SUMMARY OF STRATEGIES TO INCREASE THE AVAILABILITY OF ICU VENTILATOR CAPABILITY TO COVID-19 PATIENTS WITH RESPIRATORY FAILURE

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Several strategies are available to increase the mechanical ventilation capability at institutions where the supply of ICU ventilators becomes inadequate to meet the needs of patients. All of these strategies are underway at various stages and with different potential to address the problem. While there is existing equipment that can readily be repurposed, an important imperative is enhancing and coordinating manufacturing to produce not only new ventilation devices but also the disposables that will be essential including breathing circuits and viral filters. Maintaining an adequate supply and distribution of oxygen is also a critical need.

The following is a summary of each strategy along with an assessment of what is needed to use the strategy effectively. The potential impact in terms of the number of devices that can be available, the timeframe and how they will be distributed are essential questions to address. Those questions remain to be answered and will require a coordinated task force with the responsibility and authority to take action.

STRATEGY #1: Repurpose Existing Anesthesia Ventilators

Most immediately impactful strategy since the devices are available now and in place and work is virtually complete to insure they are deployed safely.

Anesthesia machines are no longer needed for elective surgery and tens of thousands of these devices are in place in hospitals, surgicenters, veterinary hospitals and private offices nationwide. There are also anesthesia professionals available to manage these devices. These are the most readily available devices and entirely capable of sustaining life safely. They are however, different from ICU ventilators and require special considerations to deploy them safely. Significant work is underway to operationalize this strategy on a wide scale. Individual institutions are already using this strategy. Current status:

- FDA Engagement
    - FDA has cleared the way for the off label use of these devices for long term mechanical ventilation
        - https://www.fda.gov/medical-devices/letters-health-care-providers/ventilator-supply-mitigation-strategies-letter-health-care-providers

- Manufacturer engagement – All three major anesthesia machine manufacturers in the US have issued guidance on using their anesthesia machines for long term mechanical ventilation. (Attachments 1-3) The guidance offers excellent information on safe use of the devices, but it is not very user friendly and in some cases, clinical use can be improved. Manufacturers are completely engaged in supporting clinicians to use these devices in this fashion.

    - GE
    - Draeger Medical
    - Mindray
- Professional Society Educational and Patient Management Support – A joint effort by the **Anesthesia Patient Safety Foundation (APSF) and the American Society of Anesthesiologists (ASA)** is underway to develop support for deploying and managing anesthesia machines for long term ventilation. This project is well underway and much of the information will be ready to deploy today. Here are the elements of the project:
    - Equipment Considerations – reference information on deploying the equipment safely including a bedside tool emphasizing the need for monitoring the device at specific intervals. (Attachments 4-5)
    - Intensive care management – All anesthesia professionals are trained in critical care but most have not practiced in that capacity for some time. ASA, the Society of Critical Care Medicine, the Society of Critical Care Anesthesiologists, and APSF under the leadership of Dr George Williams has an educational program intended to provide refresher information and new guidance on managing anesthesia machines to support patients with respiratory failure.
    - Support Hotline 24x7: The ASA is developing plans for a hotline number that anesthesia professionals can use when asked to deploy and support anesthesia machines for this purpose. Logistic planning is well underway following existing models for malignant hyperthermia using the Medic Alert phone system. Volunteers remain to be identified to be able to respond to the hotline and will rely upon the reference information noted above.
- Barriers to effective deployment of this strategy:
    - Distribution of devices: While tens of thousands of devices are available, they are not necessarily all in locations where they are needed. Individual regions will have varying numbers of these machines.
    - Availability of disposables: Breathing circuits, filters, CO2 absorbents, oxygen are all needed. Anesthesia machines have the potential to use oxygen more efficiently than ICU ventilators with appropriate supplies.
    - FDA Approval of new machines: Draeger Medical has a new machine (ATLAN) that is currently in the 510K approval process. Remaining questions relate to cybersecurity concerns not ventilation capability. Once approved, a significant number could be made available but the lag time is about 6 weeks due to shipping from Europe.

STRATEGY #2: BUILD LARGE QUANTITIES OF NEW VENTILATORS

NOT IMMEDIATELY IMPACTFUL BUT HAS THE POTENTIAL TO PROVIDE MANY NEW VENTILATORS OVER WEEKS NOT MONTHS. IMMEDIATE NEEDS ARE TO VET THE MOST PROMISING DESIGNS AND IDENTIFY MANUFACTURERS

Manufacturers of ICU ventilators are ramping up production. It is not clear how quickly these ventilators can be built, tested and distributed nor the total numbers that can be made

available rapidly.
Inventors have been hard at work to develop simple mechanical ventilator designs that could be produced rapidly and would be easy to deploy. Numerous projects are underway that could be viable solutions and the following is likely not comprehensive. Manufacturing capability is available to build these devices although the logistics of parts and material supplies need to be addressed. FDA has provided support for this approach: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-ventilators-and-accessories-and-other-respiratory-devices-during-coronavirus

Some examples:

- Open Source Ventilator Project: Organizing site at the University of Florida, directed by Dr. Sem Lampotang
  - https://simulation.health.ufl.edu/technology-development/open-source-ventilator-project/
- MIT Emergency Ventilator (E-Vent) Project
  - https://e-vent.mit.edu/
- Irish Project
  - https://youtu.be/etPkRYed_zY
- Belgian Project: Prototype done. Claim potential for 1000/day to be manufactured and they have identified manufacturer.
  - www.coronaventilator.be
- Resurrect old simple pneumatic ventilator designs
  - https://museum.aarc.org/galleries/early-icu-ventilators/
- Barriers to effective deployment of this strategy
  - Identify most promising designs
  - Identify manufacturers capable of producing these devices – distributed manufacturing is desirable to facilitate producing large numbers of devices but also insuring they can reach the desired locations quickly
  - Availability of disposables – circuits, filters, oxygen
  - Definition of FDA role in approving

STRATEGY #3: MODIFY VENTILATOR CIRCUITS TO ALLOW ONE VENTILATOR TO SUPPORT MORE THAN ONE PATIENT

This strategy has been discussed by many individuals and prototype parts have been developed to be able to facilitate the connections required. While most ICU ventilators have sufficient capability to provide enough gas for more than one patient, the basic physiology of respiratory failure insures that this will be dangerous and likely ineffective for most if not all patients. The engineering challenge of connecting one ventilator to multiple patients is an easy problem to solve. The patient monitoring and challenges to managing physiology safely and effectively are very significant and likely insurmountable. Desperate times call for desperate measures but this option is not likely to save large numbers of patients and should not divert resources from implementing the other strategies noted above. Anesthesia machines will NOT be suitable to be deployed in this fashion.

Attachments

1. COVID-19 - Requests for information regarding the off-label use of GE Healthcare anesthesia devices for ICU ventilation
2. COVID 19: Usage of Draeger Anaesthesia Devices for Long-Term Ventilation
3. Mindray A-Series Anesthesia Delivery System Consideration for use as a Ventilator
4. Quick Reference Anesthesia Machine: Document being prepared by APSF/ASA as bedside guidance to anesthesia professionals
5. Anesthesia Machines as ICU Ventilators DRAFT: Document under revision to provide reference material to clinicians making decisions on how best to deploy anesthesia machines for long term ventilation