Department of Veterans Affairs
Office of Inspector General

Healthcare Inspection

Reprocessing of Dental Instruments
John Cochran Division of the
St. Louis VA Medical Center
St. Louis, Missouri

Report No. 10-03346-112

March 7, 2011

VA Office of Inspector General
Washington, DC 20420

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Executive Summary

The VA Office of Inspector General Office of Healthcare Inspections received a request from Congressman Bob Filner, the then Chairman of the House Committee on Veterans' Affairs, Congressman Jeff Miller, current Chairman of the House Committee on Veterans' Affairs, and seven other members of Congress, calling for an inspection into reports that veterans in several states including Missouri could have been exposed to blood borne pathogens such as hepatitis B (HBV), hepatitis C (HCV), and human immunodeficiency virus (HIV) while receiving dental care at the John Cochran Division (JCD) of the St. Louis VA Medical Center (STLVAMC), St Louis, MO.

The purpose of this review was to determine the sequence of events involving alleged improperly cleaned and sterilized dental reusable medical equipment (RME); errors in reprocessing or sterilization; actions taken to correct deficiencies; and decisions related to patient notification of breaches in dental equipment reprocessing or sterilization at the STLVAMC.

The dental RME reprocessing issues at the JCD were a long-standing problem that went unrecognized and unaddressed by Veterans Integrated Service Network (VISN) and STLVAMC managers. The Veterans Health Administration (VHA) self-identified the deficiencies and took actions to correct them; however, those actions did not always resolve the issues. Responsible managers did not verify the adequacy of RME reprocessing practices, nor did they assure that corrective actions were consistently implemented in response to VHA guidance and the Infectious Disease Program Office (IDPO) report. As a result, standard operating procedures (SOPs) were not developed in a timely manner for the reprocessing of dental RME, SOPs did not always match manufacturers' instructions, and Dental Clinic staff had not received training on dental RME pre-treatment or reprocessing.

We concluded that the occurrence of a patient-to-patient transmission of a blood-borne infectious disease at the JCD was unlikely. Nevertheless, the Clinical Risk Board adhered to the process outlined in VHA Directive 2008-002 when it recommended disclosure to 1,812 patients potentially affected by breaches in the cleaning and sterilization processes. We concluded that the STLVAMC promptly set-up and staffed its Dental Review Clinic, made appropriate efforts to contact identified patients, and provided adequate support and follow-up to patients.

We recommended that the VISN Director require the STLVAMC Director to monitor the facility's compliance with all appropriate elements of RME reprocessing, SOPs, staff training, and staff competencies as defined in relevant VHA guidance; ensure that the VISN Supply, Processing, and Distribution Management Board provides monitoring to ensure that SOPs based on manufacturer's instructions are in place and that staff training and competencies are current; and take appropriate administrative actions based on the findings of the Administrative Board of Investigation and IDPO report.

DEPARTMENT OF VETERANS AFFAIRS
Office of Inspector General
Washington, DC 20420

TO: Director, VA Heartland Network (10N15)

SUBJECT: Healthcare Inspection—Reprocessing of Dental Instruments, John Cochran Division of the St. Louis VA Medical Center, St. Louis, Missouri

Purpose

The VA Office of Inspector General Office (OIG) of Healthcare Inspections (OHI) received a request from Congressman Bob Filner, the then Chairman of the House Committee on Veterans' Affairs, Congressman Jeff Miller, current Chairman of the House Committee on Veterans' Affairs, and seven other members of Congress, calling for an inspection into reports that veterans in several states including Missouri could have been exposed to blood borne pathogens such as hepatitis B (HBV), hepatitis C (HCV), and human immunodeficiency virus (HIV) while receiving dental care at the John Cochran Division (JCD) of the St. Louis VA Medical Center (STLVAMC), St Louis, MO. The same letter also noted that a JCD employee allegedly raised concerns and warned management of unsanitary cleaning practices of dental instruments, and 2 months later, was retaliated against and fired for unprofessional conduct.

