



**Department of Veterans Affairs
Office of Inspector General**

Office of Healthcare Inspections

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Healthcare Inspection

Inappropriate Use of Insulin Pens VA Western New York Healthcare System Buffalo, New York

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Washington, DC 20420

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Executive Summary

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted an inspection to evaluate the circumstances surrounding the reported inappropriate use of insulin pens at the VA Western New York Healthcare System, Buffalo, New York (the facility). We conducted the inspection at the requests of the Chairmen and Ranking Members of the House Committee on Veterans' Affairs and the Senate Committee on Veterans' Affairs, Senator Charles Schumer, and Congressmen Brian Higgins and Chris Collins. This report addresses questions raised by Members of Congress regarding the specific circumstances at the facility. The OIG will issue a separate report addressing broader questions pertaining to insulin pen use at other facilities, as well as Veterans Health Administration (VHA) oversight and follow-up.

In late October 2012, the facility Chief of Pharmacy discovered three insulin pens—designed for single-patient use only—with no patient labels in a supply drawer of a medication cart. Facility officials subsequently found three more pens without patient labels in medication carts on three other inpatient units, and, when queried, several nurses reportedly acknowledged using the pens on multiple patients. Inappropriately using single-patient use insulin pens on multiple patients may potentially expose patients to bloodborne pathogens.

We identified six factors that contributed to the misuse of insulin pens at the facility. We also found that misuse of the insulin pens went undetected for 2 years because even though facility staff often observed pens with no patient labels on the medication carts, they did not report it because they either did not fully comprehend the clinical risks of sharing pens, or they accepted the unlabeled pens as standard practice believing they were both multi-dose and multi-patient devices. We found that VHA did not notify Members of Congress or at-risk patients until January 2013 because of the time required for multiple levels of coordination between VA and VHA and inefficiencies in VHA's internal review process for large-scale adverse event disclosures. We concluded that the process to review and approve the facility's Communication Plan was not as efficient as it could be. Improving the efficiency of the large-scale disclosure communication planning process could lead to earlier patient notifications.

In response to the insulin pen misuse, facility leaders took immediate steps to identify at-risk patients, which included all patients who had inpatient stays and orders for subcutaneous insulin during the 2-year period the pens were in use on inpatient units. A facility infectious disease specialist, in coordination with VHA specialists, is monitoring and following up with these patients through a specially established outpatient clinic. In addition, to prevent further incidents, the facility conducted thorough inspections of inpatient unit medication storage areas, provided training to staff on proper insulin pen use and broader patient safety issues, conducted an internal root cause analysis, and ultimately discontinued the use of insulin pens on inpatient units in December 2012.

We recommended that the Under Secretary for Health finalize VHA's Clinical Operations Guideline for "Implementation of a Large Scale Disclosure Decision" to include a monitoring process that reflects the urgency of disclosing adverse events to

patients. We recommended that the Veterans Integrated Service Network Director review the facts that led to the misuse of insulin pens and take appropriate administrative action. We also recommended that the Facility Director implement a process to ensure the facility's Medication Use, Nursing Practice, and Commodity Standards Committees and other relevant leadership evaluate the risks and benefits before introducing new medical products or supplies and strengthen nurse education practices when introducing new medical products or supplies and ensure that all nurses are made aware of how to find and use the facility's nursing practice procedures.

Comments

The Under Secretary for Health concurred with our findings and recommendations and provided an acceptable action plan. (See Appendix A, pages 20–24 for the Under Secretary's comments.) We will follow up on the planned actions until they are completed.



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Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted an inspection to evaluate the circumstances surrounding the reported inappropriate use of insulin pens at the VA Western New York Healthcare System, Buffalo, New York (the facility). We conducted the inspection at the requests of the Chairmen and Ranking Members of the House Committee on Veterans' Affairs and the Senate Committee on Veterans' Affairs, Senator Charles Schumer, and Congressmen Brian Higgins and Chris Collins.

The purpose of the inspection was to determine:

- How system failures may have contributed to the inappropriate use of single-patient insulin pens on multiple patients.¹
- Why the practice of using single-patient insulin pens on multiple patients was not detected earlier.
- Why at-risk patients were not notified until more than 2 months after the practice was discovered.
- What actions the facility has taken to monitor the at-risk patients.
- What actions the facility has taken to prevent future inappropriate use of insulin pens or similar devices.

Background

The VA Western New York Healthcare System is part of Veterans Integrated Service Network (VISN) 2 and serves veterans in central and western New York and northern Pennsylvania. The Buffalo division consists of a 199-bed tertiary care facility and six community based outpatient clinics. The facility is a referral center for cardiac surgery, cardiology, and cancer care and is affiliated with the State University of New York at Buffalo School of Medicine and Biomedical Sciences. Long-term care services are provided at the Batavia division. Since 2008, the facility has had six directors, including four who served in acting or interim positions. A permanent director was appointed in March 2012.

In late October/early November 2012, during a monthly inspection of medication carts on an inpatient unit, the facility Chief of Pharmacy discovered several single-patient use insulin pens with no patient labels in a supply drawer of a medication cart. The Chief of Pharmacy and facility managers subsequently found more pens without patient labels in medication carts on other inpatient units, and, when queried, several nurses reportedly acknowledged using the pens on multiple patients. In early November 2012, facility managers notified VISN 2 leadership of the misuse of the pens, and VISN leadership

¹ Insulin pens essentially combine a syringe and insulin and were originally developed for outpatient use because they are portable and convenient for patient use away from home and for patients with vision impairment or dexterity problems.

notified Veterans Health Administration (VHA) Central Office officials, prompting further reviews and the decision to notify all the patients who may have been exposed to bloodborne pathogens as a result. In mid-January 2013, VHA notified Members of Congress, veterans service organizations, and at-risk patients of the pen misuse.

Following VHA's notification to Members of Congress, the OIG received requests for an independent review of the issues from the Chairmen and Ranking Members of the House Committee on Veterans' Affairs and the Senate Committee on Veterans' Affairs, Senator Charles Schumer, and Congressmen Brian Higgins and Chris Collins. Specifically, the Members of Congress requested that we evaluate the circumstances surrounding the reported misuse of insulin pens at the facility and address broader questions regarding insulin pen use at other facilities and VHA's oversight and follow-up on the misuse of pens. This report addresses the circumstances at the facility. The OIG will issue a separate report addressing the broader, systemwide questions.

Diabetes and Insulin Pens. An estimated 18.8 million people in the U.S. have Diabetes mellitus (DM), and 24 percent of adults diagnosed with DM inject insulin alone or insulin in combination with oral hypoglycemic medications to manage their diabetes.²

There are two basic types of insulin pens, reusable pens and disposable pens; both contain multiple doses of insulin and are intended for single-patient use.³

- Reusable pens must be loaded with a cartridge of insulin (sold separately). Cartridges hold 150 or 300 units of insulin. Each reusable pen works only with a specific set of insulin products, so the pen and insulin must be compatible. Depending on the dose, a cartridge can provide enough insulin for several days of injections. When the cartridge is empty, the user discards it and loads a new cartridge for the next dose. A reusable pen can often be used for several years.
- Disposable insulin pens have a pre-filled insulin cartridge, and the entire pen is disposed of when empty. Most disposable pens have 300 units of insulin and are sold in boxes of five. Disposable pens are generally more convenient than reusable pens because the user is not required to load any cartridges, but they usually cost more to use than reusable pens.

