

AEROSOLS IN MEDICINE

Michael McPeck BS RRT FAARC



It is my pleasure to write a new regular column on Aerosols in Medicine for Focus and this is the kickoff piece. This is a topic that is near and dear to my heart, or my lungs as the case may be. One of life's lessons is that not everything is as it appears. And so, it is with the rather "nebulous" world of aerosols in medicine. Most of us may know aerosol therapy from the perspective of a seemingly mundane task that must be done every few hours. You know, treatment rounds. Arggggh! But to those who develop aerosol delivery devices, or create new medications designed to be aerosolized, or who measure and test aerosols for various reasons, aerosols in medicine is an exciting field full of intellectual stimulation, interesting permutations, unending controversy, vexing technical questions, challenging design and development considerations and, above all, promise for more effective patient care in the future. Nevertheless, the question remains: What does it all mean to the RT in the trenches? Stay tuned. I hope I can share my excitement with you.

In the issues ahead we'll deal with many topics revolving around contemporary aerosol science as they pertain to respiratory therapy and pulmonary medicine. For example, we'll look at the business of medical aerosols. Yes, the business! Aerosols are big business, indeed. There are numerous aerosol companies, some private and some public, and all striving for a piece of the aerosol pie. Cambridge Consulting's 2006 survey predicted the global nebulizer market will grow from revenues of \$288.5 million to \$398.4 million by the year 2110. That's just nebulizers. Wait to you hear the figures for inhalers and pharmaceuticals.

And, as if sales margins, new product development and the marketing plan aren't enough to keep them occupied, the public companies also have their stock prices to worry about. These days, you must look good to Wall Street! Who are these so-called aerosol companies?

What do they do? What are their products? Quite simply, some are pharmaceutical companies, some are device manufacturers and many of the contemporary movers and shakers in the industry are both. There is a marriage of sorts happening between drugs and aerosol delivery devices. Let's take a closer look.

If you spend the better part of your workday trying to break the world's record for the greatest number of bronchodilator treatments done on a single shift, it is admittedly difficult to appreciate the vast array of medications that are or will soon be available to be inhaled. In the issues that follow, we will look at the "state-of-the-art" of many interesting aerosol drugs. For example, nearly everyone is aware that one of the most highly hyped new kids on the block is inhaled insulin. But did you know that inhaled insulin is not new at all? Insulin is one of the unique drugs that can be absorbed into the body through any of a large number of routes, including the lung. Inhaled insulin was first proposed in 1926. It's hardly new in that regard. But it has taken all these years to get to the point where presumably safe and effective products are allowed to be marketed. Stay tuned to see how this might affect your practice someday.

Here's another new drug, (or is it?): Pentamidine. Those of us who were around in the early days of HIV remember pentamidine as an aerosol for the treatment and prophylaxis of *Pneumocystis carinii* pneumonia (PCP) in AIDS patients. Pentamidine is rarely used in AIDS patients any longer. However, it is now being given via the aerosol route for PCP prophylaxis in patients who have been deliberately immunosuppressed as a result of cancer chemotherapy. Not a week goes by that I don't receive at least one new inquiry regarding aerosolized pentamidine; a whole new generation of respiratory therapists are just discovering it and learning about it for the first time.

While we're on the subject of "new" drugs we'll cover in future issues, how about inhaled morphine? Obviously, morphine is not a new drug, but the inhalation of morphine for palliative care may seem to be a relatively new use. In reality, certain specialists in palliative care have been using inhaled morphine for years. There has been scant literature on the topic and what has been written has been mostly anecdotal. Some papers report successful results; some don't. In my opinion, the underlying cause of this disparity is what I've termed "nebulizer naiveté." The palliative care folks had good intentions, but did not realize the technical limitations of nebulizer therapy. Again, every week I receive one or two inquiries on inhaled morphine which has led me to believe that the JCAHO's emphasis on improved pain management has prompted many institutions to add inhaled morphine to their palliative care regimens for terminal lung cancer and end-stage COPD patients.

We're just scratching the surface in the realm of new aerosolized drugs that we'll cover. One of the truly new classes

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of drug to be given via the aerosol route are the prostaglandin derivatives for regulating and controlling pulmonary arterial pressure. These agents (e.g., Flolan®, Ventavis®) hold a great deal of promise as a replacement for inhaled nitric oxide and we are sure to see new delivery systems and administration devices designed specifically for them. Also on the horizon are new antibiotics specifically formulated to prevent and/or treat ventilator associated pneumonia in the ICU. New agents for tackling both traditional gram negative organisms such as Pseudomonas, and gram positive bugs such as MRSA that are wreaking havoc in the contemporary ICU, are under development. It will be interesting to see how these will be given, how they will be introduced into the ventilator circuit and how they will affect our practice. Stay tuned.

