Allergic Reactions

Local Allergy—As with any insulin therapy, patients taking Humalog may experience redness, swelling, or itching at the site of the injection. These minor reactions usually resolve in a few days to a few weeks, but in some occasions, may require discontinuation of Humalog. In some instances, these reactions may be related to factors other than insulin, such as irritants in a skin cleansing agent or poor injection technique.

Systemic Allergy—Severe, life-threatening, generalized allergy, including anaphylaxis, may occur with any insulin, including Humalog. Generalized allergy to insulin may cause whole body rash (including pruritus), dyspnea, wheezing, hypotension, tachycardia, or diaphoresis.

In controlled clinical trials, pruritus (with or without rash) was seen in 17 patients receiving regular human insulin (n=2969) and 30 patients receiving Humalog (n=2944).

Localized reactions and generalized myalgias have been reported with injected metacresol, which is an excipient in Humalog (see Contraindications).

Antibody Production

In large clinical trials with patients with type 1 (n=509) and type 2 (n=262) diabetes mellitus, anti-insulin antibody (insulin lispro-specific antibodies, insulin-specific antibodies, cross-reactive antibodies) formation was evaluated in patients receiving both regular human insulin and Humalog (including patients previously treated with human insulin and naive patients). As expected, the largest increase in the antibody levels occurred in patients new to insulin therapy. The antibody levels peaked by 12 months and declined over the remaining years of the study. These antibodies do not appear to cause deterioration in glycemic control or necessitate an increase in insulin dose. There was no statistically significant relationship between the change in the total daily insulin dose and the change in percent antibody binding for any of the antibody types.

USE IN SPECIFIC POPULATIONS

Pregnancy—Pregnancy Category B. All pregnancies have a background risk of birth defects, loss, or other adverse outcome regardless of drug exposure. This background risk is increased in pregnancies complicated by hyperglycemia and may be decreased with good metabolic control. It is essential for patients with diabetes or history of gestational diabetes to maintain good metabolic control before conception and throughout pregnancy. In patients with diabetes or gestational diabetes insulin requirements may decrease during the first trimester, generally increase during the second and third trimesters, and rapidly decline after delivery. Careful monitoring of glucose control is essential in these patients. Therefore, female patients should be advised to tell their physicians if they intend to become, or if they become pregnant while taking Humalog.

Although there are limited clinical studies of the use of Humalog in pregnancy, published studies with human insulins suggest that optimizing overall glycemic control, including postprandial control, before conception and during pregnancy improves fetal outcome.

Nursing Mothers—It is unknown whether insulin lispro is excreted in human milk. Use of Humalog is compatible with breastfeeding, but women with diabetes who are lactating may require adjustments of their insulin doses.

Pediatric Use—Humalog is approved for use in children for subcutaneous daily injections and for subcutaneous continuous infusion by external insulin pump. Humalog has not been studied in pediatric patients younger than 3 years of age. Humalog has not been studied in pediatric patients with type 2 diabetes.

Geriatric Use—Of the total number of subjects (n=2834) in eight clinical studies of Humalog, twelve percent (n=338) were 65 years of age or over. The majority of these had type 2 diabetes. HbA1c values and hypoglycemia rates did not differ by age. Pharmacokinetic/pharmacodynamic studies to assess the effect of age on the onset of Humalog action have not been performed.

OVERDOSAGE

Excess insulin administration may cause hypoglycemia and hypokalemia. Mild episodes of hypoglycemia usually can be treated with oral glucose. Adjustments in drug dosage, meal patterns, or exercise may be needed. More severe episodes with coma, seizure, or neurologic impairment may be treated with glucagon or concentrated intravenous glucose. Sustained carbohydrate intake and observation may be necessary because hypoglycemia may recur after apparent clinical recovery. Hypokalemia must be corrected appropriately.

STORAGE

Do not use after the expiration date.

Unopened Humalog should be stored in a refrigerator (36° to 46°F [2° to 8°C]), but not in the freezer. Do not use Humalog if it has been frozen. In-use Humalog vials, cartridges, pens, and Humalog KwikPen™ should be stored at room temperature, below 86°F (30°C), and must be used within 28 days or be discarded, even if they still contain Humalog. Protect from direct heat and light.

PATIENT COUNSELING INFORMATION: See FDA-approved patient labeling and Patient Counseling Information section of the Full Prescribing Information.

