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Healthcare Inspection

Review of Veterans Health Administration Follow-Up on Inappropriate Use of Insulin Pens at Medical Facilities

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Executive Summary

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted an inspection to evaluate how the Veterans Health Administration (VHA) followed up on the inappropriate use of insulin pens at the VA Western New York Healthcare System, Buffalo, NY (the Buffalo facility), and to determine what controls VHA has in place to minimize the risk of other incidents involving insulin pens and similar devices. We conducted the inspection at the request of the Ranking Member, Senate Committee on Veterans' Affairs to look at issues related to VHA's management of patient safety alerts, new medical products and devices, and infection prevention activities. We prepared a separate report on the specific circumstances of the misuse at the Buffalo facility.

VHA's internal assessments following the Buffalo incident did not include clear, standard guidance to facilities on how to perform and document their audits of insulin pen use, and we found no documentation to support their internal reviews and significant variation in how facilities conducted their reviews. However, our onsite work at 4 facilities, including interviews with over 150 nurses, found no evidence of widespread, systemic reuse of insulin pens on multiple patients. The majority of nurses we spoke to understood that insulin pens were intended for single-patient use. Furthermore, on January 17, 2013, VHA generally prohibited the use of multi-dose insulin pens on inpatient units, effective February 4, 2013.

In addition to the Buffalo incident, nurses at two other facilities were found to have inappropriately used insulin pens on multiple patients. In January 2013, the W.G. Hefner VA Medical Center, Salisbury, NC, reported that two nurses had inappropriately used insulin pens on multiple patients. VHA instituted large-scale adverse event disclosure to notify 266 at-risk patients. At another facility, a nurse acknowledged using a pen on two patients on one occasion. Facility officials identified the one at-risk patient, promptly notified the patient, and provided tests for bloodborne pathogens. Furthermore, at two facilities, a significant number of nurses used the insulin pens contrary to pen design. While this practice did not put patients at increased risk for bloodborne pathogens, it may have resulted in pen damage and dosing inaccuracies.

We identified two contributing factors to explain why some nurses misused the insulin pens. Facilities did not fully evaluate the risks of using insulin pens on inpatient units, specifically in regards to the impact on nursing procedures, or provide comprehensive nurse education on the pens.

Further, we found that VHA has processes in place to identify important patient safety alerts, including product recalls, and disseminate this information to facility managers. VHA's National Center for Patient Safety and Pharmacy Benefits Management Service lead VHA's efforts to collect patient safety information and share this information with facilities. At the facility level, patient safety managers are responsible for disseminating alerts to appropriate administrative and clinical staff and tracking the facility's response through a national database.

We also found that VHA has numerous policies and procedures in place to address infection prevention. However, as medical technology continues to advance and VHA continues to serve high-risk populations, they will need to be vigilant and ensure processes are in place to continually educate staff, patients, and visitors as new risks emerge.

We recommended that the Under Secretary for Health implement procedures to ensure that future VHA internal assessments resulting from adverse events include clear guidance to facilities on minimal required steps and supporting documentation; require facilities to develop processes for assessing the risks and benefits of adopting new medical products or devices that may require significant changes in nursing procedures; and ensure that facility nursing education departments are sufficiently staffed to provide comprehensive and ongoing nursing education, especially when adopting new medical products or devices that may significantly change nursing procedures.

Comments

The Under Secretary for Health concurred with our findings and recommendations and provided an acceptable action plan. (See Appendix A, pages 19–22 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 how the Veterans Health Administration (VHA) followed up on the inappropriate use of insulin pens at the VA Western New York Healthcare System, Buffalo, NY (Buffalo facility) and to determine what controls VHA has in place to minimize the risk of other incidents involving insulin pens and similar devices. We conducted the inspection at the request of the Ranking Member, Senate Committee on Veterans' Affairs. On May 9, 2013, the OIG issued a separate report addressing the specific circumstances of the misuse at the Buffalo facility.[1] This report addresses broader questions pertaining to insulin pen use at other facilities, as well as VHA oversight and follow-up.

The purpose of the inspection was to:

- Evaluate the steps VHA took to assess the safety of insulin pen use at other facilities after the Buffalo facility reported misuse of insulin pens.
- Determine if VHA has established effective mechanisms and policies to ensure facilities are aware of important patient safety notifications.
- Identify what gaps need to be filled to ensure the proper use of new medical devices and products in facilities.
- Describe what policies and procedures VHA has in place to address infection prevention in facilities.

Background

In late 2012, during a monthly inspection of medication carts on an inpatient unit, the Chief of Pharmacy at the Buffalo facility 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. When queried, several nurses reportedly acknowledged using the pens on multiple patients; although, they changed the needles before each use.

Facility managers reported the incident to VHA officials, prompting further reviews and the decision to notify all the patients at the facility who may have been exposed to bloodborne pathogens as a result of the pen misuse. On January 11, 2013, VHA notified Members of Congress and at-risk patients of the incident. Around the same time, a second facility, the W.G. Hefner VA Medical Center, Salisbury, NC (the Salisbury facility) reported that two nurses had inappropriately used insulin pens on multiple patients. Following this incident, the Ranking Member, Senate Committee on

[1] OIG Report 13-01320-200, *Healthcare Inspection – Inappropriate Use of Insulin Pens, VA Western New York Healthcare System, Buffalo, New York*, May 9, 2013.

Veterans' Affairs, requested that we look at broader issues related to VHA's management of patient safety alerts, new medical products and devices, and infection prevention activities.

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

Insulin Pens. Insulin pens are typically the size and shape of a large marker. Insulin pens were originally developed for outpatient use because they are portable and convenient for patients when they are away from home or who may have vision impairment or dexterity problems. Facilities most commonly use disposable insulin pens that include a pre-filled cartridge containing the insulin. To use the pens, a needle is attached to the tip of the pen each time it is used; the needle is disposed of after each use.

