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ECRI UPDATE

COVID-19 Strategies – Mitigating ICU Ventilator Shortages

As the impact of the SARS-CoV-2 virus in China and Europe came into focus – and as the realization took hold that the United States would not be spared the brunt of the burgeoning pandemic – one of the first alarms to sound from the health care community was the urgent need for ventilators. Severe illnesses were requiring resource-intensive care, and health care organizations feared that the available supply of ventilators would be insufficient to meet a patient surge.

ECRI outlined its recommendations for mitigating intensive care ventilator shortages in a series of alerts and other resources issued in late March and April. For hospitals facing a patient surge, as well as for those updating action plans for future surges, we summarize the key guidance below. *Note: This article was developed in May 2020. With the rapid pace of change associated with the COVID-19 pandemic, the challenges facing hospitals and the evidence supporting various methods may evolve substantially by the time of publication.*

OPTIMIZING YOUR SUPPLY

First, find the ventilators at your disposal. 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. Don't forget to check ambulatory surgery centers and other facilities for intensive care ventilators, supplies and personnel that can be used for treating COVID-19 patients.

Make more devices available. Cancel elective surgeries and other elective procedures that could result in the use of mechanical ventilators.

Identify and rank alternatives. If an insufficient number of intensive care ventilators is available, consider alternative devices that are capable of delivering breaths or pressure support. Rank the various alternatives 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. Following is ECRI's suggested order of preference (though yours may differ):

- Intensive care ventilators
- 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)
- Anesthesia machines – modern anesthesia ventilators have been designed to approximate the function of an ICU ventilator, and thus should be fully capable of providing the support needed for COVID-19 patients
- Basic transport, sub-acute and home care ventilators
- Hospital noninvasive ventilators
- Modified home BiPAP sleep apnea therapy devices
- Unmodified home BiPAP sleep apnea therapy devices
- If all other alternatives are exhausted, care providers could consider ventilation of two patients on a single ventilator for short-term use. ECRI stresses, however, that there are significant limitations to this strategy. (For a discussion, see ECRI's webcast "Strategies to Mitigate Ventilator Shortages," which can be viewed at https://www.ecri.org/landing-covid-19-ventilator-shortages/.)

Match ventilation capabilities to the patient need. "Reserve use of more sophisticated ventilators for the sickest patients," recommends Ismael Cordero, a senior project engineer in ECRI's device evaluation group. That means triaging the ventilation devices at your disposal and matching the device capabilities with the severity of patient illness.

OTHER ESSENTIAL RESOURCES AND CRITICAL ACTIVITIES

Remember that acquiring ventilators is only one piece of the puzzle. "A ventilator by itself won't be much use if you don't have trained staff to operate the device and the supplies needed for it to function properly," cautions Brad Bonnette, a senior project officer in ECRI's device evaluation group.

In the case of using anesthesia units in the ICU, for example, plans need to include staffing the care area with anesthesia professionals who can provide guidance and support 24/7 while a unit is being used on a patient. This point was emphasized during ECRI's webcast "Using Anesthesia Units for Patient Ventilators" (which can be viewed at https://www.ecri.org/landing-covid-anesthesia-units-ventilators/.) One additional benefit of including anesthesia professionals on the care team is that you add a whole crew of highly trained people who can help during the crisis.

Just as challenging as locating

ECRI's Ismael Cordero discusses ventilator usage during a live-streamed ECRI lab webcast. The April 1, 2020 webcast was part of an ECRI series addressing technology challenges facing hospitals during the COVID-19 pandemic.

ventilators has been securing the accessories, supplies and medications required to provide mechanical ventilation. You'll need a plan that addresses the needs for each of the devices on the prioritized list. Note, for instance, that some ventilators require proprietary items for their use. Also, shortages have been reported for components like filters and breathing circuits, as well as for related products, like laryngoscope blades used during intubation. In the event of shortages, you may need to consider extending the shelf life and duration of use of accessories and supplies used for ventilation, depending on the availability of resources.

Also consider the actions that are needed to mitigate risks to patients and hospital staff. Taking appropriate environmental control precautions is one key activity. That may involve using negative pressure or additional filtration, where feasible. Other actions include adding battery backup to devices or using additional viral filters.

Other key activities, as stressed by Cordero, are performing incoming inspections for newly obtained devices and completing inspection and preventive maintenance procedures for devices retrieved from storage. "Ventilators of unknown condition are being deployed from a variety of sources and after being subject to unknown conditions. That means performance inspections and preventive maintenance are a must."

EUAS: OK FOR NOW, BUT NOT FOREVER

During the COVID-19 crisis, FDA has made available through its Emergency Use Authorization (EUA) process many ventilation devices that are not otherwise legally marketed in the U.S. for critical respiratory support. Examples of situations covered under EUAs include the following: The use of powered emergency ventilators and anesthesia gas machines for patients needing mechanical ventilation. The use of ventilators outside their cleared environment of use (e.g., using a home-care device within a health care facility). The use of devices indicated for sleep apnea to treat patients with respiratory insufficiency, provided that appropriate design mitigations are in place to minimize aerosolization. The use of breathing circuit devices beyond their indicated use. The use of ventilator support devices made by companies not previously engaged in medical device manufacturing.

It's important to note that these EUAs are effective only until FDA determines that the COVID-19 emergency is over. If you need to supplement your ventilator fleet with EUA devices, understand that the devices may need to be removed from use when the crisis is over.

While some vendors have indicated that they intend to pursue 510(k) clearance for their products, the timing and success of such applications is far from certain. ECRI recommends that hospitals assume that all EUA devices will revert to their pre-EUA state when the EUA is terminated. That is: FDA-cleared devices with EUA labelling changes will revert to their pre-EUA labelling. FDA-cleared devices with EUA modifications will be usable if the modifications are reverted or removed. And, devices that are not FDA-cleared will not be usable until or unless they receive clearance.

This article is adapted from multiple guidance documents that ECRI developed to help health care professionals mitigate ventilator shortages during the COVID-19 pandemic. The original articles and many additional resources are available through ECRI's COVID-19 Resource Center, a free public resource to help hospitals protect health care workers and patients during the COVID-19 pandemic. Access that site at www.ecri.org/coronavirus-covid-19-outbreak-preparedness-center.

For more information, visit https://www.ecri.org/solutions/device-evaluations, call (610) 825-6000, ext. 5891, or e-mail clientservices@ecri.org.