Insulin pens are a potentially convenient and discrete way for patients to carry insulin. To use an insulin pen, the user:

- Removes the pen cap, and attaches a pen needle.
- Primes the pen by dialing in a very small dose (exactly how much depends on the particular pen) and expelling the insulin into the air. Priming is done to make sure the insulin is flowing through the pen properly and that there is no air in the cartridge or needle.

² National Diabetes Information Clearinghouse (NDIC), National Institute of Diabetes and Digestive and Kidney Disease (NIDDK), National Institutes of Health (NIH), <http://diabetes.niddk.nih.gov/>, accessed on 1/22/13.

³ BD Diabetes Learning Center, <http://www.bd.com/us/diabetes/page.aspx?cat+7001&id=7254>, accessed on 1/23/13.

- Sets the dose of insulin to be administered using a dial or dose knob.
- Inserts the needle into the skin, and delivers the insulin dose by pressing on the dose knob until it is fully depressed. The needle is discarded after each injection.

Prevalence of Insulin Errors. The National Coordinating Council for Medication Error Reporting and Prevention defines a medication error as "...any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer."⁴ The Joint Commission requires that hospitals identify, in writing, their high-alert medications and have processes for managing these medications.⁵ High Alert Medications are those drugs associated with the highest risk of injury when involved in a medication error. Insulin is consistently identified as a high-alert medication.⁶

Errors associated with insulin in hospitals are common, especially with the numerous varieties of insulin products in use. The United States Pharmacopeia described 4,764 insulin errors over a 2-year period that were reported to their voluntary reporting program. Of these, 6.6 percent of the errors resulted in patient harm.⁷ In another study, Tufts-New England Medical Center conducted an analysis of adverse events involving glucose lowering agents at 21 health care organizations. Over about a 3-year period, the organizations voluntarily reported 2,125 inpatient errors involving insulin.⁸

Infection Risks Associated with Insulin Pens. Insulin pens are designed for single-patient use. Due to potential backflow of a patient's blood into the pen cartridge after an injection, using a pen on multiple patients may expose patients to bloodborne pathogens, such as hepatitis B virus (HBV), hepatitis C virus (HCV), and the human immunodeficiency virus (HIV), if a pen had previously been used on an infected patient. Although the medical literature describes the risks and potential for exposure to bloodborne pathogens, we found no documented cases of actual transmission of bloodborne pathogens related to the use of insulin pens on multiple patients.

A 1998 study of 120 patients found that "biological material, including epithelial cells, can be found in needles and cartridges after an insulin injection in diabetic patients."⁹ The study further concluded that, "This capture is not infrequent (two out of three patients in our study) and is often associated with a considerable number of cells" and that "Cells were found more frequently in cartridges than in needles."

⁴ 2013 National Coordinating Council for Medication Error Reporting and Prevention. Accessed at <http://diabetes.niddk.nih.gov/dm/pubs/statistics/index.aspx#Treatment> on 2/24/13.

⁵ EC.02.02.01, EP 8, EC.02.02.01, EP 8; MM.03.01.01, EP 9

⁶ Cohen MR. "Pharmacists' role in Ensuring Safe and Effective Hospital use of Insulin," *Journal of Health-System Pharmacy* Vol 67 Aug 15, 2010 Suppl 8.

⁷ Cohen MR. "Pharmacists' role in Ensuring Safe and Effective Hospital use of Insulin," *Journal of Health-System Pharmacy*, Vol 67 Aug 15, 2010 Suppl 8.

⁸ Amori RE, Pittas AG, Siegel RD, et al. "Inpatient Medical Errors Involving Glucose-Lowering Medications and their Impact on Patients: Review of 2,598 Incidents from a Voluntary Electronic Error-Reporting Database," *Endocrine Practice*, 14(5):535-542.

⁹ Le Floch JP, Herbreteau C, Lange F, Perlemuter L. "Biological Material in Needles and Cartridges After Insulin Injection With a Pen in Diabetic Patients," *Diabetes Care*, 21:9, 1502-1504.

Study results published in 2001 further support the infection control risks associated with using insulin pens on multiple patients. In this study, researchers used immunochromatography to examine the blood contamination in 146 insulin pen cartridges used by diabetic patients.¹⁰ Researchers detected contamination in six cartridges. Their research also looked at specific types of pen injectors, and they determined that regurgitation (or backflow) appeared “to be dependent on the devices used. . .”

In 2012, U.S. Military researchers published their findings based on follow-up of over 1,500 patients who may have been exposed to bloodborne pathogens between 2007 and 2009, when nurses at a military hospital were reportedly using insulin pens on multiple patients. While the researchers found that 31 patients were newly diagnosed with HBV (3) or HCV (28), they found “no definitive evidence of virus transmission among patients prescribed insulin pens although patient-to-patient transmission of HIV, HBV, and HCV infection could not be excluded.” The researchers further found that, “Although transmission could not be excluded, evidence did not point to a large outbreak because (1) no evidence was found of onset of acute disease after potential exposure to shared insulin pens; (2) sequencing of virus from patient samples indicated no HCV were closely related; (3) the prevalence of infection in this population (>50% preexisting) was comparable to similar populations.”¹¹

Inappropriate Use of Insulin Pens at Non-VA Facilities. Press releases and news media in recent years show that the use of insulin pens on multiple patients is not unique to VA.

- In May 2008, Nassau University Medical Center in New York reported a rumor that nurses may have been using insulin pens on multiple patients between November 2007 and May 2008.¹² In response, the medical center alerted over 840 patients and urged testing for HIV, HBV, and HCV.¹³
- In February 2009, the William Beaumont Army Hospital in Texas reported that nurses may have used insulin pens on multiple patients between August 2007 and January 2009. In response, the hospital notified over 2,100 patients who may have been exposed. In addition, prompted by a subsequent nationwide review, the Bayne-Jones Army Community Hospital in Louisiana reported that up to 15 patients may have been exposed to bloodborne pathogens due to the same practice.¹⁴

¹⁰ Sonoki K, Yoshinari M, Iwase M, Tashiro K, et al. “Regurgitation of Blood into Insulin Cartridges in the Pen-like Injectors,” *Diabetes Care* 24:3, 603–604.

¹¹ Hakre S, Upshaw-Combs DR, Sanders-Buell EE, Scoville SL, et al. “An Investigation of Bloodborne Pathogen Transmission Due to Multipatient Sharing on Insulin Pens,” *Military Medicine*, 177:8, 930–938.

¹² Nassau University Medical Center Press Release, May 7, 2008, accessed at <http://www.nuhealth.net/pressreleasedetail.asp?ID=340> on 2/19/13.

¹³ Ochs, Ridgely, “Nassau Medical Center Extends Warning Over Insulin Pen,” *Newsday*, May 17, 2008, accessed at <http://www.diabeticconnect.com/news-articles/324-nassau-medical-center-extends-warning-over-insulin-pen> on 2/19/13.

