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[COVID-19] Use of Consumer-Grade Obstructive Sleep Apnea Devices May Supplement Ventilator Supply during Shortage [ECRI Exclusive Hazard Report]

Problem

1. Many COVID-19 patients will require mechanical ventilation. However, a shortage of ventilators has led to an increased risk of patient fatality.

ECRI Recommendations:

Respiratory Therapy

1. Devices intended for obstructive sleep apnea (OSA) may be used as a temporary measure for low-acuity patients while intensive care, non-invasive ventilators, and devices cleared for other preferred therapies are in a critical shortage.
2. Before use of consumer-grade OSA devices:
    1. Consider your patient's condition and the devices' limitations.
        1. Unless modified, they allow only low-flow oxygen.
        2. They are not intended for patients who cannot breathe spontaneously.
        3. They are not indicated for use with intubated patients.
        4. Many do not provide bi-level support.
        5. Because they rely on passive exhalation through a vent, exhaled gas can be difficult to filter.
        6. They are not intended to be used for the extended durations that are typical with hospital ventilators, and the reliability in such a use case is unknown.
        7. They do not have internal batteries.
        8. Because they rely on constant pressure to flush exhaled CO_2, rebreathing is likely if device failure or loss of power occurs.
        9. Some home use devices to treat OSA do not have a humidification option.
    2. Evaluate models to meet clinical needs, such as:
        1. Prefer those with bi-level support.
        2. Prefer those that offer remote monitoring.
        3. Prefer those with a timed mode to switch between inspiratory and expiratory during periods of apnea, often referred to as ST or S/T.
        4. Attempt to standardize on a single model or product line to minimize errors associated with unfamiliarity.
        5. Establish a clinical resource to act as an on-site expert in the use of the devices.

Materials Management

1. Coordinate with manufacturers to obtain a contingency supply of devices and accessories.

Infection Control

1. Designate staff to review disinfection procedures and to disinfect devices between uses.
2. Evaluate the device and patient interface (i.e., mask) to minimize the spread of COVID-19 from the use of the device (e.g., aerosolization of expired virus).

Background:

1. Clinical guidelines are in development as information about COVID-19 and the effectiveness of therapies becomes available.
2. The availability of respiratory equipment may determine which therapies are available for patients.

3. There are differences in terminology used to describe devices.
    1. CPAP (Continuous Positive Airway Pressure): A mode of air delivery meant to sustain a constant pressure to keep the airway and/or lungs open. Also used to refer to home care devices that provide this therapy for patients with OSA.
    2. Bi-level/BIPAP: A mode on most hospital ventilators that provides a high level of pressure during inspiration and a lower level during exhalation. BIPAP is a Respironics trademark for bi-level support and in some model names. It is often used to refer to hospital non-invasive ventilators in general and the Philips Respironics V60 device in particular. It is also used to refer to home care devices that provide bi-level therapy for patients with severe OSA who require very high inspiratory pressures (because the lower exhalation pressure is easier for these patient to tolerate).
    3. Non-Invasive Positive Pressure Ventilation (NIPPV): A form of non-invasive ventilation (NIV). The other form of NIV is negative pressure ventilation, commonly referred to as an iron lung. A distinction that can be made between bi-level and NIPPV is that bi-level devices for OSA are not intended for patients who are not capable of spontaneous breathing.
4. FDA has several classifications of ventilatory assist devices and standards that each classification must meet. Consumer grade OSA devices typically fall under the least stringent class. The following distinctions are made between consumer grade OSA treatment devices and NIPPV:
    1. Not for facility use
    2. Not for continuous use
    3. Not for life support
    4. Devices cleared for NIPPV are listed as continuous use, minimal ventilatory support, facility use.
5. FDA has published a letter to healthcare providers here. Note, among FDA's recommendations, home use OSA devices are listed last. The recommendations include:
    1. Continuous Positive Airway Pressure (CPAP), auto-CPAP, and bi-level positive airway pressure (BiPAP or BPAP) machines typically used for treatment of sleep apnea (either in the home or facility setting) may be used to support patients with respiratory insufficiency **provided appropriate monitoring (as available) and patient condition**. [emphasis added by ECRI]
6. FDA has also published Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency Guidance for Industry and Food and Drug Administration Staff. Of note regarding home care devices used to treat OSA is: “The use of devices indicated for sleep apnea (including noncontinuous ventilators delivering continuous positive airway pressure (CPAP) or bilevel positive airway pressure (BiPAP)) to treat patients with respiratory insufficiency, provided that appropriate design mitigations are in place to minimize aerosolization."
7. Infection control concerns:
    1. There are concerns that non-invasive ventilation and other forms of pressure support, such as those provided by home use devices to treat OSA, may increase the spread of coronavirus by aerosolizing the virus and expelling it from mask vents. However,
    2. Features, Evaluation and Treatment Coronavirus (COVID-19) published on March 8, 2020, states that the World Health Organization's position is as follows: “Concerning HFNO or non-invasive ventilation (NIV), the experts' panel, points out that these approaches performed by systems with good interface fitting do not create widespread dispersion of exhaled air, and their use can be considered at low risk of airborne transmission.[17] Practically, non-invasive techniques can be used in non-severe forms of respiratory failure. However, if the scenario does not improve or even worsen within a short period of time (1–2 hours) the mechanical ventilation must be preferred."

Manufacturer's Perspectives or Comments:

1. Resmed has a white paper covering the use of some of its product line during the COVID-19 pandemic. There is guidance showing a hierarchy of features that may be useful in determining which devices would be most appropriate given patient status. The white paper is available here.
2. Philips/Respironics has a COVID19 response site here.
3. When asked “Can we modify Fisher & Paykel Healthcare product in an effort to reduce the risk of aerosols, or to change the intended therapy delivered?", Fisher & Paykel states that “Using improvised materials and configuring Fisher & Paykel Healthcare products in a manner that is outside their intended use raises some concerns around the safety and efficacy of our devices."

UMDNS Term(s)

Positive Airway Pressure Units, Bi-Level [20743]

Positive Airway Pressure Units, Continuous [11001]
Ventilators, Noninvasive Positive Pressure [20746]

Geographic Region(s)

Worldwide

Suggested Distribution

Clinical/Biomedical Engineering, Critical Care, Emergency/Outpatient Services, Infection Control, Pulmonology/Respiratory Therapy, Risk Management/Continuous Quality Improvement, Home Care, Sleep Laboratory, Materials Management

Comment

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