[Critical Priority] - S0398 : [COVID-19] Shortages of Intensive Care Ventilators—Strategies for Mitigation [ECRI Exclusive Special Report]

Medical Device Special Report

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UMDNS Terms:

- Ventilators, Intensive Care [17429]

Geographic Regions: Worldwide

Suggested Distribution: Anesthesia, Clinical/Biomedical Engineering, Critical Care, Emergency/Outpatient Services, Pulmonology/Respiratory Therapy, Risk Management/Continuous Quality Improvement

Problem:

1. Hospitals may experience shortages of intensive care ventilators during the COVID-19 pandemic.
2. An insufficient number of intensive care ventilators may result in an increased risk of patient death.

ECRI Recommendations:

1. Perform an inventory of available mechanical ventilation devices in your hospital, including those in service, in storage, and those that you expect to receive from purchases, rentals, donations, and emergency stockpiles.
2. Cancel elective surgeries and other elective procedures that could result in the use of mechanical ventilators.
3. Identify intensive care ventilators, supplies, and personnel from ambulatory surgery centers and other facilities that can be used for treating COVID-19 patients.
4. If the number of intensive care ventilators in your facility is low, consider alternative devices that are capable of delivering breaths or pressure support.
5. Select from the available ventilation devices in the following suggested order of preference:
    1. Intensive care ventilators
    2. Advanced transport, sub-acute, and home care ventilators that have intensive care features and are capable of treating patients with acute respiratory distress syndrome (ARDS)
    3. Anesthesia units. See ECRI Alert S0397 : [COVID-19] Anesthesia Units Can Be Repurposed to Provide Ventilatory Support for Critically Ill Patients, as Long as Precautions Are Taken [ECRI Exclusive Special Report]
    4. Basic transport, sub-acute, and home care ventilators
    5. Hospital noninvasive ventilators
    6. Modified home BiPAP sleep apnea therapy devices
    7. Unmodified home BiPAP sleep apnea therapy devices
    8. If all other alternatives are exhausted, care providers could consider ventilation of two patients on a single ventilator for short-term use; however, there are significant limitations to this strategy. See ECRI Hazard Report H0574 : [COVID-19] Use of One Ventilator to Mechanically Ventilate Two or More Patients Simultaneously Presents Risks [ECRI Exclusive Hazard Report]
6. Adjust the above priority order of ventilation devices according to the types of devices available in your hospital as well as the available expertise for safely operating and adapting these devices for ventilating patients with severe respiratory distress.
7. Triage the ventilation devices at your disposal, matching the device capabilities with the severity of patient illness.
8. Plan for the accessories and supplies required to provide mechanical ventilation for each of the devices on the prioritized list.
9. Consider extending the shelf life and duration of use of accessories and supplies used for ventilation, depending on the availability of resources.
10. Plan for actions needed to mitigate any risks to patients and hospital staff for each of the devices on the prioritized list, such as adding battery backup or using additional viral filters.
11. Perform inspection and preventive maintenance for devices retrieved from storage, and perform incoming inspections for newly obtained devices.
12. Take appropriate environmental control precautions, for example, using negative pressure or additional filtration where feasible.
    1. Ventilating patients using a single-limb circuit or noninvasive mask without an expiratory filter may contaminate the room air and increase the risk of transmission.
    2. Aerosol generation from a COVID-19 patient's exhaled gas is a key concern. Some commercially available filters can be fitted to the exhaust port of single-limb circuits and some types of masks. Check with the manufacturer to obtain these filters before using this type of interface on a COVID-19 patient.
13. Contact the device manufacturer for guidance on updated labeling and for information on the features and limitations of the device in an emergency use situation.
14. Contact the appropriate professional societies for up-to-date guidance on the use of ventilation devices for COVID-19 patients.
15. Stay informed of ventilation devices that have not been legally marketed in the U.S. for critical respiratory support but for which FDA

has taken steps to make available through its Emergency Use Authorization (EUA). If you need to supplement your ventilator fleet with some of these EUA devices, understand that they may be recalled when the crisis is over and will need to be removed from use.

Background:

1. FDA issued an EUA in response to concerns of insufficient supply and availability of FDA-cleared ventilators to treat patients with COVID-19.
    1. This covers ventilators, tubing connectors, and accessories.
    2. FDA does not intend to object to modifications to the FDA-cleared indications, claims, or functionality of these devices, without prior submission of a premarket notification where the modification will not create an undue risk in light of the public health emergency.
    3. Examples of circumstances in which FDA currently believes a modification would not create such undue risk include:
        1. The use of powered emergency ventilators and anesthesia gas machines for patients needing mechanical ventilation.
        2. The use of ventilators outside their cleared environment of use (e.g., use of a ventilator in a health care facility when it is cleared only for use at home or during transport).
        3. 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. See ECRI Hazard Report H0587 [COVID-19] Use of Consumer-Grade Obstructive Sleep Apnea Devices May Supplement Ventilator Supply during Shortage [ECRI Exclusive Hazard Report].
        4. Use of breathing circuit devices beyond their indicated use.
        5. Use of ventilator support devices not currently legally marketed in the U.S. but have marketing authorization in other regulatory jurisdictions.
        6. Use of ventilator support devices made by companies not previously engaged in medical device manufacturing.
        7. Use of modified ventilator support devices.

Manufacturer Perspectives or Comments:

1. The use of anesthesia units for long-term ventilator support constitutes off-label use.
    1. Mindray: Alert A34796
    2. Draeger: Alert A34763
    3. GE: Alert A34787
    4. Getinge: Alert A34800
2. Ventilating more than one patient with one ventilator is considered off-label use. See the following ECRI Alerts and manufacturer information:
    1. Draeger: Alert A34797 .
    2. Hamilton Medical: See the website .
    3. Medtronic: See Alert A34790 .
    4. Zoll: See the website .

References & Source Documents:

1. ECRI Lab Webcasts:
    1. Strategies to Mitigate Ventilator Shortages
    2. Using Anesthesia Machines for Patient Ventilators
2. FDA Emergency Use Authorization (EUA) for ventilators, ventilator tubing connectors, and ventilator accessories: https://www.fda.gov/media/136423/download
3. Guidance from professional societies:
    1. American Association for Respiratory Care (AARC)- Guidance Document on COVID-19: https://www.aarc.org/wp-content/uploads/2020/03/guidance-document-SARS-COVID19.pdf
    2. Anesthesia Patient Safety Foundation (APSF)- COVID-19 Anesthesia Resource Center: https://www.apsf.org/novel-coronavirus-covid-19-resource-center/
    3. American Society of Anesthesiologists (ASA)- APSF/ASA Guidance on Purposing Anesthesia Machines as ICU Ventilators: https://www.asahq.org/in-the-spotlight/coronavirus-covid-19-information/purposing-anesthesia-machines-for-ventilators
    4. Society of Critical Care Medicine (SCCM)- Ventilation Strategies: https://www.sccm.org/Disaster/Mechanical-Ventilation-Strategies

Comments:

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

Source(s):

- 2020 Apr 28. ECRI researched report