The purpose of this review was to determine the sequence of events involving alleged improperly cleaned and sterilized dental reusable medical equipment (RME); errors in reprocessing or sterilization; actions taken to correct deficiencies; and decisions related to patient notification of breaches in dental equipment reprocessing or sterilization at STLVAMC.

Background

The STLVAMC is a two-division tertiary care facility in Veterans Integrated Service Network (VISN) 15. The JCD of the STLVAMC is located in downtown St. Louis. It has 136 acute care beds and provides acute medical and surgical services as well as a wide range of specialty care. The Jefferson Barracks Division of the STLVAMC is located in south St. Louis County. This Division provides primary care and has 102 acute beds, 50 domiciliary beds, and 71 community living center beds.

The STLVAMC Dental Service workload and procedure codes indicate that the Service performs a full spectrum of dental and surgical procedures. In fiscal year 2009, it had 6 dentists and oral surgeons, 2 dental hygienists, and 11 dental assistants and dental lab technicians. Workload equaled 6,283 patient encounters. The Chief of Dental Service reports to the STLVAMC's Associate Chief of Staff for Primary Care.

In recent years, several Veterans Health Administration (VHA) medical facilities were found to deviate from recommended procedures for the reprocessing (cleaning and sterilization) of RME, resulting in patient recalls and/or temporary suspension of procedures. These events prompted Congress to ask OHI to conduct a national review, and on June 16, 2009, we reported that several VHA medical facilities had not complied with management directives to ensure compliance with reprocessing of endoscopes. We noted that, "Reprocessing of endoscopes requires a standardized, monitored approach to ensure that these instruments are safe for use in patient care."[1] We found apparent improvement in reprocessing operations during a follow-up review 3 months later.[2]

Over the past 2 years, VHA has published new guidance on RME reprocessing; directed numerous field-level activities such as an intensive "deep-dive" exercise in March 2009;[3] realigned Supply, Processing, and Distribution (SPD) under the Nursing Service; mandated annual VISN-level site visits that review RME issues; and instituted numerous quality control and improvement processes that address RME reprocessing.

In spite of these efforts, some VHA medical facilities have not sustained the improvements recognized in September 2009 and are not consistently complying with all requirements. The STLVAMC was cited in an April 2010 OHI report regarding reprocessing of endoscopes.[4] We reviewed selected aspects of RME reprocessing during OIG Combined Assessment Program reviews conducted in calendar year 2010 and found endoscope-related reprocessing deficiencies in several of the facilities visited. We cited five VHA medical facilities specifically for non-compliance with dental RME reprocessing guidelines. The aggregated results of that review will be published under separate cover.

Dental RME

Because the mouth is highly vascular, routine dental procedures such as fillings, extractions, dentures, bridges, and gum care may be associated with bleeding. Even

[1] *Healthcare Inspection—Use and Reprocessing of Flexible Fiberoptic Endoscopes at VA Medical Facilities*, June 16, 2009, Report Number 09-01784-146.
[2] *Healthcare Inspection—Follow-Up Colonoscope Reprocessing at VA Medical Facilities,* September 17, 2009, Report Number 09-02848-218.
[3] On February 4, 2009, VHA announced an "Endoscopy Step Up Week" for March 8-14. This activity, frequently referred to as the RME "deep-dive" exercise, focused on the intensive review of set-up and reprocessing procedures for all endoscopes, tubing, and other accessories throughout VHA medical facilities.
[4] *Alleged Endoscope Reprocessing Issues St. Louis VA Medical Center, St. Louis, Missouri,* April 21, 2010, Report No. 10-01141-133.

without bleeding, the oral cavity is lined by a mucosal surface that presents only a thin protective barrier to outside agents. If instruments or equipment are used with multiple patients, there must be proper cleaning, sterilization, and other preparations between patient uses.

RME refers to items which are manufactured for reuse or for which the manufacturer has provided specific written re-sterilization instructions. Dental RME includes "dental hand-pieces," referring to the high-speed dental drills used to remove tooth material prior to filling, and dental instruments such as stainless steel dental mirrors, probes, and retractors.

