Opportunities and Risks of Using Heliox in Your Clinical Practice

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Summary

Helium-oxygen mixture (heliox) has been advocated for clinical use since 1934, and there has been a growing array of clinical applications. Until recently, administering heliox has required jury-rigging by modifications and/or extension of available devices not designed for use with heliox. This paper reviews devices required to administer heliox and considers how devices designed to deliver air and/or oxygen have been adapted for use with heliox. Use of devices outside of their design limits adds risk and liability, whereas using Food-and-Drug-Administration cleared devices for heliox administration reduces the risk and liability. Key words: helium, heliox, nebulizer, ventilator, regulator, analyzer, blender, risk. [Respir Care 2006;51(6):651–660. © 2006 Daedalus Enterprises]
Since 1934, when Barach first reported clinical use of helium, clinicians have faced the necessity to improvise, jury-rig, and kluge delivery systems for helium and helium-oxygen mixture (heliox), using components that were not designed for those gases. Until very recently, clinicians had to develop their own methods to deliver and monitor heliox, using technology and specific devices that had primarily been designed for use with air or oxygen (Table 1). Some of these methods have incorporated intuitive innovations that have ranged from brilliant success to catastrophic failure.

While heliox has considerable potential to benefit patients in various settings, the success of heliox therapy depends on the methods and devices used. Innovation has been key to introducing heliox into clinical practice, but the practice of modifying commercially available devices to function outside of their intended design constraints creates considerable risk and liability for the patient, clinician, and institution. The risks include anoxia (by inadvertently administering an anoxic 100% helium) and delivering a dangerously high lung volume (because flow meters designed to measure air or oxygen flow give incorrect readings with heliox). Only by understanding how helium affects devices and by becoming familiar with how a device or system performs with heliox can researchers and clinicians safely administer heliox. One of the best ways to minimize risk is to use devices that are designed for heliox and cleared by the Food and Drug Administration (FDA) for use with heliox, as they become available on the market. This paper explores key considerations in devices used for administering heliox, and discusses reducing risk by using devices designed and cleared for heliox delivery.

### Devices Used With Heliox

#### Regulators

The most readily available component specifically designed for use with heliox, the regulator, is required to transition the compressed gas into the breathing system. Currently, regulators are commercially produced to deliver pure helium or heliox. Heliox is commonly available in concentrations of 80% helium/20% oxygen (80:20 heliox) and 70% helium/30% oxygen (70:30 heliox), and in various cylinder sizes. Both single-stage and 2-stage regulators are available. Concern has been raised that the threaded connections of the regulator-to-cylinder connectors are the same for heliox and carbogen (a mixture of 95% oxygen and 5% carbon dioxide). Both heliox and carbogen regulators use Compressed-Gas-Association 280 threaded inlet and Diameter-Index Safety System 1020/1180/1200 outlets, so there is a risk of accidentally administering carbogen instead of heliox. Therefore it is important that clinicians double-check before administering carbogen or heliox by documenting that they have read the cylinder label and analyzed the cylinder contents for oxygen.

#### Flow Meters

Helium and heliox flow through an orifice faster than do air or oxygen. Consequently, when using a flow meter calibrated for oxygen or air, a correction factor (based on the helium concentration) must be applied to correct for the difference in flow rate (Fig. 1). The heliox correction factors are generally rounded off to 1.4 for 80:20 heliox, and 1.8 for 70:30 and 1.8 for 80:20. Thus, when an oxygen flow meter delivering 80:20 heliox reads 10 L/min, it is actually delivering 18 L/min (ie, 10 × 1.8).

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**Table 1. Devices Commonly Used With Heliox**

<table>
<thead>
<tr>
<th>Device Type</th>
<th>Available Devices</th>
<th>Designed for Use With Helium?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulators</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Flow meters</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Masks</td>
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<td>Analyzers</td>
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<td>Yes</td>
</tr>
<tr>
<td>Monitors</td>
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<td>Yes</td>
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<tr>
<td>Nebulizers</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Ventilators</td>
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</tr>
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</table>

heliox = helium-oxygen mixture

Fig. 1. Diagram from which conversion factors are derived for calculating actual heliox flow rate from readings from flow meters calibrated for air or oxygen. (From Reference 5, with permission.)
Back-pressure-compensated flow meters have been designed for delivery of helium and several specific concentrations of heliox. These devices are commercially available from several manufacturers, at prices similar to those for air and oxygen flow meters of similar design. However, many clinicians persist in using readily available air or oxygen flow meters when delivering heliox.