Infection Risk 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 the human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV), if a pen had previously been used on an infected patient.[2,3] Although 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.[4]

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 2008–2009, the Institute of Safe Medication Practices (ISMP), a non-profit patient safety organization, published several articles regarding the safe use of insulin pens. The first article described the risk of regurgitation of blood into the cartridges of insulin pens and emphasized that the pens must not be shared between patients.[5] The second article provided tips to hospitals considering use of insulin pens and cited common problems with the pens, including potential for improper use on multiple patients.[6] The third article, urged hospitals to "provide education and continuous

[2] Le Floch JP, Herbreteau C, Lange F, Perlemuter L. 1998. "Biological Material in Needles and Cartridges After Insulin Injection With a Pen in Diabetic Patients," *Diabetes Care* 21:9, 1502–1504.
[3] Sonoki K, Yoshinari M, Iwase M, Tashiro K, et al. 2001. "Regurgitation of Blood into Insulin Cartridges in the Pen-like Injectors," *Diabetes Care* 24:3, 603–604.
[4] Hakre S, Upshaw-Combs DR, Sanders-Buell EE, Scoville SL, et al. 2012. "An Investigation of Bloodborne Pathogen Transmission Due to Multipatient Sharing on Insulin Pens," *Military Medicine* 177:8, 930–938.
[5] ISMP Medication Safety Alert!, "Cross Contamination with Insulin Pens," March 27, 2008, http://www.ismp.org/newsletters/acutecare/articles/20080327_1.asp, accessed on 2/22/13.
[6] 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.

monitoring to prohibit situations where an individual patient's pen might be reused for another patient."[7]

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 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.[8]

Scope and Methodology

We interviewed officials from VHA's National Center for Patient Safety (NCPS), National Infectious Disease Service, and Pharmacy Benefits Management (PBM) Service. We reviewed relevant VHA policies and procedures and documentation from VHA's internal reviews of insulin pen use.

We also conducted site visits to four VHA medical facilities identified by NCPS as high users of insulin pens in fiscal year (FY) 2012. The sites were: the Louis Stokes Cleveland VA Medical Center, Cleveland, OH (the Cleveland facility); the W. G. (Bill) Hefner VA Medical Center (the Salisbury facility); the George E. Wahlen VA Medical Center, Salt Lake City, UT (the Salt Lake City facility); and the Robert J. Dole VA Medical Center, Wichita, KS (the Wichita facility). The sites are located in four different Veterans Service Integrated Networks (VISNs). During the site visits, we interviewed facility leaders, pharmacy officials, patient safety officials, nurse educators, and infection prevention specialists. We also interviewed registered nurses (RNs) and licensed practical nurses (LPNs) on various inpatient units and shifts. We reviewed relevant facility policies and procedures, nurse training records, infection prevention risk assessments, and minutes from various facility committees, including infection prevention and pharmacy and therapeutics (P&T).

Our review periods varied by facility based on when they initiated the use of insulin pens on inpatient units. The Cleveland, Salt Lake City, and Wichita facilities introduced the insulin pens in about 2008, and the Salisbury facility introduced the pens in 2010.

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.

[7] 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.

[8] 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.

Inspection Results

Issue 1: VHA Assessment of Insulin Pen Use at Facilities

Although we found that VHA's internal assessments following the Buffalo incident should have included clear, standard guidance to facilities on how to perform and document their audits of insulin pen use, our onsite work at 4 facilities, including interviews with over 150 nurses, found no evidence of widespread, systemic reuse of insulin pens on multiple patients. The majority of nurses we spoke to understood that insulin pens were intended for single-patient use.

Following the Buffalo incident, VHA took a two-step approach to determine if nurses at other facilities were inappropriately using insulin pens on multiple patients. VHA's initial review, in early December 2012, included a small number of facilities identified as high-users of insulin pens. VHA's subsequent review of all facilities occurred on January 9, 2013—2 days before VHA notified Members of Congress and patients about the misuse of pens at the Buffalo facility. For the reviews, VHA officials asked facility officials to respond to two "yes" or "no" questions. However, they provided little guidance to facility officials about auditing their use of insulin pens or documenting the results of their audits. At the four high-use facilities we visited, we found no documentation to support their internal reviews, and we found significant variation in how facilities conducted their reviews to respond to VHA.

VHA Surveys of Facilities. In December 2012, following the Buffalo facility's report of insulin pen misuse, the Deputy Under Secretary for Health for Operations and Management (DUSHOM) instructed NCPS to survey other VHA facilities to determine if pen misuse was a system wide problem.

Initially, NCPS used Bar Code Medication Administration (BCMA)[9] data to identify all the facilities that had used insulin pens on inpatient units in FY 2012. The BCMA data showed that in FY 2012, five facilities accounted for over 90 percent of all inpatient insulin pen use in VA (reported in terms of number of unique patients who were administered insulin via insulin pens). These facilities were Buffalo, Cleveland, Salisbury, Salt Lake City, and Wichita.[10] Since Buffalo had already self-reported insulin pen misuse, in early December 2012, an NCPS official contacted the remaining four high-use facilities and requested that facility managers speak with nursing staff to find out if anyone was misusing the pens. Initially, all four sites reported that they had no instances of insulin pen misuse.

[9] BCMA is a software module that facility nurses use to document the administration of medications ordered by providers.

[10] Due to data limitations in VHA, we could not verify the accuracy of the unique patient counts NCPS obtained from BCMA. However, based on additional data we obtained from selected facilities and PBM on inpatient prescriptions, we generally confirmed that the sites identified by NCPS as high-use sites did appear to use insulin pens more frequently on inpatient units than other sites.

On January 9, 2013, NCPS sent out a notification to all VISNs requiring them to contact each facility in their network, not just high-use facilities, to report on their insulin pen use and to determine if nursing staff were misusing pens. Facilities were required to respond by the next day. NCPS provided the following instructions and questions for the VISNs:

> **Question 1: (Pharmacy)**
> Contact the chief of pharmacy (or designee) at each VA facility to determine if the facility provides any patient care units with anti-diabetic pen injectors [insulin pens] for administration to patients by VA staff. If no, complete as a negative response on the attached spreadsheet and return as directed below. If yes, complete as a positive response and continue to question 2.
>
> **Question 2: (Nursing)**
> If anti-diabetic pen injectors are currently being used on the patient care units, contact the nurse executive (or designee) to determine if the facility is sharing anti-diabetic pen injectors between patients. If no, complete as a negative response on the attached spreadsheet. If yes, complete as a positive response on the attached spreadsheet and stop use of the pen injectors by changing to multi-dose vials (follow the issue brief process after submitting the spreadsheet).

NCPS received responses from 143 VHA facilities—107 facilities responded that they did not provide insulin pens to inpatient units and 36 responded that they did provide insulin pens to inpatients. All 36 facilities that used insulin pens on inpatient units reported no instances of insulin pen misuse. However, the Salisbury facility later reported that two nurses admitted to using insulin pens on multiple patients.