¹⁴ William Beaumont Army Medical Center Press Release, February 5, 2009, accessed at <http://www.wbamac.amedd.army.mil/newsitems.aspx?articleid=02062009> on 2/19/13.

- In August 2011, the Dean Clinic in Wisconsin discovered that a diabetes nurse educator may have improperly used insulin pens and lancets (small needles used to obtain drops of blood for testing) intended for teaching purposes on multiple patients from 2006 to 2011. As a result, the clinic notified over 2,300 patients who may have been exposed to bloodborne pathogens.¹⁵
- In January 2013, following an internal review in response to the VA incident in Buffalo, Olean General Hospital in New York reported that some of its nurses may have been using insulin pens on multiple patients between November 2009 and January 2013. The hospital is in the process of notifying over 1,900 patients.¹⁶

Alerts and Warnings About Use of Insulin Pens on Multiple Patients. Since at least 2008, several patient safety and Government organizations have issued alerts and warnings related to insulin pens, specifically warning against using pens on multiple patients.

- In March 2008, the Institute of Safe Medication Practices (ISMP), a non-profit organization certified as a Patient Safety Organization by the Agency for Healthcare Research and Quality,¹⁷ published an article in its newsletter citing research findings on the risk of regurgitation of blood into the cartridges of insulin pens and emphasizing that the pens must not be shared between patients.¹⁸
- In May 2008, ISMP published an article providing guidance to hospitals considering adoption of insulin pens and citing common problems with the pens, including improperly using them on multiple patients.¹⁹
- In February 2009, in response to the incident reported at the William Beaumont Army Hospital (see above), ISMP published an article urging hospitals to “provide education and continuous monitoring to prohibit situations where an individual patient’s pen might be reused for another patient.”²⁰
- In March 2009, the Food and Drug Administration (FDA) issued an alert to health care professionals reminding them that insulin pens and insulin cartridges should never be shared among patients. The alert cited the risk of transmitting

¹⁵ Dean Clinic Patient Safety Notification, August 29, 2011, accessed at

<http://www.deancare.com/about-dean/news/2011/important-patient-safety-notification/> on 2/19/13.

¹⁶ Olean General Hospital Press Release, January 24, 2013, accessed at <http://www.ogh.org/programs-and-services/diabetes/Press%20Release-OGH%20Alerts%20Patients%20to%20Possible%20Insulin%20Pen%20Reuse.pdf> on 2/22/13.

¹⁷ The Agency for Healthcare Research and Quality is an agency within the U.S. Department of Health and Human Services.

¹⁸ ISMP Medication Safety Alert!, “Cross Contamination with Insulin Pens,” March 27, 2008, <http://www.ismp.org/Newsletters/acutecare/articles/20061130.asp>, accessed on 2/22/13.

¹⁹ ISMP Medication Safety Alert!, “Considering Insulin Pens for Routine Hospital Use?” May 8, 2008, <http://www.ismp.org/newsletters/acutecare/articles/20080508.asp>, accessed on 2/22/13.

²⁰ ISMP Medication Safety Alert!, “Reuse of Insulin Pen for Multiple Patients Risks Transmission of Bloodborne Disease,” February 12, 2009, <http://www.ismp.org/newsletters/acutecare/articles/20090212-2.asp>, accessed on 2/22/13.

bloodborne pathogens, such as HIV and hepatitis, and recommended labeling pens with patient names and other identifiers to reduce the risk of improperly using pens on multiple patients.²¹ Articles about the FDA alert were also published in popular medical and nursing journals, including the *Journal of the American Medical Association* and the *American Journal of Nursing*.

- In January 2012, the Centers for Disease Control and Prevention issued a clinical reminder on the safe use of insulin pens after becoming “increasingly aware of reports of improper use of insulin pens, which places individuals at risk of infection with pathogens including hepatitis viruses and human immunodeficiency virus (HIV).” The reminder emphasized that pens are for single-patient use.²²

Scope and Methodology

We conducted a site visit to the facility February 4–7, 2013. We interviewed the Facility Director, clinical managers, inpatient staff nurses on several shifts, and pharmacy technicians. We also interviewed the Chief of Pharmacy, Inpatient Pharmacy Supervisor, Patient Safety Manager, a nurse educator, Quality Manager, and Chief of Infectious Disease. We reviewed relevant facility policies and procedures, nurse training records and materials, and internal correspondence (including memoranda and emails).

We also interviewed the VISN 2 Director and conducted a site visit to VA Central Office in Washington, DC, February 27–28, 2013, to interview VHA officials involved in the decision to implement the adverse event notification and in reviewing and approving the facility’s communication plan of the misuse of insulin pens. Our review period was June 2010, the month facility nurses were first trained on using the insulin pens, through March 2013.

We conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

²¹ FDA Alert, 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/DrugSafetyInformationforHeathcareProfessionals/ucm133352.htm>, accessed on 2/22/13.

²² CDC Clinical Reminder. Insulin Pens Must Never Be Used for More Than One Person, <http://www.cdc.gov/injectionsafety/clinical-reminders/insulin-pens.html>, accessed on 2/22/13.

Inspection Results

Overview of Incident

As part of our inspection, we confirmed the facility's reports regarding the misuse of insulin pens on several inpatient units and obtained additional details on the incidents. In late October 2012, during an inspection of medication carts on an inpatient unit, the facility's Chief of Pharmacy discovered several single-patient use insulin pens with no patient labels in a supply drawer. She subsequently found more unlabeled pens in medication carts on other inpatient units, and, when queried, several nurses reportedly told her that they had used the pens on multiple patients.

During our review, we learned that the Chief of Pharmacy found a total of six pens with no patient labels on four (of six) inpatient units. One unit had three unlabeled pens, and the remaining three units each had one unlabeled pen. In our interviews of 37 inpatient unit nurses, including 7 nurse managers, 15 registered nurses (RNs), and 15 licensed practical nurses (LPNs), a total of 5 nurses (3 RNs and 2 LPNs) acknowledged that they used insulin pens on multiple patients. All five nurses worked on the same unit. In addition, several other nurses, on this unit and other units, stated that they frequently found unlabeled insulin pens on the medication carts—some nurses reported that they threw these pens away, and others reported that if the unlabeled pens were in patient-specific drawers on the medication carts, they typically used the pens.

Issue 1: Factors Contributing to the Misuse of Insulin Pens

We identified six factors that contributed to the misuse of insulin pens at the facility. Furthermore, we found *no* evidence that facility leaders (or any other management officials) instructed nurses to use insulin pens on multiple patients for cost-cutting purposes. Instead, most of the factors discussed below relate to poor coordination, communication, and education.

Risks of Using Insulin Pens on Inpatient Units Not Fully Evaluated. Adopting a new medical product or device in a large health care system is a significant event that requires thorough evaluation of the associated benefits and risks. However, when the facility adopted the use of insulin pens on its inpatient units in 2010, it had no process in place to ensure that facility leaders at the time, pharmacy officials, nursing officials, or a responsible facility committee fully evaluated how adopting insulin pens on the units might impact nursing practice or patient safety.