Reprocessing is the term used to encompass cleaning, disinfection, sterilization, and preparation of equipment to full readiness for use. VA Handbook 7176, *Supply, Processing, and Distribution (SPD) Operational Requirements*, states that RME should be reprocessed in the SPD decontamination area. If decontamination occurs in other areas of a medical center, all procedures listed in the handbook will apply to that area. For a time, dental RME was reprocessed in the Dental Clinic.

An important infection control practice to prevent RME cross-contamination is the removal of all visible debris as soon after use as possible. Manufacturers of dental instruments publish detailed instructions on how to clean and sterilize these items. While instructions may differ slightly, the general procedures involve:

1. Wiping instruments down with an appropriate cloth immediately after use
2. Pre-treating instruments with enzymatic foams or gels to keep residual blood and debris moist during transport
3. Cleaning instruments with specified detergents and a nylon brush to remove bioburden and debris, or using an ultrasonic machine
4. Thorough rinsing
5. Thorough drying with a lint-free cloth
6. Packaging of dried instruments for sterilization
7. Sterilization according to manufacturer's instructions

Steps 1–2 are considered pre-treatment activities. Step 1 should occur in the treatment area and Step 2 should occur in a designated processing area in or near the Dental Clinic. If items are to be transported to the medical center's SPD area for Steps 3–7, then Dental Clinic staff should "package" items for transport using cassettes or utility bins. Prior to a July 1, 2010, memorandum from VHA's Deputy Undersecretary for Health for Operations and Management (DUSHOM) to the VISN Directors, Steps 3–6 may occur in either the Dental Clinic or the SPD decontamination area. Step 7 has always been delegated to SPD.

Dental Instrument-related Infection

Infections may be transmitted through dental procedures by several routes, including transmission of infection from patient to dental health care worker (DHCW), from DHCW to patient, from patient-to-patient, and secondary transmission to an individual outside of the health care setting such as from patient or DHCW to a family member.

Direct transmission of infection from patient to DHCW, and from DHCW to patient, are the most prevalent. However, indirect transmission of blood-borne infection from patient-to-patient is an uncommon, but real, risk. A 2010 article in the *Journal of Viral Hepatitis* notes, "HBV transmission can occur in dentistry if there is any lapse in sterilization procedures or if there is transmission of infected body fluids to patients."[5]

Disclosure of Adverse Events

VHA Directive 2008-002 provides guidance for disclosure of adverse events related to clinical care to patients or to their personal representatives.[6] The directive includes instances "where the adverse event may not be obvious or severe, or where the harm may only be evident in the future." It was developed based on VHA's National Center for Ethics in Health Care report "Ethical Leadership: Fostering an Ethical Environment and Culture,"[7] which notes:

> Within the Veterans Health Administration, there is a presumptive obligation to disclose adverse events that cause harm to patients. However, in the case of an adverse event that has the potential to affect dozens or even thousands of patients, a public health response also requires a determination of the probability and magnitude of harm resulting from the adverse event as well as a weighing of additional factors, including, but not limited to salient ethical principles; risk of harm to veterans and identifiable third parties; benefit and burden of disclosure to veterans including medical, psychological, social or economic, impact on the institution's perceived integrity and its capacity to provide care and treatment for all veterans; as well as applicable policy and relevant precedent.[8]

Adverse events are defined as "untoward incidents, therapeutic misadventures, iatrogenic injuries, or other adverse occurrences directly associated with care or services provided within the jurisdiction of a medical center, outpatient clinic, or other VHA facility."

[5] Mahboobi N., et al., "Hepatitis B virus infection in dentistry: a forgotten topic."*J Vir Hep*, 17, 307-316 (2010)
[6] *VHA Directive 2008-002, Disclosure of Adverse Events to Patients, January 18, 2008.*
[7] *2007, p. 34.*
[8] *National Center for Ethics Report on Ethical Leadership: Fostering an Ethical Environment and Culture, 2007*

VHA Directive 2008-002 defines large scale disclosure of adverse events as "involving a large number of patients, even if at a single facility."[9] Authority and responsibility for large scale disclosures resides with VHA's Principal Deputy Under Secretary for Health (PDUSH). Often the issues will be clear and the PDUSH will proceed according to the facts and available medical science. However, if the issues are unclear, the PDUSH can request that the DUSHOM convene the Clinical Risk Board (CRB),[10] an ad-hoc consultative board.