Accessories for Delivery

Helium has a very high diffusion coefficient and can escape from all but the most tightly sealed containers. This creates particular problems in administering heliox to the patient’s airway, especially in nonintubated patients. The most effective heliox systems appear to be closed systems, but, except for invasive mechanical ventilation, a closed system is relatively difficult to accomplish.

To achieve a sufficient helium concentration (> 50%) to gain mechanical advantage from the helium, the system needs to be “helium tight,” which requires considerably less leak than “air tight.” The system should be high-flow, with sufficient flow to meet or exceed the patient’s requirements for minute volume and peak inspiratory flow, to minimize dilution with ambient air.

Helium is relatively rare on the Earth, and an H-size cylinder typically costs more than $80. Flushing a high flow of heliox into the patient’s airway to meet the peak inspiratory flow requirement is expensive and can be wasteful. The delivery method should include a reservoir and an on-demand delivery system that minimize total flow and helium requirements.

Masks

Several studies have used valved nonrebreather oxygen masks with reservoirs. The problem is that most of these commercial masks are not designed to provide a sufficiently snug fit to minimize heliox leakage. A disposable nonbreathing oxygen mask that rarely delivers > 60% oxygen will not be sufficient to consistently deliver an adequate heliox concentration to the patient. Typically, ambient gas enters the system between the mask and the reservoir with all but the best-fitting masks, and this dilution may be an even greater problem with heliox. To be successful, the mask must have a tight fit and a competent valve, or a valved exhalation port. Unfortunately, properly sealing, tight-fitting masks (such as those used for anesthesia or mask continuous-positive-airway-pressure systems) are more expensive and may be less comfortable when properly seated, especially with infants and small children.

Catheters and Cannulas

In adults, both catheters and cannulas are low-flow devices that do not deliver sufficient concentrations for reliable heliox administration. However, in infants cannulas made for nasal continuous positive airway pressure may provide an adequate seal and maintain pressure at the nares and might therefore be effective with heliox.

Tents and Hoods

Tents and hoods have been suggested for use with infants and small children. These may appear to provide a closed system conducive to heliox administration, but studies suggest that hoods and tents are less effective than tight-fitting masks. It has been hypothesized that helium rises to the top of the enclosure, above the nares and mouth. As with oxygen, leaks are very difficult to control if you do not get a good seal around the perimeters of the enclosure.

Hypothermia with hood or tent heliox administration has been anecdotally reported. Helium’s thermal conductivity is 6 times that of nitrogen, so the risk of hypothermia should be considered before using a hood or tent. Inside a diving helmet filled with heliox, the diver can lose body heat 6 times faster than with compressed air or nitrogen-oxygen mixture, which increases the risk of hypothermia. Heating the heliox before the diver inhales it is one strategy used to combat hypothermia. Some clinicians have cautioned against administering heliox at temperatures less than 36°C to infants and small children contained in hoods or tents.

Artificial Airways

For patients with artificial airways, closed systems with demand valves and reservoirs continue to be the commonly used systems. Open T-tubes, even with attached open reservoir tubing, will not adequately contain the helium. A valved reservoir with a valved exhalation port may be more effective in maintaining the desired concentration. An alternative to the reservoir is a demand regulator that provides adequate and immediate gas flow in response to the patient’s inspiratory effort, as does the Aptaer heliox administration system (GE Healthcare, Madison, Wisconsin).

Analyzers

Clinicians commonly use oxygen analyzers to monitor heliox concentration “by exclusion,” based on the assumption that the delivered gas is either helium or oxygen; if you know the oxygen concentration, then the remaining gas is helium. This assumes that there are no leaks in the
system and no opportunity for air or other gases to enter the system at the point of measurement. An oxygen analyzer cannot detect any addition or leak of air into the system.

