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Respiratory Care Innovation in Times of Crisis

Dear Editor:

The COVID-19 pandemic has led to a global health care crisis and put unprecedented pressure on our health care system with more than 75 million confirmed cases, 3 million hospitalizations, and 900,000 COVID-19-associated deaths in the United States alone over the past 2 years.1 The novel disease came with 2 immediate challenges: (1) building disease-specific diagnostics, and preventive measures, and (2) increasing care capacity to treat those with severe courses of the disease.

For both challenges, innovation has turned out to play a key role, most prominently demonstrated by the rapid development of the COVID-19 vaccines. In the current issue’s letter to the editors, Duprez et al4 have focused on increasing respiratory care capacity and developed a device that can reduce oxygen consumption during high-flow oxygen treatment, which is often administered in patients suffering from shortness of breath and hypoxemia.2-4 Reducing oxygen consumption would increase the number of patients who can be served in scarcely resourced areas. During a pandemic such settings rapidly transition to triage-based care, as evidenced in India in spring 2021.7

Expedited Regulatory Framework for Pandemic Innovations

Medical innovation enters the United States market after being thoroughly tested for safety and efficacy and receiving regulatory approval by the Food and Drug Administration (FDA), which can be a multi-year process. However, emergency situations require a dynamic response to rapidly changing circumstances. To enable such a response, the FDA has implemented the “emergency use authorization”. The emergency use authorization allows rapid approvals for otherwise unapproved medical products or unapproved usage of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions. Under the ventilator and ventilator accessories section, a set of guidelines was provided to assist and evaluate the safety and efficacy of modified devices.5,6 Other nations’ regulatory bodies issued similar modified processes to enable the rollout of life-critical technologies during the pandemic.

Human clinical trials can be challenging to perform during health care crises. Instead, simulators such as the Michigan test lung system and computational analyses can provide robust validation methods.7,8 Conformance with applicable International Electrotechnical Commission and International Organization for Standardization standards further increase reliability and safety of the device. The FDA also requires clear device labeling and safety alarm functionalities, which is particularly important in ventilators and ventilator modifiers.

An Innovative Approach to Reduce Oxygen Consumption In High-Flow Therapy

Duprez et al4 suggest a simple-to-implement and innovative modification of commercial nasal cannulas to further increase the oxygen concentration in inhaled air by reducing the amount of dilution with room air. At its core, the modification consists of a reservoir for oxygenated air from the cannula. Instead of being lost to room air at times other than inspiration, the oxygenated air is pooled inside the reservoir.

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This is similar in some ways to a nonrebreather mask with a reservoir bag to pool oxygenated air prior to delivery.

The technology mentioned was first described in 1991 in a similar form. Early studies showed that such a simple adaptation could increase partial pressure of oxygen in patients without increasing partial pressure of carbon dioxide, showing that expired air is in fact pushed out of the reservoir trunks by incoming cannula airflow. This double-trunk mask was also shown to be, if not more, efficient than the nonrebreather mask at maintaining and improving partial pressure of oxygen.⁸,⁹

The authors have previously shown how this design can improve oxygenation during high-flow nasal oxygen cannula therapy.² In this letter,⁴ the authors highlight how this might be used to conserve oxygen supplies in resource-limited settings to supplement low-flow nasal cannula oxygen therapy. This is of particular note given how the COVID-19 pandemic has stretched health delivery globally. Assuming a hypoxemic patient takes 30 breaths per minute and is on low flow of oxygen of 900L/h, such a device could reduce source oxygen utilization by 21%.

A question that remains, given the long history of testing such a double-trunk mask, is why both trunks have been kept the same diameter and length. In theory, increasing trunk length would increase reservoir capacity, further reducing oxygen consumption. It seems that the airflow and fluid dynamics of this device would benefit from a more thorough understanding.

Considerations for Modifying Respiratory Devices

The modification of respiratory devices is accompanied by numerous technical and safety challenges, such as cross contamination, patient-specific needs for pressure and volume support, and alarm management. During the COVID-19 pandemic, respiratory devices were multiplexed to manage the overwhelming case load experienced by some hospitals. In such cases, independent control of volume and pressure to each patient is critical for lung-protective ventilation, the standard of care for acute respiratory distress syndrome. In most multiplexed devices, the compliance and resistance of the patients become part of the same circuit and therefore must be managed with modifications that can manipulate the interdependence. System-based modifications such as resistors, clamps, and valves have enabled varying levels of control in carefully matched patients.¹⁰,¹¹ In addition, the ability to monitor, overcome ventilator self-tests, exposure, and alarms have been overcome by recent systems.¹²

Splitting high flow oxygen delivered by a mask or a nasal cannula is certainly less risky, although the rate of oxygen consumption would be increased without special valving leading to accelerated depletion of oxygen reservoirs. In 2021, insufficient oxygen reserves and widespread use for COVID-19 patients created drastic shortages, leading to increased mortality in India.¹² Technologies to cost-effectively expand high-flow nasal oxygen systems without wastage would benefit health care infrastructures experiencing high caseloads.—Shriya S. Srinivasan, PhD, Department of Mechanical Engineering, Massachusetts Institute of Technology, Division of Gastroenterology, Hepatology and Endoscopy, Brigham and Women’s Hospital, Harvard Medical School, David H. Koch Institute for Integrative Cancer Research, Massachusetts Institute of Technology, Project Prana Foundation, Cambridge 02139, Boston 02115, MA, United States; E-mail: shriyas@mit.edu. Twitter: ShriyaSrinivas3; Rajib Mondal, Harvard-MIT Division for Health-Sciences and Technology, Research Laboratory of Electronics, Massachusetts Institute of Technology, McGovern Institute for Brain Research, Massachusetts Institute of Technology, Project Prana Foundation, Cambridge, MA 02139, United States; E-mail: rmondal@mit.edu. Twitter: rajibmndl; Khalil B. Ramadi, PhD, Department of Mechanical Engineering and David H. Koch Institute for Integrative Cancer Research, Massachusetts Institute of Technology; Division of Gastroenterology, Hepatology and Endoscopy, Brigham and Women’s Hospital, Harvard Medical School; Project Prana Foundation, Cambridge 02139, MA, United States. Division of Engineering, New York University Abu Dhabi, Abu Dhabi, United Arab Emirates; E-mail: kramadi@mit.edu. ORCID identifier: https://www.doi.org/0000-0002-5864-2386.

Author Disclosures

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