Department of Veterans Affairs
Office of Inspector General

Healthcare Inspection

Oversight Review of Dental Clinic Issues Dayton VA Medical Center Dayton, Ohio

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Executive Summary

Introduction

At the request of the Chairmen and Ranking Members of the Senate Committee on Veterans' Affairs and the House Committee on Veterans' Affairs, the Office of Inspector General Office of Healthcare Inspections reviewed infection control issues at the Dayton VA Medical Center, Dayton, OH (the medical center).

On July 21, 2010, allegations of potential breaches in infection control practices were made to a VA System-Wide Ongoing Assessment and Review Strategy (SOARS) inspection team. The allegations pertained to improper infection control practices of a dentist at the medical center (the subject dentist). In consideration of these allegations the medical center temporarily suspended dental services and detailed several employees out of the dental clinic to other administrative duties. Reviews were initiated at the local VA Medical Center (VAMC), Veterans Integrated Service Network (VISN), and VA Central Office (VACO) levels. In addition, a VISN-level Administrative Investigative Board (AIB) was chartered. After a rapid response site visit by a VACO team, the Veterans Health Administration's (VHA's) Principal Deputy Under Secretary for Health, concerned about the possibility of bloodborne infection, convened a Clinical Review Board (CRB). This CRB was asked to: (1) conduct a clinical risk assessment, (2) identify the types of dental procedures at risk for disease transmission, and (3) make a recommendation as to whether a large-scale disclosure was indicated.

Results and Conclusions

We found evidence of lack of adherence to proper infection control policies and determined that the subject dentist did not comply with infection control and related procedures. We identified evidence that Dental Service management was aware of these infractions prior to the SOARS team visit. Subsequent to the SOARS visit, VHA's response to the allegations was immediate and demonstrated appropriate concern for patient safety. The AIB established that the subject dentist repeatedly violated infection control standards over a multiyear period. The CRB properly executed its charges and directives, and its recommendations followed VHA's notification for disclosure policy.

Additionally, we confirmed that staffing levels in the dental clinic were suboptimal, and this may have increased the likelihood that deviations from approved infection control practices would occur. We also found that interpersonal relations among dental clinic staff were, at times, strained and negatively impacted the dental clinic.

Recommendations

Recommendation 1: We recommended that the VISN Director review the findings related to the Dayton Dental Clinic, to include staffing issues, and take whatever action deemed appropriate.

Recommendation 2: We recommended that the VISN Director ensure that the Dayton Medical Center Director requires the Dental Service to comply with the relevant infection control policies.

Comments

The VISN and Medical Center Directors agreed with the findings and recommendations and provided an acceptable action plan (see Appendixes A and B, pages 20–22, for the Directors' comments). We will follow up on the planned actions until they are completed.

Introduction

Purpose

This review was performed at the request of the Chairmen and Ranking Members of the Senate Committee on Veterans' Affairs and the House Committee on Veterans' Affairs. During the week of July 20–23, 2010, a System-Wide Ongoing Assessment and Review Strategy (SOARS) team inspected the VA Medical Center, Dayton, OH (the medical center). On the morning of July 21, during the course of this inspection, two dental clinic employees approached a team member requesting to speak. A meeting did not occur immediately, but later in the morning, while in the dental clinic laboratory, these same two employees again encountered SOARS team members. The employees articulated allegations about aspects of a staff dentist's practice. These allegations pertained to this dentist's handling of dental burs[1] and noncompliance with dental infection control guidelines. The improprieties allegedly had been ongoing, and were continuing to occur.

The allegations, if true, would have represented significant breaches of both medical center and Veterans Health Administration (VHA) national standards regarding the handling of reusable medical equipment (RME), adherence to standards of infection control, and professional comportment expected of VHA dentists. At that time, it was also alleged that these concerns had been previously brought to Dental Service management's attention.

This encounter, and the allegations, set in motion no less than five VHA investigations (including an Administrative Investigative Board [AIB]) that produced reports culminating in the notification, on February 8, 2011, to 535 patients of the medical center, "that VA's own internal reviewers discovered that a dental clinician was not always following standard infection control practices in the Dental Clinic [sic] at the Dayton VA Medical Center."

No specific case of patient injury was asserted; rather, the allegations pertained to overall improper practices. The purpose of this oversight review is to detail the relevant facts regarding this incident and to make recommendations to address the issues discussed in this report.

[1] A dental bur is a rotary cutting device, used in a handpiece, that is intended to cut hard structures in the mouth, such as teeth or bone as well as hard metals, plastics, porcelains, and similar materials used in the fabrication of dental devices. http://de.dict.md/definition/Bohrer ,accessed 2/12/2011.

Background

A. SOARS

1. Program

VHA operates a program of proactive VA medical center inspections known as SOARS visits. Its mission "is to provide assessment and educational consultation to volunteer facilities using a systematic method for on-going self-improvement." SOARS inspection teams are composed of program staff and field (Veterans Integrated Service Network [VISN] and medical center level) health care experts.

