



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

Office of Healthcare Inspections

Report No. 17-00712-366

Healthcare Inspection

Review of Improper Dental Infection Control Practices and Administrative Action

**Tomah VA Medical Center
Tomah, Wisconsin**

September 7, 2017

Washington, DC 20420

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Table of Contents

	Page
Executive Summary	i
Purpose	1
Background	1
Scope and Methodology	4
Inspection Results	6
Issue 1. Failure to Identify Earlier Improper Infection Control Practices.....	6
Issue 2. Actions Taken by Veterans Health Administration After Becoming Aware of the Issue.....	11
Conclusions	16
Recommendations	18
Appendixes	
A. Look Back Bloodborne Pathogen Protocol	19
B. Prior Office of Inspector General Reports.....	20
C. Veterans Integrated Service Network Director Comments	21
D. Facility Director Comments	23
E. Office of Inspector General Contact and Staff Acknowledgments	26
F. Report Distribution	27

Executive Summary

The VA Office of Inspector General conducted a healthcare inspection at the request of Senators Tammy Baldwin, Chuck Grassley, and Ron Johnson, and Representatives Ron Kind and Timothy Walz to assess improper dental infection control practices and administrative action taken by Veterans Health Administration (VHA) at the Tomah VA Medical Center, (facility) Tomah, WI. These practices potentially exposed veterans to bloodborne pathogens (BBP), including human immunodeficiency virus and hepatitis B and C viruses.¹

Specifically, the objectives were to:

- Identify the factors that contributed to facility leadership not being aware of a dentist's improper infection control practices.
- Determine whether VHA took appropriate and timely actions after facility leadership learned of patients' potential exposure to BBP from a dentist's reuse of unsterile burs.

Failure to Identify Earlier Improper Infection Control Practices

Infection control and prevention guidelines are practices used in health care to prevent the transmission of BBP to patients and staff.² In October 2013, VA published, *The Infection Control Standards for VA Dental Clinics* that incorporated specific guidelines and standards from the American Dental Association, Occupational Safety and Health Administration, and the Centers for Disease Control and Prevention, including the use of reusable medical equipment (RME) for dental patients.³

Dentist A began seeing patients at the facility in October 2015. In October 2016, Dental Assistant A⁴ reported to Dentist B, who was temporarily managing clinic activities in the absence of the Acting Chief, Dental Services, that Dentist A used a non-VA unsterile bur during a dental procedure on a patient (incident).⁵ Dentist B reported the incident to the Chief of Staff (COS) office and Human Resources.

VHA policy states that if burs purchased by the facility are unsterile, facility staff must sterilize the burs according to the manufacturer's instructions prior to use. VHA policy further states that any bur used intra-orally must be disposed of after single patient

¹ Bloodborne pathogens are infectious microorganisms in human blood that can cause disease in humans. <https://www.osha.gov/SLTC/bloodbornepathogens>. Accessed January 25, 2017.

² United States Department of Labor, Occupational Safety and Health Administration. *Bloodborne Pathogens and Needlestick Prevention*. <https://www.osha.gov/SLTC/bloodbornepathogens>. Accessed January 25, 2017.

³ VA Office of Dentistry. *Infection Control Standards for VA Dental Clinics*, October 21, 2013. <http://vaww.infoshare.va.gov/sites/dental/default.aspx>. Accessed January 20, 2017.

⁴ Dental Assistant A was covering for Dental Assistant B who was Dentist A's regularly assigned dental assistant.

⁵ A dental bur is a type of drill bit used as a cutting tool to make an opening in a tooth or bone. During certain dental procedures, the dentist may need to file down adjoining teeth using a dental bur.

use.⁶ According to the October 2013 *Infection Control Standards in VA Dental Clinics*, guidelines for non-VA RME include the following:

*Any RME used in the VA facility needs first to be approved for use. Local facilities will have a process, which involves approval from SPS [Sterile Processing Services], Logistics, Biomedical Engineering, and perhaps other departments. It is unacceptable to bring RME from outside VA and use on patients, even if the outside RME is brought in sterile packaging. Similarly, demonstration or trial RME from a vendor needs to go through the approval process prior to use.*⁷

When facility leadership interviewed Dentist A in October 2016, Dentist A acknowledged he had used a non-VA unsterile bur on the day in question as he had with prior patients. Dentist A indicated that he disinfected and cleaned his non-VA unsterile bur by spraying it with Virex™ and leaving it wet for 5 to 7 minutes;⁸ he did not send his unsterile burs to Sterile Processing Services (SPS) for sterilization. Dentist A believed this was common practice in the private sector.

We did not find evidence that facility leaders were aware that Dentist A's infection control practices related to the use of non-VA unsterile burs were inconsistent with VHA policy until Dentist B notified the COS of the reported use of a non-VA unsterile bur in October 2016. Facility leaders later determined that between October 2015 and October 2016, Dentist A potentially exposed 592 patients to BBP at the facility Dental Clinic due to improper infection control practices.

We identified two factors that contributed to facility leaders not being aware sooner of Dentist A's improper infection control practices. These factors included: (1) failure of staff, despite safety and infection-control training, to report Dentist A's breach of infection control practices, including the use of non-VA unsterile burs during crown and/or bridge procedures on prior patients, and (2) advance notification and other issues associated with Dental Clinic inspections. Other factors may have been contributory, but both Dentist A and his supervisor, the former Chief, Dental Services, left VA and refused to be interviewed by the OIG.

Failure to Consistently Report

Between August 2015 and September 2016, dental staff were notified or received training through various mechanisms regarding patient safety and infection control. Despite the training, dental staff inconsistently reported noncompliant infection control practices that they observed.

⁶ VA Office of Dentistry. *Infection Control Standards for VA Dental Clinics*, October 21, 2013. <http://vaww.infoshare.va.gov/sites/dental/default.aspx>. Accessed January 20, 2017.

⁷ Ibid.

⁸ VIREX™II/256 is a disinfectant, cleaner, and deodorizer used for general cleaning and disinfection on hard non-porous environmental surfaces. The product is not to be used for end of use sterilization or high level disinfection on any surface or instrument that is (1) introduced directly into the human body, either into or in contact with the blood stream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body https://www3.epa.gov/pesticides/chem_search/ppls/070627-00024-20030403.pdf. Accessed January 20, 2017.

We identified one staff member—Dental Assistant B—who, prior to the October 2016 reported incident, saw Dentist A reuse unsterile, non-VA burs during crown and/or bridge procedures on patients. Dental Assistant B first noticed Dentist A using non-VA unsterile burs in December 2015 or January 2016 and stated this information was reported to the former lead dental hygienist (now retired). The former lead dental hygienist said that he/she was not in Dental Assistant B's supervisory chain and informed Dental Assistant B to report the use of non-VA unsterile burs to the former Chief, Dental Services (now retired). Dental Assistant B did not report Dentist A to leadership, claiming fear of reprisal and lack of appropriate action by leadership after prior reports of less serious alleged breaches of infection control practices by Dentist A.

Other dental staff indicated they were aware that Dentist A was not always washing his hands or wearing appropriate personal protective equipment (PPE), including gowns, as required by VHA and facility policy. Dental staff also reported to us that Dentist A appeared to be occasionally sleeping at his desk. We found no documentation that facility leadership counseled Dentist A for poor hand hygiene, the noncompliant use of PPE, sleeping at his desk, or the use of non-VA unsterile burs.

Dental Clinic Inspections

We found four opportunities between October 2015 and October 2016 when Dental Clinic inspections conducted by different groups (Dental Clinic staff, SPS staff, facility staff during Environment of Care rounds, and Veterans Integrated Service Network (VISN) 12 staff) might have revealed noncompliance with VHA and facility directives, handbooks, and policies. We identified two processes that may have influenced practices designed to reduce the risk of error in the Dental Clinic. First, dentists stated they usually worked in their own operatories with their regularly assigned dental assistant. Second, each dental assistant checked his/her own operatory for cleanliness and inspection of sterile items stored in the drawers. We found these processes did not ensure ongoing monitoring was occurring and effective within the Dental Clinic. A rotation of dental assistant assignments may have enhanced compliance with infection control standards. Had dental assistants checked operatory drawers other than their own, the rack of unsterile burs may have been identified as outside normal practice prior to the discovery of the improper infection control practices.

SPS staff made rounds to inspect the integrity of sterile packages in the Dental Clinic clean utility room; however, they did not inspect the individual dental operatory drawers. The facility team did not inspect all drawers within the operatories during Dental Clinic Environment of Care rounds. Prior to the August 2016 VISN 12 Lead Dentist inspection, the former Chief, Dental Services (now retired) informed the dental staff of the upcoming inspection and gave staff instructions to remove their personal items from operatory drawers.

