

Dr Fink replies:

Bruce Hayton makes a good point that makeshift devices are not ready for “prime time.” He also rightly points out the risk of third-party devices, such as spacers and adapters, for administration of MDI medications in ventilator circuits that are not redesigned as the MDI itself is redesigned. Both of these can place the consumer and patient at some risk.

In response to his example, differences in output between CFC and HFA MDIs were identified soon after the transition occurred. The output difference was less than 20% of the delivered dose, which in the case of albuterol would be too small to have a clinically important effect.¹ Subsequent researchers quantified the overall delivery in vitro with a few of these devices, to make clinicians aware of the potential performance differences.²

I for one would have hoped that the manufacturers of these spacers would have universally redesigned their devices, or made some effort to inform their customers of how device performance would be different with the new propellants. As a consumer I would give my business to the companies that responded to the CFC-to-HFA change by either sponsoring published research or modifying their design or marketing materials. This is a “vote with your feet” scenario.

What makes clinicians—whether physicians or respiratory therapists—uniquely

qualified to identify the limitations of current methods? First, these limitations affect our practice and our patients. Is there value in physicians or respiratory therapists designing prototypes to overcome these perceived limitations? If not us, who? Some of the greatest innovations and early prototypes of medical devices came from the minds of clinicians, not full-time professional researchers.

We have to be safe, so every in-house evaluation of an adaptation should go through the investigational review board and require signed consent.

Is the investment in time and effort offset by our ability to actually benefit the desired patient outcome? This type of investigation can provide the clinician with excellent insights as to what works and what doesn't work. If one group sees a problem or methods limitation, others probably have as well. The only way to assure that such explorations have a further-reaching desired impact is to have them written up, submitted to a peer-reviewed journal, and published. Many a small study has changed the industry.

I would suggest that more rather than less of these types of explorations should be pursued. They cost relatively little money and staff time, compared to the potential long-term benefits. Those benefits are as great in learning what not to do as in the great successes.

A major barrier to the use of “passive” powder inhalers (ie, that require substantial inspiratory effort to mobilize the powder

from the device and aerosolize it) is that they can't be used with small children and patients with artificial airways. In some cases the only way to access a valuable formulation is with a powder inhaler. Johnson's paper³ is a valuable first step in studying how powdered medications can be administered to those patients—which is a vital step for any new product innovation or development.

James B Fink PhD RRT FAARC
Device Development
Nektar Therapeutics
San Carlos, California

The author of this letter reports no conflict of interest.

REFERENCES

1. Fink JB, Dhand R, Grychowski J, Fahey PJ, Tobin MJ. Reconciling in vitro and in vivo measurements of aerosol delivery from a metered-dose inhaler during mechanical ventilation and defining efficiency-enhancing factors. *Am J Respir Crit Care Med* 1999; 159(1):63–68.
2. Lugo RA, Kenney JK, Keenan J, Salyer JW, Ballard J, Ward RM. Albuterol delivery in a neonatal ventilated lung model: nebulization versus chlorofluorocarbon- and hydrofluoroalkane-pressurized metered dose inhalers. *Pediatr Pulmonol* 2001;31(3):247–254.
3. Johnson DC. Interfaces to connect the Handi-Haler and Aerolizer powder inhalers to a tracheostomy tube. *Resp Care* 2007;52(2): 166–170.