Letters

More on Novel Oxygen-Concentrator-Based Equipment (Part 1)

I am responding to the editorial by Gallegos and Shigeoka in the January 2006 issue of Respiratory Care. The title “Novel Oxygen-Concentrator-Based Equipment: Take a Test-Drive First” (italics mine) suggests that the provision of the types of equipment discussed in the editorial is inappropriate or inadequately evaluated for use with patients who require supplemental oxygen in the home. I am particularly concerned to see statements such as, “Clinicians have ignored the consequences of less-than-pure O₂…”

The use of “less-than-pure” oxygen in oxygen concentrators is a battle that probably was won many years ago—to the benefit of the patient. As a therapist who has been involved in respiratory care for about 40 years, and home care for over 27 years, I recall the days of providing oxygen cylinders to patients in the home. Oxygen concentrators, even the early large, cumbersome units, were a godsend to providers in a consistent manner in homes all over America. There is voluminous documentation in the literature, beginning over 20 years ago, of the very adequate and clinically acceptable oxygenation provided to patients via oxygen concentrators.

Those of us who have been seeing patients in the home for many years remember the competitive pressure in the early days of providing some type of regular respiratory-therapy visits to the patient in efforts to impress referral sources and to “stand out” from the competition. Many of these visits included routine “spot-check” oximetry, with voluminous documentation of very adequate oxygenation per oxygen concentrator with the patient at rest. Unfortunately, at that time we were still very limited as to what we could offer the patient for portable oxygen, so there was not a lot of emphasis on evaluating the patient with activity.

Since those early days, home-care suppliers, in response to increasing costs and decreasing reimbursement, have drastically decreased clinical follow-up in the home. At the same time, younger patients are being prescribed oxygen therapy, as we intervene earlier in the course of the disease. They are also more active and desire—even demand—that oxygen therapy be integrated into their life activities. In the past couple of years, at least one major manufacturer has advertised directly to the patient community, using television extensively, to market a very small pulse-dose liquid-oxygen portable unit. This demand has been transmitted to the supplier community, as patients see this technology on television and then contact their oxygen supplier, feeling that this technology should be available to every patient and acceptable for every situation. At the same time this drives pulse-dose oxygen-delivery technology to be integrated into ever smaller and lighter portable units; both high-pressure cylinders and liquid oxygen, and then ultimately into lightweight “portable” concentrators. The combination of increasing costs, decreasing reimbursement, and demand for the most convenient technology to meet the patient’s expectations most likely leads to the patient situation described by Gallegos and Shigeoka in their editorial.

The first oxygen-conserving device I recall seeing advertised a 5:1 savings over continuous flow. It was advertised almost exclusively as a means to decrease the number of oxygen cylinders required, and consequently, a means to decrease costs for the supplier. Somewhere fairly far down the list, there was mention that patient oxygenation should probably be considered.

The oxygen supplier community is not totally without fault. Far too many suppliers have purchased and provided pulse-dose oxygen systems for purely financial reasons, perhaps as a survival strategy, but without adequate clinical evaluation of the patient’s oxygenation requirements. In contrast there are suppliers who have developed protocols, based on oximetry, to assess the patient’s tolerance of pulse-dose oxygen.

I think Gallegos and Shigeoka’s editorial is a wake-up call that should be addressed primarily to the medical community and to government reimbursement programs such as Medicare and Medicaid. The scenario described in the editorial will become endemic if Medicare and other payers are foolish enough to implement a provision in the recent Budget Reconciliation bill to require that oxygen concentrators be purchased for all patients on oxygen over 3 years. There are no provisions in the bill for any type of follow-up. The reimbursement amount for portable oxygen is totally inadequate to provide even conventional portable oxygen to a patient; liquid or other “high-tech” approaches to provide for patient mobility and activity with oxygen will be limited to only those patients who can pay for these “conveniences” privately.

Editorials, as opinion pieces, when describing unacceptable situations, generally indicate the need for further discussion and provide suggestions for resolution. I would suggest:

1. Uniform standards need to be developed for pulse-dose delivery devices, with accurate description of oxygen delivered. The calculations made in the editorial are extremely valuable, but should they really be necessary, particularly when the oxygen-conserving devices referenced all have liter-flow or equivalent markings on their selector dials?

2. As Gallegos and Shigeoka suggest, “verify that the selected...equipment provides adequate oxygenation during rest and exercise.” This verification should be a routine component of follow-up by the attending physician and/or rehabilitation program—not just the oxygen supplier.