Although rarely advertised for use in respiratory care applications, helium analyzers have been available for various commercial applications for many years. These analyzers enable leak detection in industrial applications ranging from pharmaceutical manufacturing to food-processing to tracing leaks in home floor radiant heating systems. Multiple companies market helium analyzers for gas mixtures used for diving. Most analyzers operate by comparing the thermal conductivity of the sample gas to the thermal conductivity of a reference gas housed in a sealed cell, using a temperature-sensitive heated filament mounted in each cell. These filaments are part of a Wheatstone Bridge circuit. Thermal-conductivity gas analysis is also used to measure oxygen, hydrogen, carbon dioxide, and other gases. These gases are normally measured in a background of air, but the sensors operate just as well in a background of nitrogen or when monitoring 2 inert gases. There generally is a quick (< 15 s) response to any change in gas composition. The helium concentration reading can be updated about every 1 second.

The basic assumption on which these analyzers work is that the gases in the mixture are known (eg, oxygen, nitrogen, and/or helium). Minor amounts (< 1% total) of trace gases will not significantly alter the readings and can be ignored. The sensor is nonspecific; it will not indicate if the test gas has carbon monoxide, argon, or any other gas in the mix. It will only determine the relative difference in thermal conductivity of the test gas to the reference cell. It is assumed that the difference is the result of the addition of helium to the gas mixture.

While few respiratory services have a helium analyzer for use in the emergency department or intensive care unit, many have one in the pulmonary function laboratory, although many of these helium analyzers have a range limited to 0–15% helium. The FDA has provisions for approving helium analyzers for use with pulmonary-function-testing devices, defining a helium gas analyzer as a device intended to determine the concentration of helium in a gas mixture during pulmonary function testing. The device may use techniques such as thermal conductivity, gas chromatography, or mass spectrometry.

**Blenders**

While heliox blenders abound in the diving community, they appear to be rare in the medical community. Consequently, clinicians either entrain oxygen into a pre-set heliox concentration, or use blenders designed for oxygen and air. There is limited published evidence on which, if any, blenders are satisfactory for use with heliox. Typically, the 80:20 heliox is attached to the air inlet of the blender, and an oxygen analyzer is placed immediately downstream to monitor the blended gas.

Tassaux and colleagues evaluated the fraction of inspired oxygen (FIO2) delivered through 7 commercially available ventilators and found that all but one provided ±10% of the set FIO2 (Table 2).9

Before using a blender with or without a ventilator, test the accuracy and reliability of the system’s FIO2 readings and know the difference between the set FIO2 and the actual FIO2.

**Monitors**

There are a number of ventilation monitors, both integrated in and independent of mechanical ventilators. Few are designed specifically for use with heliox. Monitors that are not designed for use with heliox may behave erratically, providing inconsistent and unreliable volume and flow readings. Monitors designed for use with heliox may allow for specifying the fraction of inspired helium and other gases being monitored.

As a general guide, any monitor or test lung that measures displaced volume should accurately measure the volume and flow of heliox. Unfortunately, no systems are currently commercially available that provide volumetric bedside monitoring for mechanically ventilated patients. There are several test lungs that use volume displacement, which simplifies in vitro testing of a ventilator’s performance with heliox (Fig. 2).

Nonvolumetric monitors usually use pressure-differential transducers or hot-wire anemometers to measure flow through the circuit. The 5-fold greater thermoconductivity of helium affects anemometer readings, whereas density

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### Table 2. Actual FIO2 During Heliox Administration With 7 Ventilators

<table>
<thead>
<tr>
<th>Set FIO2</th>
<th>Veolar FT</th>
<th>Galileo</th>
<th>Evita 2</th>
<th>Evita 4</th>
<th>Servo 900C</th>
<th>Servo 300</th>
<th>Series 7200</th>
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<td>0.99</td>
<td></td>
</tr>
</tbody>
</table>

*The set FIO2 is the fraction of inspired blender setting (as opposed to the actual FIO2). heliox = heliox-oxygen mixture (Data from Reference 9.)