2. Allegations Made to the SOARS Team

On July 21, 2010, two dental clinic employees approached a SOARS team member who later detailed the interaction in depth in a Report of Contact (ROC). This ROC indicates that two dental technicians voiced concerns of "violations of RME standards in the Dental Department." The technicians noted that "the problem involved a particular doctor that worked in Dental [sic]." In response, the SOARS Team Leader documented that "…one of the employees relayed [concerns] about processes that were taking place in the Dental Clinic [sic] related to sterilization and cleaning of dental RME. They offered that a Dentist [sic] in the Dental [sic] clinic was inappropriately cleaning and storing dental burs as well as reusing them on various patients without appropriate cleaning procedures. When asked whether leadership was aware of this concern, the employee said that [he/she] had informed the Chief of Dental, and nothing was being done." The complainants also indicated, "we have talked to everyone and no one cares, so we want to talk to you."

Further, the SOARS team cited being informed that a particular dentist "uses burs to make adjustments on dentures and will not sterilize the burs between patients…even if there is blood on the dentures [he/she] is working on." The complainants alleged that they told [the subject dentist] that [he/she] needed to have the burs sterilized between patients and were told by [the subject dentist] "leave your hands off of my burs."

3. SOARS Review Conclusions Related to the Dental Clinic

The final SOARS report stated, "During the Dental [sic] review, 3 employees notified the SOARS team of their alleged concerns with dental instruments not being properly cleaned between patients. They stated they had notified their supervisor without actions being taken. The SOARS Team notified the Medical Center Director and recommended further fact finding be completed immediately."[2]

[2] While in the dental lab, a third dental employee also made allegations.

In its final report, one of the SOARS team's "priority areas for improvement" was for the medical center to: "Complete a comprehensive assessment on the RME concerns involving the Dental [sic] clinic."

B. Dayton Dental Clinic

The dental clinic performs a full spectrum of dental and oral surgical procedures. The American Dental Association (ADA) recognized dental specialties practiced at the medical center include general dentistry, oral and maxillofacial surgery, oral and maxillofacial radiology, periodontics,[3] and prosthodontics.[4] In July 2010, at the time of the SOARS inspection, the dental clinic had seven dentists and an oral surgeon, two dental hygienists, seven dental assistants (two expanded function, five non-expanded function),[5] and three dental laboratory technicians.[6] In FY 2009, the dental clinic treated 3,164 unique patients, and in FY 2010 the clinic treated 3,005 unique patients.

The dentists, oral surgeon, administrative officer, expanded function dental assistants, registered dental hygienists, and dental laboratory technicians report to the service chief, while the non-expanded function dental assistants and administrative program staff report to the Dental Service's administrative officer. The Chief of Dental Service reports to the medical center Chief of Staff (COS).

The dental clinic has a General Practice Residency, which is an independent medical center residency (as opposed to being the recipient of university residents rotating through the dental clinic). It presently has three residents, although it is authorized for four. The last accreditation review occurred on September 20, 2006, and the Commission on Dental Accreditation adopted a resolution to grant the program the accreditation status of "approval without reporting requirements" at its January 25, 2007 meeting. The next scheduled accreditation site inspection is scheduled for September 2013.

C. 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.

[3] Periodontics is the diagnosis and treatment of gum disease.
[4] Dental prosthetics or prosthetic dentistry is the area of dentistry that focuses on the replacement of teeth and related mouth and jaw structures with artificial devices, including dentures and implants.
[5] Expanded function dental assistants have advanced patient care skills beyond the level provided by non-expanded function assistants and are at a higher pay scale level.
[6] Dental clinic staffing has evolved somewhat since July 2010. As of January 2011, the organizational chart reflects staffing as follows: 26.4 FTE: Chief, Dental Service, 1.0 FTE; Assistant Chief of Dental Service, 1.0 FTE; dentists (general), 4.0 FTE; oral surgeon, 1.0 FTE; periodontist, 0.2 FTE; endodontist, 0.2 FTE; expanded function dental assistants, 2.0 FTE; dental assistant (oral surgery), 1.0 FTE; dental assistant (lead), 1.0 FTE; dental assistants, 8.0 FTE; dental hygienists, 2.0 FTE; dental laboratory technicians, 2.0 FTE, administrative officer, 1.0 FTE; and program support assistants, 2.0 FTE.

Adverse events are defined as "untoward incidents, therapeutic misadventures, iatrogenic [physician-caused] 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."

VHA Directive 2008-002 defines large-scale disclosure of adverse events as "involving a large number of patients, even if at a single facility."[7] 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 Deputy Under Secretary for Health for Operations and Management (DUSHOM) convene the Clinical Risk Board (CRB),[8] an ad-hoc consultative board.

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:

a. Are there medical, social, psychological, or economic benefits or burdens to the veterans, resulting from the disclosure itself?

b. What is the burden of disclosure to the institution, focusing principally on the institution's capacity to provide health care to other veterans?

c. 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]

[7] 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.
[8] The CRB was formerly known as the Clinical Risk Assessment Advisory Board (CRAAB).
[9] This material is quoted from Department of Veterans Affairs Office of Inspector General, *Healthcare Inspection – Use and Reprocessing of Flexible Fiberoptic Endoscopes at VA Medical Facilities,* Report No. 09-01784-146, June 16, 2009.

Scope and Methodology

A. Onsite Visits and Interviews

We visited the medical center from December 14–16, 2010. We interviewed relevant clinical and administrative staff, including the Medical Center Director, Acting COS, Quality Manager, infection control practitioner, and the senior infectious diseases physician. We interviewed past and current staff of the dental clinic. However, we were unable to interview the original SOARS complainants due to their departure from the medical center, as well as one dentist and the former COS, due to retirement. We interviewed senior VISN 10 staff, including the Network Director, Chief Medical Officer, Quality Management Officer, and the Network Patient Safety Officer.