3. All applications of an oxygen-conserving device for delivery of oxygen must require a physician’s order. The use of an oxygen-conserving device is more than just a novel approach to delivering oxygen at a selected liter flow.

4. Hospitals and physicians must become familiar with the new technology being demanded by oxygen patients. Assessment and evaluation of oxygen patients should be made with the patients using the oxygen-delivery systems they are using in their daily lives.

5. Recognize that the demand for increasingly convenient technology may be impacted by the brutal reality of constantly decreasing reimbursement. The oxygen-supplier and manufacturing communities are very resourceful, but their ability to absorb
ever-decreasing reimbursement is not infinite.

6. Finally, recognize that the patient scenario described in this editorial is not rare or unique at all. Not all patients turn down the oxygen flow for financial or conserving reasons alone, but far too many do. Until there is a rational reimbursement formula for portable oxygen, and realization that the provision of oxygen on a long-term basis to a patient living in the community entails much more cost of just the equipment, we will continue to see patients with inappropriate equipment, inadequate follow-up, and therapy that falls far short of what the ordering physician desires for the patient.

Tim J Good CRT AE-C RPFT
GoodCare by CPCI
Logan, Ohio

REFERENCES

The authors respond:

Our editorial described an encounter with a man who purposefully under-treated hypoxemia while using novel concentrator-based O2 equipment. That anecdote was a segue to describe a potential limitation of such equipment, namely, limited O2 output may lead to inadvertent under-treatment in specific conditions, such as exercise. We recommended that clinicians verify that this novel equipment provides adequate oxygenation during rest and exercise for each patient (“test drive”).

Good uses our editorial as a springboard to discuss a much larger problem, namely, how to provide appropriate service in the current era of reduced health-care spending, rapid technical advancement, and aggressive marketing. Fair is fair. Good, who is an experienced respiratory therapist and successful home-medical-equipment supplier, provides an important perspective. All long-term O2 therapy (LTOT) stakeholders should express their opinions. We appreciate his comments.

Medicare has supported LTOT since the landmark Nocturnal Oxygen Therapy Trial and Medical Research Council Trial were reported a quarter century ago. Medicare supports the majority of LTOT, and its LTOT guidelines have become a de facto standard. These guidelines have evolved with federal mandates and input from clinical experts and industry at the consensus conferences. Consensus conference recommendations have been published since 1986. We hope Good’s concerns are addressed in the report of the most recent (6th) LTOT conference, held in late August 2005, in Denver.

We would like to express some opinions, as Good has done. He reminds us that the battle for O2 concentrators took place more than 2 decades ago, when they were novel. Concentrators are now the most common stationary O2 equipment. New devices are expensive, but costs usually drop with technological and manufacturing advances. Modern concentrators are better and cost a fraction of what the early versions cost. A new battle for “truly portable” (10 pounds and lighter) equipment is looming. Unfortunately, past problems persist, such as the high cost of delivering cylinders of compressed O2, and liters of boiling liquid O2, “High-tech” solutions, such as the novel equipment we described and tiny cryogenic reservoirs filled from home devices that liquefy concentrator-produced O2, may offer a remedy for delivery costs.

Good laments spending less time with patients and is not pleased with direct-to-patient marketing. Physicians have also complained about these 2 problems for years; they are among many problems that contribute to our national health-care woes.

History repeats, albeit with variation. We found a 1991 marketing newsletter with the headline “Why the heat is on home medical equipment” and a brief article about “medical-equipment telemarketing scams,” “fragmented billing,” and “other unscrupulous activities” that contributed to the Omnibus Budget Reconciliation Act of 1990. Industry standards, both technical and ethical, will become increasingly important. Unfortunately, dealing with a reduced budget may be more difficult.

Good describes how oxygen suppliers have given up extra services (spot oximetry checks, O2 titrations) that helped them compete for referrals. This is fortunate. To avoid potential conflicts of interest, Medicare separates those who certify medical necessity (including measuring Pao2 and Sao2) from those who provide O2 services.

Good encourages education. We agree. One of us responded to complaints from nonpulmonologists about the lack of instructions for how to complete the certificate of medical necessity that is required by the Omnibus Budget Reconciliation Act of 1990, by co-authoring a primer. Now the certificate of medical necessity has (minimal) instructions. As revisions occur, updated instructions can be accessed on the Internet for free or by subscription. Each year, new clinicians and suppliers enter the workforce and must learn this arcane information, so education must be continuing.