Prior to implementing the use of insulin pens, the facility used multi-dose vials that the pharmacy labeled for individual patient use and sent up to the inpatient units. In the spring of 2010, pharmacy officials determined that the facility should use insulin pens for patients requiring long-acting insulin. Pharmacy officials cited two reasons for the transition: (1) to reduce the risk of patient harm from accidentally mixing up long-acting and short-acting insulin vials and (2) to reduce waste associated with dispensing insulin vials containing 1000 units per vial to patients who may only use a small fraction of the total volume while in the hospital for only a few days.

The decision to use long-acting insulin pens on inpatient units was primarily made by pharmacy officials; nursing officials were not involved until after the decision was made and it was determined that staff nurses would need training on the insulin pens. We found no documentation that the decision was vetted through the facility's Medication Use Committee, Nursing Practice Committee, and/or Commodity Standards Committee—the three committees that would typically be involved in evaluating the risks and benefits of proposed new medical products or devices—or that facility leaders at the time approved the decision. The facility's Patient Safety Manager was also not involved in the decision making.

We also found no documentation to support that, as part of their decision making, pharmacy officials considered guidance published by various patient safety and Government organizations. For example, in May 2008, ISMP published an article in its newsletter entitled, "Considering insulin pens for routine hospital use? Consider this..." which describes common problems hospitals experienced after switching to insulin pens, such as needlestick injuries, errors in technique, and using the same pen on more than one patient (as though the pens were ward stock or multi-use vials).

Implementation Plan Not Developed for Rolling Out Insulin Pens. Although we found no policy that requires facilities to develop implementation plans for rolling out new medical products or devices, a well-designed and coordinated implementation plan can help to ensure a timely roll-out with minimal disruption to patient care and safety. Facility leaders at the time and pharmacy and nursing officials at the facility did not develop a plan to specify timelines and key staff, assign roles and responsibilities, and implement ongoing monitoring efforts. As a result, the roll-out was not properly coordinated between the key players, including pharmacy staff, nursing staff, and the facility's Commodity Standards Committee, and training occurred months before the insulin pens were actually introduced on the inpatient units.

In June 2010, nursing staff received training on the pens from a pharmaceutical company representative. According to emails between facility staff, the plan at the time was to introduce the pens on the inpatient units "some time mid July after training." However, in July, it was determined that safety needles, intended to reduce the risk of needlestick injuries to staff, were needed for the pens. At this time, the facility's Commodity Standards Committee began researching safety needles and obtained price quotes. According to Committee meeting minutes, the needles were purchased in September 2010 and received in October 2010. Pharmacy officials rolled out the insulin pens to inpatient units on October 19, 2010—almost 4 months after nursing staff were trained in the use of the pens.

As part of planning, facility leaders at the time and pharmacy and nursing officials also did not outline procedures to monitor the roll-out of the insulin pens to ensure they were being used properly. In our interviews, pharmacy officials and a nurse educator stated that it was their expectation that unit nurse managers were responsible for monitoring the insulin pens after the roll-out in October 2010 and providing any required refresher training. Nurse managers we interviewed generally seemed to be of the opinion that

training was already provided, and, since staff nurses did not raise any questions about the pens, no further training or monitoring was required.

Nursing Staff Not Adequately Trained on Insulin Pens. As discussed above, nursing staff received training on the insulin pens almost 4 months before the pens were rolled out on the inpatient units. Furthermore, based on our review of the training schedule and hand-outs and interviews with over 30 staff nurses and managers, we determined that the training was informal and not thorough.

The initial training in June 2010 was provided by a pharmaceutical company representative and facility nurse educators. The training involved the pharmaceutical representative spending about 30 minutes on each inpatient unit during two or three shifts over a couple of days. During this time—in between the nurses' patient care duties—the pharmaceutical representative showed the nurses how to use an insulin pen. However, if a nurse was not on duty one of the days or too busy with patient care duties, he/she did not receive the training. According to a nurse educator, refresher training was also provided when the insulin pens were rolled out in October 2010. This training primarily consisted of email reminders and information sheets, which emphasized that insulin pens were for single-patient use and not to be shared.

Of the 15 RNs we interviewed, 11 recalled “informal” training by a pharmaceutical representative and/or Nurse Educator on the unit, 1 reported learning from a patient, 1 recent graduate reported learning in nursing school, 1 recalled reading a handout, and 1 reported no training.

Of the 15 LPNs we interviewed, 6 recalled “informal” training, consisting of a demonstration by a pharmaceutical representative and a handout; 3 newer LPNs reported that they were trained during new employee orientation; 3 reported that they were trained by other nurses on the units; 2 recalled reading handouts or emails about the insulin pens; and 1 reported that she received no training but had prior experience using insulin pens.

Several of the nurses told us that their training focused mainly on the mechanics of the pen, for example, how to change the safety needle, prime the pen to avoid air bubbles, set the dial for the correct dosage, and hold the plunger down to ensure the full dose is delivered to the patient. Most of the nurses could not recall if they were explicitly told that the pens were for single-patient use. Two nurses we interviewed stated that they were told by a former nurse educator and a pharmacy staff member that it was acceptable to use the insulin pens on multiple patients; however, we were unable to verify their assertions. Furthermore, for those nurses who recalled being told the pens were single-patient use, it is not clear that they were fully informed of the clinical reason for this, that is, the risk of backflow into the cartridge, which could expose patients to bloodborne pathogens.

Failure to Follow Nursing Practice Procedures. To ensure consistency in practice, facilities use nursing practice procedures to provide nurses with step-by-step procedures for performing an array of clinical tasks, such as inserting a catheter,

collecting specimens, or administering medications. Facilities generally use commercially available nursing practice guides in conjunction with locally developed procedures.

In October 2010, when the insulin pens were rolled out, the facility's Nursing Practice Committee updated the facility's nursing procedures to describe how nurses should use and store insulin pens on the units. The procedures clearly stated that an insulin pen is "for the individual patient it was ordered for," and "The pens are NOT to be shared." The procedures also instruct nurses to label insulin pens with patients' names. The nursing procedure does not explain the clinical reason why insulin pens are for single-patient use, nor does it cite any of the safety alerts or references that describe the risk of backflow and bloodborne pathogens transmission.

Although the facility's nursing procedures were available to all nurses electronically through facility computer terminals, nurses did not consistently follow them, as evidenced by the discovery of unlabeled insulin pens on multiple units and the acknowledgement by several nurses that they used the pens on multiple patients. Some of the nurses we spoke to stated that they were not sure where to find the facility's nursing procedures, while others reported that the procedures were too voluminous and/or cumbersome to navigate. Other nurses stated that although they knew what the written procedure was, they did not follow it because the *actual practice* on their units was different.

Confusion between Multi-Dose Vials and the Insulin Pens. Several staff nurses and nurse managers we spoke with cited confusion over the term "multi-dose" as another possible factor contributing to the misuse of insulin pens. Facility inpatient units commonly stock items that contain multiple doses and that may be used for multiple patients. Examples include large bottles of liquid antacids for heartburn relief, vials of insulin, or the influenza vaccine. These multi-dose, multi-patient medications are called ward stock and come up from the pharmacy *without* patient-specific labels. If a provider orders one of these medications for a patient, a nurse will use the ward stock to administer the medication.