We interviewed senior VA Central Office (VACO) officials including the Under Secretary for Health; PDUSH; Acting Assistant Deputy Under Secretary for Health, Clinical Operations and Management; Associate Deputy Under Secretary for Health for Quality and Safety; National Program Director for Medicine; Assistant Under Secretary for Health for Dentistry; and Infection Control Consultant for VHA's Office of Dentistry. We interviewed members of the AIB, including its attorney-advisor. One AIB member was unavailable due to health reasons.

We interviewed medical consultants from the Prevention and Response Branch of the Centers for Disease Control and Prevention (CDC) and VA Office of Public Health and Environmental Hazards (OPHEH) staff. We also interviewed attorneys from VA's Office of General Counsel (OGC).

B. Document Reviews

We reviewed the AIB and its testimony. We reviewed VISN Issue Briefs; CRB charters, memoranda, and reports; relevant medical and dental literature; facility-level Standard Operating Procedures (SOPs) and policies; relevant committee minutes; credentialing and privileging documents; dental clinic infection control training records; and email communications. We also reviewed VHA directives, CDC guidelines, Occupational Safety and Health Administration's (OSHA) Bloodborne Pathogens Rule, and ADA guidelines.

During the course of our inspection, we were informed that the skills of another dentist (not the subject dentist) had been brought into question. The medical center undertook a review of the dental care provided by this individual through normal quality assurance procedures. This issue is not addressed further in this report.

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

Inspection Results and Conclusions

Issue 1: Dental Clinic Infection Control

A. Policies, Procedures, and Training

Dental infection control practices are governed by a multitude of regulations, standards, and recommendations related to the appropriate use of personal protective equipment (PPE), hand hygiene, reprocessing of RME, and other measures to safeguard the health of patients and staff. VHA, CDC, The Joint Commission (The JC), and OSHA have published documents to facilitate compliance with recommendations and requirements. The medical center has also developed local policies related to hand hygiene, RME, bloodborne pathogens, and disinfectants. The medical center requires its employees to comply with these established infection control policies.

RME is defined as any medical equipment designed by the manufacturer to be reused for multiple patients. Dental RME includes dental handpieces, which are the high-speed dental drills used to remove tooth material prior to filling, and dental instruments such as stainless steel dental mirrors, probes, burs, and retractors. These are classified as critical items[10] and must be disinfected and sterilized between patients. Applicable policies include VHA Directive 2009-004, VHA Directive 2009-031, and VHA's SPD Handbook 7176. As well as policies governing infection control practices, there are also policies governing disinfectant agents and their use.

In our review of the dental clinic staff training records provided to us by the medical center for March 2007–October 2010, we found that infection control training was not completed by many employees on an annual basis as required.

B. Bloodborne Pathogens Infection Control

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, and from patient to patient. VHA and the medical center have policies in place designed to assure that employees and patients are protected against infection by bloodborne pathogens (HIV, hepatitis B, hepatitis C).[11]

The Medical Center Director ensures the implementation and enforcement of the Dental Service Bloodborne Pathogens Exposure Control Plan. Compliance with the exposure control plan is the responsibility of the Chief of Dental Service. All employees are

[10] Critical Items: Objects that enter sterile tissue or the vascular system – for example: orthopedic prosthetic devices, surgical instruments, and ultrasound probes used in sterile body cavities.
[11] Department of Veterans Affairs Dayton VA Medical Center Dental Service, *Bloodborne Pathogens Exposure Control Plan,* November 10, 2008

responsible for complying with the procedures contained in the plan. This plan includes the following procedures:

- PPE is never worn outside the work area.
- Computer keyboards, telephones, intercoms, and similar equipment will never be handled with contaminated gloves unless there is a barrier present.
- Eating, drinking, applying cosmetics, or handling contact lenses is not permitted in the dental operatories, laboratory, or any direct patient care area.
- All impressions will be decontaminated upon removal from the mouth.
- When performing procedures involving touching blood and/or saliva the following are mandatory items of PPE: gloves, masks, face shields/glasses, and impervious gowns. Heavy duty gloves are required for instrument preparation and disinfection.

If an exposure incident occurs, the policy states that the employee will immediately report the exposure incident to the employer through their immediate supervisor with additional steps to be taken to protect the health of the employee.

The Infection Control Policy dated November 13, 2008, states that the Chief of Dental Service has the authority and responsibility for the operation of the Infection Control Program. Dental clinic employees are responsible for complying with the procedures contained within the policy.

This policy states that "Standard (Universal) precautions will be observed in the Dental Service in order to prevent contact with blood or other potentially infectious materials." The policy defines standard precautions as "a method of infection control in which all human blood and certain human body fluids (saliva in dentistry) are treated as if known to be infectious for HIV, HBV [hepatitis B virus], and other bloodborne pathogens. Standard Precautions means that the same infection control practices are used for all patients." This policy includes the following procedures:

- All dental instruments, equipment, and devices that enter the patient's vascular system or penetrate the skin, oral mucosa, or teeth must be sterilized prior to use on a patient or discarded as a single use item.
- All dental instruments, equipment, and devices that contact mucous membranes but do not penetrate the patient's skin or mucosa will be sterilized when possible or disinfected with an Environmental Protection Agency (EPA) approved disinfectant.
- Single-use, sterile burs and diamonds will be utilized whenever possible. All other burs (including lab burs) will be sterilized initially and between uses.