Also on the drawing board I have planned a number of articles about what goes on behind the scenes inside the aerosol lab. We're going to expose some of the trade secrets and reveal the true answers to nagging questions such as: How are those pesky little aerosol particles actually measured? What is the MMAD and how is it determined? Do different nebulizers really have different particle sizes? Is particle size as important as everyone seems to think it is? Stay tuned. And let's take a closer look at the new generation of electronic nebulizer and the various control schemes for "tailoring" the inhaled dose to the patient's breathing pattern. And what about the regulatory landscape? Once upon a very long time ago, anyone could bring a new nebulizer on the market. Now, nebulizer designers and manufacturers must receive premarket approval, the so-called 510(k), in order to bring a new device on the market. We'll look at this 510(k) process as it applies to nebulizers to try to reveal what it really means. Meanwhile, pharmaceutical companies must go through a similar but vastly more complicated and expensive process known as an NDA (New Drug Application) for any new agents they plan to bring on the market. The regulatory landscape rarely gets simpler; it is usually more complicated over time. Combine a brand new drug (NDA), with a brand new device (510(k)) and consider how complicated, how expensive and how many years it might take to get this through the bureaucracy and onto the hospital formulary. Stay tuned and please join me in subsequent issues as we explore the nebulous world of Aerosols in Medicine.

Michael McPeck, BS RRT FAARC is the President of Healthline Medical, Inc. Baldwin Park, CA. He is also a Clinical Assistant Professor for the Respiratory Care Program at the State University of NY in Stony Brook, NY. He can be reached at michael.mcpeck@aerosol-medicine.com.



many of these patients, especially from the past when these advances were not available, are out there. Many of these folks have been given up as lost causes by themselves and by their doctors who have not kept up with the need to update and try again. Many sleep labs don't open for clinical business until night testing begins so the availability of technical and clinical personnel accessible by patients with problems falls on primary care doctors or medical equipment dealers with poor to non-existent results. This in turn is related to the bottom line since there is no means to pay for or reimburse outpatient technical follow-up. The creation of Certified PAP Coaches or PAP Trainers whose services will be reimbursed or otherwise funded can go a long way to solving the compliance problem but surprisingly no one has suggested this. Our lab is fortunate in having several clinical and technical people available during normal business hours so currently provides such services free of charge as needed and/or ordered by a patient's doctor, under the rubric of "de-sensitization" which is a debatable term with the objective of making the patient insensitive to PAP. In effect the objective should be to make the patient highly sensitive to the need to use PAP and to try and eliminate all the patient's complaints one by one by providing them and their doctors with the options they don't know are out there.

Published surveys currently indicate that the wait time for a sleep study on average nationwide is 22 days with some areas under-served and others over-served. There are currently 2500 facility based labs in the US with new labs being set up all the time. In the past 5 years the number of accredited labs doubled. Medicare reported a 160% jump in the number of studies it reimbursed between 2000 and 2004. Demand, Epstein and Silber contend, is being met and will continue to be met but the larger problems they highlight persist. There is no reason to logically expect they will be ameliorated by home based testing, especially when PAP titration and coaching enter the picture.

In conclusion, Epstein and Silber believe that before we throw a wider net of less proven diagnostic techniques without a high level of confidence in their ability to rule-in or rule-out obstructive sleep apnea, the bread and butter issues they brought up need to be addressed immediately if not sooner. The risk to home testing besides its lack of specificity is that it removes the patient from the sleep center or lab, diminishes contact between technologist and patient and creates an unintended barrier to determining and addressing patient follow-up and compliance problems. And that makes limited channel home testing just slightly better than nothing and then for only some patients: the perfect, highly aware, well educated in sleep problems, and the highly compliant ones who love what we are trying to do for them. We need to bring the rest of our patients closer, not cast them farther away.

The other risk to portable testing is that it will, like it or not, greatly increase the number of solo polysomnographers with home testing equipment in the trunks of their cars who will test anybody, anywhere for a low cost that doesn't include the cost of reliable and professional interpretation, professional follow-up and the (currently) non-reimbursed follow-care demanded of the patient advocate group. The problem cases for follow-up will fall on the facility based labs that will be deprived of testing income and these too would then fail causing the demands of the patient advocates to fall on no ears at all... because they just won't be there anymore.