ISMP Medication Error Report Analysis

Basal Insulins Incorrectly Withheld

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Patients Needed Testing After Pen Misuse

***Diastat Acudial* Requires Setting and Locking of the Dose**

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These medication errors have occurred in health care facilities at least once. They will happen again—perhaps where you work. Through education and alertness of personnel and procedural safeguards, they can be avoided. You should consider publishing accounts of errors in your newsletters and/or presenting them at your inservice training programs.

Your assistance is required to continue this feature. The reports described here were received through the Institute for Safe Medication Practices (ISMP) Medication Errors Reporting Program. Any reports published by ISMP will be anonymous. Comments are also invited; the writers' names will be published if desired. ISMP may be contacted at the address shown below.

Errors, close calls, or hazardous conditions may be reported directly to ISMP through the ISMP Web site (www.ismp.org), by calling 800-FAIL-SAFE, or via e-mail at ismpinfo@ismp.org. ISMP guarantees the confidentiality and security of the information received and respects reporters' wishes as to the level of detail included in publications.

BASAL INSULINS INCORRECTLY WITHHELD

You may be surprised to learn that nurses sometimes inappropriately hold basal insulin doses (daily or every 12 hours) when a patient's blood glucose is normal at the time a dose is due. This may be appropriate for mealtime or short-acting insulin products, but not basal insulins that can last for up to 24 hours, such as insulin glargine (*Lantus*) or insulin detemir (*Levemir*). These events occurred with medical patients, not patients who were undergoing surgical procedures for whom it may have been appropriate to withhold doses or partial doses if they were not eating post-operatively. When a basal

dose is withheld, the patient's fasting blood glucose the following morning is likely to rise. In the hospital, staff found patients with blood glucose readings in the 200 to 300 mg/dL range. This error is more likely to be noticed if pharmacy prepares basal insulin doses and investigates when the doses have not been administered. One hospital told us that they were seeing a few cases per week until they looked into the situation and made changes. The hospital's education department chose this as a topic for a program. The hospital also has changed their *Lantus* labels, adding a reminder, "Don't hold without MD order."

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ISSUES WITH INSULIN PUMP

Office staff at an endocrinology practice were asked to see a patient who was having a mysteriously low blood glucose while receiving insulin using a Medtronic *MiniMed Revel* portable infusion pump. The pump allows information to be downloaded, and it showed that the patient was getting boluses during the night. The patient vehemently denied administering any doses. The data showed that up to 10 units at a time were being administered. It was suspected that the patient leaned over onto the pump while sleeping, putting enough pressure on the activation system that a dose was released.

We asked Medtronic about this incident, and the company told us it has received rare reports of people accidentally rolling over onto the pump at night and activating a bolus. A patient would have to activate 2 buttons for the pump to actually deliver a dose, which is why this is a rare occurrence. There is a feature to lock out the keypad so that this does not happen. The patient was shown how to use the keypad, and the problem was resolved. A second patient also had mysteriously low blood glucose levels while using the *Revel* pump. In this case, the patient was entering erroneous information into pump software. The pump has a bolus dosing “wizard” that allows patients to enter their blood glucose and the amount of carbohydrate grams they’ve eaten. The patient was accidentally entering the measured blood glucose into the carbohydrate field instead of the number of carbohydrates eaten. For example, 220 was entered in the carbohydrate field instead of 60 g.

The safest way to administer a bolus dose is to use the glucose meter that goes with the pump. This automatically communicates the glucose level information to the pump so the user does not need to manually enter the results. In this case, the patient’s insurance did not cover the test strips for this pump, so the patient was using his own glucose meter and entering the results manually. The pump will warn you when an entry is outside the usual range, but the warning can be overridden. In this case, the patient could not see the pump screens clearly, because the backlight lighting is quite dim. Medtronic told us there is no way to make the light any brighter. They agreed to pass on the information from this report internally to consider whether any enhancements were needed to improve the device.