CRB members include representatives from the Office of the DUSHOM, Office of the National Center for Ethics in Health Care, Office of Quality and Performance, National Center for Patient Safety, Office of Patient Care Services, and Office of Public Health and Environmental Hazards (OPHEH). Additionally, individuals knowledgeable about the case at hand, subject matter experts, and stakeholders affected by the decision may be asked to participate.

Key issues that the CRB is expected to address include the number of veterans exposed or potentially exposed; the probability that the adverse event will cause harm; the nature, magnitude, and duration of the potential harm; and the availability of treatment to prevent or ameliorate harm. To estimate the number of veterans potentially exposed, the CRB must consider the risk period when conditions were non-compliant or deficient. The risk period dates are referred to as "lookback" dates in the remainder of this report.

VHA Directive 2008-002 recognizes that although it is difficult to weigh all benefits and harms, situations prompting a decision whether to conduct large-scale disclosure of adverse events likely involve the following considerations:

- Are there medical, social, psychological, or economic benefits or burdens to the veterans, resulting from the disclosure itself?
- What is the burden of disclosure to the institution, focusing principally on the institution's capacity to provide health care to other veterans?
- What is the potential harm to the institution of both disclosure and non-disclosure in the level of trust that veterans and Congress would have in VHA?

The CRB may choose to recommend notification if "one patient or more in 10,000 patients subject to the event or exposure is expected to have a short-term or long-term health effect that would require treatment or cause serious illness if untreated."

[9] Attachment A of VHA Directive 2008-002 recognizes that adverse events with a known risk of serious future health consequences may be associated with an "extremely small" risk.
[10] The CRB was formerly known as the Clinical Risk Assessment Advisory Board (CRAAB).

STLVAMC Dental Clinic Problems

From March 9–12, 2010, VHA's National Infectious Diseases Program Office (IDPO) conducted a routine, facility-wide inspection of both STLVAMC Divisions. The purpose of this facility-wide inspection was "to evaluate the performance of the SPD operations and related areas performing decontamination, sterilization, high-level disinfection and storage of clean/sterile medical and surgical items."

The IDPO team inspected multiple areas of the JCD where RME reprocessing occurs and found that Dental Clinic employees were not always cleaning dental instruments according to manufacturers' instructions.

The IDPO team identified 21 unacceptable infection control-related conditions or practices in the JCD Dental Clinic. These problems included:

- Soiled items were observed being packaged and heat-sealed for sterilization without proper cleaning.
- Items were visibly dirty post-sterilization.
- Items sealed for sterilization were visibly wet.
- A basin was observed to be incorrectly wrapped prior to sterilization.
- Items were being packaged for the incorrect sterilization method.
- Standard operating procedures (SOPs), manufacturers' instructions, and staff competencies were not available for review.
- Staff was not familiar with relevant VHA guidance regarding RME.

STLVAMC managers closed the JCD Dental Clinic on March 12 pending completion of an investigation into the issues. The same day, STLVAMC's senior management provided an "Issue Brief" to the VISN which delineated a variety of corrective actions being taken or planned, including SOP updates, staff training, environmental inspections, and re-sterilization of all affected dental instruments.

Between March 12 and April 20, STLVAMC corrective actions included sterilizing all instruments removed from the Dental Clinic, training staff on the content of all VHA Handbooks and Directives related to RME, and initiation of infection control training. On March 18, the Oral Surgery and Dental Hygiene Clinics reopened and on March 26, General Dentistry reopened. STLVAMC's Chief, Infectious Diseases Service reviewed laboratory tests for patients seen in the Dental Clinic between February 1, 2009, and March 11, 2010, and provided the results to STLVAMC leaders.