For both the December and January requests, neither NCPS nor the DUSHOM's office provided specific guidance on how facilities were supposed to conduct their audits of insulin pen use; for example, if facilities were expected to interview nursing staff, document the results of interviews, or inspect units for unlabeled insulin pens. Responses from the facilities were in a "Yes/No" format, and facilities were not required to submit supporting documentation.

Reviews of Insulin Pen Use at Four High-Use Facilities. The four facilities identified by NCPS as high-use sites took varying approaches in their responses to NCPS's request to review their insulin pen use. None of the facilities maintained documentation of their audits, other than the completed spreadsheet sent to NCPS.

- Cleveland Facility. Officials at this facility reported that they initiated a review of insulin pens in early December 2012 after becoming aware of the issue at the Buffalo facility. For this review, quality management staff conducted rounds of inpatient units and queried approximately 75 nurses from various shifts and units on their knowledge of the proper use of insulin pens. None of the nurses reported using the pens on multiple patients.

- Salisbury Facility. Quality management staff reported that they initially interviewed a "limited number" of nurses in response to NCPS's December notification and had no reports of insulin pen sharing. Facility leadership later decided that all nurses on all shifts should be interviewed. Initially, none of the nurses interviewed reported using the pens on multiple patients; however, two nurses later came forward. (See detailed discussion of the Salisbury facility below.)

- Salt Lake City Facility. Quality management staff reported that they spoke to "10 or 20" day shift nurses on all 6 inpatient units. They also inspected medication refrigerators for any unlabeled insulin pens or insulin pens for discharged patients. In addition, the facility nurse executive instructed nurse managers to provide refresher training on the insulin pens and query unit nurses about possible misuse of the pens. None of the nurses reported using the pens on multiple patients, and quality management staff did not find pens in the medication refrigerators.

- Wichita Facility. Patient safety staff reported that they inspected patient drawers in the unit medication carts and determined that the drawers contained pens that were properly labeled with patients' names. As part of this review, they interviewed "a few" nurses on the units. None of the nurses reported using the pens on multiple patients.

Insulin Pen Misuse at the Salisbury Facility. The Salisbury facility was the only facility that reported insulin pen misuse to NCPS. According to officials at the facility, an LPN in the community living center admitted to using insulin pens on multiple patients. Several days later, an RN on an acute medical/surgical inpatient unit, who had been on leave during the expanded interviews, also admitted to using insulin pens on multiple patients. Both nurses reported that they changed the needles on the pens prior to use.

In response to the two nurses' admissions, facility leaders notified NCPS and the DUSHOM, initiated a "look back" process to identify at-risk patients, and discontinued the use of insulin pens on all inpatient units. During the look back process, an infectious disease specialist and clinical officials at the facility determined that a total of 266 patients may have potentially been exposed to bloodborne pathogens when the 2 nurses used the insulin pens on multiple patients. Because the 2 nurses could not recall exactly when they misused the pens or identify specific at-risk patients, the 266 represents all patients who received insulin pen injections from the 2 nurses while hospitalized between September 1, 2010, the initial roll-out date of the pens, to January 10, 2013, when the misuse was reported.

In accordance with VHA's disclosure process, the DUSHOM convened a Subject Matter Expert (SME) Review Panel to conduct fact-finding, assess the risks, and determine if large-scale adverse event disclosure was warranted.[11] The SME Review Panel

[11] VHA's disclosure process is outlined in VHA Handbook 1004.08, "Disclosure of Adverse Events to Patients," October 2, 2012.

concluded that the risk was "not negligible" and recommended large-scale adverse event disclosure. They also concurred with the number of patients the facility identified as being at-risk for HBV, HCV, and HIV. Five tests were recommended for the initial testing with additional tests based on those results.[12]

On March 7, 2013, VHA initiated the large-scale adverse event disclosure to notify patients of their possible exposure to bloodborne pathogens from the misuse of insulin pens at the Salisbury facility. 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 June 4, 2013, 190 of the 266 patients were known to be still living, and 161 (85 percent) of the living, at-risk patients had been tested. Fourteen patients were being contacted for testing or are awaiting completion of their testing. The facility has been unable to contact or obtain a response from 10 veterans. Five patients refused testing.

On June 4, 2013, 22 of the patients had at least one positive test with the facility's initial screening after exposure. Eleven patients had test results consistent with known pre-existing infection prior to insulin pen exposure; 1 of the 11 had indeterminate test results and was undergoing additional testing. None of the patients tested had evidence for new HCV or HIV infections. Eleven patients had newly discovered blood tests consistent with previous HBV exposure. None of the 11 had prior blood tests for HBV, so these patients' exposure to HBV could have occurred at almost any point in the patients' lives prior to testing. All 11 had the combination of positive blood tests indicating exposure with the development of subsequent immunity.[13] No patient had test results consistent with active or chronic HBV.

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.

OIG Follow-Up of VHA Reviews. We visited the Salisbury facility, as well as the other three high-use insulin pen facilities identified by NCPS to interview nurses from different inpatient units and all shifts.[14] We interviewed 152 nurse managers and staff RNs and LPNs to determine if any nurses had used insulin pens on multiple patients, had observed other nurses use insulin pens on multiple patients, or had received training on the pens. We also interviewed the two nurses at the Salisbury facility who admitted to using insulin pens on multiple patients.

[12] 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.
[13] Immunity would be indicated by a positive antibody to Hepatitis B surface antigen test.
[14] Our review did not include the Buffalo facility because we had previously reviewed this facility. See OIG Report 13-01320-200, *Healthcare Inspection – Inappropriate Use of Insulin Pens, VA Western New York Healthcare System, Buffalo, New York,* May 9, 2013.

Of the 152 nurses we interviewed, 1 RN reported using a discharged patient's insulin pen on another patient on one occasion. We reported this incident to facility leaders, who determined that this was an isolated case. Working with the nurse, facility leaders identified the patient on whom the pen was inappropriately used, notified the patient through the formal process of institutional disclosure,[15] and offered follow-up testing and monitoring. The patient agreed to follow-up testing, and the test results were negative.[16]

The majority of nurses we interviewed, including the two nurses at the Salisbury facility who previously admitted to using the pens on multiple patients, recalled receiving some type of training on the pens either when the pens were rolled out or during orientation. Over 60 percent of the nurses we interviewed recalled explicitly being told that the pens were for single-patient use only.