Actions Taken by VHA After Becoming Aware of the Issue

We determined that the facility, VISN 12, and VHA took appropriate follow-up actions and responded timely to patients' potential exposure to BBP. In mid-October 2016, Dental Assistant A witnessed Dentist A using a non-VA unsterile bur on a patient having a single crown procedure (incident). Soon thereafter, Dental Assistant A reported the incident to Dentist B, who was temporarily managing clinic activities in the absence of the Acting Chief, Dental Services. Dentist B initiated the removal of the non-VA unsterile bur and bur rack from the operatory and reported the incident to the COS office and Human Resources. Dentist A called in sick on October 20, 2016.

On October 21, 2016, the Associate Chief of Staff for Medicine inspected the Dental Clinic and interviewed Dentist A. Dentist A acknowledged that he used a non-VA unsterile bur and that he did not send his unsterile burs to SPS for sterilization but sprayed used burs with a disinfectant solution in his operatory.

Facility leaders initiated actions consistent with VHA policy. They briefed VISN 12 leadership and appointed the VISN 12 Lead Dentist to conduct a fact-finding inquiry.⁹ The Associate Chief of Staff for Medicine directed Dentist A to leave the clinic and disabled his patient care computer access.

On October 24, 2016, the Acting Facility Director issued a temporary reassignment memorandum to Dentist A and assigned Dentist A to administrative duties pending further review. On November 2, 2016, the VISN 12 Lead Dentist submitted a summary of his fact-finding to the facility. On November 3, 2016, the Acting Facility Director summarily suspended Dentist A's clinical privileges.¹⁰¹¹ Dentist A submitted a letter of resignation approximately one month later.

The Deputy Under Secretary for Health for Operations and Management convened a clinical episode response team (CERT). The CERT identified steps to be taken in response to the "potential exposure of patients to BBP" to include identifying, testing, and treating patients. The CERT reviewed the fact-finding provided by the VISN 12 Lead Dentist and assisted with coordination of resources in the development of a Dental Look Back Clinic.

Facility leaders made a large-scale disclosure to the 592 patients treated by Dentist A between October 2015 and October 2016.¹² Facility leaders also made public announcements and sent letters to notify all 592 patients of their potential exposure to BBP. In addition, clinicians attempted to contact the 57 patients who underwent

⁹ VHA Handbook 1004.08, *Disclosure of Adverse Events to Patients*, October 2, 2012.

¹⁰ Clinical privileges are summarily suspended when the failure to take action may result in an imminent danger to the health of any individual.

¹¹ VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012.

¹² A large-scale disclosure is a formal process by which VHA officials assist with assessment and coordination of the notification to multiple patients. The coordination process is designed to ensure that all required disclosures are based on a thorough investigation of the facts, a careful assessment of the risks involved, and the development of a plan for the best way to perform the disclosure.

preparation or completion of a crown and/or bridge procedure (a subset of the 592 patients) by telephone.

VHA defines a look-back as an organized process for identifying patients and/or staff with exposure to potential risk incurred through past clinical activities in order to notify them and offer care and recourse as appropriate.¹³ Facility managers established a Dental Look Back Clinic to counsel the identified 592 patients and obtain clinical consent for BBP testing. The Clinic initially operated from November 30 through December 22, 2016.

The Office of Public Health Surveillance and Research Department assisted in identifying an appropriate laboratory protocol to follow patients potentially exposed to BBP. Due to the large volume of patients and the limited testing provided at the facility, a coordinated effort took place to obtain and process specimens between the facility laboratory and other VISN 12 facilities (Clement J. Zablocki Veterans Affairs Medical Center, Milwaukee, WI, and Edward Hines Jr. VA Hospital, Hines, IL).

The Chief of Infectious Disease at the William S. Middleton Memorial Veterans Hospital, Madison, WI, who was the Lead Infectious Disease Physician for the facility, provided clinical consultation and follow-up for patients with BBP positive results.

The Traveling Veteran Coordinator assisted the Dental Look Back Clinic to coordinate laboratory tests for patients who declined services within VA or at the facility. If positive BBP test results were confirmed, the VHA Public Health Reference Laboratory provided additional testing if indicated per protocol. In addition, VA Central Office (Palo Alto Office of Public Health), which is part of VHA Quality, Safety, and Value, reviewed the list of 592 patients to identify pre-existing infections due to BBP.

The VISN 12 Nurse Triage Call Center was available 24 hours a day, 7 days a week, for information to assist potentially exposed patients. As of January 11, 2017, 138 patients had not responded to letters or phone calls from the Dental Look Back Clinic. Facility staff sent certified letters to the identified 138 patients notifying them of the reopened Dental Look Back Clinic from February 1–7, 2017.

As of May 23, 2017, 97 of the original 592 patients identified by the facility had not responded to initial or subsequent letters, or phone calls. Of the 97 patients, we found 9 patients had expired due to circumstances unrelated to their potential exposure to BBP. We reviewed the electronic health records (EHR) of the remaining 88 patients and did not find evidence of patients' responses to notification or flags in 7 EHRs. We informed the facility and subsequently confirmed all EHRs of patients who had not previously responded had been electronically flagged to alert primary care physicians to discuss follow-up.

¹³ VHA Handbook 1004.08, *Disclosure of Adverse Events to Patients*, October 2, 2012.

Although Dentist A refused to speak to us after he resigned, he submitted a letter to us through his attorney.¹⁴ The former Chief, Dental Services, who had retired in September 2016, also refused to speak to us. The inability to speak with Dentist A or the former Chief, Dental Services, limited our ability to assess supervision or understand the Chief's awareness of Dentist A's improper infection control practices.

We made one recommendation to the VISN 12 Director and four recommendations to the Facility Director.

We recommended that the VISN 12 Director improve oversight of the Dental Clinic by performing unannounced inspections that include opportunities to interview staff privately regarding any concerns.

We recommended that the Facility Director:

- Improve oversight of the Dental Clinic by conducting unannounced, detailed inspections to ensure adherence to VHA and facility infection control standards, patient safety guidelines, and other pertinent dental policies and procedures.
- Conduct training on when it is appropriate to report issues relating to the quality of healthcare or patient safety issues and the various options on where to report.
- Consult with the Office of Human Resources and the Office of General Counsel to determine the appropriate administrative action, if any, for staff who failed to report the reuse of unsterile burs on patients.
- Ensure Environment of Care rounds are scheduled when all areas of the Dental Clinic are available to be inspected.

¹⁴ The letter provided background information on Dentist A, as well as his perspective of the issues raised in our review. The letter also contained allegations related to the cleaning process of tools used in the facility's dental laboratory (the location where dentures and other dental appliances are adjusted). We considered the information contained in the letter in making our findings and conclusions. Allegations about the dental laboratory were referred to OIG hotline division.

Comments

The VISN and Facility Directors concurred with our recommendations and provided acceptable action plans. (See Appendixes C and D, pages 21–25, for the Directors' comments.) For Recommendations 2, 3, 4, and 5 with target dates of completion in July and August 2017, we will follow up on the recently implemented actions to ensure they have been effective and sustained. We will follow up on the planned actions for the remaining recommendation until completed.



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Purpose

The VA Office of Inspector General (OIG) conducted a healthcare inspection at the request of Senators Tammy Baldwin, Chuck Grassley, and Ron Johnson, and Representatives Ron Kind and Timothy Walz, to assess improper dental infection control practices and administrative actions taken by the Veterans Health Administration (VHA) at the Tomah VA Medical Center (facility), Tomah, WI. These practices potentially exposed veterans to bloodborne pathogens (BBP),¹⁵ including human immunodeficiency virus (HIV) and hepatitis B and C viruses.

Background

The facility is part of Veterans Integrated Service Network (VISN) 12 and provides primary care, dental services, mental health services, and nursing home care. Community based outpatient clinics located in La Crosse, Owen, Wausau, and Wisconsin Rapids, WI, provide outpatient care services. The facility Dental Clinic provides services that include cleaning and x-rays; restorative procedures such as fillings, crowns, and bridges; dentures; and tooth extractions.

OIG Notification

In November 2016, facility police notified the VA OIG Office of Investigations that a facility dentist had violated VA policy by using personal dental equipment. An OIG Special Agent researched pertinent facts and ultimately submitted all information collected to OIG Hotline for the Office of Healthcare Inspections (OHI) to review.

Specific Dental Instruments and Procedures

A dental bur is a type of drill bit used as a cutting tool to make an opening in a tooth or bone. A crown procedure is the placement of an artificial cap or cover over a missing or decayed tooth. A bridge procedure is used to cover a space if the patient is missing one or more teeth; the bridge is fixed with cement to natural teeth or implants. In order to prepare the patient for a crown or a bridge, the dentist may need to file down adjoining teeth using a dental bur.