- Dental prostheses, impressions, and other prosthodontic materials will be thoroughly cleaned, disinfected with an EPA-registered hospital disinfectant with a tuberculocidal claim, and thoroughly rinsed prior to being taken to the dental laboratory. Wex-CideE-128® is the product currently being utilized for this purpose. Prostheses/impressions/other prosthodontic materials should be immersed for at least 10 minutes.[12]
- Under no circumstances will contaminated appliances or equipment be taken into the dental laboratory for grinding or polishing.
- Contaminated gloves will not be worn into the dental lab.

VHA's Required Hand Hygiene Practices states that all VHA facility directors are responsible for ensuring that all health care workers in direct patient care areas put gloves on when contact with blood or other potentially infectious materials, mucous membranes, and non-intact skin could occur. Employees must remove gloves after caring for the patient and not wear the same pair of gloves for the care of more than one patient.

The subject dentist did not comply with infection control and related policies. A clinic dentist informed the Chief of Dental Service in a June 29, 2010, email that:

> You have [a dentist] who repeatedly violates basic infection control protocols. This includes:
>
> a. Not cleaning a room after seeing patients and then boasting that [he/she] "works without an assistant". [sic]
> b. [allegation not directly observed by the writer]
> c. Using bare hands in the patients [sic] mouth
> d. Answering [his/her] cell phone with gloves on [his/her] hands, then putting those gloves back in the patients [sic] mouth without changing the gloves and/or cleaning the phone

In a memorandum for the record dated August 16, 2010, the Chief of Dental Service indicated that "[a dentist] would perform non-patient activities (talking on the phone, cell-phone, drinking coffee), or be walking in the hallway with [his/her] purple patient-care gloves on. I have indeed witnessed this activity on several occasions."

Multiple dental clinic employees told us they had personally observed various infection control policy violations by the subject dentist. Their observations included failing to disinfect, or incorrectly disinfect, denture prostheses prior to transferring them to the dental laboratory and wearing gloves outside the operatory. They told us that the subject dentist went directly from one patient to another without changing exam gloves and did

[12] The current policy now specifies Dispatch®, which requires immersion for 1 minute.

not properly clean and disinfect the operatory. Individuals told us that unsterilized instruments were reused on more than one patient.

C. Conclusions Regarding Dental Clinic Infection Control

The subject dentist did not adhere to established infection control guidelines and policies, and multiple dental clinic staff had direct knowledge of these repeated infractions. These violations of infection control policies placed patients at risk of acquiring infections including those that are bloodborne.

Issue 2: VHA Responses to the Dental Service Allegations

Immediately after the allegations concerning the Dental Service were made to the SOARS team, VHA launched a series of reviews and investigations at the local VAMC, VISN, and VACO levels. These included a compliance review; review of Supply, Processing and Distribution (SPD) practices; onsite review by a VACO fact finding team; and convocation of an AIB. These reviews quickly resulted in temporary closure of the dental clinic, detailing of several employees out of the clinic to other administrative duties, institution of local improvements, and, at a national level, empanelling a CRB. The latter would be called upon to assess possible notification to patients of infection control breaches. Key activities and outcomes are summarized below.

A. Medical Center, VISN, and VACO Responses

The SOARS Team reported the July 21, 2010, allegations to the Medical Center Director the day they were received, and the director notified the VISN within 24 to 48 hours. The VISN 10 Director immediately notified VACO senior management. Within a matter of days, VISN leadership began the process of assessing the extent and validity of the allegations.

B. Fact Finding Processes

A series of fact finding investigations and investigative bodies were activated in parallel and had specific issues to address.

At the local level, the Medical Center Director requested a fact finding review by the compliance and business integrity officer. They placed the subject dentist on administrative detail on July 29, 2010. The VISN 10 Director convened an AIB after consultation with VACO. Furthermore, an SPD team conducted a planned assessment of SPD procedures August 10–13, 2010.

Parallel to the AIB actions, VACO assembled a rapid response fact finding team for an onsite visit August 17–18. The goal of this visit was to rapidly assess the potential risk of patient exposure to bloodborne pathogens and disclosure options and to determine the

need for a CRB. Also, the VACO team wanted to ascertain the availability of the medical records that would be needed to effectuate a large-scale notification. On August 19, the team produced an Executive Summary Report and briefed the PDUSH and other VACO senior leadership. It concluded from its interviews with key dental clinic personnel that the subject dentist had placed patients at risk of potential exposure to bloodborne pathogens through the practice of re-using dental instruments without proper reprocessing. Its two key recommendations were (1) to immediately close the dental clinic, which was implemented the following day and (2) to proceed with a CRB to fully examine the potential risks to patients and the options for disclosure.

C. Dental Clinic Stand Down

From August 19, 2010, through September 9, 2010, the dental clinic temporarily suspended operations. The VISN and medical center supervised an extensive re-organization of the dental clinic. This included employee training, employee counseling, environment of care improvements, and updates in operating procedures. Dayton's Quality Manager notified The JC and the Commission on Accreditation of Rehabilitation Facilities that "On August 19, 2010, Dental [sic] services at the Dayton VAMC were temporarily suspended as a precautionary measure to evaluate infection control practices."