We asked the nurses who reported that they *never* used the pens on multiple patients how they knew not to share the pens. The nurses cited the following factors:

- Training explicitly addressed that insulin pens are for single-patient use only
- Pharmacy labeled the pens with patients' names
- Pens stored in patient-specific medication drawers or boxes
- Standard nursing principle that medications should not be shared between patients
- Standard nursing principle that invasive devices should not be shared between patients
- Common sense

Several nurses also shared their belief that BCMA includes controls to prevent nurses from giving one patient's medication to another patient. However, these controls are only in place for limited types of medications, such as some intravenous medications. For most medications, including insulin, BCMA will only alert nurses if they attempt to administer a medication that a patient does not have a provider's order for or administer a medication at the wrong time.

We also asked the three nurses (two at the Salisbury facility and one at another facility) who admitted to using the pens on multiple patients what the circumstances were and why they believed the practice to be okay. All three nurses described situations in which they had to wait for pharmacy to deliver insulin pens for patients on their units. The nurses believed the delays to be too long, which put their patients at risk, so they "borrowed" insulin pens from other patients who were on the same type of insulin. Two

[15] VHA Handbook 1004.08, "Disclosure of Adverse Events to Patients," October 2, 2012, defines institutional disclosure as "a formal process by which facility leaders, together with clinicians and other appropriate individuals, inform the patient or the patient's personal representative that an adverse event has occurred during the patient's care that resulted in or is reasonably expected to result in death or serious injury."
[16] The patient was tested for HIV, HCV, and HBV.

of the three nurses stated that they were aware that this practice violated their facility's practice regarding insulin pens. All three of the nurses seemed unaware of the risks associated with backflow into the insulin cartridges and believed that changing the needle on the insulin pen was sufficient for infection control.

Issue 2: Policies and Procedures for Patient Safety Notifications

Within VHA, NCPS and PBM share responsibility for receiving and disseminating important patient safety alerts and notifications. Specific roles and responsibilities for managing alerts are addressed in three VHA policies—*VHA National Patient Safety Improvement Handbook;*[17] *Recall of Defective Medical Devices and Medical Products, Including Food and Food Products*;[18] and *National PBM Drug Safety Alert Distribution.*[19]

NCPS and PBM receive safety alerts or notifications from a variety of sources external to VHA, including FDA, The Joint Commission (JC), the Centers for Disease Control and Prevention (CDC), ISMP, and product manufacturers. Internal alerts may also be prompted by reports of adverse events at VHA facilities. The most critical alerts involve product recalls.

FDA is one of the primary sources of information used to create patient safety alerts and product recalls. For calendar year (CY) 2013 through May 20, 2013, FDA issued 29 safety alerts, which included recalls, pertaining to drugs and therapeutic biologics[20] and 27 safety alerts pertaining to medical devices.[21] In CY 2012, FDA issued 68 safety alerts pertaining to drugs and therapeutic biologics and 50 safety alerts regarding medical devices.[22]

NCPS Actions. NCPS uses multiple mechanisms to disseminate important patient safety information, based on the urgency and specificity of direction that can be given. Patient Safety Alerts and Patient Safety advisories are two of those communication mechanisms and are defined as follows:[23]

> **Patient Safety Advisories:** are recommendations providing guidance to address issues such as equipment design, product failure, procedures, or training and may recommend clinician action. Actions are general in nature and implementation may be subject to local judgment contingent on local conditions.

[17] VHA Handbook 1050.01, "VHA National Patient Safety Improvement Handbook," March 4, 2011.
[18] VHA Directive 2008-080, "Recall of Defective Medical Devices and Medical Products, Including Food and Food Products," November 26, 2008.
[19] VHA Directive 2008-078, "National PBM Drug Safety Alert Distribution," November 17, 2008.
[20] Therapeutic biologics include products such as gene therapy, vaccines, antitoxins, and blood and blood components.
[21] 2013 Safety Alerts for Human Medical Products, accessed on 5/20/13 at FDA website: http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm333878.htm.
[22] 2012 Safety Alerts for Human Medical Products, accessed on 5/20/13 at FDA website: http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm285497.htm.
[23] VHA Directive 2008-080.

> **Patient Safety Alerts:** are mandates providing specific actions to address actual or potential threats to life or health often requiring clinician action.

NCPS develops, and the DUSHOM disseminates, alerts and advisories to VISN and facility patient safety managers, as well as other administrative and clinical officials depending on the topic. NCPS alerts and advisories may be related to medical products and devices, including drugs, as well as clinical software system and other patient safety issues. NCPS alerts and advisories tend to focus on operational aspects of patient safety, for example, controlling risks by prohibiting routine use of insulin pens on inpatient units.

When NCPS issues an alert or advisory, as directed by the DUSHOM, facilities are required to complete the concrete actions described in the alert or advisory.[24] Facility actions are documented and tracked through the NCPS Product Recall Office's web-based database, "VHA Alerts and Recalls." The VHA Alerts and Recalls database is the primary repository of all alerts, advisories, notifications, and recalls. As of April 2013, it contained over 6,400 line items related to alerts and recalls of food products, drugs, and medical devices and products.

For FY 2013 through April 2013, NCPS issued a total of five alerts—its January 17 alert[25] prohibiting the use of insulin pens for inpatients and four alerts unrelated to insulin pens. In FY 2012, NCPS issued 10 alerts and 2 advisories. NCPS did not issue an alert or advisory in 2009, when the FDA issued its alert regarding the use of insulin pens on multiple patients.[26] According to NCPS officials, they did not issue an alert because very few facilities were using insulin pens at the time.

PBM Actions. To disseminate alerts about drugs, PBM uses two mechanisms—National PBM Bulletins and National PBM Communications, which are defined as follows:[27]

> **National PBM Bulletin:** a Drug Safety Alert that includes standard sections: Issue, Background, Recommendations, and References. . . . The recommended actions in a National PBM Bulletin include provider notification, as well as actions to be carried out by the provider. When warranted, recommended actions include patient notifications by phone call, in person, or by letter. Confirmation that actions have been completed will be required.