On April 21, members of VHA's CRB convened a preliminary meeting with STLVAMC's leadership, Dental Service and Processing and Decontamination (P&D) managers, IDPO staff, and the facility's Infectious Diseases Service Chief. This pre-

CRB meeting was a basic fact-finding exercise to determine whether the reprocessing breaches appeared to meet criteria for disclosure to potentially affected patients. If so, a formal CRB would be convened. The IDPO's position was that the risk to patients was "low but was not negligible or non-existent," and the pre-CRB attendees unanimously agreed.

According to the April 21 pre-CRB minutes, a facility quality manager visited the Dental Clinic as part of the deep-dive exercise sometime in the first week of February 2009. The quality manager observed a JCD Dental Clinic employee complete the necessary steps to place a dental cassette into a dirty bin for transport to P&D. This was the most recent acceptable assessment of reprocessing procedures in the Dental Clinic.

The DUSHOM formally chartered the CRB on April 26, and on May 6, the CRB met to review the IDPO site visit findings and other relevant facts. The CRB noted that:

- Dental instruments with visible bioburden (tissue, blood) were packaged for sterilization.
- Visibly wet instruments were packaged for sterilization.
- Different colored peel-packs were used to denote the type of sterilization needed. Dental RME requires steam sterilization; however, dental instruments were, at times, sealed in peel-packs for gas sterilization.

The equipment manufacturer would not verify the sterility of instruments that were not sterilized according to manufacturer's instructions. As such, the CRB concluded that "under these circumstances, the risk for blood borne pathogens, although low, was not negligible."

In selecting the lookback dates, the CRB considered the STLVAMC Acting Medical Center Director's statement, as noted in the April 21 pre-CRB minutes, that P&D workload had increased in 2009 due to a higher volume of endoscopies and surgeries. P&D staff were overwhelmed, and in an effort to "help," Dental Clinic staff began cleaning and packaging instruments for sterilization sometime after February 2009. The STLVAMC Infectious Diseases Service Chief's statement, which was also noted in the April 21 pre-CRB minutes, indicated that February 1, 2009, was the last time the Dental Clinic processes were deemed adequate. It was the quality manager's observation of correct practices in February 2009 that was the basis for the selection of that time as the outer limit of the lookback period.

On May 7, the CRB formally recommended disclosure to patients possibly affected by dental RME sterilization lapses occurring from February 1, 2009, to March 12, 2010. The CRB further recommended that each patient be offered serologic testing for HBV, HCV, and HIV, according to a protocol developed by the OPHEH. Disclosure letters were sent to the affected patients on or about June 28.

In a July 1, 2010, memorandum, the DUSHOM directed all VHA facilities to discontinue dental instrument pre-cleaning and sterilization outside of SPD. This change was to be completed by July 9 and VISNs were to confirm implementation. On July 23, the DUSHOM issued additional guidance clarifying that pre-treatment (wiping and using enzymatic foams) could continue to occur in the Dental Clinic. The July 23 memorandum reiterated that reprocessing activities (cleaning, decontamination, wrapping, and sterilization) shall only occur in SPD.

On July 7, VHA's DUSHOM called for an Administrative Board of Investigation (ABI) to "investigate any and all circumstances surrounding the alleged failure of the St. Louis VAMC to detect deficiencies in the pre-cleaning of dental instruments."

Scope and Methodology

We visited the JCD of the STLVAMC from August 31–September 2 and September 27–30, 2010. We interviewed relevant clinical and administrative staff, including STLVAMC's Acting Director; Quality Manager; both the former and Acting Chiefs of the Dental Service; Chief, P&D; Chief, Infectious Diseases Service; and infection control nurses. We also interviewed the CRB Chairperson, medical consultants from the Prevention and Response Branch of the Center for Disease Control, and OPHEH staff.

We reviewed the ABI and its testimony; VHA Directives 2009-004, 2009-031, and 2008-002; and VA Handbook 7176, *Supply, Processing, and Distribution (SPD) Operational Requirements*, August 16, 2002. We reviewed VISN Issue Briefs; the IDPO report; CRB charters, memoranda, and related minutes; relevant medical literature; facility-level SOPs and manufacturer instructions for cleaning and sterilization of equipment; incident reports; Dental and P&D Service training records and competencies; documents related to the Dental Review Clinic (DRC);[11] and corrective action plans.