Procurement of Dental Instruments

Prior to October 2016, VHA required facilities to establish Commodity Standards Committees.^{16,17} Currently, VHA requires facilities to establish a Clinical Product Review

¹⁵ BBP are infectious microorganisms in human blood that can cause disease in humans.

<https://www.osha.gov/SLTC/bloodbornepathogens/>. Accessed January 25, 2017. For this report, BBP specifically refers to HIV and hepatitis B and C viruses.

¹⁶ VHA Handbook 1761.02, *VHA Inventory Management*. October 20, 2009. This Handbook was rescinded and replaced by VHA Handbook 1761(1), *Supply Chain Inventory Management* on October 25, 2016.

¹⁷ VHA Handbook 1761(1), *Supply Chain Inventory Management*. October 24, 2016.

Committee that is responsible for reviewing and approving all new clinical items and ensuring commodity standardization activities are maintained. In June 2015, the facility established a Clinical Product Review Committee that reviews requests by staff or services for new medical supplies and reusable medical equipment (RME).¹⁸ Dental staff described the facility's process for requesting the purchase of new dental instruments, including burs, as follows:

- Assigned dental assistant submits the request for a new item.
- Chief, Dental Services, reviews the request and approves/disapproves.
- The Clinical Product Review Committee receives approved requests.
- Sterile Processing Services (SPS) staff identify any special handling and processing required for new dental instruments or supplies.
- Items are not put into service until the manufacturer's instructions or standard operating procedures are available for staff to reference.

The Acting Chief, Dental Services, stated the facility obtained burs from a contracted supplier and the service had no budget limitation on burs.

Infection Control

Infection control and prevention guidelines are practices used in health care to prevent the transmission of BBP such as HIV and hepatitis B and C viruses to patients and staff.¹⁹ In October 2013, VA published, *The Infection Control Standards for VA Dental Clinics*,²⁰ which incorporated guidelines and standards from the American Dental Association, Occupational Safety and Health Administration, and the Centers for Disease Control and Prevention. The Joint Commission (JC) summarizes the standards for infection control and prevention as a collaborative effort between departments and staff. They further state that everyone who works in the hospital should have infection prevention and control information available to them and should hold each other accountable.²¹ Infection control standards and guidelines include the use and availability of appropriate personal protective equipment (PPE), hand hygiene, and appropriate cleaning, disinfection, sterilization, storage, and use of dental instruments.

PPE and Hand Hygiene

PPE used in dental health care settings includes gloves, surgical masks, protective eyewear, face shields, and protective clothing (for example gowns and jackets). Dental

¹⁸ MCM LS-90-21. *Clinical Facility Product Review Committee*. June 15, 2015.

¹⁹ United States Department of Labor, Occupational Safety and Health Administration. *Bloodborne Pathogens and Needlestick Prevention*. <https://www.osha.gov/SLTC/bloodbornepathogens>. Accessed January 25, 2017.

²⁰ VA Office of Dentistry. *Infection Control Standards for VA Dental Clinics*, October 21, 2013. <http://vawww.infoshare.va.gov/sites/dental/default.aspx>. Accessed January 20, 2017.

²¹ The Joint Commission. E Edition -Accreditation Requirements. *Infection Prevention and Control*. July 1, 2016. <https://e-dition.jcrinc.com/MainContent.aspx>. Accessed March 22, 2017.

employees are required to use PPE for clinical procedures when exposure to blood or other potentially infectious material is likely to occur. The level of PPE required is dependent upon the procedure. For example, performing an oral examination does not require the same level of PPE as an extraction. In the examination scenario, gloves, and perhaps a mask and eyewear may suffice. Any procedure involving spray, splash, and/or splatter requires gown, mask, gloves, and eyewear.²² The use of rotary dental and surgical instruments (such as a dental bur) and air water syringes creates a visible spray that contains primarily large particle droplets of water, saliva, blood, microorganisms, and other debris.^{23 24}

Hand hygiene is washing with soap and water, or an antiseptic hand wash, antiseptic hand rub (that is, alcohol-based hand sanitizer including foam or gel), or surgical hand antisepsis. Dental employees should use hand hygiene before and after changing gloves and direct contact with a patient's intact skin, blood, body fluids, mucous membranes, non-intact skin, or wound dressings.^{25,26}

Sterilization of Single Use Burs

VHA policy states that if burs purchased by the facility are unsterile, facility staff must sterilize the burs according to the manufacturer's instructions prior to use. Any bur used intra-orally must be disposed of after single patient use.²⁷ According to the October 2013 *Infection Control Standards in VA Dental Clinics*, guidelines for non-VA RME include the following:

Any RME used in the VA facility needs first to be approved for use. Local facilities will have a process, which involves approval from SPS, Logistics, Biomedical Engineering, and perhaps other departments. It is unacceptable to bring RME from outside VA and use on patients, even if the outside RME is brought in sterile packaging. Similarly, demonstration or trial RME from a vendor needs to go through the approval process prior to use.²⁸

Request for Review and Objectives

OIG conducted a healthcare inspection at the request of Senators Tammy Baldwin, Chuck Grassley, and Ron Johnson, and Representatives Ron Kind and Timothy Walz, to assess improper dental infection control practices and administrative action taken by VHA

²² VA Office of Dentistry. *Infection Control Standards for VA Dental Clinics*, October 21, 2013.

<http://vaww.infoshare.va.gov/sites/dental/default.aspx>. Accessed January 20, 2017.

²³ Centers for Disease Control and Prevention. *Guidelines for Infection Control in Dental Health-Care Settings— 2003*. MMWR 2003; 52 (No. RR-17).

²⁴ Ibid.

²⁵ VHA Directive 2011-007, *Required Hand Hygiene Practices*. February 16, 2011. This VHA Directive expired February 29, 2016 and has not yet been updated.

²⁶ Centers for Disease Control and Prevention. *Hand Hygiene in Healthcare Settings*.

<https://www.cdc.gov/handhygiene/providers/index.html>. Accessed January 31, 2017.

²⁷ VA Office of Dentistry. *Infection Control Standards for VA Dental Clinics*, October 21, 2013.

<http://vaww.infoshare.va.gov/sites/dental/default.aspx>. Accessed January 20, 2017.

²⁸ Ibid.

at the facility. These practices potentially exposed veterans to BBP, including HIV and hepatitis B and C viruses. Specifically the objectives were to:

- Identify the factors that contributed to facility leadership not being aware of a dentist's improper infection control practices.
- Determine whether VHA took appropriate and timely actions after facility leadership learned of patients' potential exposure to BBP from a dentist's reuse of non-VA unsterile burs.

Relevant OIG Published Reports

We found previously published reports addressing concerns related to reprocessing of medical equipment in dental clinics and potential exposure to BBP. (See Appendix B.)

Scope and Methodology

We initiated the healthcare inspection after receiving the information for review on November 28, 2016 and made a site visit on December 15, 2016. We evaluated VHA's review of and response to patients' potential exposure to BBP at the facility within the context of Federal internal control standards for activities that provide reasonable assurance of effectiveness and efficiency of operations, and compliance with applicable laws and regulations.²⁹

We interviewed the Acting Facility Director, Chief of Staff (COS), Associate Chief of Staff for Medicine (ACOS), Acting Chief, Dental Services, Director, Performance Improvement, a facility dentist, dental hygienists, dental assistants, a medical technologist, prior Patient Safety Manager (PSM), Medical Staff Lead Manager (MSLM), Acting PSM at the time of the incident, Chief of SPS, and Infection Control Coordinator. We also interviewed the VISN 12 Lead Dentist, the VISN 12 Chief of Pathology, the facility Infectious Disease Consultant, and the Director of Public Health Surveillance and Research Department: VHA, AIDS Research Center.

Although Dentist A refused to speak to us after he resigned, he submitted a letter to us through his attorney.³⁰ The former Chief, Dental Services (FCDS) who had retired in September 2016 also refused to speak to us. The inability to speak with Dentist A or the FCDS limited our ability to assess supervision or understand the Chief's awareness of Dentist A's improper infection control practices.

²⁹ United States General Accounting Office. (GAO) Internal Control, *Standards for Internal Control in the Federal Government*. November 1999. Effective July 7, 2004, the GAO's legal name was changed from the General Accounting Office to the Government Accountability Office.

³⁰ The letter provided background information on Dentist A, as well as his perspective of the issues raised in our review. The letter also contained allegations related to the cleaning process of tools used in the facility's dental laboratory (the location where dentures and other dental appliances are adjusted). We considered the information contained in the letter in making our findings and recommendations. Allegations about the dental laboratory were referred to OIG hotline division.