[24] The OIG's 2008 report, 07-02369-107, *Healthcare Inspection: Medical Device Recall Process in Veterans Health Administration Medical Centers,* April 3, 2008, assessed VHA's medical device recall process and specific responses to a Patient Safety Alert.
[25] AL 13-04, Patient Safety Alert, Veterans Health Administration Warning System Published by VA Central Office, Multi-Dose Pen Injectors, January 17, 2013.
[26] FDA Alert, Information for Healthcare Professionals: Risk of Transmission of Blood-borne Pathogens from Shared Use of Insulin Pens, March 19, 2009.
[27] VHA Directive 2008-078.

> **National PBM Communication:** a Drug Safety Alert that does not include standard sections, but is warranted to further clarify and/or emphasize what is noted in the drug-related safety information. . . . The recommended actions in a National PBM Communication include provider notification and when warranted, patient notifications by phone call, in person or by letter. When warranted, confirmation that actions have been completed is required.

PBM disseminates bulletins and communications to an established Drug Safety Alert Mail Group that includes the DUSHOM; NCPS; VISN directors, chief medical officers, formulary leaders, and patient safety officials; and facility chiefs of staff, chiefs of pharmacy, and patient safety managers. PBM alerts typically focus on drug safety issues, such as risks for adverse reactions to a drug or interactions between drugs. If an alert is related to a drug recall, PBM and NCPS coordinate the recall together.

For FY 2013 through April 2013, PBM issued a total of 11 alerts—4 National PBM Bulletins and 7 National PBM Communications. In FY 2012, PBM issued two National PBM Bulletins and four National PBM Communications. PBM did not issue a bulletin or communication in 2009, when the FDA issued its alert regarding the use of insulin pens on multiple patients.[28] However, in February 2009, PBM's Chief Consultant sent an email to VISN pharmacy officials requesting information on insulin pen use and protocols at their facilities. Eight of 21 VISNs responded that some facilities in their networks were using insulin pens on inpatient units but generally described the use as "rarely." VISNs with facilities using insulin pens reported that the pens were individually labeled with each patient's name.

Management of Alerts and Advisories at Four Facilities. According to VHA policy, facility patient safety managers are the designated points of contact for alerts and advisories from NCPS. Drug alerts and advisories also go to facility pharmacy officials. When facility patient safety and pharmacy officials receive alerts and advisories, they are responsible for disseminating them to relevant clinical and administrative staff. Patient safety managers are responsible for tracking and documenting the facilities' actions in response to alerts and advisories and updating the VHA Alerts and Recall website.

At the four high-use insulin pen facilities identified by NCPS, patient safety managers confirmed that they are typically the points of contact for patient safety alerts and advisories from NCPS, as well as JC alerts. At the Wichita facility, the Director of Logistics, who is the facility's recall coordinator, is the primary point of contact for all alerts, advisories, notifications, and recalls. The facility officials described their processes for managing alerts and advisories, including coordinating with appropriate facility officials, such as biomedical engineering or pharmacy, and ensuring that all required actions are completed, documented, and tracked in the VHA Alerts and Recalls

[28] FDA Alert, Information for Healthcare Professionals: Risk of Transmission of Blood-borne Pathogens from Shared Use of Insulin Pens, March 19, 2009.

database. They also reported that certain types of alerts, such as FDA drug alerts are received by both patient safety and pharmacy officials.

We asked patient safety managers if they were aware of the 2009 FDA alert regarding insulin pens. Patient safety managers at the Salisbury, Cleveland, and Wichita facilities did not recall seeing this alert when it came out. However, at the Cleveland facility, the pharmacy manager was aware of the alert and reportedly disseminated it via an established email group to all nurses, physicians, and others involved in medication ordering, dispensing, and administration. At the Salt Lake City facility, officials in both patient safety and pharmacy were aware of the alert, discussed it at the facility's monthly Medication Management Committee meeting, and reviewed their internal procedures. The facility has a process in place to routinely monitor and review patient safety alerts and assess the potential impact of alerts on facility practices.

Issue 3: Ensuring Proper Use of Medical Products and Devices

As part of this review, we were asked to identify "gaps" in VHA policies, procedures, and practices that need to be filled to ensure medical products and devices are not misused in the future. The FDA classifies insulin pens as drugs;[29] therefore, the decision to use insulin pens is typically under the purview of pharmacy services. However, the design and mechanics of pens make it similar to other medical devices that are commonly used by nurses on inpatient units.

Misuse of Insulin Pens. In addition to the 3 nurses who used the pens on multiple patients, we found that at least 12 nurses at 2 facilities used the pens in a way that was contrary to the pen design. Although this misuse did not involve using the pen on multiple patients or potential exposure to bloodborne pathogens, it may have resulted in damage to the pens and dosing errors.

At two facilities, instead of attaching a safety needle to the pen and administering insulin directly from the pen, several nurses reported that they used a separate syringe to draw insulin out of the pen cartridge and administer the insulin to the patient. These nurses told us they followed this practice because they did not trust the insulin pen to deliver the full dose of insulin to a patient or because insulin pen needles were sometimes not readily available. By using the pen in this way, contrary to the manufacturer's design, nurses may have inadvertently introduced air bubbles into the pen cartridge and/or damaged the dose dialing function on the pen. As a result, if a nurse subsequently used the pen in the proper way, the dose may not have been correct as dialed, and the number of remaining doses shown in the pen would not be accurate.

At the Buffalo facility, we identified six factors that contributed to the misuse of insulin pens.[30] Two of the six factors that contributed to the misuse of pens at the Buffalo facility were found to have been contributing factors in misuse of pens at the other high-

[29] US Food and Drug Administration, National Drug Code, http://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm, accessed June 12, 2013.
[30] OIG Report 13-01320-200, *Healthcare Inspection – Inappropriate Use of Insulin Pens, VA Western New York Healthcare System, Buffalo, New York*, May 9, 2013.

use facilities as well. Specifically, the facilities did not fully evaluate the risks of using insulin pens on inpatient units or provide comprehensive nurse education on the pens.

Evaluation of Risks Prior to Introducing Insulin Pens. 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, especially if adopting an item that will impact nursing procedures. VHA has no policy or process that specifically addresses how facilities should assess the risk and benefits of adopting new medical products or devices. Although the four facilities had policies addressing the responsibilities of their Commodity Standardization (or similarly titled) Committees for evaluating new devices or equipment, these committees do not address evaluations of drugs or drug products. Within VHA, P&T Committees evaluate new drugs and drug products but do not necessarily address potential changes to nursing procedures resulting from adopting a new product.

