

## COMPOUNDING RESPIRATORY MEDICATIONS FOR HOMECARE PATIENTS

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When I first started doing homecare patient visits in the early 1970s, I came upon a most interesting case. The patient was very sensitive to Bronkosol™ (isoetharine) but the prescribing physician felt that 0.5 ml of the drug in 3 ml of normal saline would be more than sufficient to provide adequate bronchodilation and help her carry out her activities of daily living (ADLs). After administering her first treatment at home, her pulse rate went from 80 to over 120 and she became extremely agitated and nervous. The physician was notified and he changed the prescription to 0.25 ml of Bronkosol™ with normal saline for the next day's treatment. The patient experienced basically the same post-treatment response. During the next monthly visit, he suggested I try 4 drops of Bronkosol™ but she still experienced an increase in heart rate and CNS stimulation. To make a long story short, she finally was able to tolerate 2 drops of the medication in 3 ml of normal saline with good bronchodilator response and minimal side-effects.

In some bizarre fashion, this was a primitive type of compounding. We were trying to tailor an inhaled respiratory medication to meet a patient's specific need. However, actual compounding is much more detailed but the focus is the same – to meet a patient's specific needs with regard to medication delivered, response desired and/or avoidance of any perceived side-effects or untoward reactions. This article will examine the nature and extent of compounding inhaled respiratory medica-

tions for homecare patients with an eye on whether or not this practice is beneficial or potentially harmful.

Most respiratory medications that are in solution form for nebulizer use are available in standard doses. For example, generic albuterol is available in a 3 ml vial that contains 2.5 mg of albuterol in normal saline. Most adult patients are able to use this dose with excellent bronchodilation and minimal side-effects. But what about the patients that become tachycardic, nauseous or excessively nervous? The dose has to be adjusted to meet the patient's needs or the patient will become non-compliant with the prescribed aerosol therapy. Here compounding would provide a viable solution where the albuterol could be prepared in a 1.25 mg dose that would provide airway dilation with minimal side-effect.

By definition, compounding is defined as the combining of two or more chemicals or elements to form a specific mixture or substance. Pharmacologically speaking, this involves the combining of two or more raw drugs, under sterile conditions, to form a specific compound that is not available commercially. This compound must be assayed for purity, concentration and sterility. In the past, there have been a number of incidences where the chemical purity, concentration and/or sterility of inhalational compounds have been questioned. Because of poor practices and failure to assay properly, drug compounding has come under fire, especially from the pharmaceutical industry. Unfortunately, home care companies with their own pharmacies that followed strict protocols for compounding and assaying have also suffered.

As you would expect, there are advantages and disadvantages for compounding inhaled respiratory drugs for chronic lung patients. The advantages include: medications can be tailored to meet a patient's specific needs, there are fewer perceived side-effects and patients are able to obtain drug compounds that are not available commercially. An excellent example is an inhalational compound that contains 0.5 mg of budesonide with 12 mcg of formoterol that patients can use twice a day with their nebulizer. This preparation includes an inhaled corticosteroid (ICS) and a long-acting beta-agonist bronchodilator, in other words, an Advair™ analog. Another advantage to the patient with this example is cost. Medicare will reimburse for this compound since it is delivered via a compressor/nebulizer. Advair™, available as a dry-powder inhaler (DPI), is very expensive and is not a covered item at the present time. However, the new Medicare drug benefit may affect this reimbursement scenario.

There are several disadvantages to compounding and they include: questionable purity of the preparation, questionable concentration of the compounded drug, contamination of the product and overall availability. Many pharmacies do not have compounding capabilities and consequently, certain drug preparations are not available to the patient. Recently, Medicare has been reducing the average wholesale price (AWP) and dispensing fees for inhalational drugs, including those that were compounded. This has resulted in a number of home care-based

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pharmacies and certain national mail-order pharmacies to either close or stop offering inhaled respiratory medications. From the patient's point of view, this is not beneficial.

It is probably safe to say that the respiratory drug industry, at least from the home care provider's point of view, is in a period of change. So what does the future have to hold? As you might expect, the pharmaceutical industry that provides brand name prescription medications would probably like to see the compounding practice go away. They cite many instances where the unit-dose vial may or may not contain a therapeutic dose of medication. In addition, they have promoted concern among patients and practitioners alike that a compounded product may be contaminated with bacteria or contain preservatives and/or alcohol that can irritate the airway resulting in bronchospasm and cough. But how often does this happen? Not even the pharmaceutical industry knows for sure.

However, it appears that more occurrences accentuating the negative aspects of compounding continue to surface in spite of the many positive results experienced by patients with chronic lung disease. Another claim by certain pharmaceutical companies is that some patients are receiving "generic budesonide" instead of Pulmicort Respules™ for their inhalation treatments. According to these companies, there is no FDA-approved generic for Pulmicort™ and that the generic product, therefore, must be counterfeit. The question they raise is how can some pharmacies get away with the practice of compounding inhaled respiratory medications? This is the question they are bringing to the FDA, as well as to lawmakers on both the state and federal levels.

The underlying question is whether or not economics is the driving force here? Or is it really patient safety that is at issue. If physicians are writing fewer prescriptions for brand name drugs and begin to opt for compounded medications in their place, this can have a financial impact on some pharmaceutical companies. There has been a concerted effort to educate physicians, and in particular pulmonologists, on the possible dangers associated with compounded products. It appears that some physicians have accepted and will prescribe compounded bronchodilators such as albuterol and ipratropium but are concerned about ICS, especially budesonide. They question both the efficacy and safety of this medication in generic form.

So the issue of compounding rages on, at least within the home care arena. Proponents of compounding claim patients benefit from the availability of inhaled medications that are properly produced under sterile conditions followed by independent laboratory assay. Many compounding pharmacies do not use preservatives and insure the concentration and purity of their products. On the other hand, the pharmaceutical industry continues its claims that compounding inhaled respiratory medications is potentially dangerous because of contaminated or impure medications and that the practice in general is questionable and in the worst case scenario, possibly illegal. Time will tell but in a time of rising drug costs, compounding respiratory medications may be a partial solution, but only if certain strict guidelines are adhered to coupled with routine assaying of compounded products to insure sterility, concentration and purity for safe patient use.

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