In mid-August, several personnel actions were initiated. The Chief of Dental Service and the Dental Administrative Officer were placed on administrative detail. Additionally, another dentist was relieved of direct patient care responsibilities pending review of patient care allegations. An Acting Chief of Dental Service was appointed and relocated onsite from another VISN facility.

On September 8, a VHA national SPD official arrived onsite to review the changes implemented in the SPD practices and SOPs. The next day, VHA's national dental infection control consultant made a site visit to assess the policies and to review procedures and revisions made pursuant to resumption of dental clinic operations. On September 10, the dental clinic re-opened and resumed operations, guided by "internal and external review of infection control practices, employee competencies, environment of care evaluations, and RME reprocessing."

D. Local Improvements

During the dental clinic closure, the local infection control practitioners and the Infection Control Consultant to the VACO Office of Dentistry conducted special education sessions on infection control. Dental employees reorganized the clinic's equipment and supplies, and physical repairs were completed.

A number of other infection control and safety issues were addressed and remediated as a result of VHA's investigations. The dental clinic was renovated to separate designated

areas for soiled and clean utility spaces. Other improvements included revised infection control practices related to operatory instrument sets and inventories, updated SOPs for RME, established a staff lounge, and installed negative pressure monitoring devices in the dental laboratory. The Infection Control Program also made significant improvements. These included establishing a dashboard and inspection checklist to track observations and infection control compliance, appointing a dentist as a member of the Infection Control Committee, conducting routine observations of dental staff to ensure proficiencies in handling RME, and placing bloodborne pathogens training into the Learning Management System for better tracking of compliance. All dental staff employees were retrained on infection control practices and the care of RME.

E. Conclusions Regarding VHA Responses

The response to the allegations was immediate and decisive and demonstrated a clear concern for patient safety. Key dental clinic staff were immediately placed on administrative detail. The subsequent decision to temporarily close the clinic allowed the medical center to conduct assessments and implement necessary changes. An Acting Chief of Dental Service and Acting Administrative Officer were rapidly identified and assigned. They coordinated the necessary staff training and the environmental improvements and created the process of rebuilding teamwork, trust, and a culture of safety.

Issue 3: Administrative Investigative Board

VA Handbook 0700 details specific procedures to implement the objectives and requirements of an AIB. The Handbook establishes operational requirements and procedures for convening, conducting, reporting, and reviewing administrative investigations. AIBs should attempt to review all available documents, records, and other information that are material to the issues of investigation, or that may reasonably lead to discovery or development of material evidence, except as specifically prohibited. On July 29, 2010, the VISN 10 Director charged the medical center to convene an AIB. The AIB was composed of five members: the Chair (an Associate COS/podiatrist), a dentist, an infection control nurse, an SPD technical advisor, and a human resources/labor relations technical advisor (regional counsel).

The AIB's expressed purpose was to investigate the facts and circumstances regarding allegations outlined in the July 2010 SOARS ROC documents received by the VISN 10 Director from the medical center Director. Initially, the AIB was tasked to determine:

- Whether there was a deviation in any dental standard of practice and/or improper handling, cleaning and/or disinfection of dental burs during fitting procedures by the dentist as alleged in the ROC and occurring in the dental clinic and/or dental laboratory at the medical center.

- Whether there was evidence to support that the dental technicians referenced in the ROC (or others) communicated their concerns to their supervisor or other management official(s) as indicated/implied in the ROC. If so, identify who knew what, and when, or if action was taken.

On August 16, 2010, the AIB was given an extension on its expected completion date. The scope of the AIB was expanded to allow for additional testimony as requested by the CRB on September 8 and to allow for the interview of a former Chief of Dental Service.

The AIB concluded its testimony on September 14. Its findings and conclusions were accepted by the VISN 10 Network Director on October 5. The document was forwarded to the medical center Director on October 25 and was received on October 27 for appropriate action. On that same day, the medical center Director authorized a new, separate AIB to examine the work environment within the dental clinic. The second AIB was instructed to complete its work by December 18.

During the course of the AIB authorized on July 29, a total of 31 witnesses were interviewed. They offered testimony sworn under oath and in the presence of a court reporter. Select witnesses were called back two or even three times in an effort to allow AIB members to ask follow-up or additional questions and to provide an opportunity to obtain fully comprehensive testimony. All witnesses were afforded the option of having personal counsel accompany them to their depositions.

Individuals deposed during the entirety of the AIB process included the subject dentist; the current COS, the Chief of Dental Service (on administrative detail), the Acting Chief of Dental Service, the former Chief of Dental Service, the Administrative Officer of Dental Service, three current staff dentists, a retired staff dentist, two dental residents, three former dental residents, seven current dental assistants, a former dental assistant, three dental laboratory technicians, two registered dental hygienists, the Safe Patient Handling Coordinator, and two SOARS team members.

After considering the totality of the record and the discovery process testimony, the AIB concluded that the subject dentist did, in fact, repeatedly violate infection control standards over a multiyear period. The AIB also concluded that testimony supported the subject dentist's violations as beginning in 1992, and without curtailment of this dentist's privileges by knowing superiors, there was potential exposure of patients to bloodborne pathogens.

Additional AIB conclusions pursuant to the subject dentist included awareness by a former Chief of Dental Service and the current Chief of Dental Service of violations of VA regulations on the limited use of government equipment (work computers) during the subject dentist's tour of duty.

