# Dental Healthcare-Associated Transmission of Hepatitis C

Final Report of Public Health Investigation and Response, 2013





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# **Report Contributors**

#### **Editor and Contributor:**

Kristy K. Bradley, DVM, MPH State Epidemiologist Oklahoma State Department of Health (OSDH)

#### **Contributors and Reviewers:**

<u>OSDH</u> Jan Fox, RN, MPH Director, HIV/STD Service

Terrainia Harris, MPH Program Manager, HIV/STD Surveillance & Analysis

Anna Berzkalns, MPH Epidemiologist, HIV/STD Service

Janet Wilson, RN Adult Viral Hepatitis Coordinator (retired)

Debbie Purton, RN, MPH Administrative Program Manager, Care Delivery HIV/STD Service

Leslea Bennett-Webb Director, Office of Communications (retired)

Jana Winfree, DDS Director, Dental Health Service

S. Terence Dunn, PhD Director, Public Health Laboratory

Don Maisch General Counsel

**Financial Services** 

Pam Archer, MPH Director, Office of Scientific Research and Integrity <u>Tulsa Health Department (THD)</u> Bruce Dart, PhD Director

Joani Dotson, MPH Policy and Health Analytics Coordinator

Kelly VanBuskirk, MPH Division Chief, Health Data and Evaluation

Brenda Dale, RN Manager, Emergency Preparedness and Response

Priscilla Haynes Division Manager, Community Health

Kaitlin Snider, MPH Marketing Director

Leanne Stephens Community Relations Director

Tery Deshong, JD Legal Counsel

Reggie Ivey, BS, MHR Chief of Operations

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# **Final Report**

# Dental Healthcare-Associated Infections (HAI) Investigation of Tulsa Oral Surgical Clinic and Public Health Response, 2013

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# **Executive Summary**

On January 22, 2013, the Oklahoma State Department of Health (OSDH) began an investigation of an acute case of hepatitis C who had a potential healthcare-associated source of infection based on the case-patient's viral hepatitis testing background and other history. A three-member field investigation team was assembled to conduct a public health assessment of three different dental facilities where the case-patient had received oral healthcare services during the period of exposure to hepatitis C virus (HCV). The site visit conducted at the primary location of Dr. W. Scott Harrington's oral surgery practice in Tulsa, Oklahoma on March 12, 2013, revealed breaches in standard infection control practices and inappropriate management and administration of controlled drugs. These findings were promptly communicated to the Oklahoma Board of Dentistry, who requested an unannounced joint site visit on March 18. The summary findings of the two field investigations led to the determination that patients of Dr. Harrington were at risk of exposure to bloodborne pathogens. On March 20, 2013, the Oklahoma Board of Dentistry obtained voluntary suspension of Dr. Harrington's state dental incense pending a formal Board review.

On March 28, 2013, public health officials from OSDH and the Tulsa Health Department (THD) announced they were notifying over 6,000 current and former patients of the W. Scott Harrington Oral Surgical Clinic that they may have been exposed to bloodborne viruses. Health officials recommended these patients have their blood drawn for testing for hepatitis B and C and human immunodeficiency virus (HIV) infection at free screening clinics established at the THD, Oklahoma City-County Health Department, and other county health departments in the state. Free testing through the OSDH Public Health Laboratory was available through June 28, 2013. A unified incident command system was established and operational from March 22, 2013 to July 1, 2013 to manage clinic operations, patient notification, the epidemiologic investigation, and other aspects of the public health response.

In total, the Oklahoma Public Health Laboratory completed testing for 4,208 persons. An unknown number of persons also sought testing through their private healthcare provider. As a result of this public health response and combined methods of surveillance, 96 individuals were identified with hepatitis C, six with hepatitis B, and four with HIV infection. Of those who tested HCV-positive, 36 (38%) had a previous diagnosis of hepatitis C. Findings of the epidemiologic investigation and genetic testing of selected blood specimens at the Centers for Disease Control and Prevention (CDC) confirmed one event of patient-to-patient transmission of hepatitis C virus. The linked source patient and case-patient both had oral surgical procedures performed on the same date in July 2012. Both also received higher doses of intravenous sedative drugs suggesting that lapses in injection safety may have occurred, resulting in contamination of a medication vial with the blood of the source patient who was chronically infected with HCV. The reuse of the contaminated vial may have then led to the transmission of HCV to the next patient.

An epidemiologic study to evaluate potential risk factors for transmission of HCV among oral surgical patients during the time period of March 1, 2012 through March 20, 2013, was

conducted. Of 1,021 patients seen during the study period, 611 (59.8%) had a record of recent hepatitis C testing; 27 (4.4%) had laboratory evidence of HCV infection. Nine of the HCV infections were new diagnoses and served as the case cohort for analysis of risk factors including receipt of medication by type and dosage, nature of dental procedure, lead dental assistant, and other features of care. The analysis was limited by the small number of HCV incident cases and missing data in the dental patient records. Receipt of higher dosages of three separate medications administered intravenously, including propofol, Brevital<sup>®</sup>, and metoclopramide demonstrated an association with a higher likelihood of newly identified HCV infection, but the association was not statistically significant at a p-value of < 0.05.

Public health costs associated with this infectious disease investigation and public health response totaled more than \$681,000, including a combination of federal, state, and local resources. A significant finding of this public health investigation was the first identification of healthcare-associated transmission of HCV ever documented in a dental setting in the United States. Potentially there were additional cases of hepatitis C transmission associated with the oral surgical clinic, but the obstacles in conducting a large retrospective infectious disease investigation, the features of hepatitis C infection, and the substantive proportion of dental patients with unknown status prevented the elucidation of additional cases of oral healthcare-associated transmission.

This investigation revealed a need for heightened awareness and training among dental professionals regarding infection control and injection safety practices. Revisions to the Oklahoma Dental Practice Act effective July 1, 2013, addressed some of the gaps identified during this incident and added requirements for permitting and oversight of dental assistants. The OSDH would be supportive of additional policy changes that would require Oral Maxillofacial Surgery Assistants to successfully complete the Dental Anesthesia Assistant national certification examination, and have a record of training in phlebotomy, cardiopulmonary resuscitation, infection control, and injection safety. The OSDH also advocates for periodic infection control and injection safety continuing education for all licensed dental professionals as a requirement for license renewal.

# Legal Authority for Disease Reporting and Investigation

## **Disease Reporting and Investigation**

Under the authority of Title 63 Oklahoma Statute (O.S.) § 1-501 *et seq.*, the Oklahoma State Department of Health (OSDH) has been given the authority and responsibility for the prevention and control of disease in Oklahoma. Specifically, selected diseases and conditions, as established by the Oklahoma State Board of Health pursuant to regulation, are required to be reported to the OSDH by practicing physicians, clinical laboratories, penal institutions and charitable institutions for the prevention and control of disease, pursuant to 63 O.S. § 1-503. The list of diseases and conditions for the reporting system are periodically reviewed by the Oklahoma State Board of Health and revised via administrative rules. Title 310 of the Oklahoma Administrative Code, Chapter 515 requires that all patients diagnosed with human immunodeficiency virus (HIV) or hepatitis B virus (HBV) be reported to the OSDH within one working day using the state's electronic disease reporting system called "PHIDDO" or other secure electronic data transmission method, or by telephone. Hepatitis C virus (HCV) infections in persons 40 years of age or younger, or in persons of any age with jaundice or an elevated alanine aminotransferase (ALT) liver enzyme level measured at 400 or greater are also required to be reported to the OSDH within one working day of case identification.

Case reports and laboratory test results of HIV, HBV, and HCV are received by the OSDH HIV/STD Service. The Viral Hepatitis Prevention Coordinator, Hepatitis B Nurse, or the Field Surveillance Specialist reviews each case report and assigns newly identified cases of hepatitis B or C, or those requiring more follow up, to a communicable disease nurse or epidemiologist at the county health department level for investigation. The public health professional obtains information from the healthcare provider, laboratories that have performed testing for the patient, or directly from the patient as necessary. As part of the investigation of acute hepatitis B or C, information is obtained about signs and symptoms of illness, laboratory findings, and patient-reported risk factors, including dental or medical procedures they may have had during the estimated incubation period for acute hepatitis B or C.

## Confidentiality

Both state and federal laws provide protection for personal health information, while at the same time recognizing the importance of reporting communicable diseases and outbreaks to the public health authority. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) provides for the protection of personal health information, while allowing for legitimate uses of that information. HIPAA does not prohibit medical care providers from reporting diseases to legally-recognized public health authorities such as the OSDH.