We reviewed and analyzed relevant documents including facility, VISN, and VHA directives, handbooks, and standard operating procedures. We also reviewed recommendations and guidelines from the American Dental Association, Centers for Disease Control and Prevention, Occupational Safety and Health Administration, and VA Office of Dentistry. In addition, we reviewed facility meeting minutes and employee training records. We reviewed facility correspondence with VISN leadership, members of the Deputy Under Secretary for Health for Operations and Management office, and clinical episode response team (CERT). We performed an independent data analysis and concurred with the facility that 592 patients were potentially exposed to BBP.

VHA Directive 2011-007, *Required Hand Hygiene Practices*, cited in this report expired in February 2016. We considered this policy to be in effect, as it had not been superseded by more recent policy or guidance. In a June 29, 2016 memorandum to supplement policy provided by VHA Directive 6330(1),³¹ the VA Under Secretary for Health mandated the "...continued use of and adherence to VHA policy documents beyond their recertification date until the policy is rescinded, recertified, or superseded by a more recent policy or guidance."³² The Under Secretary for Health also tasked the Principal Deputy Under Secretary for Health and Deputy Under Secretaries for Health with ensuring "...the timely rescission or recertification of policy documents over which their program offices have primary responsibility."³³

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

³¹ VHA Directive 6330(1), *Controlled National Policy/Directives Management System*, June 24, 2016, amended January 11, 2017.

³² VA Under Secretary for Health Memorandum. *Validity of VHA Policy Document*, June 29, 2016.

³³ Ibid.

Inspection Results

Issue 1: Failure to Identify Earlier Improper Infection Control Practices

Infection control and prevention guidelines are practices used in health care to prevent the transmission of BBP such as HIV, and hepatitis B and C viruses to patients and staff.³⁴ In October 2013, the VA published, *The Infection Control Standards for VA Dental Clinics*³⁵ which incorporated guidelines and standards from the American Dental Association, Occupational Safety and Health Administration, and the Centers for Disease Control and Prevention, including the use of RME for dental patients.

Dentist A began seeing patients at the facility in October 2015. In October 2016, Dental Assistant A reported to Dentist B, who was temporarily managing clinic activities in the absence of the Acting Chief, Dental Services, that Dentist A used a non-VA unsterile bur during a dental procedure on a patient (incident).³⁶ Dentist B reported the incident to the COS office and Human Resources.

When facility leadership interviewed Dentist A in October 2016, Dentist A acknowledged he had used a non-VA unsterile bur on the day in question as he had with prior patients. Dentist A demonstrated to the ACOS that after using a bur, he placed the used, unsterile bur on a piece of gauze, sprayed it with Virex™ (a surface disinfectant that was available in the clinic) and left it wet for 5 to 7 minutes.³⁷ Dentist A did not send his unsterile burs to SPS for sterilization. Dentist A believed this was common practice in the private sector.

We did not find evidence that facility leaders were aware that Dentist A's infection control practices related to the use of non-VA unsterile burs were inconsistent with VHA policy until Dentist B notified the COS of the reported use of a non-VA unsterile bur in October 2016. Between October 2015 and October 2016, Dentist A potentially exposed 592 patients to BBP at the facility Dental Clinic due to improper infection control practices.

We identified two factors that contributed to facility leadership not being aware sooner of Dentist A's improper infection control practices. These factors included: (1) failure of staff, despite safety and infection control training, to report Dentist A's

³⁴ United States Department of Labor, Occupational Safety and Health Administration. *Bloodborne Pathogens and Needlestick Prevention*. <https://www.osha.gov/SLTC/bloodbornepathogens>. Accessed January 25, 2017.

³⁵ VA Office of Dentistry. *Infection Control Standards for VA Dental Clinics*, October 21, 2013. <http://vaww.infoshare.va.gov/sites/dental/default.aspx>. Accessed January 20, 2017.

³⁶ A dental bur is a type of drill bit used as a cutting tool to make an opening in a tooth or bone. During certain dental procedures, the dentist may need to file down adjoining teeth using a dental bur.

³⁷ VIREX™II/256 is a disinfectant, cleaner, and deodorizer used for general cleaning and disinfection on hard non-porous environmental surfaces. The product is not to be used for end of use sterilization or high level disinfection on any surface or instrument that is (1) introduced directly into the human body, either into or in contact with the blood stream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body https://www3.epa.gov/pesticides/chem_search/ppls/070627-00024-20030403.pdf. Accessed January 20, 2017.

breach of infection control practices, including the use of non-VA unsterile burs during crown and/or bridge procedures on prior patients, and (2) advance notification and other issues associated with Dental Clinic inspections. Other factors may have been contributory, but both Dentist A and his supervisor, the FCDS, left VA and refused to be interviewed by OIG.

Failure to Consistently Report

Between August 2015 and September 2016, dental staff were notified or received training through various mechanisms regarding patient safety and infection control. Despite the training, dental staff inconsistently reported the noncompliant infection control practices that they observed.

Dental staff received the following patient safety and infection control training:

- August 2015, the PSM presented information during a dental staff meeting about filing an electronic patient event report (ePER) and confirmed that computers in the Dental Clinic had a desktop icon accessible for use.³⁸
- July 2016, the FCDS presented, *The Infection Control Standards for VA Dental Clinics* to all staff at a dental staff meeting when it was announced there would be a VISN Lead Dentist inspection the following month.³⁹ These standards addressed PPE, cleaning and sterilization of instruments and burs, and non-VA RME.
- 2016 Mandatory Training & Education course covered a review of local policies on BBP and PPE.

All facility staff were provided the following patient safety training:

- July 24, 2016, a facility electronic newsletter, *The Daily Brief*, featured a short message, “Patient Safety is Everybody’s Job.” An attachment to *The Daily Brief* included four videos that described what an adverse event could do to a patient and a facility and why staff needed to report adverse events.
- September 8, 2016, *The Daily Brief*, featured an education initiative, “Stop the Line for Patient Safety.” This initiative encouraged employees to express their concerns about a potential safety issue. This initiative uses three steps for employees to communicate their concerns to other members of the team regardless of their position, known as the 3Ws©:
 - Say what you see

³⁸ Electronic Patient Event Reporting (ePER) is a computer software application located on facility desktops for reporting any incidents for inpatient or outpatients.

³⁹ VA Office of Dentistry. *Infection Control Standards for VA Dental Clinics*, October 21, 2013. <http://vaww.infoshare.va.gov/sites/dental/default.aspx>. Accessed January 20, 2017.

- Say what you are concerned about, and
- Say what you want to happen to keep things safe.

While we found evidence of training related to infection control practices and patient safety, we found inconsistencies in practices within the Dental Clinic that may have prevented early intervention or satisfactory resolution of concerns. By December 2015 or January 2016, Dental Assistant B was aware that Dentist A used non-VA unsterile burs in the operatory; however, he/she failed to report this timely to appropriate personnel. Dental Assistant B told us he/she reported Dentist A's use of the non-VA unsterile burs to the former lead dental hygienist (FLDH - now retired) in early 2016, because he/she thought the FLDH was his/her supervisor.

We found that the FLDH took care of administrative functions, but those functions did not include employee supervision. We found that the FCDS was the dental assistants' direct supervisor and when interviewed, other dental assistants were knowledgeable of their direct supervisor. We interviewed the FLDH, who stated he/she directed Dental Assistant B to report the use of non-VA unsterile burs to the FCDS. The FLDH did not report this information to the FCDS or complete an ePER. The FLDH also stated he/she would have reported to his/her supervisor had he/she witnessed Dentist A's use of an unsterile bur.

Dental Assistant B told us he/she reported Dentist A for his poor hand hygiene, noncompliant use of PPE, specifically not wearing gowns, and his appearance of sleeping at his desk to the FCDS. Dental Assistant B thought the FCDS discussed these issues with Dentist A. While Dental Assistant B told us he/she did not feel comfortable reporting Dentist A's use of non-VA unsterile burs to the FCDS, claiming fear of reprisal, he/she did not utilize other avenues of reporting patient care issues either, such as reporting events to the PSM or the Infection Control Coordinator. Other dental assistants and the current dental hygienist indicated they felt comfortable reporting information to the FCDS.

Other dental staff provided conflicting accounts of Dentist A's poor hand hygiene, noncompliant use of PPE, specifically not wearing gowns, and his appearance of sleeping at his desk. Dental staff also told us they did not file an ePER, contact the PSM, and/or the Infection Control Coordinator. We found no documentation that the FCDS counseled Dentist A for poor hand hygiene, noncompliant use of PPE, sleeping at his desk, or the use of non-VA unsterile burs.

