[High Priority] - H0617 : [COVID-19] Guidance for Temporary Airborne Isolation of COVID-19 Patients Undergoing Aerosol-Generating Procedures [ECRI Exclusive Hazard Report]

Medical Device Hazard Report

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UMDNS Terms:

- Air Cleaners, Particulate, High-Efficiency Filter [18112]
- Filters, Air, Particulate, High-Efficiency [20715]

Geographic Regions: Worldwide

Suggested Distribution: Cardiology/Cardiac Catheterization Laboratory, Clinical/Biomedical Engineering, Critical Care, Dialysis/Nephrology, Emergency/Outpatient Services, Infection Control, Nursing, Oncology, OR/Surgery, Pediatrics, Pulmonology/Respiratory Therapy, Risk Management/Continuous Quality Improvement, Facilities/Building Management, Point-of-Care Coordination, Staff Education, EMS/Transport, Perfusion, IV Therapy, Materials Management

Problem:

1. The COVID-19 patient surge has exceeded the available airborne infection isolation rooms (AIIRs) in most healthcare facilities; AIIRs are recommended for isolating suspected or confirmed COVID-19 patients during aerosol-generating procedures (AGPs).
2. WHO and CDC report that airborne transmission of the SARS-CoV-2 virus may be possible during AGPs (e.g., manual ventilation before intubation, cardiopulmonary resuscitation) (1,2) in healthcare facilities and during transport to healthcare facilities.
3. AIIRs in healthcare facilities are patient rooms with specific engineering features intended to isolate and more quickly remove infectious aerosols; acute care facilities are required to have at least one AIIR (3).
4. When AIIR capacity is exceeded, CDC and NIOSH recommend the use of temporary airborne patient isolation (e.g., expedient patient isolation rooms, ventilated headboards) to protect healthcare personnel (HCP) from airborne infectious diseases (4,5,6).
5. The potential consequence of this problem is HCP exposure to the SARS-CoV-2 virus during the COVID-19 pandemic.

EMS/Transport Management:

1. Review and update existing policies and procedures to ensure compliance with CDC's current emergency medical services (EMS) COVID-19 guidance, including appropriate use of personal protective equipment (PPE) (7).
2. As needed, provide staff with education, hands-on training, and competency assessment of the following:
    1. Isolation precautions and PPE requirements for their job responsibilities
    2. PPE donning and doffing
3. Before performing a needed AGP on a suspected/confirmed COVID-19 patient, EMS staff should do the following:
    1. Before patient transport, if possible, ensure that the back of the transport vehicle is facing away from pedestrian traffic, open the rear doors of the transport vehicle, and activate the HVAC system if doing so will not contaminate the vehicle.
    2. During patient transport, activate the HVAC system if doing so will not contaminate the vehicle.
4. After patient transport, ensure that the back of the transport vehicle is facing away from pedestrian traffic and open the vehicle doors. Select the highest ventilation setting for the vehicle's HVAC system and operate the system until aerosols have been cleared from the vehicle. See Appendix B. Air of CDC's environmental infection control guidance for additional information.
5. Clean and disinfect surfaces within the transport vehicle according to CDC guidance (7).

Administrators, Infection Prevention and Control Staff, Facilities, Quality, and Risk Management:

1. Ensure that your facility's ventilation/HVAC inspection and preventive maintenance program complies with OSHA requirements (8).
2. Inventory the following items that may be present in your facility:
    1. Portable HEPA filtration units with a non-ducted inlet
    2. Portable negative pressure air machines
    3. Replacement filters (e.g., pre-filters, HEPA filters) for portable units
3. Create a list of rooms within your facility that are used, or are planned to be used, for performing AGPs on suspected/confirmed COVID-19 patients/residents.
    1. For each room that could potentially host AGPs, document:
        1. Room configuration (e.g., single-patient/resident room)
        2. Bed configuration for multi-patient/resident rooms (e.g., side-by-side, across, diagonal)
        3. Location of room HVAC inlet and outlet in reference to patient bed(s)
        4. If the room is an AIIR and how the room is monitored when in use
        5. Approximate frequency of room use

