Small Daily Doses of Insulin: Wasting Money?

Alan Carter, PharmD

Newer engineered insulin products are essential tools in diabetes therapy, but there is a potential for degrading glycemic control over time once a vial/pen is opened. Both patient and practitioner need to be aware of proper storage guidelines and the decrease in insulin potency after a seal is punctured.

Basal insulins such as Lantus and Levemir are supplied in 10 ml multidose vials and 3 ml pen devices. Once the container is punctured, these products have declining potency that may result in reduced blood glucose control if used beyond the Food and Drug Administration-approved use range of 28 days for Lantus and 42 days for Levemir. When using low-dose therapy, considerable volume may remain available for use long after the insulin falls below 95% of its listed potency, setting the stage for unpredictable control and inaccurate clinical adjustment.

There have been reports of decreased control when patients exceed open container stability limits; current market factors may increase this risk. Throwing away a container before it is empty is difficult to do for many patients, especially when their budgets are tight. To complicate matters, some prescription plans in the United States have dispensing limits based on prescribed dosage units per vial or pen instead of potency after opening. These plans may not take product stability into account, instead calculating the metric quantity of doses allowed for each prescription. As an example, for a basal insulin dose of 10 units per day, a 10 ml vial would be considered as more than a 90-day supply and a 3 ml pen device 30 days, which exceeds the recommended stability limit on an open container for both sizes of Lantus and the beyond-use date of Levemir's 10 ml vial. Potential for continued use until the vial is nearly empty creates an unknown variable in the evaluation of therapy outcome.

When initiating low-dose basal insulin therapy, stability factors become a concern for all. Frequent or continuous self-monitoring of blood glucose could help determine when products will begin to lose significant potency and help defend a patient supply standard that is product appropriate. However, conducting clinical trials is costly and may not be in a manufacturer's best interest. Also, follow-up on patient compliance on proper home storage and disposal of these products is very difficult for a clinician to do.

While seemingly a small concern on the surface, prescription drug plans with dose/quantity limits and individual financial constraints are affecting home supply, increasing the opportunity for expired use. The Kansas Diabetes Action Council will be posting an updated insulin stability chart on its Web site, www.kansasdiabetesactioncouncil.org, to help match insulin products to individual patient circumstances.

Author Affiliation: School of Pharmacy, University of Missouri–Kansas City, Kansas City, Missouri; and Kansas Diabetes Action Council, Kansas City, Missouri

Keywords: budget, diabetes, insulin, potency, stability, supply

Corresponding Author: Alan Carter, Pharm.D., University Health Science Building, 2464 Charlotte Street, Kansas City, MO 64108; email address acarter29@cs.com