Dental Clinic Inspections

We found four opportunities between October 2015 and October 2016 when Dental Clinic inspections conducted by different groups (Dental Clinic staff, SPS staff, facility staff during Environment of Care (EOC) rounds, and VISN 12 staff) could have revealed noncompliance with VHA and facility directives, handbooks, and policies regarding infection control.

A. Dental Clinic

According to VHA, the Chief, Dental Services is responsible for ensuring that the facility dental program complies with VHA regulations, directives, handbooks, and policies pertaining to dental clinic operations.⁴⁰ All dental policies must comply with relevant VHA, Occupational Safety and Health Administration, and TJC safety and EOC standards.⁴¹ United States Government Accountability Office (GAO) *Standards for Control in the Federal Government* recommend that key duties and responsibilities be divided or segregated among different people to reduce the risk of error or fraud, and that no one individual should control all aspects of an event. Internal control should be designed to assure that ongoing monitoring occurs in the course of normal operations.⁴²

We identified two processes that may have influenced practices designed to reduce the risk of error in the Dental Clinic. First, dentists stated they usually worked in their own operatories with their regularly assigned dental assistant. Second, each dental assistant checked his/her own operatory for cleanliness and inspection of sterile items stored in the drawers.

We found these processes did not ensure ongoing monitoring was occurring and effective within the Dental Clinic. A rotation of dental assistant assignments may have enhanced compliance with infection control standards. Had dental assistants checked operatory drawers other than their own, the rack of unsterile burs may have been identified as outside normal practice prior to the discovery of the improper infection control practices.

B. SPS

VHA requires SPS to ensure sterile package integrity of items stored in VA medical facilities.⁴³ SPS staff conducted routine inspections of sterile burs and supplies stored in the Dental Clinic clean utility room. However, we determined that SPS staff did not inspect individual dental operatory drawers that also contained sterile burs.

C. EOC

VHA and TJC require facilities to have appropriate systems in place to ensure a safe, clean, and high quality EOC. VHA requires facility EOC committee staff conduct routine

⁴⁰ VHA Handbook 1130.01, *Veterans Health Administration Dental Program*. February 11, 2013.

⁴¹ Ibid.

⁴² United States General Accounting Office. (GAO) *Internal Control, Standards for Internal Control in the Federal Government*. November 1999. Effective July 7, 2004, the GAO's legal name was changed from the General Accounting Office to the Government Accountability Office.

⁴³ VHA Directive 1116(2), *Sterile Processing Services (SPS)*. March 23, 2016.

EOC rounds twice per fiscal year in patient care areas.⁴⁴ We found the facility had an EOC policy, identified an EOC Program Coordinator, maintained a schedule for EOC rounds, and utilized the Compliance Environment of Care (CEOC) Assessment and Compliance Tool. We found facility EOC committee staff conducted EOC rounds in the Dental Clinic twice in the year prior to Dental Assistant A's reporting of Dentist A's improper infection control practices. No Dental Clinic EOC deficiencies were identified in the January review. In the July Dental Clinic review, staff found blue bins (bins that hold supplies) on a windowsill and wheelchairs that were dusty. We found documentation that the dental staff addressed the two deficiencies.

VHA established a comprehensive EOC program that includes a checklist with review items.⁴⁵ One of the questions on the EOC checklist was, "Is there evidence of hoarding of supplies outside of the clean/sterile supply rooms"? To answer this question, EOC committee staff should have opened the operatory drawers in the Dental Clinic. We found the facility EOC team did not inspect all drawers within the operatories during Dental Clinic EOC rounds; team members cited concerns that patients were present and undergoing exams in operatories at the time of inspections. Had the EOC committee staff inspected the operatory drawers, they may have discovered the unsterile burs.

D. VISN 12

In August 2016, the VISN 12 Lead Dentist conducted an announced, annual facility inspection. This inspection included review of staffing, budget, standard operating procedures, and RME used in the Dental Clinic. The inspection checklist included specific questions regarding intra-oral burs, sterility, single patient use, and disposal in sharps containers after use. The VISN 12 Lead Dentist's inspection found the Dental Infection Control Policy was readily accessible to staff and he had no findings of lapses in infection control practices. The VISN 12 Inspection included a section of questions related to staff interviews; however, there was no list of which staff were interviewed.

The July 2016 Dental Services meeting minutes reflected the FCDS informed the staff of the upcoming VISN 12 Lead Dentist inspection and reviewed *The Infection Control Standards for VA Dental Clinics*. One dental assistant told us the FCDS briefed the staff on what to expect for the inspection. Additionally, Dental Assistant B stated the FCDS told the dental staff to remove personal items, such as bandage scissors, from their operatory drawers. The VISN 12 Lead Dentist stated there had been discussion about not announcing inspections and he was going to consider this for future inspections.

⁴⁴ Department of Veterans Affairs (VA), Veterans Health Administration (VHA), Environmental Programs Service (EPS) *Environment of Care (EOC) Assessment and Compliance Rounding Process Guide*, August 3, 2014. <http://vaww.ceosh.med.va.gov/10N/10NA7-EPS/documents/EOC%20Assessment%20%20Compliance%20Guide%20v07%208-03-2014.pdf>. Accessed February 14, 2017.

⁴⁵ VHA Directive 1608, *Comprehensive Environment of Care*. February 1, 2016.

Issue 2: Actions Taken by VHA After Becoming Aware of the Issue

The table below provides a summary of relevant events designed to facilitate understanding of VHA actions taken to address the report of Dentist A’s improper infection control practices.

Table: Summary of Relevant Events From October 5, 2015 through February 1, 2017.

Date	Event
October 5, 2015	Dentist A started at the facility.
October 16, 2015	Dentist A saw his first patient.
December 2015 or January 2016	Dental Assistant B first noticed Dentist A using non-VA unsterile burs and stated this information was reported to FLDH (now retired).
February 3, 2016	Facility managers extended Dentist A’s Focused Professional Practice Evaluation (FPPE) due to concerns regarding patient care documentation. ⁴⁶
May 16, 2016	FCDS signed Dentist A’s FPPE stating “No concerns regarding competency.”
Mid-October 2016	Dentist A used a non-VA unsterile bur on a patient having a single crown procedure (incident). Dental Assistant A witnessed the incident.
October 20, 2016	Dentist A called in sick and was not present in Dental Clinic. Dental Assistant A reported Dentist A’s use of an unsterile bur and existing rack of unsterile burs to Dentist B, who was temporarily managing clinic activities in the absence of the Acting Chief, Dental Services. Dentist B initiated removal of the unsterile bur and bur rack from the operatory. Dentist B reported the incident to the COS Office and HR.
October 21, 2016	ACOS discussed the incident with dental staff (two dental assistants, a hygienist, and Dentist B). COS Office administrative staff informed facility leadership of the incident. Facility leadership sent an issue brief to the VISN 12 leadership. The COS met with Infection Control staff, HR staff, MSLM, and the SPS Supervisor to discuss the incident and go over process questions. ACOS interviewed Dentist A. Dentist A demonstrated to the ACOS that after using a bur, he placed the used, unsterile bur on a piece of gauze, sprayed it with Virex™ (a surface disinfectant that was available in the clinic) and left it wet for 5 to 7 minutes. ⁴⁷ ACOS instructed Dentist A to stop clinical activities and disabled his patient care computer access. Infection Control Coordinator completed a risk assessment. ⁴⁸

⁴⁶ An FPPE is a time-limited period during which the medical staff leadership evaluates and determines the practitioner’s professional performance. An FPPE occurs at the time of initial appointment to the medical staff, or the granting of new, additional privileges, or when a question arises regarding a practitioner’s ability to provide safe, high-quality patient care.

⁴⁷ As noted above, VIREX™II/256 is a disinfectant, cleaner, and deodorizer used for general cleaning and disinfection on hard non-porous environmental surfaces.

⁴⁸ The Infection Control Nurse completed a risk assessment for the transmission of HIV, hepatitis B virus, hepatitis C virus, and non-bloodborne pathogen infections from improperly disinfected/sterilized dental burs.

