Letters

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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.[1] 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 home 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 O_2. . . . "

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 well remember the days of providing oxygen cylinders to patients in the home. Oxygen concentrators, even the early large, cumbersome units, were a godsend to providing oxygen 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 than 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.

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REFERENCES

1. Gallegos LC, Shigeoka JW. Novel oxygen-concentrator-based equipment: take a test drive first! Respir Care 2006;51(1):25–28.

The authors respond:

Our editorial[1] described an encounter with a man who *purposefully* under-treated hypoxemia while using novel concentrator-based O_2 equipment. That anecdote was a segue to describe a potential limitation of such equipment, namely, limited O_2 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 O_2 therapy (LTOT) stakeholders should express their opinions. We appreciate his comments.

Medicare has supported LTOT since the landmark Nocturnal Oxygen Therapy Trial[2] and Medical Research Council Trial[3] 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.[4–8] 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.[9]

We would like to express some opinions, as Good has done. He reminds us that the battle for O_2 concentrators took place more than 2 decades ago, when they were *novel*. Concentrators are now the most common *stationary* O_2 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 O_2 and liters of boiling liquid O_2. "High-tech" solutions, such as the novel equipment we described and tiny cryogenic reservoirs filled from *home* devices that liquefy concentrator-produced O_2, 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, O_2 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 P_{aO_2} and S_{aO_2}) from those who provide O_2 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.[10] 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.[2] However, the guidelines for less severe hypoxemia and hypoxemia that occurs only during exercise or sleep were *extrapolated* from the Medical Research Council Trial.[3] Recent studies raise questions about those extrapolations; for example, is there a survival benefit in patients with chronic obstructive pulmonary disease and moderate hypoxemia?[11] 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.[12] 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 O_2 equipment). A recent local newspaper had the headline "Pulling funds from kids study immoral,"[13] and the article described the profound disappointment of our children's hospital chief upon learning the 2007 budget