When the facility rolled out the insulin pens on inpatient units in 2010, pharmacy officials decided to stock pens *without* patient labels in the refrigerators of the units' automated medication dispensing units. When a patient had an order for long-acting insulin, nursing practice procedures instructed nurses to remove a pen from the refrigerator, apply a patient label, and place the pen in a patient-specific drawer on the medication cart. According to pharmacy officials, they provided the units unlabeled pens in an effort to make the pens more accessible to nurses when new orders for insulin were placed and/or replacement pens were needed (versus the nurses having to wait for the pharmacy to send up a patient-labeled pen each time a provider ordered long-acting insulin and/or a pen needed to be replaced).

Based on our interviews, however, because the pharmacy sent the insulin pens up to the inpatient units without patient labels, some nurses mistakenly believed the insulin pens to be just like any other unlabeled ward stock item—that is, multi-dose and for

multi-patient use. This belief was further supported by the fact that on some units, the pens were kept in the same location as ward stock medications instead of patient-specific drawers on the medication carts.

Insulin Pens Not Clearly Labeled for Single-Patient Use. The facility used one brand of long-acting insulin—the Lantus Solostar® pen manufactured by Sanofi-Aventis. Several facility managers and staff members we spoke to stated that the insulin pens were not labeled for single-patient use. We inspected a pen and the box it came in and verified that neither one included warning notices that the pens were not to be shared. The only warning we found was on the standard package insert provided by the manufacturer. The warning states: “Do not share disposable or reusable insulin devices or needles between patients, because doing so carries a risk for transmission of blood-borne pathogens.”

Issue 2: Detection of Insulin Pen Misuse

The facility rolled out the insulin pens on inpatient units in October 2010; yet, the misuse of the pens was not identified until 2 years later in October 2012, when the Chief of Pharmacy conducted a monthly inspection that is usually performed by a pharmacy technician. During the inspection, the Chief of Pharmacy, who had come up to a unit to assist on another matter, found three unlabeled insulin pens in the supply drawer of a medication cart. When she queried the unit nurses about the pens, they reportedly told her that it was okay because they were changing the needles on the pens. The Chief of Pharmacy immediately checked the other inpatient units and found an additional three unlabeled pens on three units (one pen per unit).

Although pharmacy and nursing staff told us that they often saw unlabeled pens on the inpatient units, we found no record that they reported concerns to nursing management, facility leadership, or the Patient Safety Manager. Based on our interviews with pharmacy and nursing staff, even though they often observed unlabeled pens on the medication carts at different times over the 2-year period, it appears that some staff did not comprehend the clinical risks of sharing pens, or they accepted the unlabeled pens as standard practice.

Pharmacy Technicians Not Aware of the Risks. At the facility, pharmacy technicians, allied health care professionals who work under the direct supervision of pharmacists, are responsible for stocking and replenishing ward stock and medication carts on the inpatient units. They are also responsible for conducting monthly inspections of medication carts and other storage locations to identify and remove expired medications or improperly stored medications.

Four of the five pharmacy technicians we interviewed recalled that, while restocking or conducting monthly inspections, they occasionally found insulin pens that did not have either patient labels and/or labels showing when the pens were first opened. One pharmacy technician stated that if she found unlabeled pens, either in patient-specific drawers or supply drawers, she left them alone because she had not been instructed to remove unlabeled pens from the medication carts. The other three pharmacy

technicians reported that, when they saw unlabeled pens, they typically removed them from the units and destroyed them in the pharmacy. However, they could not recall if they reported the problem to anyone other than to inform the unit charge nurses that they were removing the pens.

Based on our interviews with the pharmacy technicians, it is not clear if they fully understood the clinical reason why insulin pens needed to be labeled for specific patients, labeled with the date they were first opened, and stored in patient-specific drawers on the medication carts. At least one pharmacy technician acknowledged that she did not fully understand how insulin pens worked or the risks associated with using the pens on multiple patients.

Many Nurses Accepted as Standard Practice and/or Unaware of the Risks. Most of the RNs and LPNs we interviewed reported that the insulin pens they used were either already labeled with patients names or they labeled the pens when they removed them from the refrigerator for first-time use. Five nurses—all of whom worked on the same unit—acknowledged using unlabeled pens on multiple patients but considered this a standard, acceptable practice on their unit. Four other LPNs told us that they often saw unlabeled pens in patient-specific or supply drawers; when they did, they typically disposed of the pens. One of the four LPNs stated that when she reported finding an unlabeled pen to a unit charge nurse, the charge nurse instructed her to dispose of it. Another LPN reported that if she found an unlabeled pen in a patient-specific drawer, she assumed it was for that patient, and she would use it. However, during our discussion, the LPN acknowledged that she had no way of knowing if the pen had been used on other patients.

Issue 3: Notification of At-Risk Patients

VHA Handbook 1004.08, “Disclosure of Adverse Events to Patients,” October 2, 2012, describes VHA policy and procedure for disclosing large-scale adverse events. “Large-scale disclosure of adverse events (sometimes referred to as ‘notification’) is a formal process by which VHA officials inform patients, or their personal representatives, that they have been or may have been affected by an adverse event involving actual or potential harm to multiple patients, which is deemed clinically significant.”²³ Additional guidelines and procedures are outlined in VHA’s undated Clinical Operations Guideline (COG) for “Implementation of a Large Scale Disclosure Decision,” which according to a VHA official has been under development for about the past 2 years. Key steps in the disclosure process include:

- The facility identifies a harmful or potentially harmful adverse event that is a system issue.
- The facility prepares an Issue Brief (IB) describing the event and circumstances and submits it to the VISN.

²³ VHA Handbook 1004.08, “Disclosure of Adverse Events to Patients,” October 2, 2012.

- The VISN submits the IB up the chain of command to the Deputy Under Secretary for Health for Operations and Management (DUSHOM).
- The DUSHOM submits the IB to the Principal Deputy Under Secretary for Health (PDUSH) and initiates and oversees a triage process.
- The DUSHOM convenes a Subject Matter Expert (SME) Review Panel to conduct fact-finding and assess the risks that may warrant a large-scale disclosure.
- The SME Review Panel submits one of the following three recommendations to the PDUSH:
 - Negligible risk of harm. No large-scale disclosure; issue closed.
 - Clinically significant risk of harm. Proceed with large-scale disclosure.
 - Indeterminate risk of harm. Convene a Clinical Review Board (CRB), which is a multi-disciplinary board that follows a structured decision making process to consider if disclosure is ethically warranted given the indeterminate risk.
- The PDUSH makes a decision based on the recommendations of the SME. If the decision is to proceed with large-scale disclosure, the DUSHOM notifies the VISN and facility and may activate a site visit team.
- The facility develops the disclosures (commonly referred to as a Communication Plan) in coordination with the VISN and DUSHOM. The facility also collaborates with VHA's Office of Public Health to conduct a "look-back," which is a process for identifying patients who may be at risk due to exposure.

Neither the VHA Handbook nor the COG include timeliness standards or suggested milestones for large-scale adverse event disclosure. According to high-level VHA officials, establishing such a standard would be difficult because each event is different in terms of complexity, severity of risk, need for treatment, and potential number of patients at risk. Furthermore, VHA officials could not provide us an average length of time or range of days for prior large-scale adverse event disclosures at other VHA facilities because they do not track or monitor this information.