In addition to federal regulations, Oklahoma statutes, specifically 63 O.S. § 1-502.2, also provide protection for personal health information. These laws treat any personal information collected

as part of a disease report or public health investigation into such a report as confidential medical information and prohibit the release of personal information. Any released information must be done in compliance with each of these laws and in such a way that no person can be identified unless otherwise compelled by a court action.

## Dental Licensing, Regulation, and Oversight

The practice of dentistry in Oklahoma is licensed and regulated by the Board of Dentistry, an agency of state government, pursuant to the Oklahoma State Dental Act at 59 O.S. § 328.1 *et seq.* The Oklahoma Board of Dentistry has the power and authority to promulgate rules necessary: (1) to regulate the practice of dentistry in Oklahoma; and (2) to implement and enforce the Oklahoma State Dental Act, pursuant to 59 O.S. § 328.15. The Oklahoma Board of Dentistry establishes licensure and permit requirements for dental care providers, including dentists, dental hygienists, and dental assistants who hold expanded duty permits issued by the Board. Any patient complaints against a dentist practicing in Oklahoma or allegations of improper conduct by a dental health professional are investigated and managed by the Oklahoma Board of Dentistry.

# **SECTION 2**

# Identification of Public Health Threat and Initial Response

On January 22, 2013, the OSDH was contacted by the Centers for Disease Control and Prevention (CDC) regarding concerns of a potential healthcare-associated source of HCV infection for a long standing regular blood donor who screened positive for HIV and HCV infections during routine blood donation in August 2012. Testing of all prior donations, including a blood donation in April 2012, had been negative. Upon receipt of the report in August 2012 from the blood collection facility, the OSDH had launched a standard HIV case investigation and subsequent testing at the OSDH Public Health Laboratory was negative for HIV infection. Follow-up medical evaluation and testing performed through the patient's primary care physician and gastroenterologist revealed acute hepatitis C. Upon interview on February 21, 2013, the case-patient denied all major risk factors for HCV infection, but did report having multiple dental visits and oral surgical procedures within the 3-month period prior to testing positive for HCV.

An internal OSDH briefing involving the HIV/STD Service, the State Epidemiologist, and the Chief of the Dental Health Service was conducted to review the findings and determine the next steps of the investigation. On February 28, 2013, the OSDH contacted the CDC and requested technical assistance and laboratory support from the Division of Healthcare Quality Promotion and the Division of Viral Hepatitis.

A 3-person site visit team was assembled to conduct a public health assessment of the three different dental facilities where the case-patient had received oral healthcare services during the period of exposure to HCV. The methods and findings of the field investigation are reported in more detail in Section 4. Notably, the site visit at the primary location of Dr. W. Scott Harrington's oral surgery practice in Tulsa, Oklahoma on March 12, 2013, revealed breaches in infection control and inappropriate inventory management and administration of controlled drugs. These findings were communicated to the Oklahoma Board of Dentistry, who requested an unannounced joint site visit on March 18. The summary findings of the two site visits led to the determination that patients of Dr. Harrington were at risk of exposure to bloodborne pathogens, including HCV, HBV, and HIV. On March 20, 2013, the Oklahoma Board of Dentistry obtained voluntary suspension of Dr. Harrington's dental license pending a formal Board review.

To further protect the public's health, OSDH and the Tulsa Health Department (THD) determined that a large scale patient notification needed to be undertaken with recommendations for HCV, HBV, and HIV testing. It was estimated that written notifications by letter would be made to approximately 7,300 dental patients based on available patient records dating back to 2007. It was further determined that the OSDH would provide free laboratory testing through the Public Health Laboratory to dental patients of Dr. Harrington. The THD

would be the principal clinic site for phlebotomy and patient data collection; all other county health departments would also provide these services free of charge to self-identified dental patients.

#### **Response Management using Incident Command System**

Due to the size and scope of the public health response and ongoing epidemiologic investigation, the OSDH and THD activated an Incident Command System (ICS) with a unified command approach on March 22, 2013. The event response was named "2013 Dental Healthcare-Associated Infection Investigation and Response" (Dental HAI). A memorandum from the Commissioner of Health announcing the ICS activation was distributed to all OSDH personnel via the OSDH intranet (Appendix A, 2-1).

Utilizing Unified Command, OSDH and THD each assigned an Incident Commander (IC) who set objectives, maintained a solid line of communication across public health jurisdictions, and directed/approved all action steps in the response. Though each IC had specific subject matter expertise and experience preparing them for these roles, a Deputy IC was selected from the OSDH Emergency Preparedness and Response Service to ensure compliance with the National Incident Management System (NIMS) and provide guidance when necessary. Evaluation of leadership succession charts and subject matter expertise was utilized to select individuals to fill ICS roles. The Dental HAI incident activation extended until demobilization on July 1, 2013. The organizational charts utilized during the response were periodically updated as appropriate and met ICS Form 207 guidance. Two of the more comprehensive organizational charts utilized during the height of the response are located in Appendix A, 2-2.

Under Unified Command, the Planning Section created a written incident action plan (IAP) during the first operational period from March 22 – 23, 2013. The IAP was updated for each operational period and distributed to command and general staff during the briefings for a total of 17 operational periods. THD's Planning Section also instituted daily debriefs during the phlebotomy clinic operations, utilizing the Incident Briefing form 201. This allowed staff and volunteers to end each day of clinic operations with a situation status update and next operational period objectives. Situation status updates were sent hourly via e-mail to command & general staff under Unified Command and branch directors March 30 – April 6; twice daily April 8 – 12; once daily April 15 – May 27; and once weekly by the Joint Information System (JIS) May 28 – June 28.

Ongoing communication with the public was vital to this public health response and is described more fully in Section 10. A JIS was established by the two Public Information Officers for THD and OSDH, and included their support staff. The JIS coordinated all media requests for information, prepared all official situational updates, and ensured messaging to media outlets and the public stayed consistent, accurate, and timely.

Similar to the JIS, a joint approach was used for legal advisement throughout the event with Legal Officer representation from both OSDH and THD. Subject matter expertise on dental health was provided by the Chief of OSDH Dental Health Service.

During the majority of the response, the Operations Section consisted of three branches: 1) Epidemiologic Investigation, 2) Public Health Laboratory Testing, and 3) Clinic Operations. Within the Epidemiologic Investigation Branch, there was a unit to manage individual patient notifications and case interviews of dental patients who tested positive for HIV, HBV, or HCV. Another unit under the Epidemiologic Investigation Branch was detailed to managing the sizeable databases associated with patient tracking, reporting of test results, and epidemiologic data collection. On April 15, 2013, the THD began transitioning from a full scale clinical operation to day-to-day activities when the number of clients seeking services and calls to the phone bank were not exceeding regular clinic and phone capacity.

The Logistics Section was staffed to support the Command and General Staff and phone bank personnel at the THD James Goodwin Health Center. In addition to the Supply and Phone Bank Units, separate units were established to provide logistical support for communication between response personnel, the electronic patient medical record system, and other informational technology needs.

The Finance Section was supported by the daily operations of OSDH and THD finance staff. The majority of the equipment and supplies utilized for the Dental HAI investigation and response were purchased through OSDH.

OSDH, THD, and all response partners were able to maintain day to day continuity of operations during the response and provide essential services to the public at all locations.

# **SECTION 3**

# Dental HAI Investigation and Response Goals

## **Public Health Investigation**

In the initial stages of the public health investigation, the OSDH and THD collaborated to identify the source of a suspected healthcare-associated infection of HCV and prevent further transmission. Once a determination was made that others were at risk of previous exposure to HCV or other bloodborne viruses, the goals of the public health investigation were to:

- Determine the scope of the problem and identify additional cases of disease
- Conduct an epidemiologic study to determine risk factors for infections potentially associated with exposures occurring during dental procedures
- Share information learned to guide public policy and future regulatory decisions aimed at prevention.

## Public Health Response

In an infectious disease-related response, there is overlap between the epidemiologic investigation and the public health response. Based on the preliminary epidemiologic and field investigation, the goals of the public health response were to:

- Notify dental patients of their potential exposure and recommend testing for HIV, hepatitis B, and hepatitis C
- Provide access to testing in an efficient manner using county health department clinics and OSDH Public Health Laboratory resources
- Effectively communicate test results to all persons tested through the Public Health Laboratory and provide appropriate recommendations for follow-up medical care and treatment to those persons with positive test results
- Offer counseling and support resources for persons affected by the incident
- Provide risk communication and public releases of information at appropriate intervals throughout the response
- Coordinate communication with healthcare providers statewide, public health agencies in other states providing services to a former dental patient, CDC, and other partner agencies at the state and federal levels.

