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!

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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 to ensure appropriate oxygenation, we have concerns that 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 O_2 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 $90 \pm 3\%$, 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 (F_{IO_2}). The clinical reality is that large differences in oxygen concentration yield only nominal differences in F_{IO_2}. Let us compare the F_{IO_2} 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* F_{IO_2}. This minor difference is clinically insignificant, as it consistently produces the same net clinical effect as that of United States Pharmacopeia 99.6% oxygen.[1,2]

Low-flow oxygen delivery via nasal cannula with an oxygen concentration of $\geq 85\%$ 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 hypoxemic subjects during various activities, including rest, exercise, and sleep.[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_{IO_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* × *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.[6] They found that as respiratory rate increases, pulse-dose devices more consistently maintain a target F_{IO_2} than does continuous flow, because the pulse-dose devices deliver a larger net minute volume of oxygen (respiratory rate × bolus volume). These results have also been supported by several clinical trials.[7–11]

Gallegos and Shigeoka's emphasis on the gas-mixing equation and calculation of F_{IO_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 plagues 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.

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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 manufac-