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## LETTERS TO THE EDITOR

Letters to the Editor are encouraged and may be submitted at [jenonline.org](http://jenonline.org) where submission instructions can be found in the Author Instructions.

### A Modified Aerosol Mask Could Significantly Save Oxygen Supplies during SARS COV 2 Pandemic



Dear Editor:

Coronavirus disease (COVID-19) is predominantly a respiratory illness that can evolve to hypoxemic respiratory failure. In those cases, oxygen therapy is used as first-line treatment and is still the most supportive treatment of the disease.<sup>1</sup> Therefore, oxygen supply is key for an effective health care response, and meeting the surging oxygen demand is vital during the COVID-19 emergency. Of note, the World Health Organization recently published an interim guide on oxygen source and distribution during the COVID-19 pandemic, estimating that an average of 90 m<sup>3</sup> of oxygen per hour would be necessary to cover the needs of a hospital managing 100 concurrent COVID-19 cases.<sup>2</sup>

Unfortunately, epidemic waves have put health care systems under stress, and oxygen supply scarcity has been encountered in some regions of the world, such as India, Africa and Latin America.<sup>3</sup> Oxygen supply and oxygen-saving strategies are thus of utmost importance for those regions.

To treat severe hypoxemia, the main systems currently used are the non-rebreathing mask or high flow nasal oxygen.<sup>4</sup> However, these systems consume large amounts of oxygen and have thus limited usefulness in places where hospital capacities are overwhelmed and oxygen storages have been depleted.

The Modified Aerosol Mask (MAM) is an original hand-made oxygen delivery system that can be self-assembled with few and easily available disposables. Indeed, the MAM is made of 1 aerosol mask onto which 2 pieces of corrugated tubing (15 cm length) are connected (Figure 1). The whole system is placed above the classical nasal cannula (NC), which remains the source of oxygen distribution. During expiration, the continuous oxygen flow from the NC is collected in the 2 tubes instead of being immediately dispersed into the room. During the next inspiration, the patient will receive, when

inspiratory flow exceeds NC flow, this oxygen-enriched gas mixture from the tubes instead of atmospheric room air. Of course, once the tidal volume exceeds the mask and tubing volume (210 mL), atmospheric air will penetrate the tubes and will be inspired by the patient. In doing so, the increased dead space from the corrugated tubes of the MAM theoretically acts as a collector of wasted oxygen during the expiratory phase or in the case of mouth breathing (Figure 2). This set up may have the advantage of increasing the fraction of inspired oxygen for a given oxygen flow delivered by NC, without clinically significant arterial CO<sub>2</sub> increase.<sup>5</sup> Hence, for this fraction of inspired oxygen, the addition of the MAM allows lower oxygen flows and thereby saves oxygen supplies. The MAM can spare up to 50% of oxygen flow while preserving a target arterial oxygen pressure.<sup>6</sup> This mask is an experimental prototype, used under an emergency exemption and with approval from the two main ethics committees of our country. The device has not yet been approved for use in the United States. The MAM can be used with either oxygen cylinders or oxygen concentrators. This device could thus be valuable in those countries in need of enormous amounts of oxygen and undergoing actual oxygen scarcity. In addition to hospital use, an online video tutorial (shared by a Quick Response-code on oxygen bottles) or documentation included with oxygen bottles could allow implementation of this simple device among the population for at-home care. In addition to saving oxygen, proper use of this device could have a significant economic impact on and reduce the risk of catastrophic health expenditure faced by families taking care of their relatives at home because of overwhelmed hospitals.—Duprez F, PT, RT, PhD, ICU Epicura Hospital Hornu Belgium and Laboratory of Motion and Respiratory Physiology Condorcet School, Tournai, Belgium; De Terwangne Ch, MD, PhDs, Department of Geriatric Medicine, Université Catholique de Louvain, Brussels, Belgium; Poncin W, RT, PhD, Service de Pneumologie, Cliniques; and secteur de Kinésithérapie et Ergothérapie, Cliniques Universitaires Saint-Luc, Brussels, Belgium; Bruyneel A, RN, CCRN, PhDs, Health Economics, Hospital Management and Nursing Research Department, School of Public Health, Université Libre de Bruxelles, Brussels, Belgium. **Twitter:** @ArnaudBruyneel. **ORCID identifier:** <https://orcid.org/0000-0001-6276-2762>; De Greef J, MD, PhDs, Service de Médecine Interne et Maladies Infectieuses, Cliniques Universitaires Saint-Luc, Brussels, Belgium and Louvain Centre for Toxicology and Applied Pharmacology, Institut de Recherche