Clinical experts have always encouraged research. The National Heart, Lung, and Blood Institute sponsored the Nocturnal Oxygen Therapy Trial, which studied patients with chronic obstructive pulmonary disease and severe hypoxemia. However, the guidelines for less severe hypoxemia and hypoxemia that occurs only during exercise or sleep were extrapolated from the Medical Research Council Trial. Recent studies raise questions about those extrapolations; for example, is there a survival benefit in patients with chronic obstructive pulmonary disease and moderate hypoxemia? There is some good news. The National Heart, Lung, and Blood Institute plans to study the efficacy of LTOT for improving survival in patients with chronic obstructive pulmonary disease and less-than-severe hypoxemia.

However, these studies may take more than 4 years to complete. Today’s chilling news (see below) raises concerns that Medicare could drop past agreements that were based on extrapolated information.

Good condemns the recent Budget Reconciliation Bill, which caps equipment rental at 36 months (after which the patient owns the equipment), because there are no provisions for follow-up maintenance and repair. He describes this as a wake-up call. We think it is a “shot across the bow” that reflects the seriousness of the national budget situation and may adversely affect patient care.

Finally, Good feels these problems should be addressed to the medical community and government reimbursement programs. We feel these problems should be addressed to all stakeholders, including patients, their families, their representatives (Congress), and the Executive. National priorities will have to be discussed. Otherwise, as budgets fall, advocates for one therapy (eg, motorized wheelchairs) may fight advocates for another therapy (eg, truly portable O2 equipment). A recent local newspaper had the headline “Pulling funds from kids study immoral,” and the article described the profound disappointment of our children’s hospital chief upon learning the 2007 budget
has no funds for the National Children’s Study,14 which was approved by Congress in 2000 and funded through 2006; enrollment was to begin in 2007. Our budget woes are pitting generation against generation!

Linda C Gallegos RRT
John W Shigeoka MD
Respiratory Care Center
Veterans Affairs Medical Center
Salt Lake City, Utah

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More on Novel Oxygen-Concentrator-Based Equipment (Part 2)

While we agree with Gallegos and Shigeoka’s final position, that oxygen technologies should be evaluated with each patient and concerning some of their technical data regarding oxygen concentrators and pulse-dose oxygen-delivery devices are inaccurate and misleading. We feel that Gallegos and Shigeoka’s editorial may perpetuate a number of common misconceptions regarding home-oxygen technologies and LTOT administration in the home.

Gallegos and Shigeoka’s introductory story regarding the patient who ran out of oxygen during a clinic visit can, unfortunately, be repeated daily for many O2 patients, using all types of home-oxygen technology. The unfortunate reality is that some oxygen users occasionally fail to adequately plan their time away from home and/or simply experience unplanned delays. The 19-hour clinic visit described by Gallegos and Shigeoka is well beyond the norm, and very few portable oxygen technologies can supply oxygen for 19 hours. We feel that Gallegos and Shigeoka inappropriately infer that the lightweight cylinder and pulse-dose device that their patient was using was the cause of the problem. Specifically, they express concern about oxygen concentrators and concentrator-based cylinder-filling systems, and suggest that the small cylinder and pulse-dose device contributed to the under-treatment of a patient’s hypoxemia. We feel this is not a technology issue, but rather the result of poor matching of cylinder size and oxygen need with the outing duration.

Gallegos and Shigeoka also suggest that the proprietary filling connections of the transfill cylinder played a role in the incident and would have been avoided if the patient was using a traditional oxygen device. However, if the patient had a standard oxygen cylinder, they still would have been required to provide the patient cylinders for his trip home. Numerous state and federal regulatory guidelines govern the refilling of compressed oxygen cylinders, including cleaning, purity testing, and lot tracking, which would prevent a clinic or other facility from refilling a cylinder owned by another organization. This partly explains why few home-oxygen providers offer a while-you-wait cylinder refilling service.

Gallegos and Shigeoka correctly point out that concentrators typically generate a less-pure oxygen-concentrate than the 99.6% oxygen specified in the United States Pharmacopeia. Although manufacturer specifications differ slightly, most modern concentrators deliver 90 ± 3%, although many units consistently deliver greater than 93%. These devices are intended for oxygen delivery via low-flow systems, which by nature and design deliver a varying fraction of inspired oxygen (F1O2). The clinical reality is that large differences in oxygen concentration yield only nominal differences in F1O2. Let us compare the F1O2 difference between using 85% oxygen and 100% oxygen, given a tidal volume of 500 mL, a 1-second inspiratory time, and a flow of 2 L/min (33.3 mL/s). With 100% oxygen the equation is:

\[ 0.21(500 – 33.3) + (1.0 (33.3))/500 = 26.3\% \]

With 85% oxygen the equation is:

\[ 0.21(500 – 33.3) + (0.85 (33.3))/500 = 25.3\% \]

Thus, a 15% difference in supplemental oxygen concentration results in only a 1% difference in F1O2. This minor difference is clinically insignificant, as it consistently produces the same net clinical effect as that of United States Pharmacopeia 99.6% oxygen.