VHA officials cited several factors that slowed the notification process down, including a change in the Communication Plan template from VA Central Office, individual reviews of the Communication Plan instead of VHA's preferred group review process, concerns about notifying patients during the holiday season, and an internal review by VHA's National Center for Patient Safety to determine if other facilities were misusing pens.

Although VHA has no timeliness standards for large-scale disclosure of adverse events and does not monitor the timeliness of such events, we concluded that the VA/VHA process to review and approve the facility's Communications Plan was not as efficient as it could be. Improving the efficiency of the large-scale disclosure communication

planning process could lead to earlier patient notifications. Based on various disclosure documents, internal emails, and interviews, we constructed the following timeline for VHA’s large-scale adverse event disclosure, which commenced on January 11, 2013—72 days after the facility identified the misuse of insulin pens.

Table 1. Timeline of Key Events for the Buffalo Disclosure

Date	Elapsed Days (from 10/31/12)	Event
10/31/12		Facility Chief of Pharmacy discovers misuse of insulin pens on at least four inpatient units.
11/1/12	1	Facility Chief of Pharmacy notifies facility leadership of findings.
11/2/12	2	Facility leadership submits an IB to VISN leadership.
		VISN leadership submits IB to VHA via Issue Tracker Program.
11/5/12	5	Facility leadership initiates “look-back” process to identify patients potentially at risk.
11/12/12	12	DUSHOM convenes an SME panel.
11/16/12	16	SME panel recommends adverse event disclosure since risk is “not negligible,” and concurs with the number of patients identified by the facility as potentially at risk.
		VHA instructs VISN and facility to develop a Communication Plan and provides examples of required documents.
11/19/12	19	Facility director requests an extension from the VISN for submitting the Communication Plan.
11/27/12	27	Facility submits Communication Plan to VISN.
		VISN submits Communication Plan to VHA.
11/30/12	30	The Assistant Deputy Under Secretary for Health (ADUSH) for Clinical Operations (10NC) clears Communication Plan.
12/3/12	33	PDUSH (10A) clears Communication Plan with edits.
		VHA Public Communications (10B2B) clears Communication Plan with edits and forwards to VHA Congressional and Legislative Affairs (10B3).
12/7/12	37	Office of General Counsel (OGC) has questions about the issue at Buffalo; the ADUSH for Administrative Operations (10NA) provides written response.
12/11/12	41	Teleconference between OGC, facility, VISN, and VHA to further clarify OGC questions.
12/12/12	42	VISN submits revised Communication Plan based on teleconference with OGC.
12/13/12	43	OGC makes “extensive changes” to the Communication Plan.
		OGC-revised Communication Plan sent to VISN for review and additional changes; VISN sends to facility with 12/14 deadline.
12/14/12	44	Facility returns Communication Plan to VHA.
12/18/12	48	Revised Communication Plan sent back to ADUSH for Clinical Operations (10NC), PDUSH (10A), and OGC for review. Question raised concerning authority to disclose certain protected information to next of kin.
12/19/12	49	Communication Plan sent to Health Information Governance (10P2C) to address next of kin disclosure question.
12/20/12	50	VHA advises VISN that Communication Plan telephone script must be updated to clarify that certain protected information may not be shared with next of kin.
		VHA Chief Communications Officer (10B2) provides technical edits and comments on Communication Plan.

Date	Elapsed Days (from 10/31/12)	Event
12/21/12	51	VISN submits revised telephone script to address next of kin disclosure question.
		Additional edits and comments to Communications Plan by ADUSH for Clinical Operations (10NC).
12/28/12	58	Additional edits and comments to Communications Plan by VHA Public Communications (10B2B); comment addressed by ADUSH for Clinical Operations (10NC).
12/31/12	61	VHA Public Communications (10B2B) edits sent to VISN.
		VISN approves edits and returns to VHA.
		Further edits to Communication Plan based on review by VHA Congressional and Legislative Affairs (10B3).
1/2/13	63	Facility concurs with edits made by VHA Congressional and Legislative Affairs (10B3).
1/2/13	63	VA Office of Public Affairs (80) approves Communication Plan.
1/4/13	65	Director, Network Support (10NA3) clears Communication Plan.
		VHA Deputy Chief of Staff (10B) sends VHA-cleared Communication Plan to Strategic Communications in the Office of the Secretary.
		Strategic Communications returns plan with edits and comments to VHA; VHA returns to VISN.
		VA Office of Congressional and Legislative Affairs (OCLA) inform VHA that they will clear the plan once the Secretary has been briefed.
1/7/13	68	VHA makes further edits to the plan based on Strategic Communications and OCLA reviews.
		VHA receives clearances from OCLA, Office of Public and Intergovernmental Affairs, and Strategic Communications; facility given clearance to proceed with notification on 1/8/13.
1/8/13	69	VISN 2 requests to begin notifications on 1/9/13 to better prepare and coordinate; approved by VHA Deputy Chief of Staff (10B).
1/8/13	69	VISN leadership and VHA officials brief VA Secretary.
1/10/13	71	VHA makes additional edits to the timeline of the Communication Plan.
1/11/13	72	VA Chief of Staff and Secretary approve notification to begin at 2:00 p.m.

Source: VAOIG

Issue 4: Actions to Monitor At-Risk Patients

As part of its “look back” process to identify patients who may have potentially been exposed to bloodborne pathogens as a result of the insulin pen misuse, the facility considered any patient treated with an insulin pen while hospitalized between October 19, 2010, the initial roll-out date of the pens, until November 1, 2012, when the misuse of pens was reported, as an at-risk patient. The SME Review Panel considered these individuals at risk for HBV, HCV, and HIV. Five tests were recommended for the initial testing with additional tests based on those results.²⁴

²⁴ The five tests recommended for the initial testing were: Hepatitis B Surface antigen, Hepatitis B core, the antibody to Hepatitis B surface antigen, Hepatitis C, and HIV.

Initially, 716 patients were identified as being at-risk from possible misuse of the insulin pens. While some of the at-risk patients have died since being hospitalized at the facility, none of the deaths were attributed to bloodborne pathogens. As of March 6, 2013, 542 of the 716 patients were known to be still living, and 395 (73 percent) of the living, at-risk patients have been tested. Twenty-four patients refused testing. The entire group of at-risk patients is being tracked in a dedicated database by an infectious disease specialist. Because individuals infected by these viruses would generally demonstrate positive blood tests within 6 months of the exposure, the facility plans to test and follow all at-risk patients at least 6 months after their last inpatient exposure to an insulin pen. Those individuals with negative test results after the 6-month period will not require further follow-up.

As of March 6, 2013, 84 patients had at least one positive test on initial screening. Of these, 29 patients had a pattern of test results consistent with prior HBV vaccinations; 28 had test results consistent with prior positive tests (that is, infection prior to insulin pen exposure); 7 were indeterminate and undergoing additional testing; and 2 were found not to be infected, as their initial tests were falsely positive. No patients tested showed evidence for new HIV infections or active infections with HBV. Eighteen patients had newly discovered blood tests consistent with recent or past exposure to bloodborne pathogens, and all have met with the infectious disease specialist in a clinic created for the at-risk patients.

