

Statement
FDA Advisory Committee
May 5, 2004

Thank you for the opportunity to present to you today. My name is Karen J. Stewart and I am a registered respiratory therapist. I have been a respiratory therapist since 1971. I am here today as the spokesperson for the American Association for Respiratory Care representing respiratory therapists from around the county.

Respiratory Therapists like all other health care professionals are very concerned about medication errors. In recent years since the elimination of most paper labels on unit dose vials of medication, it has become increasingly difficult to determine the content of the unit dose vials. I will share with you pictures later in this presentation.

Now not only is the print on the vial difficult to read, the size and shape of the vial, contributes to the difficulty.

In 2001 the American Association for Respiratory Care completed a human resource survey. At the time of the survey the average age of a respiratory therapist was 44, another contributing factor in the difficulty of reading the content of the medication vial. While I may have just emphasized the current relative age of the respiratory therapist, and the difficulty the older therapist experiences in reading the labels, I also want to clearly state that deciphering respiratory medication labels is a problem that cuts across all ages of respiratory therapists. The problem is how many medications are labeled, or in the case of respiratory medications not labeled adequately.

The workflow of a respiratory therapist typically includes delivering medications and treatments to a number of patients for a local geographic region of a hospital. The patients that are assigned may have a variety of medications prescribed. Once the medication is checked by a pharmacist for drug interactions, the therapist typically carries the medication with them as they begin rounds. It would not be unusual for the therapist to carry 14 or 15 doses of medications with them. The medications must be under control so many therapists carry medications in a fanny pack.

In some institutions the medication is obtained through a medication delivery system like Pyxis. In this situation the medication can be placed in a medication drawer specific for a patient or can be obtained from a stock supply of many medications.

Another concern facing respiratory therapists is the lack of bar coding on the vial. Many hospitals are moving toward the scanning of medication bar codes. The driving force for this use of technology is to identify the correct patient, identify the correct medication, confirm the correct dose of medication, confirm the correct route and to record the time of medication delivery.

I am going to read some comments from respiratory therapists that I have received in recent weeks;

- Staff complained about the inability to clearly see the medication information. For this reason, we switched to a different product that is individually wrapped in clearly labeled, color-coded foil packaging. The current situation with raised letter labeling is an accident waiting to happen.
- I complained bitterly when the look-alike vials came out. We did not leave them for any nurses to confuse. We do not know of any medication errors because of the look-alike. Doesn't mean it didn't happen. We just don't know.
- We have had problems with the unit dose Xoponex and Atrovent looking alike and labeled the same in the clear package. We use the Pyxis and it is still a problem.
- One encouraging thing I have seen is differing shapes and sizes on VERY FEW medications. Since the death of the multi-dose vial of Albuterol, we have a supplier who sends us 0.5ml UD vials of Albuterol that actually have a very distinctive teardrop shape and a much smaller size and look for the actual vial of medicine. Bravo! A similar thing has happened with the small octagonal UD vials of Pulmicort we get. But still, the most common medications, Atrovent and Albuterol, and also Levalbuterol, come in UD vials that one can't tell apart without the eyes of a teenager or the magnifying glass of an older codger!
- We color the ends with a color code so no one gives the wrong dosage. So far, this has worked for us but I don't understand why a company would not place a label that you can see well.
- I have no specifics, but mainly because it can happen without the therapist realizing it and the side effects are relatively mild. I don't think we realize how often it is occurring. I helped out on night shift and was amazed at the difficulty I had. As an over 40 worker, I have come to realize I have to be cognizant of the shapes and the colors on the vials, because the reading is next to impossible. This is an important issue. We appreciate your help and efforts in improving our field. Part of the issue I see is that there ISN'T any labeling on the vials any more. I remember when the unit dose

(UD) vials had a paper label, with contrasting colors, stuck on to the individual vial. Ah....there's a rare example of the good old days actually being good! Nowadays the master goal of cost cutting has apparently mandated that this practice is long dead. To add to that confusion, the vast majority of the UD vials come packaged LOOKING exactly the same...five vials in a row, held on a plastic molding piece. You have to tear the vials off the molding exactly the same way. A 2.5ml – 3ml vial is essentially the same size and feel, no matter what chemical is in it, and no matter what the clear-on-clear lettering says. So now all of us old folks with changing vision we to deal with clear plastic vials that have color plastic slightly raised letters as the only labeling, and that labeling is BARELY 1mm in height!! My God! How much harder do they think they can make it to see what medication you're about to make somebody inhale into their lungs???

On behalf of the American Association for Respiratory Care I appreciate the opportunity to share our Association's comments, and those comments of concerned respiratory therapists. Here are a few brief pictures to illustrate what I have presented.

I also have with me some of the inventory from my hospital of the common medications that a therapist will carry while delivering treatments. Missing from the bag of medications is Xopenex, which requires refrigeration.

Respectfully Submitted,
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