Low-flow oxygen delivery via nasal cannula with an oxygen concentration of ≥ 85% is considered by most experts to be clinically equivalent to United States Pharmacopeia 99.6% oxygen for most stable, mildly hypoxemic patients. Three recent studies demonstrated the clinical efficacy of pulse-dose oxygen derived from transfill cylinders and portable oxygen concentrators delivered
to hypoxic subjects during various activities, including rest, exercise, and sleep.\textsuperscript{3–5} These studies demonstrated the clinical efficacy of the devices evaluated and proved the clinical equivalency to continuous flow.

Gallegos and Shigeoka used the air-dilution equation to illustrate how respiratory rate affects \( F_{\text{O}_2} \), but in their discussion they failed to fully account for how anatomical dead space and the changes in inspiratory time impact the net oxygen delivered via a continuous-flow system. In their example they compare a total flow of 1 L/min continuous to a minute volume of \( O_2 \) delivered via pulse-dose (using a 10-mL-per-breath bolus model) and suggest that a patient breathing 20 breaths per minute receives one fifth (200 mL) the \( O_2 \) they get from a 1 L/min continuous flow. This example fails to account for dead space and the fact that oxygen flowing during exhalation and the pause between breaths does not participate in gas exchange.

In modern, fixed-volume, pulse-dose devices, the net minute volume of \( O_2 \) delivered is the product of respiratory rate \( \times \) bolus volume, independent of the inspiratory-expiratory ratio or inspiratory flow demand. Newer pulse-dose conservers deliver oxygen at higher flows and for shorter durations, limiting delivery to the first 100 ms of each breath and thus maximizing alveolar oxygen delivery. Using Gallegos and Shigeoka’s example, a patient breathing 30 breaths/min with exercise on the same device (10 mL/breath) would get a total of 300 mL of \( O_2 \) per minute. Breathing 1 L/min continuous flow, maintaining a consistent inspiratory-expiratory ratio of 1:2 and assuming anatomical dead space of about 33%, the same 30-breaths/min patient would inspire about 7.3 mL of \( O_2 \) per breath, yielding a minute volume of 219 mL of oxygen, which is 81 mL less than the pulse-dose device. Even when correcting for a slightly reduced \( O_2 \) percentage (eg, 89%), the pulse-dose device still provides 267 mL of \( O_2 \), which is 48 mL more net \( O_2 \) to the lungs.

A recent study by McCoy et al evaluated the performance of pulse-dose oxygen-conserving devices under various respiratory rates.\textsuperscript{6} They found that as respiratory rate increases, pulse-dose devices more consistently maintain a target \( F_{\text{O}_2} \) than does continuous flow, because the pulse-dose devices deliver a larger net minute volume of oxygen (respiratory rate \( \times \) bolus volume). These results have also been supported by several clinical trials.\textsuperscript{7–11}

Gallegos and Shigeoka’s emphasis on the gas-mixing equation and calculation of \( F_{\text{O}_2} \) is accurate and highlights the variability of oxygen concentration common to low-flow oxygen devices. Oxygen device manufacturers have recognized this for years, which is why most pulse-dose-device manufacturers recommend patient- and product-specific titration to ensure appropriate oxygen delivery. It is also the reason many pulmonary experts urge titration of all low-flow oxygen systems to the patient’s specific activity level.

Gallegos and Shigeoka state, “Clinicians have ignored the consequences of less-than-pure \( O_2 \), because of the shape of the hemoglobin-\( O_2 \) dissociation curve, limitations of pulse oximetry, and the ease of raising the flow to compensate.” We disagree with that statement and note that, while the variables listed may explain why patients can clinically tolerate various devices, the patient’s oxygen saturation has really been the driver of clinical acceptance and tolerance.

Technological advances in LTOT have resulted in a number of lighter, quieter, more efficient, and longer-lasting systems that, when properly matched to the patient’s clinical requirements and lifestyle needs, essentially offer an unlimited supply of portable oxygen, with proven clinical performance. The goal is to improve the patient’s quality of life by cutting the tether of the stationary oxygen device that has, historically, anchored the patient at home.

