facilities immediately:

1. Inventory the following PAPR components that may be present in your facility and have passed visual inspection:
    1. Half- and full-facepieces, helmets, and hoods
    2. Blowers and tubing
    3. High efficiency (HE) filters/filter cartridges
    4. AC power cords, batteries, and battery chargers
    5. Belts
    6. Air flow indicators
2. Keep a stock of spare PAPR batteries.
3. Place all assembled ready-to-use PAPRs in a secure, accessible monitored site.
4. Minimize the number of individuals who need to use respiratory protection through the use of engineering and administrative controls (4).
5. As needed, provide HCP with education, hands-on training, and competency assessment of:
    1. Isolation precautions and PPE requirements for their job responsibilities
    2. Personal protective equipment (PPE) donning and doffing

For facilities that have respirators, ECRI recommends to:

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, faceshield, isolation gown, and gloves as PPE (2,5).
    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 where respiratory protection is most important and for the care of patients with pathogens requiring airborne precautions (e.g., tuberculosis, measles, varicella) (2).
        1. HCP should use a N95 FFR, faceshield, isolation gown, and gloves as PPE (2,6).

For facilities that have respirators, ECRI recommends that Procurement staff:

1. Continue attempts to source respirators, including filtering facepiece respirators (FFRs), surgical N95 respirators, elastomeric respirators, and PAPRs.

1. Links to NIOSH-approved respirators that include vendor website and contact information are provided below:
    1. PAPRs
        1. HEPA PAPR with Full Facepiece
        2. HEPA PAPR with Half-Mask Facepiece
        3. HEPA PAPR with Helmet
        4. HEPA PAPR with Hood
    2. FFRs
        1. N95 FFRs
        2. N99 FFRs
        3. N100 FFRs
        4. R95 FFRs
        5. P95 FFRs
        6. P99 FFRs
        7. P100 FFRs
    3. Surgical N95 Respirators
    4. 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
2. Check FDA's Establishment Registration & Device Listing to verify that a vendor is registered with FDA as a respirator manufacturer (7).

For facilities that have PAPRs and have not altered routine care practices, ECRI recommends that relevant administrators and frontline HCP:

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 HCP designate HCP to provide care for all patients with suspected or confirmed COVID-19 (e.g., physicians, nurses, Environmental Services staff).
4. Follow CDC's Conventional Capacity Strategies for optimizing the supply of PAPRs, which include (3):
    1. Use PAPRs in accordance with OSHA Respiratory Protection Program requirements (8).
        1. Use NIOSH-approved PAPRs.
        2. Follow instructions for use (IFU) of the PAPR facepiece/hood/helmet, blower, breathing tube, battery, and battery charger.
        3. Have a PAPR inspection and preventive maintenance (IPM) program supported by trained staff.
            1. NIOSH-approved devices cannot be modified from the certified configurations.
            2. The manufacturer's NIOSH-approved parts designed for the PAPR must be used for maintenance.
            3. Maintenance and repairs should be performed according to the PAPR IFUs.
    2. Designate and train staff to perform PAPR cleaning and disinfection. Staff should wear appropriate PPE during this work (3).
    3. Clean and disinfect PAPRs that are visibly soiled or removed by HCP:
        1. According to the manufacturer's instructions for cleaning and disinfection using a disinfectant that appears on EPA's List N: Disinfectants for Use Against SARS-CoV-2 , or
        2. According to OSHA and CDC recommendations for products that do not have thorough manufacturer-recommended

cleaning and disinfection instructions (3,9), perform the following:

1. Remove and discard HE filters or filter cartridges.
2. Detach the facepiece/hood/helmet, breathing tube, battery pack, and waist belt from the blower assembly. If a disposable cover was used over the breathing tube, discard the cover.
3. Disassemble components for reprocessing following the PAPR IFU.
4. Inspect and repair or replace damaged components (e.g., facepiece/hood/helmet, breathing tube, blower, belts) according to the PAPR IFU.
5. Do not soak, dip, or immerse PAPR components in cleaning or disinfection solutions unless stated in the PAPR IFU.
6. Thoroughly wipe PAPR components with a clean cloth/wipe/sponge moistened with a warm water (up to 43°C [110°F]) solution of mild pH neutral (pH 6 to 8) detergent or cleaner recommended by the manufacturer.
7. Rinse PAPR components with a clean cloth/wipe/sponge moistened with warm water.
8. Thoroughly wipe PAPR components with a clean cloth/wipe/sponge moistened with a bleach solution (diluted per product label instructions), 70% or greater ethyl alcohol solution, or an EPA List N disinfectant recommended by the manufacturer. Ensure that surfaces remain visibly wet for the contact time specified on the disinfectant label.
9. Rinse PAPR components with a clean cloth/wipe/sponge moistened with warm water.
10. Thoroughly dry PAPR components with clean, lint-free cloths or air dry in an uncontaminated atmosphere with a temperature less than 43°C.
11. Reassemble the PAPR according to the IFU. Replace the HE filter or filter cartridge.
12. Test the PAPR to ensure that all components work properly.
13. Place the assembled ready-to-use PAPR in the appropriate secure, accessible monitored site.