4. For non-AIIRs on your facility's AGP room list:
    1. Determine which method for temporary airborne patient isolation is appropriate.
        1. The COVID-19 Airway Management Isolation Chamber (CAMIC) recently received Emergency Use Authorization (EUA) from FDA for use by HCP in U.S. Army and Military Health Service healthcare settings (9). The chamber consists of a hollow PVC frame and a large, clear plastic bag that is placed over the head, neck, and shoulders of the patient. The CAMIC captures and removes particles emitted from a patient's nose and mouth via flow of medical air, which comes in through holes in the PVC frame on one side and is removed by a vacuum on the other side. The CAMIC is authorized for use with hospital vacuum lines and portable vacuum pumps with in-line HEPA filters (10). ECRI has a concern that it may not be possible to perform some AGPs on confirmed/suspected COVID-19 patients/residents during use of the CAMIC.
        2. Expedient patient isolation rooms are used for single- or two-patient/resident rooms in healthcare facilities. Expedient patient isolation is created using a non-ducted portable HEPA filtration unit, flame retardant plastic curtain, tape, utility chain, and a PVC frame. The suction side of the HEPA filtration unit creates an inner containment zone for patient(s)/resident(s) (5).
        3. Portable negative pressure air machines can be used for any patient/resident room configuration in healthcare facilities and do not require additional materials to create a near-patient/resident region of negative pressure. These machines should be used according to your facility's policy and the manufacturer's instructions for use (IFU).
        4. Ventilated headboards can be used for any patient/resident room configuration in healthcare facilities (6). ECRI has a concern that it may not be possible to perform many AGPs on confirmed/suspected COVID-19 patients/residents while a person's head is within the ventilated headboard.
    2. Gather the materials needed to establish temporary airborne patient isolation.
        1. If resources are limited, prioritize frequently used non-AIIRs.
        2. Additional information on NIOSH methods for temporary airborne patient isolation are provided below:
            1. The required materials and instructions for establishing expedient patient isolation rooms and ventilated headboards
            2. If needed, request a consultation with NIOSH engineers by telephone at 800-232-4636 or via CDC-INFO .
    3. Establish temporary airborne patient isolation according to facility policy or the instructions provided for the method.
    4. Monitor the function of portable HEPA filtration units and negative pressure air machines according to the manufacturer IFU.
    5. Replace HEPA filters according to the replacement interval recommended by the manufacturer of portable HEPA filtration units and negative pressure air machines.

Background:

1. WHO and CDC guidance describe possible airborne transmission of the 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 (e.g., 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, and cardiopulmonary resuscitation) (1).
    2. CDC guidance states: Some procedures performed on known or suspected COVID-19 patients may 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).
        1. 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.
2. CDC guidelines specify the requirements for AIIRs in healthcare facilities (3).
    1. Acute care facilities need at least one room equipped to house patients with airborne infectious disease.
    2. Every healthcare facility, including ambulatory and long-term care facilities, should undertake an Infection Control Risk Assessment (ICRA) to identify the need for AII areas. Once the need is established, the appropriate ventilation equipment can be identified (see Appendix B. Air: Ventilation Specifications for Health-Care Facilities).
3. NIOSH developed the expedient patient isolation room and ventilated headboard methods for temporary airborne patient isolation (11).
    1. These isolation configurations use materials and HEPA filtration systems that are commonly found within healthcare facilities.
    2. The isolation configurations were universally successful in their ability to contain surrogate infectious aerosol within the inner isolation zones (including within the ventilated headboard's receiving hood).

References & Source Documents:

1. World Health Organization. Modes of transmission of virus causing COVID-19: implications for IPC precaution recommendations [online]. 2020 Mar 29 [cited 2020 May 20]. Available here .
2. Centers for Disease Control and Prevention, U.S. Interim Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed Coronavirus Disease 2019 (COVID-19) in Healthcare Settings [online]. 2020 May 18 [cited 2020 May 20]. Available here .

3. Centers for Disease Control and Prevention, U.S. Guidelines for Environmental Infection Control in Health-Care Facilities. Recommendations from CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC) [online]. 2019 July [cited 2020 May 20]. Available here .
4. Centers for Disease Control and Prevention, U.S. Strategies for Optimizing the Supply of N95 Respirators [online]. 2020 Apr 2 [cited 2020 May 20]. Available here .
5. The National Institute for Occupational Safety and Health (NIOSH). Engineering Controls To Reduce Airborne, Droplet and Contact Exposures During Epidemic/Pandemic Response. Expedient Patient Isolation Rooms [online]. 2020 Apr 2 [cited 2020 May 20]. Available here .
6. The National Institute for Occupational Safety and Health (NIOSH). Engineering Controls To Reduce Airborne, Droplet and Contact Exposures During Epidemic/Pandemic Response. Ventilated Headboard [online]. 2020 Apr 27 [cited 2020 May 20]. Available here .
7. Centers for Disease Control and Prevention, U.S. Interim Guidance for Emergency Medical Services (EMS) Systems and 911 Public Safety Answering Points (PSAPs) for COVID-19 in the United States [online]. 2020 Mar 10 [cited 2020 May 20]. Available here .
8. Occupational Safety and Health Administration (OSHA). OSHA Technical Manual. Section III, Chapter 3, Ventilation Investigation [online]. [cited 2020 May 20]. Available here .
9. Food & Drug Administration, U.S. Personal Protective Equipment EUA, COVID-19 Airway Management Isolation Chamber (CAMIC) [online]. 2020 May 19 [cited 2020 May 21]. Available here .
10. Food & Drug Administration, U.S. Fact Sheet for Healthcare Providers. Emergency Use Authorization of the COVID-19 Airway Management Isolation Chamber [online]. 2020 May 20 [cited 2020 May 21]. Available here .
11. The National Institute for Occupational Safety and Health (NIOSH). Expedient Methods for Surge Airborne Isolation within Healthcare Settings during Response to a Natural or Manmade Epidemic [online]. 2012 Apr [cited 2020 May 20]. Available here

Source(s):

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