

Patient Safety Alert

Veterans Health Administration Warning System
Published by VA Central Office

AL13-04*

January 17, 2013

Item: Multi-Dose Pen Injectors

Specific Incident: While inspecting inpatient units of a VA facility, the Chief of Pharmacy discovered several insulin pen injectors that were not labeled for individual patients. It was determined that the pen injectors were used to administer insulin to multiple patients by changing the needle between patients. Multi-dose pen injectors are intended for use by one patient only, and the pen injector and cartridges within them should never be shared between patients. The sharing of pen injectors may expose patients to blood-borne pathogens (e.g., HBV, HCV, HIV) through cross contamination in the pen cartridge.

General Information: A similar incident occurred in a VA facility in 2008 involving the use of the same heparin syringe for intravenous line flushes on multiple patients. NCPS published Patient Safety Alert AL08-20 on August 8, 2008 (see references). This alert prohibited the use of the same syringe to administer medications to multiple patients, even if the needle is changed for each patient.

Actions: 1) By close of business (COB) February 04, 2013, the **Facility Director (or designee)**, in consultation with the **Chief of Pharmacy (or designee)**, shall prohibit the use of multi-dose pen injectors (see attachment 1) on all patient care units (i.e., any unit where a staff member is involved in the storage, preparation or administration of a multi-dose pen injector).

Exceptions to Action 1 include the following:

- Patients being educated prior to discharge to use a patient-specific multi-dose pen injector.
- Eligible patients participating in the VA medical center's Self-Medication Program (SMP) as established by VHA Handbook 1108.03 (see references).
- Patients requiring treatment with a medication delivered in a multi-dose pen injector, and no alternative formulation is available from the manufacturer for

treating the patient while on a patient care unit (see attachment 2).

- Patients participating in a research protocol requiring a multi-dose pen injector while on a patient care unit.
- Pen injectors dispensed directly to the patient as an outpatient prescription.

2) By COB February 15, 2013, the **Chief of Staff (or designee)**, in consultation with subject matter experts from **Nursing, Infectious Diseases, and Pharmacy (or their designees)**, shall review and update the local facility policy for the use of multi-dose pen injectors on patient care units. While multi-dose pen injectors are prohibited on patient care units, exceptions as designated in Action 1 require a comprehensive policy that addresses, at a minimum, the following key elements:

- Multi-dose pen injectors shall be stored in the pharmacy and dispensed with an individual patient label consistent with the VA facility's labeling requirements. Multi-dose pen injectors shall not be ward stocked.
- Multi-dose pen injectors are to be used by a single patient only and should never be shared with other patients, even when the needle is changed.
- Disposable safety needles with shield guards must be used to ensure OSHA compliance on patient care units. The needles should be promptly and properly discarded after each injection and a new safety needle attached prior to each additional injection (see references).
- Education on facility policy and safe use of pen injectors must be provided to applicable current and new employees, and be a part of their annual competency assessment.

3) By COB March 01, 2013, the **Patient Safety Manager** shall document on the VHA Hazard Alerts and Recalls website that Medical Center leadership has reviewed and implemented these actions at all VHA facilities under their jurisdiction (including CBOCs, CLCs, etc.) or indicate actions are not applicable to your facility.

References:

NCPS Patient Safety Alert AL08-20. Same syringe used for IV (intravenous) line heparin flushes for multiple patients. August 8, 2008.

Department of Veterans Affairs. VHA Handbook 1108.03. Self-Medication Programs (SMP). February 3, 2010.

http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=2166

U.S. Department of Labor. Occupational Safety and Health Standards. Blood-borne pathogens; 29 CFR 1910.1030.

http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_tab=standards&p_id=10051

Department of Veterans Affairs. VHA Directive 7701. Occupational Safety and Health (OSH). August 9, 2010.

http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=240

Centers for Disease Control and Prevention (CDC) and the Safe Injection Practices Coalition (SIPC). One and only campaign. Safe injection practices: education materials for safe use. December 2012.

http://www.oneandonlycampaign.org/safe_injection_practices

CDC clinical reminder. Insulin pens must never be used for more than one person. <http://www.cdc.gov/injectionsafety/PDF/Clinical-Reminder-insulin-pen.pdf>

FDA news release. Information for healthcare professionals: risk of transmission of blood-borne pathogens from shared use of insulin pens. March 19, 2009.