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affects pressure-differential transducers. To determine how a monitor works with heliox, test inline with a volumetric monitor, considering the volumetric device the standard (see Fig. 2).

Nebulizers

Heliox improves aerosol deposition, with up to 50% more drug delivered, primarily because helium’s density is lower than air or oxygen, and the lower density means less gas turbulence and less aerosol-particle-impaction loss in the tubing and airways. The lower gas density of helium also affects pneumatic (jet) nebulizers. At a given gas flow, a jet nebulizer produces less aerosol output per unit time with heliox than with air or oxygen. Hess et al found a smaller particle size and lower aerosol output rate with jet nebulizers (all operated at 8 L/min) with 80:20 heliox than with air. Increasing the heliox flow rate to 11 L/min increased the particle size and the output rate to values similar to those achieved with air at 8 L/min.

Corcoran and colleagues also found lower aerosol output with heliox, but they did not find a comparable difference in particle size. They attributed this to a difference in methods; they used a Doppler method of aerosol characterization, whereas Hess et al used the cascade impactor method.

Goode et al found a similar heliox-flow-related impact on nebulizer output (Fig. 3). In their experiments, 10 L/min of heliox generated similar output to 6 L/min of oxygen, but 15 L/min of heliox generated 2-fold more aerosol than did 10 L/min of oxygen. Aerosol output is directly correlated to the density of the driving gas (Fig. 4).

It is important to recognize that when delivering 80:20 heliox through a flow meter that is calibrated to measure air or oxygen flow, a reading of 6 L/min indicates an actual flow of > 10 L/min of heliox, which is sufficient to produce a similar nebulizer output to air at 6 L/min. Volumetric and corrected flow at 8 L/min with oxygen and heliox has been reported to provide similar inhaled aerosol mass (Fig. 5). The output of aerosol-generation technologies other than pneumatic (jet) nebulizers, such as pressurized metered-dose inhalers and vibrating-mesh nebulizers, is not changed by heliox. However, heliox reduces turbulence (with a linear correlation to gas density), which reduces aerosol-particle-impaction loss to the walls of the tubing and airways. A comparison of deposition from a pressurized metered-dose inhaler with spacer chamber in a ventilator circuit with oxygen versus 80:20 heliox showed a > 50% in-
crease of aerosol delivered to a filter beyond the endotracheal tube (Fig. 6).\textsuperscript{12}

Nebulizers Cleared for Use With Heliox

The Hope nebulizer (B&B Medical Technologies, North Highlands, California) was the first large-volume pneumatic nebulizer cleared by the FDA for administration of aerosol with heliox. In this device, the primary gas inlet, which generates the aerosol, is driven by air or oxygen; a secondary inlet allows heliox to be added, with flows > 40 L/min, without affecting aerosol-particle size or output.\textsuperscript{15} Other pneumatic nebulizers, such as the Flo-Mist (DHD Healthcare, Wampsville, New York), which has a similar dual-gas-inlet design, are entering the marketplace.

A vibrating-mesh nebulizer (Aeroneb Pro, Nektar Therapeutics, Mountain View, California) has been FDA-cleared for use with the Aptaér heliox delivery system (GE Healthcare, Madison, Wisconsin), based on evidence that the aerosol output and particle size was consistent with oxygen or heliox (Table 3).\textsuperscript{14} The Aptaér system is a pressure-support device for use with a sealed mask, with an integrated vibrating-mesh nebulizer. The use of a coaxial circuit and placement of the nebulizer proximal to the delivery system increased aerosol deposition to 35% of nominal dose, compared to 18–22% with a standard ventilator circuit and placement proximal to the patient, at the Y-piece.\textsuperscript{14} Deposition of aerosol in an in vitro model with an unobstructed airway was similar with air and heliox, at 35% inhaled mass. Only when a partially obstructed airway was simulated was a 50% increase in deposition observed with heliox (Fig. 7 and Table 4).\textsuperscript{14}

Mechanical Ventilators

Until recently, no ventilators were FDA-cleared for heliox. Tassaux and colleagues\textsuperscript{9} evaluated the functioning of 7 ventilators with heliox, some of which worked well with heliox, and some of which did not (Table 5). Ventilators that work with heliox may require a conversion factor to adjust settings (Fig. 8).\textsuperscript{9} The 80:20 heliox is typically attached to the air inlet.