A. Conclusions Regarding the AIB

The AIB was thorough in its fact finding process, deposing 31 witnesses, some witnesses being called back for a second or even third appearance before the AIB. Witnesses included current and former leadership in the Dental Service as well as current and former staff, support staff, and trainees.

Witness testimony may be gathered by various methods, including such instruments as written affidavits, verbatim transcripts, or recordings of live testimony. The AIB members spent a significant amount of time travelling onsite, preparing for the examination of witnesses, conducting in-person depositions, and reviewing/weighing the testimony generated. All witnesses were sworn under oath, and testimony was recorded in its entirety by a court reporter in attendance. Conducting the AIB was a time-consuming assignment and was carried out seriously and conscientiously by the AIB.

VA Handbook 0700 (Ch. 5, sec. b-1) states that witnesses do not have the "due process" rights that apply to, for example, adverse personnel actions. While the AIB did successfully generate a very thorough document, there were select instances of appearing to lead a witness or of warning a sworn witness of their duty "to tell the truth." While these instances occurred relatively sparingly and do not undermine the substantive merit of the AIB's conclusions, they were, nonetheless, unnecessary and otherwise detracted from the procedural tenor of the hearings.

In conducting the AIB, investigators sometimes discover significant information concerning matters that may merit some action or further inquiry but may be outside the scope of the assigned original investigation, as happened here. In such a circumstance, VA Handbook 0700 specifies that the AIB should provide such information promptly to the Convening Authority. Appropriately, this was done in the present case, and the scope of the investigation was expanded by the Convening Authority as documented.

VACO, upon receiving the AIB conclusions, conferred with the OGC, seeking their advisory role regarding disclosure deliberations. The OGC met with VHA on November 3, 2010, and was specifically asked to review the transcripts from the AIB, receiving access to them on November 5. The review was completed and submitted to VHA on November 16, and the OGC again met with VHA on November 17 to review their findings.

Issue 4: Clinical Review Board and Patient Notifications

The need to convene a CRB was anticipated early on during VHA's initial investigations into the allegations. Once it was clear that infection control violations had likely occurred, it was necessary to identify and outline the extent of the exposures, identify which patient populations were placed at risk, and analyze if and how those patients

should be informed of their potential exposure. An analysis of this scope would be complex and require an in-depth assessment of infectious disease transmission risk, patient safety, and ethical concerns. The initial CRB charge letter was sent September 1, 2010. Subsequently, the CRB convened four times over 4 months, refining and clarifying its assessment and disclosure recommendations throughout the process.

A. Initial CRB Deliberations

On August 30, 2010, VACO senior leadership held a meeting with subject matter experts in which the decision was made to convene the full CRB. The initial scope of the CRB as outlined in the charge letter was to: (1) conduct a clinical risk assessment, (2) identify the types of dental procedures at risk for disease transmission, and (3) make a recommendation as to whether a large-scale disclosure was indicated. If the CRB recommended a large-scale disclosure, it was to identify which patients should be notified, determine whether the disclosure should include deceased veterans' next of kin, and define the lookback timeframe. The CRB was also tasked to provide justification for its recommendations.

The CRB met on September 2, and issued its first report to the PDUSH on September 3. It conducted its review with members of the medical center, the VISN 10 leadership team, members of the site visit team, the VHA dental program office, and the VHA National Director for Infectious Diseases. Multiple documents for fact finding included the charge letter, the issue brief and update, AIB testimony of one dental clinic staff member, the AIB summary, the VACO August fact finding team report, a dental office review by the Office of Dentistry Consultant for Infection Control, OPHEH reviews, VACO's summary of the site visit to the medical center, a timeline of events, and universal precautions history and synopsis.

The CRB report identified three practices by the subject dentist that posed a potential risk for infection transmission. First, the subject dentist did not properly disinfect dentures when taking them to and from the dental laboratory. This practice breach potentially contaminated laboratory equipment and surfaces. Second, the subject dentist wore soiled gloves and gowns outside the dental operatory and the dental clinic and did not change gloves between patients, potentially contaminating common use areas. Third, the subject dentist used the same dental equipment (such as burs, handpieces, and hand instruments) on patients without cleaning or sterilizing the equipment between patients. These violations increased the risk of patient-to-patient disease transmission.

In forming its recommendations, the CRB considered only the risk of transmission of bloodborne viral infections (HIV, hepatitis B, and hepatitis C). To assess the risk to patients posed by these practices, the CRB also considered reviews of the medical and dental literature on the transmission of bloodborne viral infections in dental clinics. It was able to risk stratify the patients based on the invasiveness of the procedure a patient received in the clinic, including removable and fixed (crowns and bridges)

prosthodontics, restorative fillings, and invasive procedures such as extractions and periodontal scaling.

The initial September 3, 2010, CRB report recommended disclosure to all patients who had received invasive dental procedures and restorative care from the subject dentist since 1975. It recommended that testing for the bloodborne pathogens (HIV, hepatitis B, and hepatitis C) should be offered to these patients. The CRB also recommended that the AIB obtain further testimony from the dental staff to determine whether the subject dentist was reusing needles and/or drug vials and to clarify the subject dentist's infection control practices prior to 1990. The CRB advised that, with evidence that the subject dentist did not reuse needles or vials and practiced with a dental assistant who monitored the dentist's infection control practices prior to 1990, it could narrow its disclosure recommendations to include fewer patients and shorten the lookback timeframe.