VHA Handbook 1108.08, "VHA Formulary Management Process," describes VHA's process for identifying and reviewing drugs and supplies for addition to the VA National Formulary (VANF), which is "a listing of products (drugs and supplies) that must be available for prescription at all VA facilities, and cannot be made non-formulary by a VISN or individual medical center."[31] Facility P&T Committees are responsible for reviewing requests for additions to the VANF and making recommendations to the VISN Formulary Committee.

The decision to introduce the pens at the four facilities was primarily made by pharmacy staff, and although the facilities' P&T Committees were aware of the transition to insulin pens, they were generally not involved in evaluating the risks and benefits of adopting insulin pens on inpatient units. Furthermore, we found no evidence of structured risk-benefit analyses in terms of how the introduction of the pens might impact nursing procedures or of consideration of prior patient safety alerts concerning inappropriate sharing of pens. Pharmacy officials at all four facilities reported that the decision to adopt insulin pens was prompted by patient safety concerns regarding medication errors and the potential for confusing different types of insulin or other medications in multi-dose vials. Officials also cited cost-savings and reduction in waste as deciding factors.

While we recognize that not all new medical products require in-depth risk-benefit analyses, and that it would not be feasible for facilities to conduct risk-benefit analyses on all new products, implementing a process to ensure that relevant facility committees and leadership evaluate the risks and benefits before introducing new medical products or supplies that require changes in nursing procedures may help to reduce the risk of misuse.

Comprehensive Nurse Education. In their article, "Promoting Safe Use of Medical Devices," two FDA Senior Project Managers state that, "Professional nurses in clinical practice are the principal users of medical devices at the point of care. . . Over time,

[31] VHA Handbook 1108.08, "VHA Formulary Management Process," dated February 26, 2009.

these devices have become increasingly complex and sophisticated, reshaping the delivery of healthcare both in the hospital and the home, and subsequently creating more challenges for nurses."[32] The authors stress the critical need for comprehensive medical device education for nurses that focuses on seven areas.

- Knowledge of the intended use of the device
- Manufacturer's instructions for use, labeling, warnings, contraindications, and known complications
- Outcomes of proper use of a device
- The agency's clinical practice manual and nursing education department guidelines
- The importance of complying with expiration dates (given by manufacturers) that indicate the time period for optimal use of 'shelf life'
- Recognition that device sterility may be guaranteed only until the expiration date
- Insight into differences in device use and design between similar devices

Insulin pens are not technically categorized as a medical device. However, the fact that nurses at three of the four high-use facilities visited were misusing the pens in some way (either by using them on multiple patients or using them in a manner contrary to manufacturer design), is an indication that the nurses at these facilities may have benefitted from training that addressed the areas identified by the authors above.

While all four high-use facilities provided insulin pen training to nurses when the pens were rolled out or as part of nurse orientation, with the exception of the Cleveland facility, most of the training was not comprehensive. Instead, as with the Buffalo facility, the training generally focused on the basic mechanics of using the pen—that is, attaching a safety needle, priming the pen to remove air bubbles, dialing the dose, and holding down the plunger to ensure the full dose. Although the majority of nurses we interviewed recalled explicit instructions not to share insulin pens between patients, it is not clear how many of these nurses fully understood the reason why (that is, risk of backflow into the cartridge).

The Cleveland facility, which had no identified incidents of misuse, provided the most comprehensive training, which was coordinated by the facility's nurse education department. Training was provided by a pharmaceutical company representative when the facility introduced the pens in 2008. The representative also provided facility nurse educators with training kits to conduct ongoing training for nurses who may have missed the initial training and for newly hired nurses. The facility also provided several examples of on-going education provided to nurses after the roll-out of insulin pens. Nurse educators trained nurses to demonstrate the mechanics of using the pens but also provided the clinical reasons why nurses should never share pens between

[32] Swayze SC and Rich SE. 2011. "Promoting Safe Use of Medical Devices," *The Online Journal of Issues in Nursing* 17:1.

patients, including a paragraph in a "Nursing Tidbits" newsletter in September 2012, reiterating the risk of backflow and contamination of pens.

Dedicating sufficient resources to nurse education and strengthening nurse education practices when introducing new medical products or supplies to address the seven areas identified above could help to reduce the risk of misuse by providing more in-depth clinical information to nurses beyond the basic mechanics of using a product.

Issue 4: VHA Infection Prevention Activities

Medical technology, including everyday use medical products and devices, has become more complex over the last few decades. As technology becomes increasingly complex, so too does infection prevention. "Modern medical care has become more invasive and therefore associated with a greater risk of infectious complications."[33] Specific risks include an "…aging population, the AIDS epidemic, the growth of chemotherapeutic options for cancer treatment, and growing transplant population…"[34] as well as patients who "…move freely within sometimes loosely defined elements of the health care system: between long-term care or rehabilitation facilities, to acute-care facilities, to free-standing surgical care providers."[35]

Infection Prevention Standards and Policy. JC has numerous standards related to infection prevention at facilities. These standards focus on identifying individuals who are responsible for infection prevention activities at a facility, allocating sufficient resources to support activities, identifying risks through risk assessments, setting goals to address identified risks, developing and implementing plans to reduce risks and prevent infections, and implementing measures to evaluate plans.

To ensure compliance with JC standards, VHA's infection prevention practices are governed by a multitude of regulations, standards, and recommendations related to hand hygiene, risk assessment, personnel protective equipment, vaccinations, influenza, reprocessing of reusable medical equipment (RME), water testing, construction safety, and antimicrobial stewardship. VHA's National Infectious Disease Service has primary responsibility for policy development, as well as for developing national strategies and training. Day-to-day operations and infection prevention activities occur at the local facility level, which is appropriate given that infection risks vary by facility depending on location, services offered, populations served, facility age, availability of resources, and other factors.

Infection Prevention Activities at Four Facilities. In accordance with JC and VHA requirements, the four high-use insulin pen facilities all have infection prevention programs including a physician who specializes in infectious disease and a nurse infection preventionist (or infection control coordinator). The facilities' programs also

[33] Sydnor ERM and Perl TM. 2011. "Hospital Epidemiology and Infection Control in Acute-Care Settings," *Clinical Microbiology Reviews* 24:1, 141–173.
[34] Sydnor ERM and Perl TM. 2011. Note: Patients in these four categories are considered high risk because they may be immune system compromised, making them more susceptible to infections.
[35] Sydnor ERM and Perl TM. 2011.

include infection prevention committees, generally with representation from nursing, patient safety, sterile processing services, environmental management services, and clinical areas, such as dental, laboratory, and surgical services.

