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STATEMENT OF
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OFFICE OF INSPECTOR GENERAL
U.S. DEPARTMENT OF VETERANS AFFAIRS
AT A FIELD HEARING BEFORE THE COMMITTEE ON VETERANS' AFFAIRS
UNITED STATES SENATE IN DAYTON, OHIO
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Senator Brown and other Members of the Committee, thank you for the opportunity to testify on the results of our review involving the Dental Clinic at the VA Medical Center (VAMC), in Dayton, Ohio. 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 (OIG) reviewed infection control issues at the Dental Clinic at the Dayton VAMC and on April 25, 2011, we issued our report, Healthcare Inspection - Oversight Review of Dental Clinic Issues, Dayton VA Medical Center, Dayton, Ohio. We concluded that 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.

BACKGROUND
Dental Clinic – The Dayton Dental Clinic performs a full spectrum of dental and oral surgical procedures. The dental specialties recognized by the American Dental Association (ADA) practiced at the medical center include general dentistry, oral and maxillofacial surgery, oral and maxillofacial radiology, periodontics, and prosthodontics. In July 2010, the dental clinic had seven dentists and an oral surgeon, two dental hygienists, seven dental assistants (two expanded function, five non-expanded function), and three dental laboratory technicians. In fiscal year (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 VAMC Chief of Staff. 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). At the time of the review, there were three residents, although it is authorized four. The last accreditation review occurred in September 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.

VA Oversight – The Veterans Health Administration (VHA) operates a program of proactive inspections through its System-Wide Ongoing Assessment and Review Strategy (SOARS) program. 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.

During the week of July 20–23, 2010, a SOARS team inspected the Dayton VAMC. On the morning of July 21, 2010, during the course of this inspection, two dental clinic employees approached a team member. The employees articulated allegations about aspects of a staff dentist's practice that pertained to this dentist's handling of dental burs and noncompliance with dental infection control guidelines. These improprieties allegedly were ongoing.

The allegations, if true, would have represented significant breaches of both medical center and 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.

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 Joint Commission (The JC) and the Commission on Accreditation of Rehabilitation Facilities that as of August 19, 2010, as a precautionary measure in order to evaluate infection control practices, dental services at the Dayton VAMC were temporarily suspended.

The allegations set in motion no less than five VHA investigations culminating in the notification, on February 8, 2011, to 535 patients of the medical center, that infection control practices in the Dayton Dental Clinic were not always followed.

OIG REVIEW

As a result of the requests from Congress, the OIG began a review of infection control issues at the Dayton Dental Clinic. Our review encompassed a review of VHA actions in response to the allegations as well as an evaluation of selected aspects of the daily functioning of the dental clinic and its management oversight.

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, Centers for Disease Control and Prevention (CDC), The JC, and the Occupational Safety and Health Administration (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.

We visited the VAMC from December 14–16, 2010. We interviewed relevant clinical and administrative staff at all levels of VHA, extending to the Under Secretary for Health, as well as

medical consultants from the Prevention and Response Branch of the CDC, VA's Office of Public Health and Environmental Hazards (OPHEH), and attorneys from VA's Office of General Counsel.

We reviewed already completed VHA investigations as well as Issue Briefs; VHA Clinical Review Board (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 e-mail communications. We also reviewed VHA directives, CDC guidelines, OSHA's Bloodborne Pathogens Rule, and ADA guidelines.

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 VA Central Office (VACO) levels. Additionally, VHA convened an Administrative Investigative Board (AIB) and Clinical Review Board (CRB).

Administrative Investigative Board

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 Chief of Staff/Podiatrist), a dentist; an infection control nurse; a Supply, Processing and Distribution 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 Report of Contact (ROC) documents received by the VISN 10 Director from the VAMC 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.

The AIB concluded its testimony on September 14, 2010, and its findings and conclusions were accepted by the VISN 10 Network Director on October 5. During the course of the AIB, 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.