Based on the September CRB report recommendations, the scope of the AIB was expanded. The AIB team revisited the medical center and obtained further testimony. However, senior VACO leadership reviewed the AIB testimony and had reservations regarding the credibility of key testimony relative to infection control breaches. Subsequently, it requested that the OGC review the testimony in order to identify which witnesses had direct first hand observation of breaches and the nature of these breaches.

After multiple senior level discussions, the DUSHOM re-convened the CRB to further clarify the risk assessment and disclosure issues. In his November 19 letter to the Chair of the CRB, the DUSHOM revised its scope. The CRB was to review the additional testimony indicating that the subject dentist did not reuse needles or vials and that he/she had a dental assistant prior to 1992. The CRB was also directed to review the AIB's supplemental testimony and reports. Using this additional information, it was to again outline a recommendation on disclosure, identify the specific patient population and dental procedures, and define the lookback timeframe.

The CRB met again on November 23 and December 2 to consider the new information provided by the subsequent AIB testimony, the analysis of the testimony by the OGC, and additional VACO and VISN 10 summary reports and findings. The meetings were conducted with members of the VISN 10 leadership team, members of the site visit team, the VHA dental program office, the AIB Chair, the VHA National Director for Infectious Diseases, and the Director of Public Health Surveillance and Research, and the Senior Medical Advisor of OPHEH. In all, 45 additional documents were reviewed.

B. The CRB's Final Recommendations

A key factor in determining the CRB's final recommendations was its conclusions regarding the extent and duration of the subject dentist's infection control infractions. In its review of the testimony, the CRB felt there was sufficient evidence to support a conclusion that major infection control breaches did not likely occur prior to 1992, when

the subject dentist was practicing with a dental assistant. It was also able to limit the size of the patient population placed at risk to those undergoing only more invasive procedures which might provide a portal of entry into the bloodstream. Such exposure could thus result in disease transmission from one patient to another.

The CRB submitted its revised set of recommendations to the PDUSH on December 3, 2010. By a six to one vote, it recommended that the original disclosure recommendations be narrowed to include only more invasive dental procedures and that the lookback be limited to patients treated from January 1, 1992, onward. It identified specific invasive dental procedures to include: extractions and periodontal scaling, some restorative fillings, and fixed prosthodontics (crowns and bridges). The dissenting voter felt there was insufficient clinical or scientific proof that hepatitis C or HIV have been transmitted in dental settings. The dissenter also noted that "the risk of patient-to-patient transmission of bloodborne pathogens from occult blood in saliva cannot be determined and is biologically plausible."

The CRB further recommended that the disclosure "should emphasize that the risk of a bloodborne infection to patients is low." It also recommended that each patient be offered serologic testing for hepatitis B, hepatitis C, and HIV. This testing would be part of an investigation for the purpose of identifying whether exposure in a dental clinic is associated with transmission of bloodborne pathogens, as there is little scientific evidence of known transmission. OPHEH would conduct the investigation in collaboration with the medical center.

On reviewing the final CRB recommendations, VACO senior leadership required further clarification regarding the specifics of its decision-making process and justification of its conclusions. In a letter dated December 14, 2010, the PDUSH requested that the CRB specifically address additional issues, including: how it chose the 1992 date, whether other dates were considered, and whether it considered the availability of electronic versus paper records; what was its estimate of risk to patients and was it quantified; what information should be disclosed and to provide evidence supporting disclosed information; did it consider input from the OGC's evaluation of the credibility of the witness' testimony; did it consider the testimony of the dental residents; and, why did it defer the issue of employee risk assessment and disclosure to the local medical center and local public health officials rather than VISN leadership and OPHEH?

The CRB met for a fourth and final time on December 17, 2010, to address the questions brought by the PDUSH regarding its decision-making process and risk assessments. It submitted a written response to the PDUSH on December 17, 2010. The Chair of the CRB then met with senior VACO staff to review and discuss its written response. On January 4, 2011, VACO senior management made the decision to proceed with a disclosure as recommended by the CRB's final report.

The patient selection for notification was based on those patients who received invasive procedures performed by the subject dentist from January 1, 1992, to July 28, 2010. The invasive procedures were identified by Current Procedural Terminology (CPT) codes as defined by the criteria set by the CRB in its final report. An algorithm and process were developed that indentified 535 patients who met the CRB criteria for disclosure. At the time of this report, chart reviews of another 150 patients were pending, which may indentify a small number of additional patients who should be notified.

C. Conclusions Regarding the CRB

We found that the CRB acted in good faith to address the potential risks to VA patients. The CRB incorporated an extensive amount of data from which to base its decisions. All recommendations were carefully considered, with input from a solid counsel of national subject area experts. The fact that its deliberations extended over 4 months is a testament to the daunting task of integrating sometimes conflicting data to formulate recommendations that would impact such a large patient population in an area in which there are not precise guidelines.

The CRB was thorough in implementing its initial and subsequent charges and directives. Its recommendations appropriately followed VHA's notification for disclosure policy. The changing nature of its reports and recommendations reflect the complexity of the underlying issues surrounding infectious diseases, the ethics of disclosure, and public health risk assessments. In formulating its recommendations, the CRB insisted on transparency and fully considered any potential risk of harm to patients.

Issue 5: Staffing and Workplace Environment

Our oversight review included evaluation of selected aspects of the daily functioning of the dental clinic and its management oversight. These review areas included staffing levels, work environment, and senior management oversight.