While we recognize that not all new oxygen devices are appropriate for all patients, the same holds true for all oxygen systems. Technological advances play an important role in improving the quality and cost of care provided. We strongly agree that oxygen-technology users should be thoroughly familiar with the function and application of the devices they employ. Misunderstandings, misconceptions, and the traditional dogma that so often plagued health care must be overcome. As clinicians we must spend more time understanding and adapting to systems and technology that can improve the quality of care and the lives of our patients.

Joseph S Lewarski RRT FAARC
Inogen Incorporated
Goleta, California

Robert Messenger RRT
Invacare Incorporated
Elyria, Ohio

Thomas J Williams MBA RRT
Strategic Dynamics
Scottsdale, Arizona

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The authors respond:

We appreciate the comments of Lewarski, Messenger, and Williams about our editorial. We are pleased they agree with our conclusion that \( O_2 \) equipment should be evaluated with each patient, to ensure it provides adequate oxygenation: the “test drive.” It is gratifying because they represent manufactur-
To expand on the problem of air-entrainment, we used a simple calculation familiar to students of respiratory care: the gas-mixing equation. We are pleased that Lewarski and colleagues used a form of this equation and obtained results similar to those in our editorial’s Table 1, at setting “3” (approximately 30 mL) under columns A and B, for O₂ concentrations of 100% and 85%, with which the final delivered O₂ concentrations are 25.7% and 24.8%, respectively, which is a difference of less than 1%. These tiny O₂ concentrations are one way to demonstrate how well demand valves conserve O₂ under conditions established by the manufacturer.

Manufacturers commonly describe demand-valve “efficiency” (ability to conserve O₂) by comparing O₂ dispensed by their valve with O₂ dispensed by conventional continuous-flow valves (eg, 200 mL/min at “setting 1” vs 1,000 mL/min at 1 L/min, which is a 5:1 savings). Clinicians, suppliers, and patients understand that simple comparison.

The important problem of “equivalent-flow” settings was addressed by McCoy¹ and revisited by Bliss et al,² who proposed a volume-referenced (“flow”) setting system to help patients and clinicians compare devices. It is unclear if manufacturers have agreed to adopt a uniform system.

Lewarski and colleagues describe a sophisticated approach to reduce the effects of air-entrainment; they account for dead space, O₂ rebreathing, and the timing of the O₂ bolus during inspiration. However, this requires highly specialized knowledge, is considered arcane by many, and is often a proprietary secret that promises performance advantages over a competitor’s product. The average clinician and patient often do not possess this knowledge. The problem of flow equivalency and lack of published evaluations, discussed above, are pertinent.

Clinicians commonly face a big problem: that of trying to account for variability between patients, their illnesses, and circumstances (such as exercise) when more O₂ is needed to meet increased metabolic demand. This is more complicated than air-entrainment. A patient walking briskly on a treadmill may need to raise (pure) O₂ flow by 2 L/min above baseline resting flow with conventional equipment, may not have to raise flow with one brand of demand valve, and may fail to achieve adequate oxygenation with another brand of demand valve at the highest setting. When that patient requests a third brand of equipment, which provides less-than-pure O₂ through an integrated demand valve that is different than previously tried demand valves, the clinician and supplier may not be able to extrapolate performance. Potential and reality may be different. This explains our recommendation for a test drive.

We apologize for confusing people with our terse statement that clinicians have ignored the consequences of less-than-pure O₂ because of the shape of the oxyhemoglobin curve, limitations of pulse oximetry, and the ease of raising flow. The context was conventional 100% O₂. Implicit in the following sentence and Reference 3 in our editorial¹ was the use of P_{aO₂} (oxygen partial pressure measured via blood-gas analysis), not pulse oximetry (S_{pO₂}). These factors raise problems and controversies about the limitations of pulse oximetry too complex to be addressed in a short editorial. We refer interested readers to the report by McGovern et al.⁴ This may be seen in practice when patients who wish not to use LTOT hyperventilate just before staff obtain S_{pO₂} readings. Finally, experienced clinicians recognize that Medicare oximetry values that determine LTOT support span 3 saturation values (88%, 89%, and 90%), which is the same as instrument tolerance (± 3%) of commonly used pulse oximeters!

We appreciate the opportunity to participate in an exchange of opinions about novel O₂ equipment. We are pleased that others agree with our recommendation to carefully match patient and equipment; that is, to take a test drive! We look forward to more published information about this novel equipment.

Linda C Gallegos RRT
John W Shigeoka MD
Veterans Affairs Medical Center
Salt Lake City, Utah

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