# **SECTION 4**

# **Field Investigation**

Upon the recognition that a case of acute hepatitis C was most likely acquired from a healthcare-associated source (refer to Section 2), a 3-member multi-disciplinary site visit team was assembled to conduct a public health assessment of the three different dental facilities where the case-patient had received oral healthcare services during the period of exposure to HCV. The team was comprised of two OSDH employees and one THD employee; collectively, the team had expertise regarding dental procedures, viral hepatitis transmission, and epidemiologic investigative methods.

#### Methodology and Summary of Key Investigative Steps

The field investigation began on March 8, 2013, with subsequent site visits occurring on March 12 and March 18, 2013. The field investigation involved site visits to three dental offices in Tulsa, Oklahoma. Two sites had a singular site visit, while the clinic of W. Scott Harrington, DMD, received two visits by the team. The team utilized the *Infection Prevention Checklist for Outpatient Settings: Minimum Expectations for Safe Care*, a guideline from the Centers for Disease Control and Prevention (CDC), to conduct a standard assessment of the dental practice. This checklist consists of two sections: Section I - Administrative Policies and Facility Practices, and Section II - Personnel and Patient-care Observations. While direct patient care was not observed, questions were asked by the team regarding direct patient care and personnel procedures.

The public health investigators presented the signed consent for release of information form from the index case to obtain all medical information relating to the dental visits during the window of time the index patient was probably infected. In addition, the investigators obtained the names and dates of birth for individuals who received services at the dental facility on the dates associated with the index case, including those individuals seen the day before, the day of, and the day after each of the index patient's visits. The clinic dates of interest were: June 19, July 17, and July 27, 2012. This patient listing was cross-matched with the OSDH hepatitis C case registry to identify any dental patients known to be chronically infected with HCV who received dental care shortly before the index case-patient. The team also received the names and dates of birth for all employees of the dental offices that were scheduled and worked on the applicable dates.

Initial visits to the three dental clinics were scheduled at the dentists' convenience when they did not have patients in the office. Two of the sites were observed to meet or exceed the minimum expectations for safe care during the initial visit and were not revisited. Deviations from standard practices were identified at the oral surgical clinic of W. Scott Harrington, DMD, on March 12, 2013. The oral surgery clinic located at 2111 S. Atlanta Place in Tulsa, Oklahoma was re-visited on March 18, 2013 and included the addition of two individuals employed by the

Oklahoma Board of Dentistry. This report summarizes the observations of the W. Scott Harrington, DMD oral surgery clinic by the public health investigative team.

## **Clinic Layout**

The oral surgery clinic was a stand-alone building. The clinic consisted of a patient waiting room, the clinic offices, three operatory rooms, and a sterilization room that also served as the area for storage and the location of the medication cabinet. The offices within the suite consisted of a reception area, an office manager area, medical records storage, and a room with seating for patient recovery.

## **General Clinic Operations**

Direct patient care was not observed during the field investigation. The patient waiting area was observed to be clean and provided ample seating. A lodge-like appearance was the décor used in this area. The patient waiting area was open and accessible to the receptionist.

The medication cabinet, located in the sterilization room, was a locking cabinet. The medication cabinet was unlocked at the time of the team's observation. The oral surgery staff reported that the medication cabinet was unlocked for retrieval of the dental assistant's medicine tray and then locked during the day. The staff reported that all employees knew the location of the medication cabinet key. The staff reported that there were drug logs for the medications at which time the investigative team asked to view the medication logs; however, the staff did not produce a medication log at the initial visit. There was no inventory sheet for the logging in and out of controlled substances. During the second site visit to the oral surgery clinic, a medication log was presented to the team for review. This log book contained the patient's first initial and last name, the amount of a pre-listed medication log did not have documentation indicating the staff who administered the drugs, the lot numbers of the source vial for each medication given, or the expiration dates of the medications used.

Several stored items were observed in the sterilization room, including but not limited to: 1 cc syringes with 1" 21 gauge needles attached, 20 ml syringes with 1" 18 gauge needles attached, an Infection Control Manual, containers of EPA-approved environmental cleaner solution, dental instruments, an autoclave, and a cold sterile apparatus. A sharps container was also noted in the sterilization room.

The sterilization room was observed to be unorganized and unclean in areas around the sink and counters. The investigators observed the autoclave and the cold sterile tray on the countertop. The investigative team requested to see the autoclave log. The staff stated they did not perform biological testing; therefore, there was no autoclave log to be inspected or obtained. The staff stated the cold sterilization unit is cleaned every 28 days per the manufacturer instructions. Dental instruments were observed to be located in built-in shelves in the cabinet. The staff retrieved a set of instruments from a shelf and indicated these instruments were reserved for use for patients that were infected with HIV, hepatitis, or other communicable diseases. The staff reported these instruments were sterilized so much that the sheen was worn off. The investigative team observed these "separate" instruments. (Additional details are provided in the Infection Control section.)

The staff reported that individual patients are called back from the reception area and placed in an operatory room. Patients receive an intravenous (IV) line placement performed by the dental assistant. The patients receive IV sedation medication administered by the dental assistant. The medications, including the IV sedation medications, are kept in a plastic tray in the operatory room. The staff reported that a new bag of IV fluids (normal saline) is hung for each patient. The investigative team observed an IV pole in Operatory Room 1 that had an IV fluid bag and connected tubing hanging. No date or time was recorded on the fluid bag indicating when the tubing had been inserted into the bag, thereby breaking the sterility of the bag, nor was a patient name or identification number noted on the bag.

The staff reported that after an oral surgical procedure was completed, the patient was walked to the recovery area accompanied by a staff member. The recovery area was an office furnished with a recliner and an upholstered sofa. The staff reported the patients remained in the recovery area for a period of time after which a family member or friend escort, present in the dental office, would be allowed to come back and retrieve the patient to take them home.

# **Injection Practices: IV Catheter and Line Placement**

The dental assistants reported that they were responsible for placing the patients' IV catheters and lines. The staff stated that the IV catheter placement was performed in the operatory room. The investigative team asked where the IV is placed on the patient, and the dental assistant stated wherever she can get it started—in the arm or hand. When asked who provided the training for placement of IV catheters, the dental assistants stated the oral surgeon trained them. One dental assistant also mentioned she attended an Oral and Anesthetics training in Chicago in 1988 or 1989.

## **Injection Practices: Sedation**

The dental assistants stated they prepare and administer the controlled substances for anesthetization of the patients. One dental assistant stated she uses a "formula" to determine what sedation medications are used and how much of each medication is administered. The dental assistant stated the "formula" was usually Valium<sup>®</sup> 5 mg, ketamine 25 mg, and propofol 150-200 mg. The dental assistant stated that the amount of each controlled drug administered is adjusted according to the weight of the patient. A body weight scale was located at the oral surgical clinic and the staff reported the patients were weighed the day of their dental procedure. Upon review of patient charts, the investigative team observed that some patients' body weights were recorded, but the recording of weight on all patients was not consistently documented. When one investigative team member asked how it was determined if the patient was sedated adequately for procedures, the dental assistant stated she "tickles the eyelashes to see if the patient is asleep enough, sometimes I talk to them (patient), and administer more (medications) if needed."

The dental assistant stated multi-dose medication vials are kept in each dental assistant's plastic tray. The tray is taken from the drug cabinet to the immediate patient treatment area at

the beginning of the day for use, and is returned to the drug cabinet at the end of the day after the last patient appointment. Multi-dose vials of medications, including controlled substances, used for anesthesia, were observed in the tray that was examined. Medications that were noted included the following: naloxone HCL 0.4 mg/ml, unopened and expired; atropine sulfate 0.4mg/ml, opened and expired; midazolam 2mg/2ml, unopened (2 vials); heparin lock flush 100 usp units/ml, expired; labetalol hydrochloride 100mg/20ml; propofol 1% 20 ml bottle, unopened; ketamine HCL 500mg/10ml, opened; and diazepam 5mg/ml 10 ml, bottle opened (2 vials). No dates were marked on the medication vials indicating when the sterility seals were broken and the vials had been opened. No patient names were marked on the medication vials indicating individual patient use. The staff reported that multi-dose vials of controlled substances used for anesthesia were used on multiple patients—not dedicated to individual patients. A vial of open, expired atropine sulfate was noted to be in one of the dental assistant's trays. The dental assistant stated that the atropine sulfate was used on African American patients to control excessive salivation.