The issue of alleged whistleblower retaliation is not addressed herein as the Office of Special Counsel (OSC), an independent federal investigative and prosecutorial agency charged with evaluating alleged reprisal for whistleblower disclosure, has jurisdiction in these matters.[12,13]

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

[11] The "Dental Review Clinic" (DRC) was implemented to notify patients about the possible exposure and testing instructions. It included a location for patients to obtain information, receive counseling, and undergo testing related to the possible exposure. It also included a call center for appointment scheduling as well as address patient concerns related to the possible exposures.
[12] http://www.osc.gov/wbdiscOverview.htm, accessed November, 20, 2010
[13] 5 U.S.C. Section (§) 1213

Inspection Results

Issue 1. Inconsistent Pre-treatment and Cleaning of Dental RME

We found inconsistency in the performance of instrument pre-treatment (Steps 1–2) prior to cleaning. Because Dental Clinic staff did not document their activities, we could not confirm whether enzymatic foams were consistently used.

We found inconsistency in the performance of cleaning instruments (Steps 3–6). Because Dental Clinic staff did not document their reprocessing activities, we could not confirm that the appropriate detergents were used, that instruments were brushed to remove bioburden, or that the ultrasonic machine contained the correct concentration of detergent to ensure adequate pre-cleaning.

Issue 2. Problematic and Absent SOPs

SOPs were not developed in a timely manner for the reprocessing of dental RME, and the SOPs did not always match the manufacturers' instructions as required by Directive 2009-004. We found that dental RME SOPs were generally not published until July and September 2010, a year after the Directive was issued. Of the dental instrumentation used at the STLVAMC that we reviewed, the majority still did not have a corresponding published SOP at the time of our September 27–30, site visit. Additionally, we found discrepancies between the SOPs and the manufacturers' instructions in all five cases where manufacturers' instructions were available.

We also found that SOPs were not posted or otherwise readily available to staff with responsibility for pre-treatment and reprocessing of dental RME, either in the Dental Clinic or in P&D.

Issue 3. Inadequate Staff Training and Competencies

Managers were not able to produce documentation to support staff training on dental RME pretreatment or reprocessing. Directive 2009-004 requires staff to be trained on the reprocessing of RME prior to initial use. However, staff reported that they did not receive dental RME training; rather, they followed procedures they learned in school, practiced in previous private-sector jobs, or observed others doing.

Directive 2009-004 defines competence as "the assurance that an individual has received the appropriate training and has demonstrated an achieved skill level required to independently and appropriately perform an assigned reprocessing task or responsibility" and calls for "documented" initial and continued staff competence at least annually. Neither P&D nor Dental Clinic staff had current documented competencies for the 12 pieces of dental instrumentation used at the STLVAMC.

We noted that multiple managers referred to a procedural change in early February 2009 when Dental Clinic employees began to "help" P&D by assuming responsibility for pre-treatment, but also cleaning of instruments using detergents and brushes. We found no evidence that responsible managers took action to assure that Dental Clinic staff received training on these "new" responsibilities or verified staff competencies to perform these added duties.

Issue 4. Inadequate Oversight of SPD Functions

As noted, there were ongoing deficiencies related to dental RME reprocessing, SOPs, and staff training and competencies.

We also found that the VISN 15 SPD Management Board did not provide the necessary level of oversight as required by VHA Directive 2009-031. VISN 15 chartered a Board to provide "oversight of all reprocessing of RME occurring within the VISN. The Board has the accountability and authority for ensuring reprocessing (and other SPD functions) occurs to exacting standards." We reviewed meeting minutes for September 14, 2009, through July 26, 2010, and found that the Board held quarterly meetings to discuss implementation of a facility SPD query review tool and quality assurance report and also addressed plans for unannounced facility SPD site visits. However, we did not find evidence that the Board monitored that SOPs based on manufacturer's instructions were in place and that the staff training and competencies were current.

