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Ventilator and Non-Invasive Ventilator Decontamination and COVID-19

Executive Summary

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Situation

In the midst of the COVID-19 pandemic, Infection Prevention measures are on the rise as healthcare systems are continuing to learn more about effective disinfectants, decontamination methods, as well as overall cleaning protocols to reduce the spread of SARS-CoV-2.

Invasive and non-invasive ventilation measures especially require careful cleaning in order to prevent cross-contamination in the clinical setting. Hypoxemic respiratory failure in ARDS commonly results from intrapulmonary ventilation-perfusion mismatch or shunt and usually requires mechanical ventilation (WHO, 2020). With a large influx of high acuity patients requiring intubation and invasive mechanical ventilation, providers have also investigated the use of noninvasive ventilation methods as an alternative for ventilators.

Mechanical ventilators are considered closed systems which contain exhaled CO2 posing less of a risk than the non-invasive ventilation open systems that release CO2 into the air. As contamination of COVID-19 is of great concern due to aerosol generating procedures and respiratory management, knowledge of cleaning and air filtration is high priority in the hospital setting.

Problem Statement:
What are best practice considerations for disinfection and cleaning of invasive mechanical ventilation and non-invasive ventilation equipment utilized for COVID-19 patients?

Technology Under Evaluation:
Disinfection methods for the following types of respiratory equipment during the COVID-19 pandemic:

1. Invasive Mechanical Ventilators (including Anesthesia machines)
2. Continuous positive airway pressure (CPAP)
3. Bilateral positive airway pressure (BiPAP)
4. High-flow oxygen therapy (HFOT)

Background

Mechanical Ventilators, BiPAP, CPAP, and HFOT are utilized to treat COVID-19 diseased patients *per strict clinical monitoring*. COVID-19 is easily transmitted from patient coughing, aerosol generating procedures, and open ventilation systems such as a CPAP machine with a vented face mask. Closed systems via invasive mechanical ventilation can trap pathogens thru breathing tubes and filters. Non-invasive ventilation delivers air and oxygen through masks or specialized nasal cannulas connected to tubing and machines.

According to the World Health Organization:

> The COVID-19 virus is primarily transmitted between people through respiratory droplets and contact routes. Droplet transmission occurs when a person is in close contact (within 1 m) with someone who has respiratory symptoms (e.g., coughing or sneezing) and is therefore at risk of having his/her mucosae (mouth and nose) or conjunctiva (eyes) exposed to potentially infective respiratory droplets….. airborne transmission may be possible in specific circumstances and settings in which procedures or support treatments 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, and cardiopulmonary resuscitation (WHO, 2020).

The COVID-19 virus can survive up to two to three days on plastic and stainless steel. Viral particles can stay suspended in the air for up to three hours before they fall (Harvard, 2020). ***This data explains why there is an increased risk of cross contamination of patients that are on mechanical ventilators if they are not decontaminated properly between patients. Decontamination methods of these pieces of equipment are vital to prevent further infection from spreading between patients.***

Assessment

Decontamination Process:
There are two basic strategies for properly decontaminating mechanical ventilators and NIV equipment:

1. Preventative contamination measures for internal parts and machinery
2. Disinfection post patient use

Invasive Mechanical Ventilators and Anesthesia Ventilator:

Preventative Contamination Measures

During the COVID-19 pandemic, precautions should be enforced to prevent cross-contamination of SARS-CoV-2. To properly prevent contamination of a medical device, the healthcare worker must become familiar and educated with the equipment.

Ventilators consist of 3 basic sections: 1) the pumping system 2) the control mechanism (controls, monitors and alarms) and 3) the breathing circuit.

- This design allows the pumping and the control mechanisms to be isolated from the patient's exhaled breath via filters.
- The breathing circuit, filters, suction, and humidifier will be exposed to the infected patient and their exhaled CO2, so it is encouraged to use single-patient use circuits with water-trap and one-way valve, closed suctioning, and dual heating wires with use of a heated humidifier to prevent further cross-contamination.
- Filters used with humidification, *between valves*, are used with *each* patient use.