## **Infection Control**

Direct patient care was not observed, however, questions were asked in relation to direct patient care and personnel procedures. The dentist advised that the facility "probably did not" have written infection prevention policies and procedures in place. However, an infection control manual from 1996 that belonged to one of the dental assistants was retrieved. This manual was not being used and the dentist was unaware of it. Dr. Harrington deferred questions regarding infection control to his two dental assistants. The facility did not have standard written protocols or procedures for staff to follow to manage or prevent occupational exposures to bloodborne pathogens or healthcare-associated infections.

The facility provided necessary supplies for adherence to proper hand hygiene practices and the supplies were readily available, including soap and water in the restroom. The facility had appropriate personal protective equipment (PPE) available. Staff reported hand hygiene is performed correctly before and after contact with a patient. Staff reported gloves are disposed between patients, they do not wash or reuse gloves, and that PPE is worn when procedures are conducted. The dentist stated that the practice takes care of a lot of patients infected with HIV and hepatitis and that his staff is attuned to PPE. The staff reported they clean all environmental surfaces with Sani-Cloth<sup>®</sup> wipes, including countertops and chairs; Clorox bleach or alcohol is used to clean blood spills. Sani-Cloth wipes are bactericidal, tuberculocidal, and virucidal, and are EPA approved.

The staff reported that all reusable devices are sterilized prior to reuse. Sterilization consisted of autoclaving or cold sterilization. Sterilization was performed in a central room also used for storage and where the medicine cabinet was located. The dentist advised they use separate instruments for patients known to be infected with HIV, hepatitis, or a communicable disease versus patients without such infections. Staff reported the instruments used on patients known to be infected in full strength bleach and scrubbed before putting in the autoclave. The doctor stated these instruments are "sterilized so much that the sheen is worn off." Upon inspection, it was observed that these instruments had brownish/orange spots on them. These specific instruments were wrapped in gauze with steri-

strip (Comply<sup>™</sup> tape) around them. The assistants said they use Comply tape in "almost every load." Staff advised they soak certain instruments in the cold sterile unit and that the cold sterile solution is changed every 28 days per manufacturer instructions. The practice did not have an ultrasonic machine, but they used ultrasonic solution in the sink to soak instruments. The investigators observed many instruments soaking in the sink.

The dental assistants reported that the suction traps on vacuum units are cleaned once a week. When asked to view the vacuum trap, a dental assistant had a difficult time trying to remove the filter for observation. The staff advised the tubing for the suction apparatus was cleaned on a weekly basis. The assistants reported that after a tooth extraction, the tubing is cleaned but not necessarily disinfected. Sharps disposal containers were located in the operatories and in the sterilization area.

## **Procedure Documentation**

During the field investigation, treatment records for the index case-patient were obtained for the dates of interest. A review of records for these dates identified a number of problems with documentation. The Consultation Record for June 19, 2012, has the patient's name, date of visit, age, and the referring dentist's name. The chart has teeth #30 and #31 circled and notes concerning implants and abutments. Also, there is a note stating, "Bone graft – no charge from drilling process." This document is not signed, and the treatment plan is not clearly defined. The Surgery Record is dated July 17, 2012, a key date of interest in the investigation. On this document, staff advised that the assistants' initials are presented by the first letter of their first names in the top left corner, and "wife" is named as escort. The chart has tooth #30 circled with the word "remove." Teeth #4 and #31 are marked. The Notes section has a copy of an implant label with reference and lot numbers. The pre-op blood pressure and pulse are documented, but not the post-op measurements. There is no place on the form to record the weight of the patient. The patient's weight was not documented on the June 19, 2012, Consultation Record or the July 17, 2012, Surgery Record. The Meds Given section has check marks on Oxygen, Nitrous, and Local, but doesn't provide any service delivery details; the medicines marked as administered are Reglan<sup>®</sup>, Decadron<sup>®</sup>, propofol, Versed<sup>®</sup> and Cleocin<sup>®</sup>. While there is a numerical value given, only Cleocin has a unit of measurement. The IV location is interpreted to read as LACF (left antecubital fossa), but this is difficult to read. The Recovery section states the patient's condition as "good"; the post-op care notes are nearly illegible, but do state to return to the office in 10 days. There is no signature on the Surgery Record.

A review of the index case-patient's records from earlier visits illustrates documentation to be variable and remarkably brief. Documentation is inconsistent concerning the intravenous drugs given to the index patient when comparing the Surgery Record of July 17, 2012 to the July 2012 drug log. The drug log page for July 2012 has no signatures or initials of staff and the patients are listed by first initial and last name. The medication log was not observed on the initial visit, but was obtained on the subsequent visit. Investigators asked for a drug inventory identifying contents of the medicine cabinet and a controlled substance inventory – no documentation was available. Staff advised that the multi-dose medications were neither dated nor labeled for individual use.

A thorough chart abstraction was conducted as part of an epidemiologic risk factor study after the field investigation (Section 11).

# **SECTION 5**

# **Patient Notification**

#### **Patient Information Request**

On March 21, 2013, the OSDH received a hardcopy list from the Oklahoma Board of Dentistry containing information for approximately 7,300 patients who had visited the Tulsa or Owasso location of Dr. W. Scott Harrington's oral surgical practice. The information on this list included patient account number, patient name, work and personal phone numbers, birth date, and last visit date. Another hard copy list was received of patients who visited the oral surgeon's office between March 1, 2012, and March 20, 2013. This list included the patient's name, brief appointment summary, phone numbers, previous medications, last visit date, insurance coverage, appointment time and date, and the chair for the procedure (later referred to as the "scheduler list"). Both lists were entered into a database created by the OSDH for analytic and recordkeeping purposes.

The OSDH subsequently requested an electronic file of patient contact information for Dr. Harrington's practice. The file was received on March 22, 2013, and included the name, full home address, date of birth, phone number, and social security number for 6,016 patients. The file was provided to the OSDH in Microsoft Excel format. Determining the completeness and accuracy of both the scheduler list and the patient contact information in the Excel file was a challenge, because many of the entries contained a combination of patients' nicknames, middle names, and full names.

After discussion, the decision was made to begin patient notification by mail starting with the patients on the scheduler list. The first batch of notification letter mailings coincided with the public media announcement of the public health investigation and recommendation for all patients of Dr. Harrington to be tested for HIV and hepatitis B and C. Ten data entry personnel were used to enter the hard copy data from the scheduler list into a spreadsheet. This spreadsheet was then electronically cross-matched with the address spreadsheet to find addresses for each patient. To reduce mailing costs, the mailing list was also periodically cross-matched with an OSDH Public Health Laboratory database containing information on persons recently tested as part of the Dental HAI Investigation and Response to avoid unnecessary renotification.

## **Completeness and Accuracy**

The address review protocol (Appendix A, 5-1) was followed to verify the patients' addresses each day on the patient notification lists. The protocol was approved on March 28, 2013, for the verification of address for first class letters sent to patients who needed to be notified of the potential exposure to a contagious disease and the availability of free testing. The protocol followed the same terms used by the OSDH in notifying individuals during a past HIPAA breach, which occurred in 2011. The terms of the OSDH HIPAA Breach protocol were submitted to the

Department of Health and Human Services Office of Civil Rights, who had the opportunity to review it in 2011.

The initial patient notification letter (Appendix A, 5-2) was created and approved by Unified Command on March 27, 2013. Once approved, the letter was sent to the OSDH mail center where the Satori Software's Bulk Mailer version 5 Professional (NEOPOST owns Satori), utilizing the National Change of Address (NCOA) database from the United States Postal Service (USPS), was used to verify and/or correct addresses. If an address could not be verified or corrected, the patient's name was sent back for additional background checks.

As the public health response unfolded, three sequential revisions (dated April 8, May 6 and June 14, 2013) of the initial patient notification letter were adopted, largely to reflect the changes in the clinical operation schedule and accessibility of the patient information hotline. A total of 5,810 patient notification letters were mailed covering all known patients since January 2007, with nearly 96% of Dr. Harrington's patients currently living within the state of Oklahoma, although there were patients from 34 other states. The Kansas Department of Health and Environment, Arkansas Department of Health, and the Texas Department of State Health Services worked closely with the OSDH to contact and test patients currently residing in their states.

A total of 1,123 letters were returned from the USPS. If a returned label was not included on the returned letter, each patient with a returned letter was searched using either LexisNexis<sup>®</sup>, Accurint<sup>®</sup>, or CLEAR for more accurate address information and mailed again. After receiving a returned letter, at least one more mailing attempt was made before considering the patient lost to follow up. All information was documented and data entered into both an Excel tracking spreadsheet and the OSDH secure web-based disease reporting and investigation system called "PHIDDO" (Public Health Investigation and Disease Detection of Oklahoma).