Issue 5. Well-structured Patient Notification Processes

We found that VHA acted promptly to evaluate the nature of the apparent exposure, determine the potential rate of infection, and make recommendations for disclosure. The CRB recommended disclosure on May 7, about 8 weeks after identification of the dental RME problems. The STLVAMC then created and staffed its DRC and Call Center for potentially affected patients to schedule blood tests and receive counseling, if desired. Patient notification letters were sent around June 28. Overall, the STLVAMC's recall effort was well-structured and organized, and staff appropriately followed up with potentially affected patients.

When the lookback period came under scrutiny in late August due to preliminary OHI findings that the February 2009 demarcation may not have been accurate, VHA's PDUSH re-chartered the CRB on September 14 to reassess the dates (and the possible need to expand the pool of notified patients.) On October 8, the CRB made the following recommendations:

> Based on our deliberations at the September 16th, 2010 CRB meeting and the responses to our questions, the CRB unanimously recommends that the current lookback for the period February 2009 to March 2010 should be completed and the testing results analyzed. If clustering (or grouping) of cases of blood borne viral infections are documented (indicating patient to

> patient transmission of viral disease within the Dental Clinic), then the CRB should be re-convened to recommend if further look back is required prior to February 2009. The Office of Public Health and Environmental Hazards will propose a definition for clustering of cases.

The CRB concluded that a total of 1,812 patients were potentially affected by the dental instrument cleaning and sterilization issues. Forty-three patients were since deceased, and thus, disclosure notices were sent to 1,769 patients (1,812–43). Of these 1,769 patients to whom disclosure was attempted, 1,763 made contact with or otherwise were contacted by the STLVAMC. There were 105 patients who refused testing.

OPHEH informed us that as of November 16, 2010, four patients who had either not been tested before or had previously tested negative, now tested positive—two were newly diagnosed with HBV, and two with HCV. However, the OPHEH did not find evidence of clustering, and concluded that additional disclosures were not indicated.

We found that this case caused the CRB role and processes to undergo re-evaluation. We were informed that the release of a new VHA handbook that further delineates the CRB roles and processes and will serve to replace VHA Directive 2008-002 is pending.

Conclusions

The dental RME reprocessing issues at the JCD were a long-standing problem that went unrecognized and unaddressed by VISN and STLVAMC managers. In this instance, VHA self-identified the deficiencies and took actions to correct them; however, some conditions still existed at the time of our site visits.

Responsible managers did not verify the adequacy of RME reprocessing practices nor did they assure that corrective actions were consistently implemented in response to VHA guidance and the IDPO report. As a result, SOPs were not developed in a timely manner for the reprocessing of dental RME, SOPs did not always match manufacturers' instructions, and Dental Clinic staff had not received training and did not have documented competencies on dental RME pre-treatment or reprocessing.

We concluded that the occurrence of a patient-to-patient transmission of a blood-borne infectious disease at the JCD was unlikely. Nevertheless, the CRB adhered to the process outlined in VHA Directive 2008-002 when it recommended disclosure to 1,812 patients potentially affected by breaches in the cleaning and sterilization processes. We concluded that the STLVAMC promptly set-up and staffed its DRC, made appropriate efforts to contact identified patients, and provided adequate support and follow-up to patients.

Recommendations

Recommendation 1. We recommended that the VISN Director requires the STLVAMC Director to monitor the facility's compliance with all appropriate elements of RME reprocessing, SOPs, staff training, and staff competencies as defined in relevant VHA guidance.

Recommendation 2. We recommended that the VISN Director ensure that the VISN SPD Management Board performs monitoring to ensure that SOPs are in place and that staff training and competencies are current.

Recommendation 3. We recommended that the VISN Director take appropriate administrative actions based on the findings of the ABI and IDPO report.

Comments

The VISN and Medical Center Directors agreed with the findings and recommendations (see Appendixes A and B, pages 13–16, for the Directors' comments). The implementation plans are acceptable, and we will follow up on the planned actions until they are completed.