Facility-level activities include preparing annual risk assessments, training patients and staff on infection prevention issues, and determining and monitoring facility infection prevention surveillance activities, such as hand hygiene; proper use of personal protective equipment; central line and catheter infection rates; or rates of Methicillin-resistant Staphylococcus aureus (MRSA), clostridium difficile,[36] and other hospital-acquired infections.

According to infection prevention staff at all four facilities, none were involved in the decision to use insulin pens on inpatient units at their facilities or the initial training of nursing staff. In part, this was because the decision to use the pens at the facilities was primarily made by pharmacy, not interdisciplinary teams. Furthermore, several of the officials we spoke to, including the Director of VHA's National Infectious Disease Service, acknowledged that, until the incident at the Buffalo facility, they did not consider insulin pens to be a significant infection risk. Instead, these officials continued to focus on prevention of known high-risk, high prevalence issues, such as MRSA and clostridium difficile.

OIG Prior Reviews of VHA Infection Prevention Activities. As part of the OIG's Combined Assessment Program (CAP) reviews, we routinely review various aspects of facilities' infection prevention activities. Since 2011, we have issued two reports addressing these activities.

- In October 2011, we published a CAP summary report on "Management of Multidrug-Resistant Organisms in Veterans Health Administration Facilities."[37] We made three recommendations to the Under Secretary for Health to strengthen patient, family, and staff education and develop policies and programs to control and reduce antimicrobial agent use. As of January 2013, all three recommendations were closed.

- In September 2011, we published a CAP summary report on "Evaluation of Infection Prevention Practices in Veterans Health Administration Facilities."[38] We made five recommendations to the Under Secretary for Health to ensure corrective actions when hand hygiene performance falls below thresholds, ultraviolet germicidal irradiation fixtures are turned on and functioning, negative pressure is monitored in airborne infection isolation rooms, employees with occupational exposure risks receive annual bloodborne pathogens training, and designated employees complete annual N-95 respirator fit testing. As of February 2013, all five recommendations were closed.

[36] Clostridium difficile (commonly referred to as "C *diff*") is a bacterium that causes severe diarrhea.
[37] OIG Report 11-02870-04, *Combined Assessment Program Summary Report – Management of Multidrug-Resistant Organisms in Veterans Health Administration Facilities,* October 14, 2011.
[38] OIG Report 11-03361-274, *Combined Assessment Program Summary Report – Evaluation of Infection Prevention Practices in Veterans Health Administration Facilities,* September 13, 2011.

In addition, we have issued several hotline and follow-up reviews that found that selected VHA facilities need to strengthen policies and procedures related to the reprocessing (that is, cleaning, disinfection, and sterilization) of RME. Furthermore, we cited VHA's continued challenge of "…maintaining compliance with RME directives," in the OIG's 2012 Major Management Challenges.[39]

VHA and facility officials we spoke to recognize that infection prevention is an on-going challenge in health care facilities (not just VHA facilities). These officials also correctly pointed out that responsibility for infection prevention does not solely rest with one department or service in a facility—it is the responsibility of all staff and requires constant vigilance; management support; and continuing education of staff, patients, and visitors.

Conclusions

Our onsite work at 4 facilities, including interviews with over 150 nurses, found no evidence of widespread, systemic reuse of insulin pens on multiple patients. The majority of nurses we spoke to understood that insulin pens were intended for single-patient use.

VHA's internal assessments following the Buffalo incident did not include clear, standard guidance to facilities on how to perform and document their audits of insulin pen use.

While two other incidents of using pens on multiple patients did occur—one reported by a facility and one we identified—the incidents were isolated, and facility leaders responded immediately. In January 2013, the Salisbury facility reported that two nurses had inappropriately used insulin pens on multiple patients. As a result, VHA instituted large-scale adverse event disclosure to notify 266 at-risk patients. In addition, we identified an incident of misuse by one nurse at another facility. Facility officials identified the at-risk patient, promptly notified the patient, and provided tests for bloodborne pathogens, which were negative. Furthermore, at two facilities, we found that a significant number of nurses used the insulin pens contrary to pen design. While this practice did not put patients at increased risk for bloodborne pathogens, it may have resulted in pen damage and dosing inaccuracies.

As with the Buffalo incident, we found no single cause as to why nurses misused insulin pens at the other facilities. Instead, we identified two contributing factors—facilities did not fully evaluate the risks of using insulin pens on inpatient units or provide comprehensive nurse education on the pens. On the surface, these factors may appear to have "simple fixes"; yet, to fully address them, VHA and facilities must consider their processes for evaluating new medical products and devices, especially in relation to how these products or devices will impact nursing procedures; the roles and

[39] Major Management Challenges in an annual report prepared by the OIG, in accordance with Section 3516 of Title 38, that provides a summarization of the most serious management and performance challenges within VA identified through OIG work.

responsibilities of facility committees and departments; the sufficiency of resources dedicated to nurse training; the content and comprehensiveness of nurse training; and underlying cultural issues regarding the acceptance of new technology and procedural changes.

As part of this review, we were also asked to evaluate broader issues within VHA regarding how it collects and disseminates important patient safety alerts and manages infection prevention activities. We found that VHA has processes in place to identify important patient safety alerts and disseminate this information to facility managers. NCPS and PBM lead VHA's efforts to collect patient safety information and share this information with facilities. At the facility level, patient safety managers are responsible for receiving alerts, disseminating them to appropriate administrative and clinical staff, and tracking the facility's response through the VHA Alerts and Recalls database. We also found that VHA has numerous policies and procedures in place to address infection prevention. However, as medical technology continues to advance and VHA continues to serve high-risk populations, they will need to be vigilant and ensure processes are in place to continually educate staff, patients, and visitors as new risks emerge.

Recommendations

1. We recommended that the Under Secretary for Health implement procedures to ensure that future VHA internal assessments resulting from adverse events include clear guidance to facilities on minimal required steps and supporting documentation.

2. We recommended that the Under Secretary for Health require facilities to develop processes for assessing the risks and benefits of adopting new medical products or devices that may require significant changes in nursing procedures.