# **Office of Juvenile Affairs Mailing**

During the course of the patient notification effort, it was discovered that Dr. Harrington had contracted to provide dental care and oral surgery for detainees at a local juvenile detention center, which had closed within the last several years. The Office of Juvenile Affairs (OJA) in Oklahoma was contacted to determine methodology to provide patient notification to these individuals. With the assistance of the OJA and the Oklahoma Health Care Authority, OSDH received a complete list of an additional 189 patients to be notified regarding possible exposure and recommendation for testing.

# **Negative Results Mailing**

All patients who obtained blood draws through the THD and tested negative on all tests performed at the OSDH Public Health Laboratory were sent a negative results letter. If the patient was tested within six months of their last dental procedure at Dr. Harrington's clinic, they received a letter which stated they should be retested (Appendix A, 5-3) to assure negative test results at least six months past their last patient encounter. Patients who obtained their blood draws at non-THD county health department sites were contacted by a public health

nurse at the respective health department regarding their negative test results and informed of any recommendations for follow up testing.

# **SECTION 6**

# **Clinic Organization and Operations**

#### **Overview of County Health Department Clinics**

Patients of W. Scott Harrington, DMD, who elected to receive free laboratory testing through the OSDH Public Health Laboratory, were instructed to present to a county health department for blood collection. Most former dental patients resided in or near Tulsa County; therefore, the THD was the principal clinic site for phlebotomy and patient data collection. All other county health departments also provided these services free of charge to self-identified dental patients. As of the close of clinic operations on June 27, 2013, a total of 3,991 persons had visited county health departments across the state to have their blood drawn for HIV, HBV and HCV testing. Of these, 3,251 (81.5%) were seen at THD; 676 (16.9%) visited other OSDH county health departments, and 64 (1.6%) had their blood drawn at the Oklahoma City-County Health Department.

In anticipation of a large influx of patients shortly after the media release and press conference announcing the dental patient notification effort, the THD utilized extended clinic hours and emergency response protocols and procedures to provide efficient operations. Coordination of the response was aligned with the Points of Dispensing (POD) operations under THD's Mass Immunization/Prophylaxis Strategy (MIPS) Annex. The MIPS was used to develop the plan of action for the operational response.

## **Phone Bank**

Phone bank operations began simultaneously with the press conference on March 28, 2013, at THD to facilitate and answer questions from the public, patients of Dr. Harrington, concerned medical facility personnel, and insurance companies. The phone bank operations ran twelve hours a day for several days and continued through April 12, 2013, scaling back as call volume decreased, and operating as needed through April 22. The phone bank was staffed with up to six operators for three weeks after the initial press conference.

Phone bank operators were provided Frequently Asked Questions (FAQs) documents regarding HBV, HCV and HIV, as well as FAQs specific to the Dental Public Health Investigation [Appendix B]. The phone bank was very customer service oriented. The pre-written script helped the process run smoothly and enabled operators to refer callers to the right resources; this was especially helpful during times of high call volumes. Mental health professionals were scheduled to staff the phone bank as available; a process was in place to refer callers by phone to the necessary mental health resources in their absence.

Communication flow between Phone Bank Unit Leaders and the Operations Section within the ICS chain of command utilized a variety of communication methods, including text messaging, email and phone. Questions arising from the phone bank were answered in a timely manner and frequent updates to public information were communicated to the phone bank. Unit

Leaders provided "just in time" training to all operators at the start of a shift or when updated information was received.

THD also established a 24-hour public information hotline (918-595-4500) on March 28, 2013, immediately following the initial press conference. The hotline directed callers to a main message which was a recording of the most recent information regarding the investigation. Callers were given options to speak to a public health professional in English or Spanish from 7am to 7pm on weekdays, and shortened hours on the first two Saturdays of the public health response.

# **Phlebotomy Clinic**

THD began phlebotomy clinic operations on Saturday, March 30, 2013. The clinic was located at the Tulsa Health Department North Regional Health and Wellness Center (NRHC) at 5635 North Martin Luther King Jr. Blvd in Tulsa and was open on a walk-in basis. This location was selected due to the large parking area, building layout, loading dock, accessible computer network and the capacity to expand registration and phlebotomy work stations. Operations and Logistics staff began clinic set up on March 28, 2013. The free clinic ran daily Monday through Friday and two Saturdays (March 30 and April 6) at NRHC through April 12, 2013.

The phlebotomy clinic flow was set up using the POD model in the THD MIPS Plan. A schematic drawing of the clinic organization and flow is located in Appendix A, 6-1. Job Action Sheets and Staffing Worksheets from the MIPS Plan were modified to reflect the unique tasks associated with phlebotomy operations. Two Clinical Branch Directors led the operation of the clinic. Staffing included a physician consultant, a mental health professional and unit leaders assigned to specific functions until April 12, 2013, when the clinic began to transition to appointment-based operations with reduced staffing and combined functions.

Phlebotomy personnel were instructed to obtain three serum separator tubes of blood per patient; all specimens were couriered daily to the OSDH Public Health Laboratory where two tubes were used for initial HBV, HCV, and HIV testing. Positive tests flagged the third tube to be shipped to external laboratories for confirmatory and/or additional testing.

The THD began transitioning from a full scale clinical response to day-to-day activities on April 15, 2013, when the number of clients seeking services and the number of calls to the phone bank were not exceeding regular clinic and phone capacity. From April 15 until June 27, 2013, modifications were made to accommodate patients requesting to receive testing through the Dental HAI response. Phlebotomy services were transitioned to an appointment basis with continued walk-in services provided at the NRHC and Central Regional Health Center (CRHC).

Additional phlebotomy and laboratory staff were requested to supplement clinic staffing during the transition. Time tracking, daily numbers reporting and other incident documentation was not maintained at the same level or frequency after the transition, though Incident Command was still in effect. During the step-down period, phone bank calls were directed to THD reception staff who provided general information and transferred calls needing technical assistance to subject matter experts accordingly. THD epidemiologists began case investigations and assisted reception staff with responding to technical questions.

## Staging

ICS Form 211 was used for the sign-in sheet for medical and non-medical personnel. The THD Staffing Worksheet was modified from POD and RDS functions to reflect the positions on the phlebotomy clinic organizational chart. Personnel job assignments were tracked to assist with documentation of and accountability for on-site personnel resources. Additional personnel were provided just in time training to assist with this function, including an Oklahoma Medical Reserve Corps (OKMRC) volunteer.

## Positions

## Greeter Unit

The Greeter Unit is typically limited to forms distribution or combined with Registration under one Unit Leader during MIPS Plan activation. This incident expanded the Greeter function to include directing foot traffic through the clinic, collecting completed paperwork, and providing printed material at the exit table. Greeter Unit personnel were stationed in multiple locations throughout the clinic; the Unit Leader made rounds to ensure accessibility to all staff.

## Exit Table

The Exit Table was the collection point for consent forms, laboratory forms and completed supplemental epidemiological investigation forms. A volunteer assigned to the Exit Table during the initial clinic operation created an updated Job Action Sheet, including form handling instructions and provided it to the Clinical Branch which assisted with just in time training of new personnel in subsequent clinics.

## **Registration Unit**

The nature of the Dental HAI Investigation and Response incident required collection of epidemiologic data in Oklahoma's electronic disease reporting and investigation system called "PHIDDO" (Public Health Investigation and Disease Detection of Oklahoma), which presented a limitation on who could fill the Registration Unit positions – users needed to be a THD or OSDH employee with a user name, password and approval of access to the system. Many existing users of PHIDDO are also public health nurses who were needed elsewhere in the clinic to perform phlebotomy. The phlebotomy skills were considered priority over PHIDDO access, so new users had to be identified and trained on the PHIDDO system. The Clinical Branch had to coordinate with Staging to identify daily assignments for dually skilled employees.

A total of eight registration stations were set up in the lobby of the NRHC: five were existing reception work stations with computer equipment and partitions and three were converted waiting rooms, wired for internet access, and equipped with computers and printers by IT/Communications staff the day before the clinic opened. This allowed for greater throughput and maintained privacy of individuals seeking service.

Registration Unit staff entered client information into PHIDDO, generated and printed lab requisitions, and distributed supplemental epidemiological investigation forms to individuals who had seen the dentist within the previous 12 months. Individuals were then directed to the phlebotomy waiting room where they were provided snacks and beverages and an opportunity to fill out the supplemental form.