- With an ***anesthesia machine***, there are three types of breathing circuit filters:
    - **Mechanical Filters**: Viral Filtration Efficiency (VFE) is >99.99%
    - **Electrostatic Filters**: VFE ≤ 99.99%
    - **Heat and Moisture Exchange Filters** (HMEFs): Ideal in the breathing circuit to provide filtration and heat and humidity conservation (London, 2020)
  - *High quality viral filters are recommended in order to eliminate the risk of contaminating the anesthesia machine.* Recommendations for using high quality viral filters are intended to eliminate the risk of contaminating the anesthesia machine internally so special cleaning procedures should not be needed. Although it is unlikely that the machine would be contaminated and capable of infecting a subsequent patient, there are no objective data that recommended practices can absolutely prevent cross infection of patients (APSF, 2020).
- With a traditional ventilator, specific filters are utilized that are effective against virus particles (COVID-19 virus is approximately 0.12 microns).
  - **Standard ventilator filters** are designed to filter particles 1 to 5 *microns*.
  - **High Efficiency Particulate Air (HEPA)** filter technology captures 99.7 of particles larger than 0.3 microns.
  - **Ultra-Low Penetration Air (ULPA)** filters capture 99.99% of particles 0.12 microns and larger (Elias et al., 2020).
  - ***The World Health Organization (WHO) recommends the use of single bacterial and viral filter (ULPA filter) in both the inspiratory and expiratory ports to prevent contamination of the internal ventilator air path. This is instead of a standard or HEPA filter (WHO, 2020).***

Invasive Mechanical Ventilator:

Disinfection Post Patient Use

Ventilators are typically disinfected upon patient discharge or when visibly soiled according to the health system's respiratory policy and governed by the Respiratory Therapy department. Per APSF, if the machine is used for long term ICU ventilation of a COVID + patient, it is reasonable to assume that the risk of internal machine contamination is increased. If internal contamination of the machine is suspected, the manufacturers' recommendations for cleaning and sterilization should be followed. This can be a time consuming, labor intensive process, and may result in keeping the machine out of service longer than desired (APSF, 2020).

The process for discontinuing the ventilator and preparing for disinfection begins with *placing the ventilator in "Stand-by function" prior to disconnecting the ventilator from the patient.* This stops the air flow and prevents moisture and mucus dispersion from the breathing circuit.

It is highly recommended to refer to the manufacturer's instructions for disinfection and cleaning. Health Management published post ventilator disinfection recommendations that will be effective with inactivating COVID-19. Proposed cleaning methods are ventilator surface disinfection, disinfectant and high temperature treatments for reusable circuits, utilization of high

efficiency filters, and disinfection of flow sensors in the exhalation valve and expiratory side of the ventilator (Health Management, 2020). It is not necessary to routinely clean respiratory and pressure lines within a ventilator between patients, because the lines are not exposed to the patient or the patient's respiratory secretions. Dispose of the patient circuit and treat them as infectious waste.

The frequency of when filters should be changed varies by type of filter and clinical use of the ventilator. Airway filters are susceptible to blockage due to secretions. These may need to be changed if resistance to flow and airway pressures become too high. Expiratory limb filters are less likely to need replacement due to occlusion. Follow the manufacture's recommended intervals for changing filters. These recommendations should be observed unless shortages make replacement difficult or impossible, in which case continuing to use the filter is better than nothing. As long as the filter is not soiled, viral filtration effectiveness should be maintained (APSF, 2020).

