

Heliox Should Be Available in Every Community Hospital

The June special issue of *RESPIRATORY CARE* features 6 symposium papers about the use of heliox gas. I agree with the guest editor, James Fink, that the issue is a "valuable resource for clinicians."¹ I write this letter because I think heliox has a special role in community hospitals; in fact, I believe that heliox should be available in every community hospital. In community hospitals, surgeons and anesthesiologists with advanced airway skills are not always readily available (eg, 10:00 pm Sunday on a holiday weekend). Patients who develop acute life-threatening upper-airway obstruction under such circumstances are in a terrible predicament. In addition, the respiratory therapist who will undoubtedly be summoned to such an emergency will be in the agonizing position of not having much to offer to the suffocating patient.

Heliox is unique in that it can reduce airway resistance, work of breathing, and improve ventilation without changing the diameter of the airway. This makes heliox a life-saving bridge to definitive therapy (eg, tracheostomy) for the patient dying of severe upper-airway obstruction. Are there large randomized controlled trials to support my contention? No, and there never will be. There are simply not enough patients in this predicament to study, and even if there were, it would be unethical to deny patients a potentially life-saving therapy, which would be required to have a control group.² We have used heliox at our community hospital for many years now, mostly for upper-airway obstruction, but occasionally for hypercapnic asthma exacerbations.³ We need to use it only a few times per year, but when we have needed it, heliox has proven to be a valuable tool to have available. Heliox is easy to administer, and directions for use can be kept with the tank if a department uses it only on rare occasions.

In my mind, heliox in a community hospital should be viewed no differently than an automated defibrillator stationed in a public place, in that, even if you need

it only once every 10 years to save a life, it is still worth having around.

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The author reports no conflict of interest related to the content of this letter.

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Heliox Therapy and Devices Cleared by the FDA: After the Engineers Produce Effective Designs, Why Do Clinicians Still Feel the Need to Jury-Rig?

The June 2006 special issue of *RESPIRATORY CARE*, on heliox therapy, reminds clinicians that there are still some shortcomings to applying heliox with equipment designed for oxygen and room air. The article by James Fink¹ addresses the issue of jury-rigging devices for heliox delivery in clinical practice. He cautions about the high risk of liability and the need for institutional safeguards,¹ and he strongly encourages clinicians to use heliox devices cleared by the Food and Drug Administration (FDA), to reduce risk. He discusses certain ventilators that have been bench-tested with heliox, and he lists several FDA-cleared heliox-delivery products available for rapid, first-line heliox treatment, two of which (Hope, B&B Medical Technologies, North Highlands, California; Flo-Mist, DHD Healthcare, Wampsville, New York) warrant comment that

partly explains why clinicians still may want to jury-rig heliox devices.

The Hope is powered by oxygen or air at 10 L/min to nebulize a solution. Heliox (up to 40 L/min or more) is then added via a separate port. With the Flo-Mist, 22–32 L/min of heliox gas can be added to the 13 L/min drive flow. The manufacturer claims that aerosol particle size and output are unchanged with heliox.

The way in which some devices are cleared by the FDA can cause 2 problems that cause clinicians to feel the need to use products in ways not cleared by FDA.

1. *Clinical practicality* may be lost when the package instructions for these 2 continuous nebulizer devices are followed. The addition of the heliox flow increases total output to 40–50 L/min, while the patient's average minute ventilation may be 5–10 L/min, depending on the severity of symptoms. The clinician may wonder if the high flow dilutes the medication delivery to the patient by 3–4-fold, and may not want to deliver heliox at more than twice the flow rate of average heliox therapy, because this uses (and wastes) much more helium. When novel devices are approved in this manner, it may "force" the clinician to try to apply the theory under relevant conditions linked to the approved standard.

2. *FDA requirements may be too restrictive.* New products are developed by engineers and designers, who spend months with bench and some "real-life" testing. Fink mentions that, while some jury-rigged devices can be innovative, it is safer to leave the testing to combination teams of clinicians and engineers.¹ Some products receive 510(k) clearance based on similar properties and specifications from the bench test alone.² This clearance is granted to manufacturers who demonstrate substantial equivalence to an existing cleared device. The use of heliox, in any percentage, is not included as the drive gas to power the nebulizer in those device studies. The FDA holds strict standards that these 2 products deliver appropriate aerosol particle size, whether the clinical application is practical or not. A study by Goode et al found that aerosol delivery improved when an oxygen-driven