3. We recommended that the Under Secretary for Health ensure that facility nursing education departments are sufficiently staffed to provide comprehensive and ongoing nursing education, especially when adopting new medical products or devices that may significantly change nursing procedures.

Appendix A

Under Secretary for Health Comments

Department of Veterans Affairs **Memorandum**

Date: July 12, 2013

From: Under Secretary for Health (10)

Subject: **OIG Draft Report, Review of VHA Follow-Up on Inappropriate Use of Insulin Pens at Medical Facilities (VAIQ 7370598)**

To: The Assistant Inspector General for Healthcare Inspections (54)

1. I have reviewed the draft report and concur with the report's recommendations. Attached is the Veterans Health Administration's (VHA) corrective action plan for the report's recommendations. I am pleased that the OIG review of insulin pen use within VA facilities resulted in similar conclusions as VHA's assessment following the Buffalo incident. Specifically that there is no evidence of widespread, systemic reuse of insulin pens on multiple patients within VA, and nurses understand that insulin pens are intended for single-patient use.

2. VHA, through the National Center for Patient Safety Alert (AL13-04), provided strong actions to all medical facilities regarding the future use of insulin pens or similar combination medical products (drugs/devices) on patient care units. VHA was the first healthcare organization to prohibit the routine use of insulin pens on patient care units and expanded this action to include all multi-dose pen injectors. Other patient safety organizations have since followed VHA's lead. The Patient Safety Alert also required facilities to update local policies to ensure individual patient labeling, proper storage, and continuous nursing education with annual competency assessment on the use of pen injectors by hospital staff. All VA facilities reported compliance with the Patient Safety Alert through the National Center for Patient Safety (NCPS) Product Recall Office's web-based database.

3. VHA's and OIG's reviews were also consistent in determining that the risk for blood-borne pathogen transmission from insulin pens is low. While the risk of infection is low, it is not negligible and VHA provided appropriate disclosure and follow-up to patients potentially affected through any inappropriate use of insulin pens. Both

reviews were also congruent regarding the scope of insulin pen use within the VA as small. Only 5 of 153 medical facilities identified high inpatient use of insulin pens in fiscal year 2012, while the majority had no to very low use.

4. VHA's assessment of the potential for inappropriate use of insulin pens at other medical facilities was led by NCPS who followed an effective and efficient process of investigating patient safety issues. NCPS identified the other four high-use facilities and provided detailed guidance and critical information to the facilities to investigate the potential for inappropriate use of insulin pens. This was accomplished through an established patient safety network of Veterans Integrated Service Network Patient Safety Officers and facility Patient Safety Managers with advanced training and experience in patient safety assessment and improvement. The investigation also included pharmacy operation managers in the four high-use facilities. While NCPS provided clear guidance and information to the four high-use facilities to conduct an internal audit, guidance was not prescriptive as each facility has the necessary patient safety network and professionals with training and knowledge on how to conduct a safety audit. Flexibility is also required with the facility's internal assessment as there are leadership structure and clinical diversity variations between facilities. NCPS also investigated the risk and potential scope of inappropriate use of insulin pens across VA, and identified potential systems issues with the use of insulin pens for VA patients. As a result of VHA's assessment, inappropriate use of insulin pens was identified in a second facility.

5. Thank you for the opportunity to review the draft report. If you have any questions, please contact Karen Rasmussen, Acting Director, Management Review Service (10AR) at (202) 461-6773.

Original signed by:

Robert A. Petzel, M.D.

Attachment

Comments to OIG's Report

The following Under Secretary for Health's comments are submitted in response to the recommendations in the OIG report:

OIG Recommendations

Recommendation 1. We recommended that the Under Secretary for Health implement procedures to ensure that future VHA internal assessments resulting from adverse events include clear guidance to facilities on minimal required steps and supporting documentation.

Concur

Target date for completion: August 30, 2013

VHA response: In October 2012, the Veterans Health Administration (VHA) issued Handbook 1004.08, *Disclosure of Adverse Events to Patients*. This handbook established required steps for a medical center/ VISN to follow when there is an adverse event or the potential need for a large-scale disclosure. The handbook improved the standardization of clinical and institutional disclosure; provided clear definitions; provided a process for assessment of adverse events; established mechanisms for convening subject matter expert panels to conduct fact finding; and provided standards for communication processes. To enhance these already established processes, the National Center for Patient Safety (NCPS) will develop a template for systematically conducting internal VHA assessments in response to specific adverse events. The template will reference policies and procedures relevant to the coordination of large-scale disclosures. The template will ensure that the Director; Chief of Staff; and Associate Director, Patient Care Services (Nurse Executives), at a minimum, are involved in the process and resulting policy or process changes.

Recommendation 2. We recommended that the Under Secretary for Health require facilities to develop processes for assessing the risks and benefits of adopting new medical products or devices that may require significant changes in nursing procedures.

Concur

Target date for completion: September 30, 2013

VHA response: NCPS will collaborate with the Office of Nursing Services in the development of a matrix for determining the level of risk and a companion list of Human Factors Engineering related actions (e.g., labels, checklists, usability testing) for the use of new medical products or devices for nursing practice. The matrix will include the requirement for a communication and an appropriate education plan to be coordinated with the Associate Director, Patient Care Services (Nurse Executives) Office before distribution to the units. This matrix will be provided to Office of the Deputy Under

Secretary for Health Operations and Management for review, concurrence, and dissemination.

Recommendation 3. We recommended that the Under Secretary for Health ensure that facility nursing education departments are sufficiently staffed to provide comprehensive and ongoing nursing education, especially when adopting new medical products or devices that may significantly change nursing procedures.

Concur

Target date for completion: September 30, 2013

VHA response: NCPS will provide relevant Human Factors Engineering training/education materials to the Veterans Integrated Service Network (VISN) and facility leadership for distribution to clinical leaders and staff to assist in mindfulness and education for use of new medical products or devices. The Associate Director, Patient Care Services (Nurse Executives) and Chiefs of Staff will enlist Clinical Nurse Leaders, Clinical Nurse Specialists, and hospitalists at the unit level in each facility to be mindful of risks in adopting new medical products or devices that impact clinical care (positively impacting the overall culture of safety on each unit).

Appendix B

OIG Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the OIG at (202) 461-4720.
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Appendix C

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