The Puritan Bennett 700 series ventilator (Puritan Bennett, Pleasanton, California), which incorporates a frictionless piston, provides accurate volume and flow measurements and monitoring in vitro, but the oxygen sensor alarm must be disabled.

The eVent ventilator (eVent Medical, Vista, California) also works well with heliox, but the Puritan Bennett 7200 and 800 series, the Dräger Evita 2 and 4 (Dräger Medical, Telford, Pennsylvania), and the Engström Carestation ventilator (GE Healthcare, Madison, Wisconsin) do not work with heliox.

Berkenbosch and colleagues found considerable differences between displayed and delivered tidal volume (Fig. 9 and Table 6) and consumption rates of heliox among various modes of ventilation and ventilator brands.\textsuperscript{16} Some bi-level devices have been reported to perform erratically with heliox.\textsuperscript{17}

Ventilators Cleared for Delivery of Heliox

The Avea ventilator (Viasys Healthcare, Conshohocken, Pennsylvania) was the first ventilator cleared for use with air, oxygen, and heliox. Several other ventilators will probably receive approval soon.
The greatest risk with heliox is in the use of a jury-rigged device operated by a person who does not understand the implications of the device or the gas being administered.

For many years, respiratory therapists have prided themselves on their ability to modify, extend, or jury-rig available components and adapters to create effective devices for “off-label” applications. This was how technical innovations such as intermittent mandatory ventilation and continuous positive airway pressure were initiated. In today’s risk-averse environment, the hospital risk manager would be at risk for apoplexy upon finding unproven, jury-rigged devices being applied to critically ill patients.

The safety and effectiveness of jury-rigged devices are only as good as the ingenuity and diligence of the clinician who rigs them. Some of these devices are brilliant and innovative, whereas some are not so good, and some are downright dangerous. Few clinicians are trained to design medical devices, just as few engineers are trained to provide respiratory care. The formal device-development process occurs with teams of competent engineers and designers working for months or years to be sure that the device works as intended to meet each specification, with extensive real-life testing to minimize unanticipated variations in performance. On the clinical side, we rarely spend more than a few hours developing a device modification, and we rarely spend adequate time with in vitro performance analysis prior to patient application.

If an institution decides to use heliox device configurations that are not within the intended use of the devices, 2 safeguards should be strongly encouraged. First, comprehensive and detailed policies and procedures should be written, reviewed, and taught to all relevant staff. Second, extensive bench testing should be undertaken to confirm the consistent functioning and operation of the device.

### Hazards of Heliox Use

#### Anoxia

One of the greatest hazards with helium administration is the possibility of delivering a gas mixture that contains < 21% oxygen. This risk is reduced by never administering 100% helium to a closed system, and always using heliox that contains at least 20% oxygen in clinical applications. The use of an oxygen analyzer in line with the gas output provides some assurance that sufficient oxygen is present in the gas mixture delivered to the patient.

In 1990, a hospital that used a medical gas cylinder labeled “certified mixture of 30% oxygen and 70% helium” and intended for patient inhalation found, after beginning administration of the gas to a patient, that the cylinder delivered an FiO2 < 0.21, because the gases in the cylinder had not been mixed before delivery to the hospital, even though the mixture had been labeled as certified. Following this discovery, the remaining cylinders in the lot were tested, and some of them contained unmixed gases.

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Suppliers add pure gases to a cylinder one at a time, using a gravimetric method (weighing the cylinder and contents during filling) to provide the most accurate gas mixture. However, the gases are stratified and do not quickly mix. Highly compressed gases behave almost like liquids, and they mix slowly if diffusion is the only mixing process and no additional mixing method (such as rotating the cylinder on rollers until the components are thoroughly mixed) is used. Once the mixture is homogenized, it will not stratify again at room temperature and can be delivered to the user.