After considering the totality of the record and the depositions, 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.

Clinical Review Board

VHA Directive 2008-002, Disclosure of Adverse Events to Patients (January 18, 2008), provides

guidance for disclosure of adverse events related to clinical care to patients or to their personal representatives. This directive 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."

We found that the need to convene a CRB was anticipated early on during VHA's initial investigations into the allegations. 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:

• Conduct a clinical risk assessment.
• Identify the types of dental procedures at risk for disease transmission.
• 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 look back timeframe. The CRB was also tasked to provide justification for its recommendations.

The CRB met on September 2, 2010, and issued its first report to the Principal Deputy Under Secretary for Health (PDUSH) on September 3, 2010. It conducted its review with VAMC members, 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, a 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 a 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 on patients without cleaning or sterilizing the equipment between patients.

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 prosthodontics (crowns and bridges), restorative fillings, and invasive procedures such as extractions and periodontal scaling.

Initial CRB Recommendations

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 look back timeframe.

Second CRB Review

After multiple senior level discussions, the CRB was re-convened to further clarify risk assessment and disclosure issues. The CRB was to review additional AIB 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 look back timeframe.

The CRB met again on November 23, 2010, and December 2, 2010, to consider the new information provided by the subsequent AIB testimony, the analysis of the testimony by the Office of General Counsel, 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, the Director of Public Health Surveillance and Research, and the Senior Medical Advisor of OPHEH.

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 that 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 look back 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 has 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 VAMC.

CRB Recommendations and Final CRB Review

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 address issues including the following:

- 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?
- 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 PDUSH's questions 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. An algorithm and process were developed that identified 535 patients who met the CRB criteria for disclosure.

OIG Conclusions

We concluded that 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.

This was based on many facts including:

• A June 29, 2010, e-mail, from a clinic dentist to the Chief of Dental Services reporting violations of basic infection control protocols by one specific dentist.
• An August 16, 2010, memorandum for the record in which the Dental Service Chief indicated that he witnessed violations of basic infection control protocols by the same dentist on several occasions.
• Multiple dental clinic employees telling us they had personally observed various infection control policy violations by the same dentist. Violations included failure 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 not properly clean and disinfect the operatory. Individuals told us that unsterilized instruments were reused on more than one patient.

We concluded that the AIB was thorough in its fact finding process. It deposed 31 witnesses, some witnesses were called back for a second and 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. Testimony was gathered by various methods including such instruments as written affidavits, verbatim
transcripts, or recordings of live testimony. Conducting the AIB was a time-consuming assignment and was carried out seriously and conscientiously by the AIB.

We also concluded 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. Its recommendations appropriately followed VHA's notification for disclosure policy.

With regards to staffing and workplace environment issues, 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. Senior leadership and committees at the VAMC did not fully support efforts to staff the dental clinic at these optimal ratios.

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, and 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.

OIG Recommendations
The OIG made two recommendations:

• The VISN Director review the findings related to the Dayton Dental Clinic, to include staffing issues, and take whatever action deemed appropriate.
• The VISN Director ensure that the Dayton VAMC Director requires the Dental Service to comply with the relevant infection control policies.

The VISN Director and Medical Center Director agreed with the findings and recommendations and provided acceptable action plans. We will follow up on the planned actions until they are completed.

CONCLUSION

Established infection control practices and policies were not properly or consistently adhered to at the Dayton VAMC Dental Clinic. There was evidence that staff assigned to the Dental Clinic observed these poor infection control practices over an extended time period. While Dental Clinic management was notified of these unacceptable practices, it was not until a VACO review body was at the Dayton VAMC conducting a routine inspection that definitive actions began. These practices constitute unacceptable breaches of patient safety precautions and a violation of the OSHA Bloodborne Pathogens Standard—standards that veterans have a right to expect are followed with care and diligence.

Senator Brown and other Members, this concludes our statement and we would happy to answer any questions that you may.