A. Staffing and VHA Response

The dental clinic is staffed by dentists, dental assistants, and dental hygienists. The clinic also has an accredited dental residency program. A VHA study evaluated the impact of dental staffing ratios on staff dentists' productivity. The VHA study recommends 1.5 dental assistants per dentist as optimal in clinics with residency training. In addition, the VA Assistant Under Secretary for Health for Dentistry and the current Acting Chief of Dental Service informed us that a ratio of 1.5 is optimal in clinics with dental residents. A review of the dental clinic staffing levels revealed they were below organizational approved FTE levels and also below the cited optimal ratio of 1.5. Efforts by the current Chief of Dental Service to recruit and fill vacant dental assistant positions were not fully supported by the medical center with necessary funding even though the Chief of Dental Service cited an impact on safety and infection control issues. This

occurred during a period of time when the medical center was under a facility-wide "Controlled Hiring Plan" to reduce cost and operate within funding levels. Limited dental assistant positions were approved for hiring coupled with the expectation that the number of dental residents would be reduced to address the impact on safety.

B. Conclusions Regarding Staffing and VHA Response

We found that the staffing levels at the dental clinic were persistently below their organizational approved FTE levels and the level recommended by VHA for optimal performance. Optimal staffing may have decreased the likelihood that deviations from approved infection control practices would occur. Medical center administration did not fully support efforts to staff the dental clinic at these optimal ratios.

C. Work Environment

During our dental clinic staff interviews, employees discussed concerns as to work climate and morale. We heard multiple concerns regarding ongoing staff shortages, favoritism, and demeaning comments to staff. We were told of staff altercations that resulted in formal police investigations. We found indications that interpersonal staff relations were strained, which negatively impacted the dental clinic.

Recommendations

Recommendation 1: We recommended that the VISN 10 Director review the findings related to the Dayton Dental Clinic, to include staffing issues, and take whatever action deemed appropriate.

Recommendation 2: We recommended that the VISN 10 Director ensure that the Dayton Medical Center Director requires the Dental Service to comply with the relevant infection control policies.

Comments

The VISN and Medical Center Directors agreed with the findings and recommendations and provided an acceptable action plan (see Appendixes A and B, pages 20–22, for the Directors' comments). 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: March 28, 2011

From: Director, VA Healthcare System of Ohio (10N10)

Subject: **Healthcare Inspection – Oversight Review of Dental Clinic Issues, Dayton VA Medical Center, Dayton, Ohio**

To: Assistant Inspector General, Office of Healthcare Inspections

Thru: Director, Management Review Service (10B5)

1. The subject report, "Healthcare Inspection—Oversight Review of the Dental Clinic Issues, Dayton VA Medical Center, Dayton, Ohio" has been carefully reviewed by VISN l0 leadership. The report is thorough and reflects the facts as we know them to be. I appreciate the extensive review and work of the OIG team and their professional interactions throughout the review.

2. VISN 10 concurs with the report findings and two recommendations.

(*original signed by*:)
Jack G. Hetrick, FACHE
Director, VA Healthcare System of Ohio (10N10)

Appendix B

Medical Center Director Comments

Department of Veterans Affairs **Memorandum**

Date: March 28, 2011

From: Director, Dayton VA Medical Center (552/00)

Subject: **Healthcare Inspection – Oversight Review of Dental Clinic Issues, Dayton VA Medical Center, Dayton, Ohio**

To: Director, VA Healthcare System of Ohio (10N10)

I have reviewed the "Healthcare Inspection – Oversight Review of Dental Clinic Issues, Dayton VA Medical Center, Dayton, Ohio", report and concur with the two recommendations. A plan to finalize corrective actions is underway.

(*original signed by*:)
William Montague, FACHE
Director, Dayton VA Medical Center (552/00)

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 10 Director review the findings related to the Dayton Dental Clinic, to include staffing issues, and take whatever action deemed appropriate.

Concur **Target Completion Date:** June 30, 2011

Medical Center's Response:

Complete administrative actions against parties responsible for appropriate infection control practices and oversight. Modify Dental Service organizational structure and assigned FTE levels to enhance clinical operations oversight and improve dental assistant staffing ratios. Implement actions resulting from Veterans Health Administration (VHA) National Center of Organizational Development (NCOD) Dental Service Workforce Reassessment to include the facilitation of the team building CREW (Civility, Respect, and Engagement in the Workplace) initiative. Personnel administrative actions and staffing level adjustments are being addressed and close to resolution.

Recommendation 2. We recommended that the VISN 10 Director ensure that the Dayton Medical Center Director requires the Dental Service to comply with the relevant infection control policies.

Concur **Target Completion Date:** May 30, 2011

Medical Center's Response:

All Dental Service mandatory infection control training will be entered and tracked for compliance in the Dayton VAMC Learning Management System (LMS). Periodic random audits of Infection control training compliance, observations (e.g., hand hygiene, wearing PPE, etc.), and staff knowledge infection control checklist will be documented in the Dental Dashboard.

Appendix C

OIG Contact and Staff Acknowledgments

OIG Contact	For more information about this report, please contact the Office of Inspector General at (202) 461-4720
Acknowledgments	George B. Wesley, MD Monika Gottlieb, MD Kathleen Shimoda, RN Toni Woodard Simonette Reyes, RN Thomas Jamieson, MD, JD Maureen Reagan, RN, JD

Appendix D

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