## Phlebotomy Unit

The large multipurpose room at NRCH was utilized as the phlebotomy clinic location for its ability to support the patient flow of the clinic. The phlebotomy unit originally incorporated both blood draw and laboratory functions. The clinic began operations with ten phlebotomy stations. The number of stations open at one time was dependent on phlebotomists' availability and patient flow. On average, 5-10 stations were open with the capacity to scale up and down. The phlebotomy unit had the capacity to open up 20 stations at a time. At the end of each clinical operating period, stations would begin demobilizing.

During the first day of clinic operations, 420 patients went through the clinic in four hours. This generated 1,200+ tubes of blood to be processed. Span of control was difficult to maintain due to the number of staff needed to draw blood and process blood samples in the laboratory. Thus, laboratory functions were separated from the phlebotomy unit on the second day of operations.

Tulsa Fire Department and Emergency Medical Services Agency (EMSA) paramedics were onsite serving as the Medical Unit. They provided assistance on the first day with difficult blood draws and eventually provided additional staff for the phlebotomy function, integrating well within the clinic operations structure. A specialized protocol from the THD Medical Director was necessary to accommodate blood draw from patients with indwelling ports. A skilled THD nurse was identified to perform the procedure and the Regional Medical Response System (RMRS) provided the necessary drugs and supplies. During the second week of clinic operations, curbside phlebotomy service was offered for individuals with access and functional needs by appointment through the phone bank.

# Strike Teams

Strike Teams were organized to conduct in-home blood draws for home bound individuals with access and functional needs. Strike teams conducted eight home visits.

# Laboratory Unit

Materials to support the Laboratory Unit during initial set up were gathered from other THD locations and a limited number of centrifuges were available internally. RMRS quickly provided centrifuges on the first day of operations before the shipment of equipment and supplies was received from OSDH vendors. This allowed for more efficient processing of blood samples. Laboratory Unit personnel stayed until all samples were logged and processed. Laboratory Unit procedures were streamlined and ran efficiently and effectively with no reports of samples rejected from the Public Health Laboratory.

## Material Support

Equipment and supplies for the phlebotomy clinic were obtained from multiple programs within THD, OSDH and community partners. The ICS 211 form was implemented in the supply room to enable accurate tracking of equipment and supplies status during operations and for demobilization.

# Staff Support

The American Red Cross provided food and beverages for clinic workers and clients during the first two weeks of clinic operations. This enabled staff to stay on-site for breaks and meals and was essential for maintaining continuity of services to the public. Client access to snacks and hydration before reaching the phlebotomy unit was also critical to the success of the blood draw. Bottled water was delivered to personnel at their work stations between breaks.

## Information Technology (IT)/Communications

IT/Communications staff set up PHIDDO access, laboratory requisition printing and network accessibility to eight registration stations and to the Clinic Branch Director workspace in two days. Additional computer access points and test results printing processes were added during the duration of the incident.

For the public health response, a Dental HAI module was rapidly added to the PHIDDO system as a central repository for data collection, case investigations, and analysis. Two OSDH staff members provided long term, on-site technical support for the PHIDDO functionality and ensured new users gained access to the system and were trained.

## Security Unit

The Tulsa County Sheriff's Office provided outdoor security for early clinic operations, and THD Security Officers provided indoor security and building access control. Various THD and OKMRC personnel were assigned safety roles to monitor workspaces and common areas for slip, trip and fall hazards; proper lifting techniques; adherence to bloodborne pathogen safety protocols; and to document incidents. Twelve incident reports were recorded, the majority of which were fainting spells or similar vasovagal response reactions to phlebotomy procedures. Only one slip-trip incident and a single clean needle stick incident were reported.

# Epidemiology Unit

The THD Epidemiology Unit used the OSDH-developed supplemental epidemiological investigation form for individuals who had seen the dentist within the last year [Appendix A, 6-2]. The three-page form asked detailed questions about the date/time of the last visit and procedures the patient had undergone at the Harrington oral surgical clinic. The form was provided to the patient at the time of their blood draw, filled out at the clinic, and collected before the patient's departure. The supplemental forms were then separated from the consent forms and transported in a lock box back to the James Goodwin Health Center. The THD Epidemiology Unit entered data from the forms into PHIDDO.

## **Affiliated Community Partners**

The OKMRC, the RMRS, the Tulsa Fire Department, the Tulsa County Sheriff's Office, the American Red Cross, and Tulsa EMSA partnered with THD during clinic and phone bank operations to provide medical assistance, supplies, patient and volunteer support, and to respond to additional requests as needed. The Tulsa Area Emergency Management Agency was a liaison agency. The 2-1-1 Helpline was provided the FAQs documents to field general questions and refer clients to THD for assistance. Antioch Baptist Church provided overflow parking during the clinic operations at the North Regional Health and Wellness Center as needed.

## **Mental Health Services**

Mental health professionals from community partner agencies were utilized at the phlebotomy clinic during the first phase of the clinic operation. These individuals provided emotional support to clients during the blood draw process and also to the public health workforce. Mental/behavioral health support was also provided by OKMRC volunteers as well as employees from the Counseling and Recovery Services of Oklahoma, Family and Children Services, and the Oklahoma Department of Mental Health and Substance Abuse Services.

#### Staffing

The extended hours of the phone bank and opening of the phlebotomy clinic on a holiday weekend with one day's notice presented a challenge for finding personnel available and willing to work. Emails were sent to all THD employees and OKMRC volunteers requesting assistance, and follow up phone calls were made throughout the holiday weekend, including Easter Sunday, to solicit staffing for the clinics. THD employee participation was voluntary. A total of 152 THD employees participated in the public health response with all other THD staff detailed to maintaining day to day operations.

Region 7 OKMRC activation was requested for clinical and phone bank operations starting on March 28, 2013. The phone bank staffing request was sent in advance of the press conference. The OKMRC Administrative Team provided support to the response by performing credential checks on medical personnel and vetting documentation for volunteers. The State of Oklahoma has no standardized license or credential for phlebotomists.

OKMRC volunteers were integrated into the public health response in every clinical and phone bank role, except Registration/PHIDDO because of restricted access to the PHIDDO system. A total of 185 OKMRC volunteers assisted in the Dental HAI Response from March 28 through May 2, 2013, representing sixteen counties across Oklahoma: Craig, Creek, Garfield, Logan, Love, Mayes, Muskogee, Oklahoma, Okmulgee, Payne, Rogers, Seminole, Texas, Tulsa, Wagoner, and Washington.

Volunteers were sent home at the end of their shift and thank you notes were sent to participating volunteers. OKMRC returned to pre-incident status in May 2013.

# Section 7

# Public Health Laboratory Testing

#### **Specimen Collection and Processing**

Testing for hepatitis B and C and HIV through the OSDH Public Health Laboratory was offered to all patients of W. Scott Harrington, DMD as a core component of the public health response. Blood collection and shipping protocols were developed for use by Oklahoma county health departments, Oklahoma physicians, and out-of-state public health departments [Appendix A, 7-1, 7-2, 7-3]. The majority of the persons who requested testing (3,348) presented to the THD for specimen collection. Others received blood draws at various county health department clinics and physician's offices from around the state of Oklahoma (841 patients) and other facilities located outside of Oklahoma (17 patients). In addition, OSDH collected blood samples from 4 current or previous employees who had direct contact with patients.

All blood samples collected at THD and other county health department clinics were drawn by licensed nursing or laboratory personnel and submitted, accessioned and handled through previously-established laboratory procedures. Slight modifications to the times of regular courier pick-up of specimens from clinics (later in the day and Saturdays) for delivery to the testing site (OSDH Public Health Laboratory in Oklahoma City) were made to accommodate work schedules at the Public Health Laboratory and weekend clinics specifically implemented at the THD as part of this investigation and response.

Three full serum separator tubes of whole blood were requested for each patient: one for HIV testing, one for HBV and HCV testing and the third (supplemental) tube for possible re-testing or viral load testing and/or genotyping. Thirty minutes to one hour after collection of blood, serum separator tubes were centrifuged (10 minutes at ~1000 X g) then refrigerated at 2 - 8°C prior to transport to the OSDH Public Health Laboratory.

A minority of specimens were initially collected in red-stopper clot tubes; following blood draw, the tube was gently inverted 3 to 5 times, kept at room temperature for 10 minutes to clot, centrifuged for 10 minutes at ~1000 X g to separate the serum, which was then transferred to a polypropylene tube with no additives, and finally refrigerated at 2 - 8°C for transport to the OSDH Public Health Laboratory.

Separated serum was accessioned into the laboratory information management system as per routine protocols by the OSDH Public Health Laboratory. Serum used for HIV, HBV and HCV immunological-based testing was refrigerated at 2 - 8°C for up to 7 days from the time of collection or, if delayed testing was anticipated, was frozen at  $-20^{\circ}$ C or colder until testing was completed. Additional serum was poured-off and frozen (-20°C or colder) upon receipt. Repeat freeze-thaws were avoided.