Date (continued)	Event
October 24, 2016	Acting Facility Director issued a temporary reassignment memorandum to Dentist A and assigned Dentist A to administrative duties pending further review.
October 26, 2016,	Acting Facility Director requested VISN 12 Lead Dentist conduct a formal fact-finding. VISN 12 Lead Dentist made a site visit to the facility Dental Clinic, interviewed staff, and inspected the clinic.
November 2, 2016	VISN 12 Lead Dentist submitted a summary of his fact-finding to the facility.
November 3, 2016,	Acting Facility Director summarily suspended Dentist A's clinical privileges.
November 7, 2016	Deputy Under Secretary of Health for Operations and Management convened a CERT.
November 17, 2016	Acting Facility Director signed a memorandum to convene a Summary Review Board.
November 28, 2016	OIG OHI accepted the hotline referral.
November 29, 2016	Facility notified TJC, the National Practitioner Data Bank, and the State of Texas Licensing Board of Dentist A's use of unsterile burs. Facility leaders initiated a large-scale disclosure ⁴⁹ and made a public statement. Facility providers notified of an "infection control lapse" and the establishment of a Dental Look Back Clinic.
November 30, 2016	Facility Dental Look Back Clinic opened.
December 2, 2016	Dentist A submitted a resignation letter. Dentist A's resignation prompted the facility to report to the National Practitioner Data Bank.
December 15, 2016	OHI Site Visit.
January 11, 2017	Facility sent certified letters to the patients in the large-scale disclosure who had not responded to the original notification.
February 1, 2017	Facility Dental Look Back Clinic was extended for 7 days for patients who did not previously respond.

Source: *OIG analysis of VHA data*

We determined that the facility, VISN 12, and VHA took appropriate follow-up actions and responded timely to patients' potential exposure to BBP. As of May 23, 2017, 97 of the original 592 patients identified by the facility had not responded to initial, subsequent letters, or phone calls. Of the 97 patients, we found 9 patients had expired due to circumstances unrelated to their potential exposure of BBP. We reviewed the electronic health records (EHR) of the remaining 88 patients and did not find evidence of patients' responses to notification or flags in 7 EHRs. We informed the facility and subsequently confirmed all EHRs of patients who had not previously responded had been electronically flagged to alert primary care physicians to discuss follow-up.

⁴⁹ VHA Handbook 1004.08, *Disclosure of Adverse Events to Patients*, October 2, 2012. A large-scale disclosure is a formal process by which VHA officials assist with assessment and coordination of the notification to multiple patients. The coordination process is designed to ensure that all required disclosures are based on a thorough investigation of the facts, a careful assessment of the risks involved, and the development of a plan for the best way to perform the disclosure.

Immediate Facility Actions

Dentist B notified the facility ACOS of Dentist A's use of a non-VA unsterile bur on October 20, 2016. The next day, the ACOS gathered information from dental staff concerning the use of the unsterile bur. Facility leadership sent an issue brief to the VISN 12 leadership. On October 21, 2016, Dentist A attended clinic and saw four patients but did not perform any crown and/or bridge procedures in the morning. Later in the morning, the ACOS inspected the Dental Clinic and interviewed Dentist A.

Dentist A informed the ACOS that he re-used a non-VA unsterile bur for the patient's crown procedure as he had with prior patients. Dentist A demonstrated how he disinfected and cleaned his non-VA unsterile burs. After using a bur, he placed it on a piece of gauze, sprayed it with Virex™ (a surface disinfectant that was available in the clinic), and left it wet for 5 to 7 minutes.⁵⁰ Dentist A told the ACOS that he believed this was common practice in the private sector. Dentist A did not send his unsterile burs to SPS for sterilization.

Facility leaders began a preliminary review of the allegations to determine whether further administrative investigation was warranted. Leaders initiated actions according to VHA policy that included a request for Dentist A to be reassigned outside of the dental clinic and the disabling of his patient care computer access. The Acting Facility Director briefed VISN 12 leadership and appointed the VISN 12 Lead Dentist to conduct a fact-finding.

VISN 12 Actions

The VISN 12 Lead Dentist conducted a fact-finding and identified 592 patients treated by Dentist A between October 2015 and October 2016. The 592 patients were considered low risk for developing infectious diseases from potential exposure to BBP. The VISN 12 Lead Dentist determined that Dentist A preferred to use a non-VA issued bur during a crown and/or bridge procedure but did not properly sterilize such burs before or after use. The VISN 12 Lead Dentist identified 57 of the 592 patients treated by Dentist A who underwent preparation or completion of a crown and/or bridge procedure.

VHA Actions

The Deputy Under Secretary for Health for Operations and Management convened a CERT. The CERT included representatives from local, regional, and national offices including the Assistant Deputy Under Secretary of Health, Patient Care Services for

⁵⁰ VIREX™II/256 is a disinfectant, cleaner, and deodorizer used for general cleaning and disinfection on hard non-porous environmental surfaces. The product is not to be used for end of use sterilization or high level disinfection on any surface or instrument that is (1) introduced directly into the human body, either into or in contact with the blood stream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. https://www3.epa.gov/pesticides/chem_search/ppls/070627-00024-20030403.pdf. Accessed January 20, 2017.

Public Health, Office of General Counsel, VHA Central Office, Office of Nursing, VHA National Infectious Disease Services, VHA National Center for Patient Safety, VHA National Center for Ethics in HealthCare, VHA Public Communications, Organizational Excellence, Access and Clinic Administration Program, and facility and VISN 12 leadership. The CERT identified steps to address the “potential exposure of patients to BBP” at the facility. The CERT reviewed fact-finding provided by the VISN 12 Lead Dentist and provided direction to the facility to proceed with a large-scale disclosure. CERT members agreed and emphasized, “that the risk of the exposure including both groups (crown/bridge and non-crown/bridge) were [sic] low, the risk of the exposure for crown/bridge group may be little bit increase [sic], but still be considered low.”

In addition, the CERT coordinated resources to assist with development of (a) a Dental Look Back Clinic to notify and test patients for potential exposure to BBP, (b) a communication plan, (c) provision of clinician consultation and laboratory services, and (d) follow-up services for patients.

Ongoing Facility Actions

A. Disclosure of an Adverse Event

VHA defines an adverse event as an occurrence of harm or potential harm associated with care or services provided to the patient.⁵¹ A large-scale disclosure is a formal process by which VHA officials assist with assessment and coordination of the notification to multiple patients. The coordination process is designed to ensure that all required disclosures are based on a thorough investigation of the facts, a careful assessment of the risks involved, and the development of a plan for the best way to perform the disclosure. Decisions regarding large-scale disclosure of adverse events are made by the Principal Deputy Under Secretary for Health or designee, followed by a multi-step process. Facility leadership must submit an issue brief to VA Central Office within 24 hours of discovery of the event. If the adverse event is only recognized after the episode of care, it is appropriate to wait until the required VHA coordination process for large-scale disclosure is completed. This process usually includes public notification and direct communication to key stakeholders. Disclosure of adverse events to patients and the reporting of adverse events to regulatory agencies are separate requirements.⁵²

Facility leadership made a large-scale disclosure to the 592 patients treated by Dentist A, made public announcements, and sent letters to all 592 patients. Clinicians attempted to contact the 57 patients that underwent preparation or completion of a crown and/or bridge procedure by telephone. Facility leaders also reported the adverse event to TJC, National Practitioner Data Bank, and the State of Texas licensing board.⁵³

⁵¹VHA Handbook 1004.08, *Disclosure of Adverse Events to Patients*, October 2, 2012.

⁵²Ibid.

⁵³Ibid.

B. Dental Look Back Clinic

VHA defines a look-back as an organized process for identifying patients and/or staff with exposure to potential risk incurred through past clinical activities, and to notify, offer care and recourse as appropriate.⁵⁴

Facility managers established a Dental Look Back Clinic to counsel the identified 592 patients and obtain clinical consent for treatments and procedures that tested for BBP. The clinic initially operated from November 30 through December 22, 2016, Monday through Friday 8:00 a.m. to 5:30 p.m., and Saturdays from 8:30 a.m. to 12:00 p.m. The MSLM was responsible for coordinating the clinic. The MSLM sent an email to notify facility providers about an “infection control lapse” and request that they route potentially exposed patients through the Dental Look Back Clinic in order to ensure consistency and tracking of care. The MSLM contacted other VAs and private facilities for patients who contacted the Tomah VA and requested other arrangements be made.

The Office of Public Health Surveillance and Research Department assisted in identifying an appropriate laboratory (lab) protocol to follow patients potentially exposed to BBP. (See Appendix A.) Due to the large volume of patients and the limited testing provided at the facility, a coordinated effort took place to obtain and process specimens between the facility lab and other VISN 12 facilities (Clement J. Zablocki Veterans Affairs Medical Center, Milwaukee, WI, and Edward Hines Jr. VA Hospital, Hines, IL).

The Chief of Infectious Disease at the William S. Middleton Memorial Veterans Hospital, Madison, WI, the Lead Infectious Disease Physician for the facility, provided clinical consultation and follow-up for patients with BBP positive results.

The Traveling Veteran Coordinator assisted the Dental Look Back Clinic to coordinate lab tests for patients who declined services at the facility or within the VA. If positive BBP test results were confirmed, the VHA Public Health Reference Laboratory provided additional testing if indicated per protocol. In addition, VA Central Office (Palo Alto Office of Public Health), which is part of VHA Quality, Safety, and Value, reviewed the list of 592 patients to identify any pre-existing infections due to BBP.