*Health Devices* journal recommends that users always verify the contents of a cylinder of mixed gases when it is received and again before connecting it into a system and administering gas to a patient. Always use an oxygen monitor in a breathing system.18

Hypoxia has been reported with heliox in preterm infants who have a history of bronchopulmonary dysplasia and subglottic stenosis.19 It has been hypothesized that hypoxia in preterm infants secondary to heliox adminis-

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### Table 4. Aerosol Deposition With Heliox Versus Air, With and Without a Fixed Obstruction in the Model

<table>
<thead>
<tr>
<th>Gas, % Heliox</th>
<th>Mean ± SD Deposition Percent at Resistance of 20 cm H2O/L/s</th>
<th>Mean ± SD Deposition Percent at Resistance of 50 cm H2O/L/s</th>
</tr>
</thead>
<tbody>
<tr>
<td>Air</td>
<td>36.8 ± 1.9</td>
<td>32.2 ± 1.8</td>
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<tr>
<td>70:30 heliox</td>
<td>47.8 ± 2.5</td>
<td>44.3 ± 1.1</td>
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70:30 heliox = mixture of 70% helium and 30% oxygen

V_T = tidal volume

(Data from Reference 9.)

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### Table 5. Correction Factors for Inspiratory and Expiratory Volumes With 7 Ventilators

<table>
<thead>
<tr>
<th>Ventilator Model</th>
<th>Veolar FT</th>
<th>Galileo</th>
<th>Servo 900C</th>
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</tbody>
</table>

FIO2 = fraction of inspired oxygen

Insp = inspiratory volume correction factor, calculated as delivered V_T divided by set V_T

Exp = expiratory volume correction factor, calculated as V_T reported by the ventilator divided by actual measured expired V_T

Inop = inoperative

NL = nonlinear relationship

(Data from Reference 9.)

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Fig. 8. Relationship between the tidal volume set on the ventilator and the tidal volume actually delivered by the ventilator, at various fractions of inspired oxygen (FIO2), with corresponding regression equations, for 3 ventilators: Veolar FT, Galileo, and Evita 2. (Adapted from Reference 9.)
tration is related to the reduction of lung volume and the increase of intrapulmonary shunt. Delivery of Too Much Volume

If the mechanical ventilator delivers more than the set volume, there is a risk of volume-induced injury, pressure-induced injury, or hypocarbia. This is of particular concern with ventilators not designed for heliox administration.

Delivery of Too Much or Too Little Bronchodilator

Running a jet nebulizer with too low a flow of heliox can result in inadequate aerosol delivery to the patient at a time when aerosol delivery is critical. On the other extreme, heliox can increase the lung delivery to well above the intended dose, though relatively few adverse effects have been reported in the literature.

Hypothermia

Hypothermia has been associated with hood administration of heliox to infants. Heliox must be used with caution because of its high thermal conductivity and the consequent risk of hypothermia when the gas temperature is < 36°C, especially when heliox is administered for long periods. The risk of hypothermia can be avoided with adequate warming and humidification of the heliox, using standard devices.

Liability With Heliox Devices

When devices are used outside their intended “labeled” design limits, liability shifts from the device manufacturer to the institution and clinician. As devices designed for and cleared by the FDA for use with heliox become available, integrating those devices into your practice reduces risk for the patient, clinician, and institution. Continued use of jury-rigged systems places patients and institutions at risk. It is always better policy to use a device that has FDA approval for a specific application, irrespective of price. Continued use of a jury-rigged setup would be very difficult to justify to a jury if there were a catastrophic device failure and resulting lawsuit, and such use would almost certainly be considered negligence.

Summary

Evidence continues to evolve that heliox can effectively reduce airway resistance and work of breathing in patients with severe airway obstruction and can improve delivery of aerosol by reducing turbulence and aerosol-particle-impaction en route to the lungs. As the practice of heliox administration continues to evolve, it is very important for clinicians to understand how heliox works, what it can and cannot do, and how it will affect devices and patients. No heliox-administration device should be used clinically without ample training and bench testing. As FDA-cleared devices are introduced in the market, jury-rigged devices must be eliminated to reduce risk for patients, clinicians, and institutions.

REFERENCES