FUTURE DEVICES FOR U-500 INSULIN

In response to questions we posed to Eli Lilly about the availability of a dedicated U-500 device for the company’s U-500 insulin, a Lilly representative confirmed that 2 projects are underway in an effort

to meet the needs of patients using U-500 insulin. Lilly is working to develop a prefilled pen designed to deliver *Humulin R* U-500 (insulin human), and the company is also working with a development partner on the design of a dedicated U-500 insulin syringe. These dedicated devices, if approved, will allow administration of *Humulin R* U-500 in actual units without dose conversion to nondedicated syringe markings (unit markings with a U-100 insulin syringe or volume [mL] markings with a volumetric syringe).

Due to the complexity and risks inherent in device development and regulatory review, Lilly is unable to speculate on the timing of availability of these devices. Until then, *Humulin R* U-500 must be administered using a U-100 insulin syringe or a volumetric (tuberculin or allergy) syringe.

PATIENTS NEEDED TESTING AFTER PEN MISUSE

Once again, a US hospital must contend with the fact that thousands of the hospital’s patients may have received an insulin injection from an insulin pen previously used for another patient (<http://newyork.cbslocal.com/2014/03/11/l-i-hospital-reused-insulin-pen-part-may-mean-hepatitis-hiv-risk-for-patients/>).

In this recent event, patients are being notified of possible transmission of blood-borne pathogens and being told they should be tested for hepatitis and human immunodeficiency virus (HIV), although the risk is low. No actual cases of disease transmission have been tied to any of the previous “outbreaks” we’ve published. However, there is strong evidence that retrograde travel of blood carrying hemoglobin, red blood cells, and squamous cells into the pen cartridge occurs after injection (<http://www.ajhp.org/content/70/14/1244.abstract?sid=ff9dab0f-4fe9-47c5-be85-bea86bc25ab0>). So it won’t be surprising if transmission is eventually documented.

In this latest case, one of the nurses at the hospital said she believed that reusing insulin pen reservoirs on multiple patients was an acceptable practice. This problem is well known and not easily overcome with employee education and ongoing monitoring. Patients should be educated to not accept their insulin injection from an insulin pen unless they see their name on an attached label.

DIASTAT ACUDIAL REQUIRES SETTING AND LOCKING OF THE DOSE

The *Diastat Acudial* (diazepam rectal gel) delivery system is available for rectal administration to manage selected refractory epilepsy patients who are on stable regimens of anti-epileptic drugs and also

require intermittent use of diazepam to control bouts of increased seizure activity (cluster seizures). The product is available in 10 mg or 20 mg rectal syringes designed to deliver minimum dosages of 5 mg or 12.5 mg, respectively, with dosage increments of 2.5 mg up to a maximum of either 10 mg or 20 mg. (There is also a 2.5 mg syringe available for pediatrics.) There are 2 unlocked rectal syringes per package.

Since the introduction of the device, a number of errors have occurred because the device was not properly dialed and locked prior to administration. This led to the administration of too much medication. Some of these errors have resulted in respiratory depression requiring emergency intervention. Before the product is dispensed, syringes must be dialed, set, and locked to the prescribed dose by the pharmacist, even when the maximum dose is pre-

scribed. Once set and locked, the prescribed dose will appear in the dose display window, and the locking ring, designated with a green “ready” band, will be engaged. This helps to prevent the wrong dose or an overdose from being administered by the caregiver.

Managers should reinforce the need for pharmacists to lock the syringes and educate patients and caregivers about the proper use of the device, including confirming that the prescribed dose is visible in the display window; the green ready band is visible; and the smaller rectal tip size is used if the patient is a child. A 2007 US Food and Drug Administration Patient Safety News video (produced in cooperation with ISMP) on proper use of *Diastat* is available at: <http://www.accessdata.fda.gov/psn/transcript.cfm?show=59#7>. ■