The VISN 12 Nurse Triage Call Center was available, 24 hours, 7 days a week for information to assist potentially exposed patients. As of January 11, 2017, 138 of the original 592 patients had not responded to letters or phone calls from the Dental Look Back Clinic staff. Facility staff sent certified letters to the identified 138 patients notifying them of the reopened Dental Look Back Clinic from February 1–7, 2017.

As of May 23, 2017, we determined that the EHRs of all patients who had not responded to notifications had been electronically flagged to alert primary care physicians to discuss follow-up.

⁵⁴Ibid.

Conclusions

We identified two factors that contributed to facility leaders not being aware sooner of Dentist A's improper infection control practices. These factors included (1) failure of staff, despite safety and infection-control training, to report Dentist A's breach of infection control practices, including the use of non-VA unsterile burs during crown and/or bridge procedures of prior patients, and (2) advance notification and other issues associated with Dental Clinic inspections. Other factors may have been contributory, but both Dentist A and his supervisor, the FCDS, left VA and refused to be interviewed by the OIG.

Between August 2015 and September 2016, dental staff were notified or received training through various mechanisms regarding patient safety and infection control. Despite the training, we found inconsistencies in practices within the Dental Clinic that may have prevented early intervention or satisfactory resolution of concerns. We found no documentation to support that facility managers counseled Dentist A for poor hand hygiene, noncompliant use of PPE, sleeping at his desk, or the use of unsterile burs.

We found four opportunities between October 2015 and October 2016 when Dental Clinic inspections conducted by different groups (Dental Clinic staff, SPS staff, facility staff during EOC rounds, and VISN 12 staff) might have revealed noncompliance with facility and VHA directives, handbooks, and policies regarding infection control.

We identified two processes in the Dental Clinic that likely hampered inspectors' ability to detect Dentist A's use of unsterile burs. First, dentists stated they usually worked in their own operatories with their regularly assigned dental assistant. Second, each dental assistant inspected his/her own operatory for cleanliness and inspection of sterile items stored in drawers. We found these processes resulted in dentists operating within silos without necessary cross-checks between dental staff and operatories, which did not ensure effective, ongoing monitoring of the Dental Clinic. A rotation of operatories and/or dental assistant assignments may have enhanced detection of noncompliance with infection control standards. Had dental assistants checked operatory drawers other than their own, Dentist A's rack of unsterile burs may have been detected before 592 patients were potentially exposed to HIV and hepatitis B and hepatitis C viruses.

SPS staff made rounds to inspect the integrity of sterile packages in the Dental Clinic clean utility room; however, they did not inspect the individual dental operatory drawers. The facility team did not inspect all drawers within the operatories during Dental Clinic EOC rounds. Prior to the August 2016 VISN 12 Lead Dentist inspection, the FCDS informed the dental staff of the upcoming inspection and gave staff instructions to remove their personal items from operatory drawers.

We determined that the facility, VISN 12, and VHA took appropriate follow-up actions and responded timely to patients' potential exposure to BBP. An event summary in the body of the report illustrates the sequence of events and actions taken. Facility leaders learned in mid-October 2016 that Dentist A used a non-VA unsterile bur on a patient having a single crown procedure. Facility leaders took appropriate action by removing

Dentist A from the clinical area, disabling his patient care computer access, and providing an issue brief to VISN 12. The ACOS inspected the Dental Clinic and interviewed Dentist A and dental staff. Dentist A demonstrated to the ACOS that after using a bur, he placed the used, unsterile bur on a piece of gauze, sprayed it with Virex™ (a surface disinfectant that was available in the clinic), and left it wet for 5 to 7 minutes. Dentist A told the ACOS that he believed this was common practice in the private sector. Dentist A did not send his unsterile burs to SPS for sterilization.

Between October 24, 2016 and November 7, 2016, the Facility Director reassigned Dentist A to administrative duties, pending further review. The VISN 12 Lead Dentist submitted a summary of his fact-finding to the facility, and Dentist A's clinical privileges were summarily suspended. The Deputy Under Secretary for Health for Operations and Management convened a CERT to assess how best to identify, test, and treat patients potentially exposed to BBP at the facility. The CERT reviewed the fact-finding provided by the VISN 12 Lead Dentist and assisted with coordination of resources in the development of a Dental Look Back Clinic.

The facility made a large-scale disclosure to the 592 patients treated by Dentist A between October 2015 and October 2016. Facility leaders made public announcements and sent letters to all 592 patients. In addition, clinicians attempted to contact the 57 patients who underwent preparation or completion of a crown and/or bridge procedure (a subset of the 592 patients) by telephone.

The Office of Public Health Surveillance and Research Department assisted in identifying an appropriate lab protocol to follow patients potentially exposed to BBP. (See Appendix A.) Due to the large volume of patients and the limited testing provided at the facility, a coordinated effort took place to obtain and process specimens between the facility lab and other VISN 12 facilities (Clement J. Zablocki Veterans Affairs Medical Center, Milwaukee, WI, and Edward Hines Jr. VA Hospital, Hines, IL).

The Chief of Infectious Disease at the William S. Middleton Memorial Veterans Hospital, Madison, WI, the Lead Infectious Disease Physician for the facility, provided clinical consultation and follow up for patients with positive results.

The Traveling Veteran Coordinator assisted the Dental Look Back Clinic to coordinate lab tests for patients who declined services within the facility or the VA. If positive test results were confirmed, the VHA Public Health Reference Laboratory provided additional testing if indicated per protocol. In addition, VA Central Office (Palo Alto Office of Public Health), which is part of VHA Quality, Safety, and Value, reviewed the list of 592 patients to identify any pre-existing infections due to BBP.

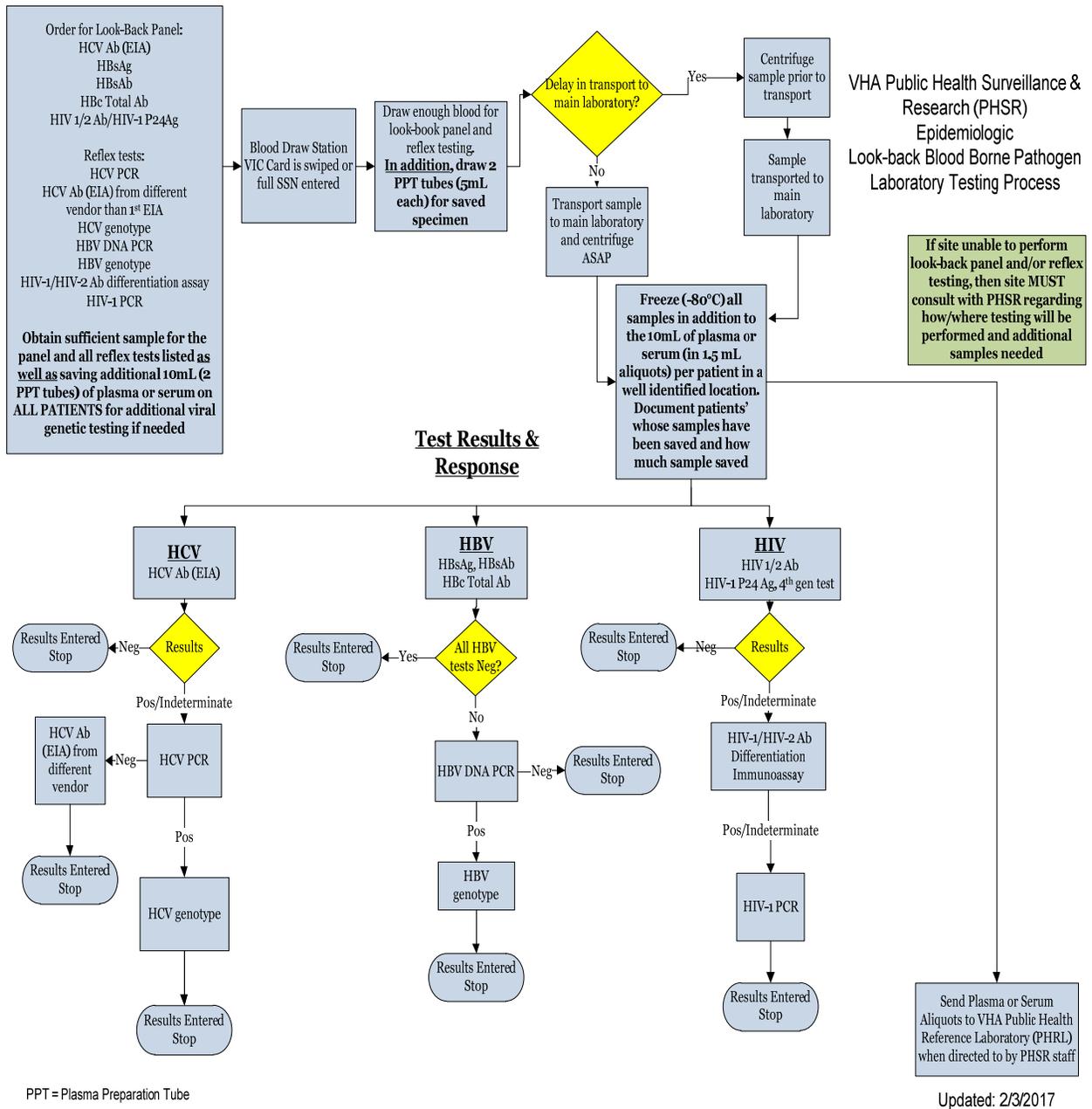
The VISN 12 Nurse Triage Call Center was available to assist potentially exposed patients with information, 24 hours, 7 days a week. Facility managers established a Dental Look Back Clinic to counsel the identified 592 patients and obtain clinical consent for treatments and procedures that test for BBP. The Dental Look Back Clinic initially operated from November 30 through December 22, 2016.