Twelve of the 18 patients had newly discovered blood tests consistent with recent or past HBV exposure; however, none of the 12 patients had the combination of positive blood tests for active HBV infections.²⁵ One patient had prior negative HBV testing in 2003, and the remaining 11 patients had no prior blood tests for HBV. These patients' exposure to HBV could have been at any point since their last negative test. In the case of those without prior testing, the exposure could have occurred at almost any point in the patients' lives prior to testing. For example, one of the patients with newly discovered HBV exposure had positive blood tests within a month of his exposure to insulin pens. However, his pattern of positive blood tests is quite unlikely in a patient who had recently been exposed to HBV,²⁶ strongly suggesting that his bloodborne pathogen exposure had been prior to his treatment with insulin pens.

Six of the 18 patients had newly discovered blood tests consistent with recent or past HCV exposure. None of these six patients with newly documented positive blood tests for HCV had ever had prior testing for the virus. Similar to the above patients with HBV exposure, the exposure could have occurred at almost any point in the patients' lives prior to testing. Four of the six patients had no detectable virus in their blood. The two patients with detectable HCV continue to be followed by the infectious disease specialist for further follow-up and treatment.

²⁵ Active HBV infection would be indicated by a positive Hepatitis B core and positive Hepatitis B surface antigen test.

²⁶ Hepatitis B Surface Antigen test would be expected to be positive 1 month after an acute infection with Hepatitis B.

The facility is taking the most conservative approach and assuming that the insulin pens are a possible cause if the pens cannot be “100 percent excluded” as the source of infection. Determining the actual cause of exposure in these patients is problematic, as patients had other risk factors for bloodborne pathogens besides insulin pens. In none of the cases could an insulin pen exposure be identified as the definitive cause of a positive blood test.

Issue 5: Actions to Prevent Further Incidents

In addition to monitoring the at-risk patients, following the discovery of the insulin pen misuse, facility leadership took immediate actions and implemented ongoing system improvements to reduce the risk of further incidents. Examples of actions taken by facility leadership include:

Unit Inspections. On November 1, 2012, the Chief of Pharmacy and pharmacy staff conducted an inspection of all medication carts and replaced any unlabeled pens with pens that were labeled with patient names. Pharmacy placed these labeled pens in patient-specific drawers. Furthermore, on November 9, the facility’s Infection Prevention Nurse and Quality Management staff conducted another inspection to ensure pens were still labeled and located in patient-specific drawers on the medication carts and that nursing staff were following proper procedures.

Refresher Training. On November 2, 2012, a facility nurse educator provided all nurse managers with a detailed training packet to review and discuss with unit staff nurses no later than November 9. During their inspection on November 9, the facility’s Infection Prevention Nurse and Quality Management staff verified that the refresher training occurred.

Root Cause Analysis. On November 7, 2012, the Facility Director chartered a team to conduct a root cause analysis (RCA) of this incident. An RCA is a structured and protected quality assurance process to identify system failures that contributed to an adverse event and to recommend action plans to address these failures. The RCA was completed on December 21, 2012.

Discontinued Use of Insulin Pens. In December 2012, the facility’s Medication Use Committee evaluated the use of insulin pens and decided to discontinue the use of pens on inpatient units and return to using individually patient-labeled multi-dose vials.

Patient Safety Training. In March 2013, representatives from VHA’s National Center for Patient Safety provided training to facility staff on promoting a culture that supports patient safety at the facility.

Furthermore, on January 17, 2013, VHA Central Office issued a Patient Safety Alert to all facilities prohibiting the use of multi-dose insulin pens on all inpatient units effective February 4, 2013.²⁷ The Alert identifies the following exceptions to the prohibition:

- For patients being educated on the use of insulin pens prior to discharge.
- For patients eligible to participate in a facility's Self-Medication Program.
- When no alternative formulation is available from a manufacturer.
- For patients participating in a research protocol requiring insulin pens.
- When insulin pens are dispensed directly to a patient as an outpatient prescription.

Conclusions

Inappropriately using single-patient use insulin pens on multiple patients may potentially expose patients to bloodborne pathogens such as HBV, HCV, and HIV. This risk has been documented in medical literature since at least 1998, and private and Government patient safety organizations have published alerts on the risk since at least 2008. However, when pharmacy officials at the VA Western New York Healthcare System introduced the insulin pens on inpatient units in 2010 in an effort to prevent medical errors and reduce waste related to insulin use, they failed to fully consider and/or mitigate the risks associated with using insulin pens. Furthermore, once the decision was made to use the pens, former facility leaders and pharmacy and nursing officials failed to ensure proper planning and coordination, adequate and timely training, and clear and ongoing guidance on the difference between insulin pens and multi-dose vials that have traditionally been used on inpatient units. These factors also contributed to the facility's delay in identifying that some nurses were inappropriately using the pens on multiple patients.

Once facility managers recognized that the pens were being misused, they acted immediately and appropriately to remove all unlabeled pens from the inpatient units, notify the VISN of the misuse, retrain the nursing staff, and identify all patients who may have been affected by the misuse. VHA officials further determined that due to the potential risk of exposure, a large-scale adverse event disclosure was warranted. Therefore, on January 11, 2013—72 days after the facility identified the misuse—facility and VHA officials began notifying Members of Congress, veterans' service organizations, and at-risk patients. Although VHA does not have timeliness standards for large-scale disclosure of adverse events, we consider 72 days to be too long a delay for notifying patients. We found that the delay was due to the time required for multiple levels of coordination between VA and VHA and inefficiencies in VHA's internal review process for large-scale adverse event disclosures. We concluded that the process to

²⁷ AL 13-04, Patient Safety Alert, Veterans Health Administration Warning System Published by VA Central Office, January 17, 2013.

review and approve the facility's Communication Plan was not as efficient as it could be. Improving the efficiency of this process could lead to earlier patient notifications.

On January 17, 2013, VHA prohibited the use of multi-dose insulin pens on inpatient units, with several exceptions, effective February 4, 2013.

Recommendations

1. We recommended that the Under Secretary for Health finalize VHA's Clinical Operations Guideline for "Implementation of a Large Scale Disclosure Decision" to include a monitoring process that reflects the urgency of disclosing adverse events to patients.
2. We recommended that the VISN Director review the facts that led to the misuse of insulin pens and take appropriate administrative action.
3. We recommended that the Facility Director implement a process to ensure the facility's Medication Use, Nursing Practice, and Commodity Standards Committees and other relevant leadership evaluate the risks and benefits before introducing new medical products or supplies that require changes in nursing procedures.
4. We recommended that the Facility Director strengthen nurse education practices when introducing new medical products or supplies and ensure that all nurses are made aware of how to find and use the facility's nursing practice procedures.