Anesthesia Ventilator:

Disinfection Post Patient Use

None of the manufacturers are recommending cleaning procedures that involve the internal components of the machine as long as high-quality filters are used with each patient to prevent exhaled virus from entering the machine and gas sampling lines are connected to the machine side of the filter. In the absence of data, manufacturers' recommendations for cleaning may be excessively restrictive due to medicolegal concerns. *Placing a high-quality viral filter on the inspiratory limb that can be reused between patients is a viable option for putting a machine back in service quickly after following sterilization procedures (APSF, 2020).*

The APSF/ANA Guidance on Repurposing Anesthesia Machines as ICU Ventilators addresses cleaning the anesthesia machine between patient uses:

- If viral filters have been used as directed, there should be little increased risk of passing COVID-19 virus to a subsequent patient via the anesthesia machine. Usual hospital procedures for cleaning anesthesia machines between patients should then be followed including wiping of external surfaces and replacing disposables.
- CO2 absorbent does not necessarily need to be replaced between patients. If viral filters have been used as directed, there should not be any contamination of the CO2 absorbent. Since it is a readily replaced disposable, some institutions are choosing to replace absorbent after a patient suspected, or documented to be, COVID +. There is no evidence that absorbent can be contaminated if exhaled gas is appropriately filtered. It is possible that absorbents may become in short supply which argues for not changing the absorbent unless it is necessary.
- If an anesthesia machine has been used long-term on COVID-19 infected patients, or there is evidence that the internal surfaces of the machine have become contaminated, it should be terminally cleaned before using it in the operating room on non-COVID infected patients. Specific procedures can be found in the manufacturer guidelines. Some guidelines recommend quarantining the anesthesia machine from 21-28 days if there is suspected internal viral contamination to provide enough time for the virus to die

before use with the next patient. This approach is not only impractical but may impede the ability to care for patients. While there are no data to understand what cleaning procedures will eliminate the risk of viral transmission, the following procedure could be considered.

- Remove and discard all disposables - circuit, filters, CO2 absorbent, mask, sampling line and associated water trap.
- Following manufacturer instructions, sterilize the internal breathing system and ventilator components.
- Wipe external surfaces with appropriate anti-viral cleaning solution.
- Replace the disposables with new clean/sterile replacements.
- Place a viral filter on the inspiratory limb for two to four weeks. This filter could be left in place between patients to conserve supply (ASA, 2020).

Continuous Positive Airway Pressure (CPAP) and Bilateral Positive Airway Pressure (BiPAP):

Preventative Contamination Measures & Disinfection Post Patient Use

CPAP and BiPAP systems are considered non-invasive devices. CPAP and BiPAP machines can be viable solutions for low acuity patients but require modifications. These modifications should incorporate viral filtering, oxygenated air, and non-vented facemasks due to leaks.

- Per the American Academy of Sleep Medicine (AASM), it is recommended to clean the PAP machine according to manufacturer's instructions for hospital inpatient care.
- The PAP humidifier's water chamber requires cleaning and drying between patient use.
- Post patient discharge, PAP filters and disposable accessories need to be changed out.

The American Thoracic Society's tips on daily mask cleaning for home use:

- For PAP devices, the following must be cleaned post use: device, humidifier chamber, tubing, and mask or nasal pillows.
- Refer to the American Thoracic Society's (ATS) Patient Education for COVID-19 and Home Positive Airway Pressure (PAP) Therapy: https://www.thoracic.org/patients/patient-resources/resources/pap-care-and-cleaning.pdf
- Refer to ATS's Patient Education for The Care and Cleaning of your PAP Device: https://www.thoracic.org/patients/patient-resources/resources/pap-care-and-cleaning.pdf

High Flow Oxygen Therapy:

Preventative Contamination Measures & Disinfection Post Patient Use

It is recommended to refer to the manufacturer instructions for HFOT devices in addition to policies and procedures in place by the hospital facility. Consumables and filters should also be disposed of safely after use.

Financial Considerations

An up-to-date inventory of all types of ventilatory support and corresponding service records will provide an accurate depiction of supply, and guide surge planning if needed. Existing contractual agreements should be leveraged for best pricing of consumables and/or EPA approved disinfectants required for disinfection methods. If shortages exist, refer to benchmark pricing.