As of January 11, 2017, 138 patients had not responded to previous letters or phone calls from the Dental Look Back Clinic. Facility staff sent certified letters to the identified 138 patients notifying them of the reopened Dental Look Back Clinic from February 1–7, 2017. We continued to monitor and as of May 23, 2017, determined 97 of the original 592 patients identified by the facility had not responded to initial or subsequent letters, or phone calls. Of the 97 patients, we found 9 patients had expired due to circumstances unrelated to their potential exposure of BBP. We reviewed the EHRs of the remaining 88 patients and did not find evidence of patients' responses to notification or flags in 7 EHRs. We informed the facility and subsequently confirmed all EHRs of patients who had not previously responded had been electronically flagged to alert primary care physicians to discuss follow-up.

Recommendations

1. We recommended that the Veterans Integrated Service Network 12 Director improve oversight of the Dental Clinic by performing unannounced inspections that include opportunities to interview staff privately regarding any concerns.
2. We recommended that the Facility Director improve oversight of the Dental Clinic by conducting unannounced, detailed inspections to ensure adherence to Veterans Health Administration and facility infection control standards, patient safety guidelines, and other pertinent dental policies and procedures.
3. We recommended that the Facility Director conduct training on when it is appropriate to report issues relating to the quality of healthcare or patient safety issues and the various options on where to report.
4. We recommended that the Facility Director consult with the Office of Human Resources and the Office of General Counsel to determine the appropriate administrative action, if any, for staff who failed to report the reuse of unsterile burs on patients.
5. We recommended that the Facility Director ensure Environment of Care rounds are scheduled when all areas of the Dental Clinic are available to be inspected.

Look Back Blood Borne Pathogen Protocol



Source: VHA Public Health Surveillance & Research (PHSR)

Prior OIG Reports

Dental Clinic RME Reports

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

3/7/2011. Report No. 10-03346-112.

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

4/25/2011. Report No. 10-03330-148.

Healthcare Inspection: - Follow-Up Evaluation of Dental Instrument Reprocessing Deficiencies St. Louis VA Medical Center, St. Louis, Missouri.

4/5/2012. Report No. 10-03346-152.

Healthcare Inspection: Effectiveness of Actions to Correct Dental Instrument Reprocessing Deficiencies, St. Louis VA Medical Center, St. Louis, Missouri.

9/12/2012. Report No. 10-03346-270.

Healthcare Inspection: Issues at a VA Mid South Healthcare Network Dental Clinic.

2/27/2013. Report No. 12-03753-121.

OIG reports are available on our web site at www.va.gov/oig.

VISN Director Comments

**Department of
Veterans Affairs**

Memorandum

Date: July 7, 2017

From: Director, VA Great Lakes Health Care System (10N12)

Subj: Healthcare Inspection—Review of Improper Dental Infection Control Practices and Administrative Action, Tomah VA Medical Center, Tomah, Wisconsin

To: Regional Director, Denver Office of Healthcare Inspections (54DV)
Director, Management Review Service (VHA 10E1D MRS Action)

1. Thank you for the opportunity to review the draft report of the Tomah Veterans Affairs Medical Center inspection. I have reviewed the report and concur with the recommendations.
2. I concur with the corrective action plans and the timeline of completion.



Renee Oshinski
Network Director VISN 12

Comments to OIG's Report

The following VISN Director's comments are submitted in response to the recommendation in the OIG report:

OIG Recommendation

Recommendation 1. We recommended that the Veterans Integrated Service Network 12 Director improve oversight of the Dental Clinic by performing unannounced inspections that include opportunities to interview staff privately regarding any concerns.

Concur

Target date for completion: October 1, 2017

VISN response: Unannounced inspections will be conducted by the VISN Dental Lead to provide quality oversight to ensure adherence to VHA guidelines, appropriate infection control practices, and policies related to reusable medical equipment. Inspections will include opportunities for private staff interviews to discuss any concerns.

Facility Director Comments

**Department of
Veterans Affairs**

Memorandum

Date: July 7, 2017

From: Director, Tomah VA Medical Center (676/00)

Subj: Healthcare Inspection— Review of Improper Dental Infection Control Practices and Administrative Action, Tomah VA Medical Center, Tomah, Wisconsin

To: Director, VA Great Lakes Health Care System (10N12)

1. Thank you for the opportunity to review the draft report of the Tomah Veterans Affairs Medical center inspection. I have reviewed the document and concur with the recommendations.
2. Corrective action plans have been established with planned completion dates, as detailed in the attached report. If additional information is needed please contact my office at (608) 372-1777



Victoria P. Brahm, MSN, RN, VHA-CM
Medical Center Director

Comments to OIG's Report

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

OIG Recommendations

Recommendation 2. We recommended that the Facility Director improve oversight of the Dental Clinic by conducting unannounced, detailed inspections to ensure adherence to Veterans Health Administration and facility infection control standards, patient safety guidelines, and other pertinent dental policies and procedures.

Concur

Target date for completion: July 7, 2017 completed.

Facility response: Unannounced monthly quality inspections, initiated as of November 2016, will continue to be conducted in the Dental Clinic. These monthly inspections are conducted by Infection Control and Sterile Processing Service to ensure adherence to VHA guidelines and facility infection control standards, patient safety guidelines, and other pertinent policies and procedures related to reusable medical equipment.

Recommendation 3. We recommended that the Facility Director conduct training on when it is appropriate to report issues relating to the quality of healthcare or patient safety issues and the various options on where to report.

Concur

Target date for completion: August 1, 2017

Facility response: All facility staff will continue to receive annual mandatory training on infection control and patient safety topics, including procedures for anonymous reporting of any quality, safety, or other healthcare related issue. Additional information regarding anonymous reporting via hotlines for The Joint Commission and Office of Inspector General, the electronic patient event report (ePER) system, and the facility anonymous SharePoint website (Speak Up) have been provided to facility staff via Town Hall on November 29, 2016 and December 22, 2016. On November 9, 2016, Dental staff was educated in a face-to-face session regarding the following: Whistleblower Protection, Psychological Safety, and Safety Reporting. The facility will do a refresher at the next Town Hall on July 27, 2017, as well as meet again with dental staff, as there are some new staff in the area.

Recommendation 4. We recommended that the Facility Director consult with the Office of Human Resources and the Office of General Counsel to determine the appropriate administrative action, if any, for staff who failed to report the reuse of unsterile burs on patients.

Concur

Target date for completion: July 7, 2017 completed

Facility response: The Facility Director consulted with the Office of Human Resources and the Office of General Counsel regarding the staff member who failed to report the reuse of unsterile burs on patients. Appropriate action has been taken and completed. The Chief of Dental retired effective September 30, 2016. The involved dentist had a proposed termination but resigned effective December 2, 2016 prior to final termination. The Lead Dental Hygienist retired on September 30, 2016.

Recommendation 5. We recommended that the Facility Director ensure Environment of Care rounds are scheduled when all areas of the Dental Clinic are available to be inspected.

Concur

Target date for completion: July 7, 2017 completed

Facility response: The facility Safety Manager, who coordinates the Environment of Care (EOC) inspection program will collaborate closely with the Chief, Dental Services and the EOC team to ensure that rounds in the Dental Clinic occur when all areas are available for inspection. An EOC inspection was conducted in Dental on July 6, 2017. All areas of the dental suite were inspected inclusive of patient exam areas. EOC rounds are conducted twice a year in all areas.

OIG Contact and Staff Acknowledgments

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