New Thinking Inside the Vial...

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The pharmacy benefits community has made amazing progress in improving both access to and implementation of medication utilization and adherence programs. It is no longer enough for a prescription to be written and filled. We now ask whether the patient really took the medicine and even more importantly, whether it worked. These programs have helped both to improve patients' quality of life and to control costs.

The medication utilization and adherence programs were developed by individuals willing to think outside the box. They created literally from nothing a system that both saves money and makes us feel better. We need more of this kind of change.

There is another giant side to medications in a pharmacy, what I like to call the "back of the house." Unseen and behind locked doors is an area known only to pharmacy specialists. It is here that parenteral products are bought, managed, manipulated, and sold from and through pharmacies everywhere. We know that the future pipeline of products in line for the marketplace is filled with amazing agents that come in small liquid quantities in little bottles that are usually sold without being viewed by consumers. This is the domain of specialty pharmacies that work to ensure access to and often control the sterility of products for safe delivery to consumers. Historically, this domain has gone unnoticed.

Now, with the exploding development of products created as monoclonal antibodies, we have seen an increasing need for specialty pharmacy services to provide drug delivery. Usually these drug products are expensive, parenteral, and sold in "single use" nonpreserved vials. Current mandates from the United States Pharmacopeia specify that nonpreserved or single-use drugs must be discarded 1 hour after opening outside International Organization for Standardization (ISO) 5 air conditions or after 6 hours when ISO 5 air conditions are maintained for the entire time.[1] Throughout the United States, that has meant that pharmacies end up wasting unused product at often-extraordinary expense. If we could find a way to store these products safely for more than the 6 hours currently allowed, cost savings could be realized in the current system.

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In the January 2011 issue of *The American Journal of Pharmacy Benefits*, we saw how Derek M. McMichael, PharmD, and his team evaluated a system for controlling contamination in single-use vials for up to 168 hours.[2] They demonstrated that a single-use vial may not in fact have to be discarded quickly and ultimately may be used for multiple patients. The cost savings that would result are obvious.

What is not discussed is the pink elephant in the room, which is liability. Single-use vials ensure that once the sterile field is broken (and assuming the product is sterile in the container), the last operator is the one who ensures that sterility is maintained until the medication is delivered to and essentially into the patient. However, any pharmacist or institution that manipulates a single-dose vial for a specific patient is already assuming this liability.

McMichael and colleagues are simply proposing a safe method to increase the duration of product sterility to possibly allow use for multiple patients.

Another barrier to the change in practice proposed by McMichael et al might be pharmaceutical manufacturers. Some may embrace the PhaSeal system as a way to enhance utilization of product by more patients. Others may believe that PhaSeal poses a risk to them if in fact the product is not delivered in a sterile manner and a patient is harmed. Or companies might believe that the PhaSeal system would harm sales of their products, as institutions could buy larger quantities of expensive drugs for a theoretically lower price. My take is that the Pharmaceutical Research and Manufacturers of America would embrace the PhaSeal system as a way to show that they do want to see more use of their products to help consumers, because they have an obligation both to aid patients and to maintain a bottom line. This technology helps both.

At the Pharmacy & Therapeutics Society we work to advance the safe use of all pharmaceuticals and to promote utilization of products for the maximum benefit to the greatest number of people. It is not lost on us that specialty pharmaceuticals are increasing the bottom line everywhere. As president, I salute the team from Indiana University Hospital led by Dr McMichael and the affiliated institutions who are thinking "inside the vial" for ways to both control costs and to provide safe use of these medications.

REFERENCES

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2. McMichael DM, Jefferson DM, Carey ET, et al. Utility of the PhaSeal closed system drug transfer device. *Am J Pharm Benefits*. 2011;3(1):9-16. ajpb