Occasionally, volumes of serum submitted on individual patients were insufficient for the planned testing. For these patients, testing was prioritized as follows: HCV then HIV then HBV. Serum was combined from two or more tubes, as needed, to complete as much immunologic and/or molecular testing as possible. For cases that screened positive for HCV, if sufficient serum remained, priority was given to viral load and/or genotyping determinations over HIV and HBV screening. If initial volumes of serum submitted were insufficient to complete testing on any patient, a redraw of blood was requested. As standard protocol, redraws of blood were also requested for patients with indeterminate results on HIV or HBV screening tests.

# Laboratory Testing

Specimens were initially screened by immunological-based testing for evidence of HCV, HBV, and HIV infection by laboratory methods routinely used in the OSDH Public Health Laboratory. Specimens reactive for HCV were referred to a commercial reference laboratory for additional HCV viral load determination. If the HCV viral load test result was above a certain cut-off value, the specimen was then reflexed for testing to determine HCV genotype. Specific specimens indicating active HCV infection were also submitted to the CDC for quasispecies analysis as part of the epidemiologic investigation.

# HIV, HBV and HCV Screening Methodologies

Patient specimens were screened for HCV, HBV, and HIV infection by the OSDH Public Health Laboratory using standard protocols, as follows:

- HBV:
  - **Bio-Rad Genetic Systems HBsAg EIA 3.0** for detection of hepatitis B surface antigen (HBsAg)
    - **initially non-reactive** specimens are considered **negative** for HBsAg and are not tested further
    - initially reactive specimens are re-tested in duplicate
      - if both tests are non-reactive on re-testing, specimens are considered negative for HBsAg and are not tested further;
      - ➢ if one test is reactive and the other non-reactive on re-testing, the specimen is considered repeatedly reactive and a neutralization test is performed;
      - if both tests are reactive on re-testing, specimens are reflexed to a confirmatory neutralization test.
  - **Bio-Rad Genetic Systems HBsAg Confirmatory Assay** is a qualitative assay intended for the confirmation of HBsAg-reactive specimens detected by GS HBsAg EIA
    - specimens which are neutralized <50% are considered indeterminate for HBsAg and either an additional specimen is requested or a different test methodology is recommended.
    - repeatedly reactive specimens which can be neutralized by ≥50% are considered **positive** for HBsAg and are not tested further.
- HCV:
  - **Ortho HCV Version 3.0 ELISA Test System** uses recombinant HCV antigens (c22-3, c200 and NS5) for qualitative detection of antibody to HCV

- **initially non-reactive specimens** are considered **negative** for HCV and are not tested further
- initially reactive specimens are re-tested in duplicate
  - if both tests are non-reactive on re-testing, specimens are considered negative for HCV and are not tested further;
  - if one test is reactive and the other non-reactive on re-testing, specimens are considered repeatedly reactive for the presence of HCV and these specimens were referred to a commercial laboratory for supplemental molecular testing;
  - if both tests are reactive on re-testing, specimens are considered repeatedly reactive for HCV. In the current investigation, these cases were referred to a commercial laboratory for supplemental molecular testing.
- HIV:
  - Avioq HIV-1 Microelisa System (ELISA) uses inactivated, purified HIV-1 lysate proteins, which are coated onto the wells of microwell plates, for the qualitative detection of antibodies to HIV type 1
    - initially reactive specimens are re-tested in duplicate;
      - if both tests are non-reactive on re-testing, specimens are considered negative for HIV and are not tested further;
      - if one test is reactive and the other non-reactive on re-testing, specimens are considered repeatedly reactive for HIV and reflexed to Western Blot confirmatory testing;
      - if both tests are reactive on re-testing, specimens are reflexed to confirmatory Western blot analysis.
  - Bio-Rad Genetic Systems HIV-1 Western Blot uses proteins of HIV-1, fractionated by SDS-PAGE and immobilized on a nitrocellulose strip, which are then reacted with serum for the detection of antibodies to HIV-1
    - specimens with no bands present are reported as unsatisfactory, and another specimen is requested for testing;
    - specimens with one or more bands present but not meeting the criteria for being positive are considered indeterminate and another specimen is requested for testing;
    - specimens with **at least two major bands** (gp160/120, gp41, or p24) present of the correct intensity are considered **positive** for HIV-1 and are not tested further.

# Molecular Testing Methodology

Serum from HCV screen-positive patients were submitted to a commercial reference laboratory for molecular testing, which included:

- Roche Molecular Systems, COBAS<sup>®</sup> Ampliprep/COBAS<sup>®</sup> TaqMan<sup>®</sup> HCV Test, v2.0, a realtime, reverse transcriptase-polymerase chain reaction (PCR) assay for quantitation of HCV RNA
  - Specimens with values <43 IU/mL are below the level of quantitation of the assay and are not tested further;
  - Specimens with values  $\geq$ 43 IU/mL are considered positive for HCV;

- Specimens with values ≥300 IU/mL are reflexed to an HCV genotyping line blot assay.
- INNO-LiPA Hepatitis C Viral RNA Geotyping Test is a reverse transcriptase-PCR/reverse line blot method based on genotype-specific oligonucleotides to the 5-UTR and core region of the HCV genome, and is able to distinguish among major types and most common subtypes of HCV, including: 1, 1a, 1b, 1a/b; 2, 2a/c, 2b; 3, 3a, 3b, 3c, 3k; 4, 4a/c/d, 4b, 4e, 4f, 4h; 5, 5a; and 6, 6a/b, 6c-l.

# **Reporting of Results**

Laboratory test reports were issued to the submitting facility, as per routine laboratory procedures, via electronic fax and/or US mail (physician's offices). All patients who obtained blood draws through the THD and tested negative on all tests performed at the OSDH Public Health Laboratory were sent a negative results letter. If the patient was tested within six months of their last dental procedure at Dr. Harrington's clinic, they received a letter which stated they should be retested (Appendix A, 5-3) to assure negative test results at least six months past their last patient encounter. Patients who obtained their blood draws at county health departments other than THD were contacted by public health nurses at the respective local county health department regarding their negative test results and informed of any recommendations for follow up testing. All patients with a positive or indeterminate test result were assigned to the case investigation team for personal notification and counseling.

# Results

A total of 4,209 specimens from patients of the oral surgical facility were received by the OSDH Public Health Laboratory; 21 specimens were submitted for re-test due to insufficient sample volume or otherwise inadequate specimen requirements and 60 specimens were submitted for re-testing 6 months after initial testing on individuals who were recent patients of the dental facility and, if exposed, may not have had time to develop antibodies. Four patients tested were confirmed positive for HIV, 13 tested repeatedly reactive for HBV, of which 4 were confirmed positive by neutralization, and 9 were indeterminate. Eighty-two specimens were reactive for HCV antibodies indicating prior exposure to HCV, 49 of which were confirmed by HCV viral load testing demonstrating active hepatitis C infection. Of the 49 specimens testing positive for HCV RNA, 44 were of sufficient viral load to genotype. The following genotypes were determined: 29 were type 1 (25 were 1a and four were 1b), 12 were type 2 (one was type 2a, 10 were type 2b, and one was type 2a/2c), and three were type 3 (all type 3a).

All samples obtained from employees of the oral surgical practice screened negative for evidence of infection with HCV, HBV, and HIV.

# **SECTION 8**

# Hepatitis C Genotypes and Quasispecies Analysis

#### **Hepatitis C Virus Genotypes**

When conducting an epidemiologic investigation of potential patient-to-patient transmission of HCV, an important variable to know is the genotype of HCV with which each case patient is infected. Genotypes of HCV are genetically distinct groups of the virus that have arisen during its evolution. Each area of the world has its own distribution of HCV genotypes. Approximately 75% of Americans with HCV infection have genotype 1 of the virus (subtypes 1a or 1b), and 20-25% have genotypes 2 or 3. Very small numbers of persons in the U.S. are infected with genotypes 4, 5, or 6. Most persons with HCV are found to have only one principal genotype, but it is possible to have a co-infection with more than one genotype of HCV.

#### **Quasispecies and Viral Mutation**

Within all individuals, slightly different genetic versions of the person's genotype are present because viral mutations occur over time spontaneously and in response to pressure from the person's immune response, forming genetically distinct viral groups called quasispecies.<sup>1</sup> Genotypes represent major genetic differences, and quasispecies represent minor genetic differences. Quasispecies continue to evolve in an individual over time, whereas the infecting genotype does not change. Quasispecies analysis can be used to establish linkage between the source of HCV infection and the recipient, e.g., mother to infant, nosocomial transmission between healthcare provider and patient, and healthcare workers with needlestick injuries to the source patient.

