

Drug Shortages Spread, Lead to Higher Costs

BY ALICIA AULT

The persistent shortages of several medications, especially injectable and infusion products, are now affecting virtually every hospital department, according to two separate surveys.

The American Hospital Association (AHA) and the American Society of Health System Pharmacists (ASHP) surveyed their memberships and found that 99.5% of hospitals had experienced one or more drug shortages in the last 6 months.

Most hospitals reported delaying treatment or rationing certain products, and almost all said that the shortages have led to increased drug costs.

This is not the first time the shortages have been reported to be a major problem. But it appears from the new data that shortages have grown from affecting mostly oncology departments to affecting the majority of clinical care areas at the hospital.

The AHA survey included responses from 820 hospitals, collected during June 2011. Of all respondents, 90%-95% said

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that within the last 6 months they had experienced shortages of medications for the following clinical uses: surgery and anesthesia, emergency care, cardiovascular, gastrointestinal/nutrition, and pain management.

Shortages were also noted in infectious diseases, oncology, neurology, endocrinology, obstetrics/gynecology, allergy, and psychiatry.

Three-quarters of hospitals said they rarely or never received advance notice of the shortages.

Strategies to deal with the shortages varied. The vast majority of hospitals reported that they purchased a more expensive alternative or bought excess inventory. Three-quarters of respondents either bought a more expensive therapeutic alternative or product from a direct manufacturer.

In a separate study published online in the American Journal of Health-System Pharmacists, researchers from the University of Michigan and the ASHP reported that the number of shortages in 2010 (211) was the highest ever recorded in a single year. The researchers surveyed ASHP members about the impact of 30 recent shortages; 353 pharmacists responded.

Overall, pharmacists spent about 9 hours each week managing shortages, with an estimated annual labor cost of \$216 million. The shortages seemed to hit bigger hospitals harder. When asked

if drug shortages created an increased burden, 97% of the respondents agreed or strongly agreed; 93% said that shortages increased costs, and 55% said that shortages compromised care (Am. J. Health-Syst. Pharm. 2011;68:e13-e21 [doi:10.2146/ajhp110210]).

"Our results confirm what prior surveys have shown: Pharmacy directors believe that the burden of drug shortages continues to increase and that drug

shortages have changed clinical practice and compromised patient care," the investigators wrote.

The shortage problem is attracting more attention in Congress. In February, Sen. Amy Klobuchar (D-Minn.) introduced the Preserving Access to Life-Saving Medications Act (S. 296), which would give the Food and Drug Administration the authority to require early notification from pharmaceutical com-

panies when a shortage appears to be imminent. At press time, the bill had 11 cosponsors.

Rep. Diana DeGette (D-Col.) and Rep. Tom Rooney (R-Fla.) introduced the bill in the House in mid-July. "The early warning system this bill creates represents an immediate safeguard to help prevent sudden shortages of these life-saving medications," Rep. DeGette said in a statement. ■

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— Can be used in 6 straightforward steps

Easy to use¹

— Only long-acting insulin pen in which dose can be set from 1 to 80 units in 1-unit steps, dialed both up and down
— Once opened, Lantus[®] SoloSTAR[®] can be used for up to 28 days and is not refrigerated

Easy to inject¹

— Dose cannot be dialed past the number of units left in the pen
— It is important to keep the injection button pressed all the way in and to **slowly count to 10 before withdrawing the needle from the skin**. After a full injection, the number in the dose window will return to zero. These steps help ensure that the full dose has been delivered

Indications and Usage for Lantus[®]

Lantus[®] is a long-acting insulin analog indicated to improve glycemic control in adults and children (6 years and older) with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus. Lantus[®] should be administered once a day at the same time every day.

Important Limitations of Use: Lantus[®] is not recommended for the treatment of diabetic ketoacidosis. Use intravenous short-acting insulin instead.

Important Safety Information for Lantus[®]

Contraindications

Lantus[®] is contraindicated in patients hypersensitive to insulin glargine or one of its excipients.

Warnings and Precautions

Monitor blood glucose in all patients treated with insulin. Insulin regimens should be modified cautiously and only under medical supervision. Changes in insulin strength, manufacturer, type, or method of administration may result in the need for a change in insulin dose or an adjustment in concomitant oral antidiabetic treatment.

Do not dilute or mix Lantus[®] with any other insulin or solution. If mixed or diluted, the solution may become cloudy, and the onset of action/time to peak effect may be altered in an unpredictable manner. Do not administer Lantus[®] via an insulin pump or intravenously because severe hypoglycemia can occur. Insulin devices and needles must not be shared between patients.

Hypoglycemia is the most common adverse reaction of insulin therapy, including Lantus[®], and may be life-threatening.

Severe life-threatening, generalized allergy, including anaphylaxis, can occur.

A reduction in the Lantus[®] dose may be required in patients with renal or hepatic impairment.

Drug Interactions

Certain drugs may affect glucose metabolism, requiring insulin dose adjustment and close monitoring of blood glucose. The signs of hypoglycemia may be reduced in patients taking anti-adrenergic drugs (e.g., beta-blockers, clonidine, guanethidine, and reserpine).

Adverse Reactions

Other adverse reactions commonly associated with Lantus[®] are injection site reaction, lipodystrophy, pruritus, and rash.

Important Safety Information for Lantus[®] SoloSTAR[®]

Lantus[®] SoloSTAR[®] is a disposable prefilled insulin pen. To help ensure an accurate dose each time, patients should follow all steps in the Instruction Leaflet accompanying the pen; otherwise they may not get the correct amount of insulin, which may affect their blood glucose.

Please see brief summary of full prescribing information for Lantus[®] on the following pages.

References: 1. Data on file, sanofi-aventis U.S. LLC. 2. Lantus Prescribing Information. April 2010.