For facilities that have a low supply of PAPRs, ECRI recommends that relevant administrators and frontline HCP:

1. Cancel all elective, non-urgent procedures and appointments for which respiratory protection is typically needed by HCP.
2. Refer to CDC's Conventional, Contingency, and Crisis Capacity Strategies for optimizing the supply of PAPRs (3). Contingency and crisis capacity strategies include (3):
    1. Review and update the facility's Respiratory Protection Program with procedures used during emergencies, including alternative cleaning and disinfection practices.
    2. Use PAPRs with HE filters or filter cartridges that prevent fluid ingress into the filter material.
    3. Implement a practical replacement cycle for HE filters and filter cartridges.
        1. CDC does not recommend a specific replacement cycle for PAPR filters used during COVID-19 patient care (3).
        2. Discard HE filters and filter cartridges that are visibly damaged or have reduced airflow.
    4. When cleaning and disinfecting PAPRs, also clean and disinfect HE filters or filter cartridges that are between replacement cycles. See the above recommendations for cleaning and disinfecting other PAPR components.
        1. Remove HE filters or filter cartridges from PAPRs.
        2. Insect PAPR filters for damage. Discard PAPR filters that fail inspection.
        3. Do not soak, dip, or immerse PAPR filters in fluid. Do not get the filter material wet during cleaning and disinfection.
        4. Thoroughly wipe the outside of the HE filter or filter cartridge with a clean cloth/wipe/sponge moistened with a warm water (up to 43 °C [110 °F]) solution of mild pH neutral (pH 6 to 8) detergent or cleaner recommended by the manufacturer.
        5. Rinse the outside of the HE filter or filter cartridge with a clean cloth/wipe/sponge moistened with warm water.
        6. Thoroughly wipe the outside of the HE filter or filter cartridge with a clean cloth/wipe/sponge moistened with a bleach solution (diluted per product label instructions), 70% or greater ethyl alcohol solution, or an EPA List N disinfectant recommended by the manufacturer. Ensure that surfaces remain visibly wet for the contact time specified on the disinfectant label.
        7. Rinse the outside of the HE filter or filter cartridge with a clean cloth/wipe/sponge moistened with warm water.
        8. Thoroughly dry the outside of HE filters or filter cartridges with clean, lint-free cloths or air dry in an uncontaminated atmosphere with a temperature less than 43°C.
        9. Reassemble the PAPR according to the IFU. Use the reprocessed HE filter or filter cartridge.

For facilities that have zero PAPRs, ECRI recommends that relevant administrators and frontline HCP:

1. See ECRI's Strategies for Addressing Expected or Known N95 Respirator Shortages for additional guidance.

Background:

1. PAPRs use a blower to force air through HE filters or filter cartridges into the breathing zone of the wearer. This process creates an airflow inside either a tight-fitting facepiece or a loose-fitting hood or helmet (3).
2. FDA is aware of challenges throughout the supply chain that are affecting the availability of PPE products and is taking steps to mitigate shortages that healthcare facilities are already experiencing (10).
3. WHO and CDC guidance details possible airborne transmission of SARS-CoV-2 virus:
    1. WHO guidance states: 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: 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. Promptly clean and disinfect procedure room surfaces.
4. A March 27, 2020, survey of U.S. infection preventionists conducted by APIC revealed that (11):
    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.
5. A recent JAMA article details several approaches for sourcing PPE that may be useful to facilities with dwindling PPE supply (12).

References & Source Documents:

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Comments:

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

Source(s):

- 2020 May 12. ECRI Researched Report