(original signed by:)
JOHN D. DAIGH, JR., M.D.
Assistant Inspector General for
Healthcare Inspections

Appendix A

VISN Director Comments

Department of Veterans Affairs **Memorandum**

Date: February 15, 2011

From: Director, VA Heartland Network (10N15)

Subject: **Healthcare Inspection – Reprocessing of Dental Instruments, John Cochran Division of the STLVAMC, St. Louis, Missouri**

To: Director, Atlanta Office of Healthcare Inspections (54AT)

Thru: Director, Management Review Service (10B5)

I have reviewed the recommendations and concur with the St. Louis Medical Center's response and action plans. If you have any questions, please contact VISN office at (816)-701-3000.

(original signed by:)
JAMES R. FLOYD, FACHE

Appendix B

Medical Center Director Comments

Department of Veterans Affairs **Memorandum**

Date: February 15, 2011

From: Director, St. Louis VA Medical Center, John Cochran Division (657/00)

Subject: **Healthcare Inspection – Reprocessing of Dental Instruments, John Cochran Division of the STLVAMC, St. Louis, Missouri**

To: Director, VA Heartland Network (10N15)

1. Our comments and action plans have been entered directly into this report as requested.

2. Should you need additional information, please contact Patricia Hendrickson, RN, MSN, CPHQ, Director of Quality Management at (314)-289-7020.

(original signed by:)
RIMAANN O. NELSON, RN, MPH/HSA
St Louis VA Medical Center Director

Director's Comments to Office of Inspector General's Report

The following Director's comments are submitted in response to the recommendations in the Office of Inspector General's report:

OIG Recommendations

Recommendation 1. We recommended that the VISN Director requires the STLVAMC Director to monitor the facility's compliance with all appropriate elements of RME reprocessing, SOPs, staff training, and staff competencies as defined in relevant VHA guidance.

Concur **Target Completion Date:** February 28, 2011

STLVAMC Director will continue to monitor compliance with all appropriate elements of RME processing. The STLVAMC RME Committee, co-chaired by Associate Director Patient and Nursing Service and Deputy Chief of Staff will enhance oversight by reviewing, monitoring, and implementing of all necessary action plans to maintain compliance with relevant VHA RME guidance through standing agenda items in the RME Committee. These agenda items include: 1) Staff Competencies, 2) Standard Operating Procedures, 3) Staff Education and Training, 4) Workload Level Evaluation, 5) Quality Indicators such as Early Releases, Environmental Monitoring, and Biological Testing.

STLVAMC will complete a minimum of six self inspections using standardized review tools with a multi-disciplinary team including nursing leadership, chief P&D, infection prevention, patient safety, quality management, two members of the RME committee, and area staff. Action plans will be developed, reported, and tracked in STLVAMC RME Committee and VISN SPD Management Board.

The RME meeting minutes, containing the oversight information from items 1–5 listed above, will be reviewed by the Executive Management Team on a monthly basis in the Executive Committee Meeting chaired by the Medical Center Director.

Recommendation 2. We recommended that the VISN Director ensure that the VISN SPD Management Board monitors to ensure that SOPs are in place and that staff training and competencies are current.

Concur **Target Completion Date:** March 28, 2011

The VISN SPD Board is using the tool developed by Central Office in FY11 for the VISN oversight reviews. This tool provides detailed information on SOPs, competency completion and training documentation. The VISN SPD Board is also adding two sections to its SPD query tool. Those two sections are:

1. The Medical Center process for maintaining SOPs.
2. The Medical Center processes for maintaining competencies.

In addition, SOPs, competencies and training are being added as a standing agenda item to each Board meeting.

Recommendation 3. We recommended that the VISN Director take appropriate administrative actions based on the findings of the ABI and IDPO report.

Concur **Target Completion Date:** January 24, 2011

The VISN Director and STLVAMC Directors have taken the recommended administrative actions based on the findings of the ABI and IDPO report.

Appendix C

OIG Contact and Staff Acknowledgments

OIG Contact	George Wesley, MD Office of Healthcare Inspections
Acknowledgments	Toni Woodard, Team Leader Victoria Coates Kathleen Shimoda

Appendix D

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