Under Secretary for Health Comments

Department of Veterans Affairs

Memorandum

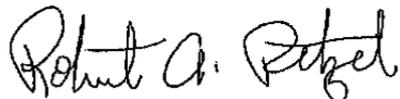
Date: April 29, 2013
From: Under Secretary for Health
Subject: **Healthcare Inspection – Inappropriate Use of Insulin Pens, VA Western New York Healthcare System, Buffalo, New York**
To: Assistant Inspector General for Healthcare Inspections (54)

1. I have reviewed the draft report from the Office of the Inspector General (OIG) and concur with the report's recommendations. I am optimistic that improvements to coordination between multiple levels of VA and the Veterans Health Administration could lead to earlier patient notification. VHA makes large-scale disclosures deliberately and thoughtfully. VA Central Office, the Veterans Integrated Service Network, and the facility coordinate with each other to ensure the large-scale disclosure is based on a thorough investigation of the facts. We take the time required to accurately identify and collect relevant data on potentially affected patients through an organized look back. We compile an accurate patient disclosure list to prevent undue alarm to patients who may not be affected. While deliberative and thoughtful actions are necessary, I do agree with OIG's conclusion that the process for review and approval of communication plans for large-scale disclosures is not as efficient as it could be.

2. VHA is committed to a health care environment where staff understands what constitutes an adverse event and where senior leaders endorse a culture of safety in which staff feels psychologically safe to report adverse events and empowered to change clinical practices to prevent adverse events. At VA Western New York Healthcare System, upon learning about the clinical practice of using insulin pens on multiple patients, the facility immediately disclosed the adverse event to at-risk patients admitted at the time, and prohibited the use of insulin pens in the hospital.

3. VHA has published VHA Handbook 1004.08, Disclosure of Adverse Events to Patients, which provides clear direction on disclosing to patients harmful adverse events that they have sustained during the course of their VA care, including cases where the harm may not be obvious, or where there is potential for harm to develop over time.

4. VHA's goal is to perform large-scale disclosure with the care, thoughtfulness, and consideration our Veterans deserve. If you have any questions regarding the content of this memorandum, please contact Dr. Karen M. Rasmussen, Acting Director, Management Review Service (10AR) at (202) 461-6643.



Robert A. Petzel, M.D.

Attachment

Comments to OIG's Report

The following comments are submitted in response to the recommendations in the OIG report:

OIG Recommendations

Recommendation 1. We recommended that the Under Secretary for Health finalize VHA's Clinical Operations Guideline for "Implementation of a Large Scale Disclosure Decision" to include a monitoring process that reflects the urgency of disclosing adverse events to patients.

VHA Response:

Concur

Target date for completion: June 30, 2013

VHA uses the published policy document Handbook 1004.08, Disclosure of Adverse Events to Patients, which provides clear direction on determining timeliness and the urgency of disclosing adverse events to patients. The handbook describes in detail the monitoring of clinical, institutional, and large scale disclosure procedures to ensure patients receive transparent and factual information. Additionally, VHA uses an internal, administrative workflow Clinical Operations Guideline to assist the functional activities of processing large scale disclosures through fact finding, verification of scientific information, decision making, and dissemination of disclosure findings.

VHA will review VHA's internal guidance regarding the Clinical Operations Guideline for "Implementation of a Large Scale Disclosure Decision" for a monitoring process that reflects the urgency of disclosing adverse events to patients. This review will be completed by the end of FY 3rd Qtr and result in updated internal functional processing guidance

Recommendation 2. We recommended that the VISN Director review the facts that led to the misuse of insulin pens and take appropriate administrative action.

VHA Response:

Concur

Target date for completion: May 31, 2013

The Network Director in conjunction with Executive Leadership will conduct a review of the facts that lead to the misuse of insulin pens to determine if administrative actions would be appropriate.

Recommendation 3. We recommended that the Facility Director implement a process to ensure the facility's Medication Use, Nursing Practice, and Commodity Standards Committees and other relevant leadership evaluate the risks and benefits before introducing new medical products or supplies that require changes in nursing procedures.

VHA Response:

Concur

Target date for completion: May 15, 2013

1. Policy and procedure for the Medication Use Committee was revised to reflect practice changes within the committee to include the following: 1) Performance of a risk assessment for all new medications and medication delivery methods/devices under consideration prior to a vote to approve usage at VA Western New York Healthcare System. This risk assessment will include a look back into related safety alerts, advisories and recalls. 2) Review of all Patient Safety Alerts received, including but not limited to those issued by the Food and Drug Administration and Pharmacy Benefits Management Services and make any recommendations regarding any actions required. 3) The Medication Use Committee will function in conjunction with the Nursing Practice Committee to govern use of medication delivery methods/devices not previously in use, in administration by nurses within the medical center inpatient units and/or clinics. 4) Committee membership was expanded to include a broader representation by nursing service and Nursing Practice Committee. 5) A standing agenda and minutes format was developed for the Committee to ensure that the new processes are followed and documented.

2. Policy and procedure for the Clinical Product Review Committee (replaced the Commodity Standardization Committee in March 2012) will be reviewed and revised to incorporate practice changes to evaluate the risks and benefits before introducing new medical products or supplies that require changes in nursing procedures. Revisions made to the Medication Use Committee will be reviewed then either adopted or adapted for the Clinical Product Review Committee.

Recommendation 4. We recommended that the Facility Director strengthen nurse education practices when introducing new medical products or supplies and ensure that all nurses are made aware of how to find and use the facility's nursing practice procedures.

VHA Response:

Concur

Target date for completion: May 31, 2013

1. A third full-time Nurse Educator position was established and filled on March 10, 2013.

2. A standardized and systematic process was developed providing education guidelines for new medical products, supplies, and medical devices. A facility policy and procedure was developed to support this process. This new policy defines that all identified staff receive targeted education/training on newly approved medical products and devices based on risk analysis. A risk assessment will be conducted and approved by the initiating party and authorizing committee prior to approval of the item for use to include trials. The risk assessment will categorize products into a low, medium, or high-risk category by utilizing a defined risk stratification system. Each risk category will have educational requirements defined within this policy. The education/training mandated by risk category will take place prior to initial product dissemination, during new staff orientation, and annually or just-in-time as warranted. Initial and follow-up training documentation will occur using the Talent Management System (TMS) for the educational components rated as medium and high. Education and training will be provided by the appropriate department as identified by the authorizing committee in collaboration with the Education Department and Nurse Educators.
3. Nursing Service communications were standardized to provide easy access to resources. All nursing policies were reviewed and updated or rescinded. A SharePoint was created and currently houses nursing policies and procedures. Nursing staff received an e-mail message about the changes with instructions on how to place an icon on their desktop for easy access. When policies and procedures are updated or added, the Nursing Practice Committee Chair will send communication via Microsoft Outlook to the nursing staff to alert them to this information.
4. The Acting Associate Director of Patient Nursing Services identified a Best Practice Nursing Education Program. The Chief of Nursing Education from the Louisville VAMC will conduct a consultation visit the week of April 22, 2013. This consultation visit will include a complete review of the Nursing Education program; review of resources including full-time employment equivalents; review of current courses and education on devices and equipment; review of evaluation data with outcomes; and an assessment of relationships between Education Service, Nursing Education, and end users. This visit will also include an assessment of the use of technology, i.e., TMS and Sim Man. A report will be provided back to the facility following the consultation visit and is expected to be received by early May 2013.

OIG Contact and Staff Acknowledgments

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