LETTERS

ERRATUM

A practice recommendation in "Travelers diarrhea: Prevention, treatment, and post-trip evaluation (*J Fam Pract*. 2013;62:356-361) incorrectly called for self-treatment with a fluoroquinolone (or azithromycin) and loperamide for diarrhea that is bloody or accompanied by fever. In fact, both the Centers for Disease Control and Prevention and the Infectious Diseases Society of America advise *against* the use of loperamide by travelers with fever or bloody diarrhea. The practice recommendation should have read: "Advise travelers to initiate self-treatment for travelers' diarrhea with a fluoroquinolone (or azithromycin if in South or Southeast Asia) at the onset of diarrhea if it is bloody or accompanied by fever."

Another treatment option for keloids

I did not see the use of plain lidocaine (without epinephrine) included in "Keloids: Which treatment is best for your patient?" (*J Fam Pract.* 2013; 62:227-233) as one option to manage keloids. Treating keloids with intralesional 2% lidocaine plain has been very rewarding for my patients and for me.

This approach has a distinct advantage over injections containing steroids because it can be repeated more frequently (every 2-4 weeks) without fear of subcutaneous atrophy, telangiectasias, or pigment change. I no longer see sections of excessive scar atrophy with uneven, patchy, "skipped" areas from the inconsistent effect that steroids can have on lesions. Lidocaine is infiltrated superficially and forced into the mid and deep sections of the keloid; the underlying and immediate neighboring subcutaneous tissue is treated as well. With repeated injections, there typically is more uniform shrinkage and color change that closely matches that of the surrounding skin.

The mechanism of action of lidocaine in the scar is a matter of conjecture. Clinicians with ex-

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perience in treating keloids in such a manner believe that the lidocaine has a weak anti-inflammatory effect and may serve as an irritant to stimulate the healing process.

Louis A. Kazal Jr, MD, FAAFP
Hanover, NH

A plea for acupuncture coverage

I was happy to see acupuncture recommended for patients with type 2 diabetes with neuropathy and other symptoms that have not fully responded to conventional therapy (Targeting diabetes: The benefits of an integrative approach. *J Fam Pract*. 2013;62:337-344). My wife is a board-certified Chinese acupuncturist and has successfully treated many patients with neuropathic symptoms.

While I'm delighted that Western medicine has finally acknowledged acupuncture as an adjunct to traditional therapy, I'm concerned about insurance coverage. It is still true that most health insurers (including Medicare) do not cover acupuncture, and most patients can't afford to self-pay.

Our health care system can do better.

Phillip Kim, MD, MPH
Madera, CA

No one measures whether you made the right diagnosis or whether the patient got better—a point the media have remained stunningly ignorant of.

Bureaucracy leaves little time for acute care

As a family physician for 18 years, I really related to Dr. Hickner's editorial, "Have family physicians abandoned acute care?" (*J Fam Pract*. 2013;62:333). I ran a solo practice for the past 10 years, and my staff and I were able to offer same-day visits to most people who needed acute care.

I recently sold my practice to a federally qualified health center (FQHC) to become an office in that system. The FQHC receives federal and state funding as well as grants, which make it possible to see patients regardless of their ability to pay. However, each entity has its own agenda.

The result is that a host of issues and scripted questions are inserted into the exam room. The questions may be medically justifiable, but given the time pressures of a typical visit, my ability to prioritize based on patients' individual needs is hampered. If you actually asked all the recommended questions, you would use up most of the time allotted for the visit without ever hearing the patient's 3 or 4 complaints—which usually hold the key to the real health issues.

The data we are required to submit in order to continue receiving support nearly always track process measures. No one measures whether you made the right diagnosis or whether the patient got better—a point the media have remained stunningly ignorant of.

Jay A. Zaslow, MD, MPH
Brewster, NY

I absolutely agree with Dr. Hickner that we are now practicing medicine to be evaluated, not to treat patients. We are being judged the way teachers are with No Child Left Behind. We spend so much time on our agenda that we miss what medicine is really about.

I work at a large health care system, seeing patients in preventive medicine. I'm also in charge of teaching medical students physical examination and history. I have tried to keep the focus on patients' chief complaints and immediate needs, as Dr. Hickner advocates, but the students do not see that approach when they go to their preceptors' offices.

What a pity. We need to preserve what the practice of medicine is all about, not just meet the numbers.

Mary Marcinko, MD
Riverside, Calif