For additional benchmark pricing for consumables and EPA approved disinfectants, please refer to TractManager's reports titled, Product Comparison of Cleaning Agents with Implications for Surface Type in Cleaning Hospital Equipment for Eradication of COVID-19 Virus -AND- *Non-invasive ventilation for the Treatment of COVID-19 Diseased Patients.*

Ventilator Filter Consumables Pricing		
Manufacturer	Description	List Price (Each)
Ventilator Filters	Standard Ventilator Filters	$2--$8
	High-Efficiency Particulate Air (HEPA) filter	$30--$40
	Ultra-Low Penetration Air (ULPA) filter	$60--$80

***TractManager Consumables Benchmarking Database*

Operational Considerations

Invasive and Non-invasive Ventilation Methods are utilized to treat COVID-19 diseased patients per strict clinical monitoring. Due to the nature and concern of aerosolization from these respiratory measures, infection prevention protocols must be enforced.

- Establish Infection Prevention protocols for severe respiratory illnesses within the health system's Respiratory Program and Policy.
    - Alignment of Environmental Services, Infection Prevention, and Respiratory Teams to govern protocols for COVID-19.
    - EVS Staff must adhere to strict infection prevention and disinfection guidelines when cleaning and disinfecting patient rooms and equipment.
    - Monitor the EPA's List N: Disinfectants for Use Against SARS-CoV-2 when discussing cleaning equipment to source or on hand: https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2

- Correspond with manufacturer of ventilators on hand in regard to the following:
    - Cleaning and disinfection protocol (i.e. Proper disinfectants approved for use on exterior of ventilator and screens)
    - Proper filters to use with ventilator
    - Restrictions or special actions to be performed on ventilators after COVID-19 diseased patient use
    - Precautions with ventilator suspected of COVID-19 contamination prior to necessary service and maintenance issues
    - Recommended length of time and routine change for circuits and sets per patient
- Guidance should be enforced for disposal of medical waste (circuits, filters, etc.)
    - Medical waste should be sorted and disposed of without delay. All the medical waste should be double-bagged and labeled "COVID-19," along with the name of the department, institute, date and time, and the category.
    - Before being taken out of the contaminated area, all the packing bags should be sealed and sprayed with chlorinated disinfectant or covered with an additional bag and sealed. Medical waste produced in the clean area can be treated in a routine fashion (Xiangdong, Chen et al., 2020).
- Between patients, discard disposable items – breathing circuit, reservoir bag, patient mask, gas sampling tubing, filters placed at the airway and elsewhere if supply is sufficient. Wipe all exposed surfaces. Manufacturers' cleaning recommendations are useful for individual devices (APSF, 2020).
- Monitor and conserve available supplies and consumables proprietary to respiratory equipment.
- Establish Patient Education for Discharged patients
    - Home Care of Home-Based Mechanical Ventilation,
        - The American College of Chest Physicians (ACCP) pulmonary and lung health experts, along with the Home Mechanical Ventilation and Neuromuscular Disease Network released recommendations and guidelines for known or suspected COVID-19 infected patients: https://www.thoracic.org/professionals/clinical-resources/disease-related-resources/chest-care-recommendations-for-the-home-based-ventilation-patient-with-suspected-or-known-covid-19.pdf

- Discuss recommended cleaning for patients using a spirometer. (Refer to manufacturer and facilities' policy for decontamination instructions.)

Recommendation

According to the World Health Organization, approximately 14% of COVID-19 diseased patients develop severe disease that requires hospitalization and oxygen support, and 5% require admission to an intensive care unit (WHO, 2020). With a surge for invasive mechanical ventilation and non-invasive ventilation, it is imperative to develop system-wide infection prevention measures to prevent cross contamination; this may include policy revisions to accommodate for crisis practices, with ensuing changes to procedures. It is important to ensure these policies and procedures are monitored and enforced as non-traditional equipment (ie anesthesia machines) have been converted for alternative use, and subsequently move back into regular service. Developing policies and protocols with Respiratory Therapy, Infection Prevention, and EVS should be enforced and communicated to all clinical staff. Maintaining a strong business relationship with suppliers is key to ensure best pricing as well as proper instructions for decontamination measures.

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