U.S. Food and Drug Administration

Information for Healthcare Professionals: Risk of Transmission of Blood-borne Pathogens from Shared Use of Insulin Pens

FDA ALERT [03/19/2009]: The FDA is issuing this alert to remind healthcare providers and patients that insulin pens and insulin cartridges* (see description below) are never to be shared among patients. Sharing of insulin pens may result in transmission of hepatitis viruses, HIV, or other blood-borne pathogens.

The FDA has received information that insulin pens may have been shared among numerous patients (two thousand or more) in one hospital in the United States from 2007-2009 (http://www.wbamc.amedd.army.mil/[1]), and in a smaller number of patients in at least one other hospital. Although the disposable needles in the insulin pens were reportedly changed for each patient, there is still a risk of blood contamination of the pen reservoir or cartridge. Patients who were treated with insulin pens at the hospitals in question are being contacted by the hospitals, and are being offered testing for hepatitis and HIV. Some of the potentially exposed patients have reportedly tested positive for hepatitis C; however it is not known if the hepatitis infection occurred through insulin pen sharing, or if those who tested positive had previously undiagnosed hepatitis C.

The current instructions for use for all insulin pens already state that the pens are not to be shared among patients. The FDA reminds healthcare providers, healthcare facilities, and patients that each insulin pen (and each insulin pen cartridge) is designed for single-patient use only and is never to be shared among patients. Insulin pens are not designed, and are not safe, for one pen to be used for more than one patient, even if needles are changed between patients because any blood contamination of the pen reservoir could result in transmission of already existing blood-borne pathogens from the previous user. The FDA is working with the Centers for Disease Control and Prevention (CDC), professional societies and healthcare organizations to reinforce patient and healthcare provider education about proper and safe use of insulin pens.

This information reflects FDA's current analysis of data available to FDA concerning this drug. FDA intends to update this sheet when additional information or analyses become available.

To report any unexpected adverse or serious events associated with the use of insulin pens or insulin cartridges, please contact the FDA MedWatch program using the contact information at the bottom of this page.

*Insulin pens are pen-shaped injector devices for insulin that are intended for use by a single patient. The pens have an insulin reservoir, or an insulin cartridge, that usually contains enough insulin for a patient to self-administer several doses (injections) of insulin before the reservoir or cartridge is empty. The patient changes the needle before each insulin injection. Insulin pens are designed to be safe for one patient to use one pen multiple times, with a new, fresh needle for each injection.

Recommendations and Information for Healthcare Professionals Regarding Insulin Pens and Insulin Cartridges, and other reusable injector devices:

- Insulin pens containing multiple doses of insulin are meant for use **by a single patient only,** and are not to be shared between patients.

- Identifying the insulin pen with the **name of the patient and other patient identifiers** provides a mechanism for verifying that the correct pen is used on the correct patient, and can help minimize medication errors. Ensure the identifying patient information does not obstruct the dosing window or other product information such as the product name and strength.

- Be aware that the likelihood of sharing insulin pens and cartridges is increased when the pens are not marked with the patient name or other patient identifiers.

- The disposable needle should be ejected from the insulin pen and properly discarded after each injection. A new needle should be attached to the insulin pen before each new injection.

- Although the incident leading to this FDA alert occurred with insulin pens, the same risk may exist with shared use of any reusable injection device.

- Hospitals and other healthcare facilities should review their policies and educate their staff regarding safe use of insulin pens.

Information for Healthcare Professionals to Provide When Counseling Patients:

- Patients should be instructed that insulin pens containing multiple doses are meant for use **by a single patient only.**
- Patients should be instructed to never share their insulin pen with another person.
- Patients should be advised that sharing of their insulin pens could result in transmission of hepatitis viruses, HIV, or other blood-borne pathogens.

Background Information

The FDA has received information that insulin pens may have been shared among numerous patients (two thousand or more) in one hospital in the United States from 2007-2009 (http://www.wbamc.amedd.army.mil/[2]), and in a smaller number of patients in at least one other hospital. At these hospitals, the same insulin pens may have been used for multiple patients, although the disposable needles were reportedly changed for each patient. Because each of these devices can result in blood contamination of the pen reservoir or cartridge, even if the needle is changed before each use, patients who were treated with insulin pens at the hospitals in question are being contacted by the hospitals, and are being offered testing for hepatitis and HIV. Some of the potentially exposed patients have reportedly tested positive for hepatitis C; however it is not known if the hepatitis infection occurred through insulin pen sharing, or if those who tested positive had previously undiagnosed hepatitis C.

The current instructions for use of insulin pens already state that the pens are not to be shared among patients. The FDA reminds healthcare providers and patients that insulin pens and insulin cartridges are never to be shared among patients. Pathogenic contaminants can enter the cartridge after injection while the needle is still attached to the pen. Thus, insulin pens are not safe for use in multiple patients because of the risk of cross-contamination. The FDA is working with the Centers for Disease Control and Prevention (CDC), professional societies and healthcare organizations to determine if further actions or communications are needed.

How to Report Side Effects and Medication Errors

The FDA urges both healthcare professionals and patients to report side effects and medication errors from the use of insulin, insulin pens and insulin cartridges to the FDA's MedWatch Adverse Event Reporting program, using the information at the bottom of this page

Reference

1. *ISMP Medication Safety Alert! Acute Care*, Institute for Safe Medication Practices (ISMP). February 12, 2009, Vol. 14, Issue 3.