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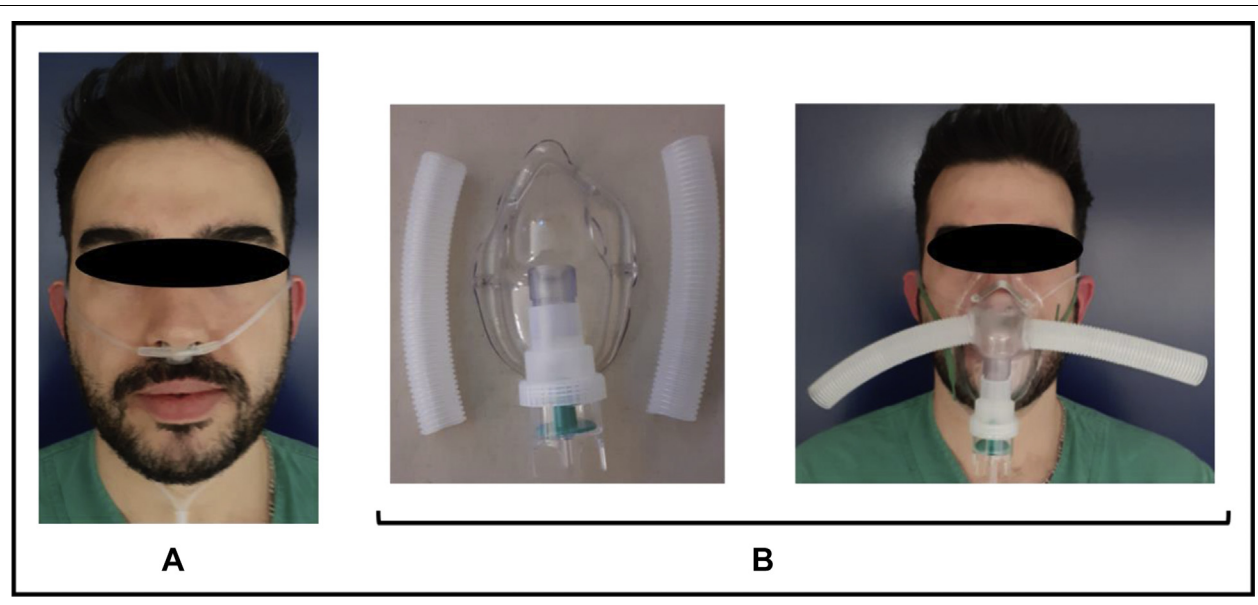


FIGURE 1

(A) Subject receiving low flow oxygen by classical NC. (B) The first image depicts the MAM: a classical aerosol mask with 2 lateral holes on which 2 corrugated tubes ISO (tube radius 22 mm  $\pm$  15 cm length for adult) are connected. The second image depicts a subject with a MAM and classical NC (subject always receives oxygen low flow by classical NC). MAM, Modified Aerosol Mask; NC, nasal cannula; ISO, International Organization for Standardization.

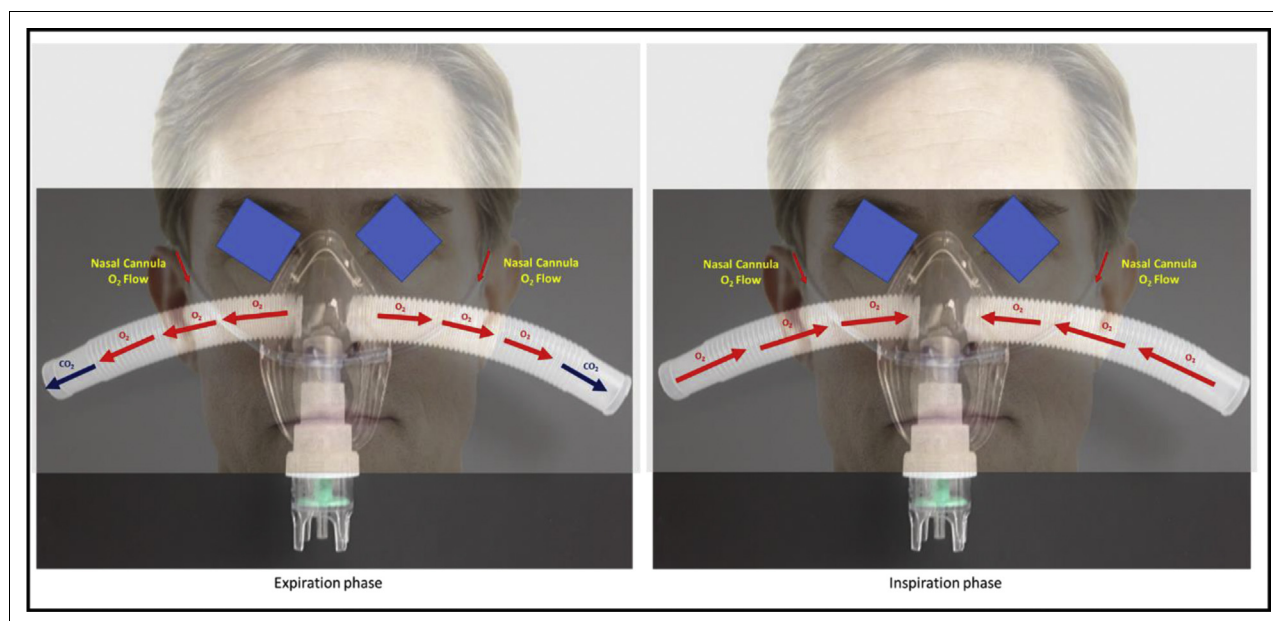


FIGURE 2

How does MAM work? During expiration (left side), the continuous oxygen flow from the nasal cannula is collected in the 2 tubes instead of being immediately (with expiratory CO<sub>2</sub>) dispersed into the room. During the next inspiration (right side), the patient receives this oxygen-enriched gas mixture from the tubes instead of atmospheric room air. MAM, Modified Aerosol Mask; CO<sub>2</sub>, carbon dioxide; O<sub>2</sub>, oxygen.

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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.<sup>1</sup> The novel disease came with 2 immediate challenges: (1) building disease-specific diagnostics, therapeutics, 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 al<sup>2-4</sup> 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.<sup>2-4</sup> 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.<sup>5</sup>

## 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.<sup>5,6</sup> 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.<sup>7,8</sup> 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 al<sup>4</sup> 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.