<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHealthcareProfessionals/ucm133352.htm>

ISMP Medication Safety Alert. Considering insulin pens for routine hospital use? consider this... May 8, 2008.

<http://www.ismp.org/newsletters/acute/acute/articles/20080508.asp>

Department of Health & Human Services. Centers for Medicare & Medicaid Services-Office of Clinical Standards & Quality/Survey & Certification Group. Use of insulin pens in health care facilities.

May 18, 2012. <https://www.cms.gov/Medicare/Provider-Enrollment-and-certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-12-30.pdf>

Sonoki K, et al. Regurgitation of blood into insulin cartridges in the pen-like injectors. *Diabetes Care*. 2001; 24(3):603-4.

<http://care.diabetesjournals.org/content/24/3/603.long>

Le Floch JP, et al. Biological material in needles and cartridges after insulin injection with a pen in diabetes patients. *Diabetes Care*. 1998; 21(9):1502-4.

<http://care.diabetesjournals.org/content/21/9/1502.full.pdf>

Hakre S, et al. An investigation of bloodborne pathogen transmission due to multipatient sharing of insulin pens. *Military Medicine*. 2012; 177(8):930-38.

<http://www.ncbi.nlm.nih.gov/pubmed/22934373> (abstract only)

Attachments:

1. Multi-dose Pen Injectors Available in Alternative Formulations
2. Multi-dose Pen Injectors Unavailable in Alternative Formulations

Source:

Initial report from a Department of Veterans Affairs medical center

Contacts:

Mr. Keith Trettin, Dr. Bruce McIntosh or Mr. Bryanne Patail at the National Center for Patient Safety at (734) 930-5890 or, Dr. Vincent Calabrese at the Pharmacy Benefits Management.

ATTACHMENT 1: Multi-Dose Pen Injectors Available in Alternative Formulations

These are examples of prohibited products, unless an exception as designated in [Action 1](#) is allowed. This list may not include all multi-dose pen injectors currently available in alternative formulations.

Generic Name	Brand Names
Insulin Pen Injectors	
Insulin Glargine	Lantus [®] SoloStar [®]
Insulin Detemir	Levemir [®] FlexPen [®]
Insulin Glulisine	Apidra [®] SoloStar [®]
Insulin Aspart	Novolog [®] FlexPen [®]
Insulin Aspart Protamine/ Insulin Aspart	Novolog [®] Mix 70/30 FlexPen [®]
Insulin Lispro	Humalog [®] KwikPen [™]
Insulin Lispro Protamine/ Insulin Lispro	Humalog [®] Mix 75/25 KwikPen [™] , Humalog [®] Mix 50/50 KwikPen [™]
Insulin NPH	Humulin [®] N Pen
Insulin NPH/ Insulin Regular	Humulin [®] 70/30 Pen
Miscellaneous Pen Injectors	
Follitropin Alfa	Gonal-F [®] RFF Pen
Follitropin Beta	Follistim [®] AQ
Interferon Alfa-2b	Intron [®] A
Somatropin	Norditropin FlexPro [®] , Nutropin AQ Pen [®] , Omnitrope [®] , Humatropen [®] , Nutropin [®] AQ NuSpin [™] , Norditropin [®] NordiFlex [®]

ATTACHMENT 2: Multi-Dose Pen Injectors Unavailable in Alternative Formulations

These are examples of products designated as an exception in Action 1. This list may not include all multi-dose pen injectors currently unavailable in alternative formulations.

Generic Name	Brand Names
GLP-1 Receptor Agonist Pen Injectors	
Exenatide	Byetta [®]
Liraglutide	Victoza [®]
Pramlintide	SymlinPen [®]
Miscellaneous Pen Injectors	
Apomorphine	Apokyn [®]
Teriparatide	Forteo [®]