## **Dental Patient Case Linkage Analysis**

In order to analyze for any clustering of dental patients with hepatitis C that may represent patient-to-patient transmission, patient encounters during the scheduler period (March 1, 2012 – March 20, 2013) were plotted graphically by procedure date, virus genotype, and diagnosis of hepatitis C relative to their first dental visit at the Harrington oral surgical clinic [Appendix A, 8-1]. Each HCV-positive patient was assigned a patient number, which was plotted on the y-axis. The dates of patient visit were represented on the x-axis, by the day number assigned to each date during the investigation period. Every visit for each HCV-positive patient was represented by a marker on the day number of the visit. The genotype (if known) was represented by a different color. After the graphic was created, possible transmission clusters were identified by looking at days and weeks with multiple patients testing positive and with similar genotypes. Special attention was paid to time periods where a patient previously-diagnosed with hepatitis C had a visit within one week of a newly-identified HCV-positive patient. Once the case linkage analysis was complete, patients who had procedures performed during the possible cluster time period with no history of HCV testing were contacted by phone to encourage testing.

A cluster of seven dental patients with procedures occurring in July 2012 was identified (referenced around days 110 to 150 on graphic in Appendix 8-1). Three persons were infected with HCV genotype 1a, one with genotype 1b, one with genotype 2b, and two with unknown genotype. Samples from the five patients with known genotype (and sufficient viral load to perform molecular testing) were sent to the CDC for quasispecies analysis.

## Molecular Testing Methodology at CDC

Patient samples submitted to the CDC for genetic testing were first genotyped by sequencing and analysis of a 300-nucleotide segment of the NS5B region. Each quasispecies was isolated from samples with a 95% or greater NS5B sequence homology to other submitted samples, and the HVR-1 region of NS5B of each viral isolate was sequenced according to standard methods used by the CDC Viral Hepatitis Laboratory. Included in the phylogenetic analysis was a reference group of randomly selected samples from the National Health and Nutrition Examination Survey III participants.

## **Results of Quasispecies Analysis**

Phylogenetic analysis identified one confirmed patient cluster consisting of a patient with chronic hepatitis C (source patient, C13OK2.0) and another patient with acute disease (infected index patient, C13OK1.1). Both patients had dental procedures with IV sedation performed on July 17, 2012, and the source patient had his/her procedure performed prior to the infected index patient. The maximum genetic relatedness of the hepatitis C viruses tested from the source and index patients was 100% [Appendix A, 8-2]. The other three patient samples and the reference samples were distinct and unrelated [Appendix A, 8-3].

# **SECTION 9**

# Investigation of Positive Laboratory Results, March – September, 2013

#### Methodology

Title 63 Oklahoma Statute (O.S.) § 1-503 mandates the reporting of cases of diseases and conditions by Oklahoma healthcare providers and laboratories to the OSDH. Providers and laboratories are required to report hepatitis C diagnosis in persons  $\leq$ 40 years of age, or in persons of any age having jaundice or ALT  $\geq$ 400 with laboratory confirmation of HCV infection. Case reports and laboratory results are received by OSDH through mail, fax or secure electronic transmission to the Public Health Investigation and Disease Detection of Oklahoma (PHIDDO) system.

Once a positive report is received by the OSDH HIV/STD Service, field surveillance specialists review each case; those cases which need additional follow up are assigned to a communicable disease nurse or an epidemiologist at the county level for case investigation and patient education. The OSDH aims to have all hepatitis C investigations completed within 90 days.

All hepatitis C case reports and HCV-positive laboratory results received electronically through PHIDDO from March 1, 2013 through the end of September, 2013, were cross-matched with the list of Dr. Harrington's patients using Statistical Analysis Software (SAS). The two data sets were matched using patient first name, patient last name, patient date of birth, and patient social security number (if available). The cross-matching was performed once a week during the investigation period. All laboratory results and case reports that were received by mail or fax during the investigation period were manually record searched and compared to the dental patient list to find matches.

All of the matches identified through regular viral hepatitis surveillance activities along with those cases identified through testing at the OSDH Public Health Laboratory were assigned to the Dental HAI Response Team. The purpose of this team was to notify patients with positive test results for hepatitis B, hepatitis C, or HIV of the laboratory findings, complete an interview, and provide referral resources. The Dental HAI Response Team included members from OSDH and THD and was staffed by field surveillance specialists, disease intervention specialists, surveillance nurses, and epidemiologists. Cases were assigned through PHIDDO to the team by the Adult Viral Hepatitis Prevention Coordinator. The response team contacted the patients via telephone and left messages for patients that were not available. Patients who were not successfully contacted on the first call were attempted to be reached a minimum of three times before being classified as lost to follow-up.

A standard case report form was completed for all of the patients successfully contacted and who agreed to be interviewed. The interview included questions about signs or symptoms of the disease, potential exposures or risk factors, high risk settings, and previous diagnosis of hepatitis or HIV. In addition, patients were asked specifically about the dates of visits to Dr. Harrington's oral surgical clinic. If a case-patient reported a dental visit on or after March 1, 2012, and did not have a Dental HAI Epidemiologic Intake Form [Appendix A, 6-2] completed at the time of testing, then the form was completed during the interview. After all of the interviews were completed, the patients with positive hepatitis C results were classified according to the following categories:

- Hepatitis C case, but not a Harrington dental patient
- Diagnosis of hepatitis C preceded first dental visit to Harrington clinic (laboratory record documentation exists)
- Diagnosis of hepatitis C after first dental visit to Harrington clinic with self-report of personal risk factors\* for HCV exposure
- Diagnosis of hepatitis C after first dental visit to Harrington clinic and no self-report of personal risk factors
- Timing of hepatitis C diagnosis in relationship to dental visits is unknown; self-report of personal risk factors for HCV exposure
- Timing of hepatitis C diagnosis in relationship to dental visits is unknown; no self-report of personal risk factors
- \* recreational injection drug use, incarceration, tattoo receipt in unlicensed facility, healthcare worker with history of occupational exposure

# **Test Results**

In addition to conducting hepatitis C screening and case investigations, HIV and hepatitis B testing was also a component of this public health investigation. Although patients were highly encouraged to be tested for all three bloodborne viruses, patients did have the ability to refuse testing. One individual waived testing for HIV. A total of 4,208 people were tested for HIV; 4,209 were tested for hepatitis B and C through the OSDH Public Health Laboratory. An unknown number of dental patients sought testing through their private physician or other healthcare source. From OSDH public health laboratory testing and other surveillance sources identifying persons related to this investigation, 96 (2.3%) individuals tested positive for hepatitis B, and 4 (0.096%) tested positive for HIV. Of those who tested HCV-positive, 36 (38%) had a previous hepatitis C diagnosis.

Upon initial interviews with three HIV case-patients, a source of transmission could not be readily identified; therefore, assistance from the CDC was sought for a more in-depth case investigation. A Case of Public Health Importance (COPHI) investigation was started for each of these case-patients and additional specimens were collected for phylogenetic testing at the CDC HIV Laboratory. Upon completion of the investigation, it was determined that there was no evidence of HIV transmission associated with having an oral surgical procedure at Dr. Harrington's clinic.
A total of 96 persons had HCV-positive test results; however, six persons were not a dental patient of Dr. Harrington's but were household contacts of a Harrington dental patient. Of the 90 cases of hepatitis C among persons known to be patients of Dr. Harrington, 11 (12%) patients did not have an interview completed. These patients either refused to be interviewed, or were lost to follow-up. Nineteen (21%) had a diagnosis of hepatitis C before their first dental visit to Harrington's clinic, 63 (70%) were diagnosed after their initial dental visit, and for 8 patients (9%), the timing of the dental visit in relation to their hepatitis C diagnosis could not be determined. Among the 63 persons diagnosed after their initial dental visit, 32 (51%) reported high risk behaviors for exposure to HCV, 26 (41%) reported no or low risk behaviors, and 5 (8%) were not interviewed so risk ascertainment was not possible.

## **SECTION 10**

## Public Information Outreach

## Background

In March 2013, an investigation of the W. Scott Harrington oral surgical facility by professional staff from the OSDH and the THD and representatives from the Oklahoma Board of Dentistry documented numerous conditions and practices that violated health and safety laws. The potential for current and former patients to be at risk of blood-borne diseases that may have been acquired as a result of their dental procedures at the Harrington practice led to the realization that a massive notification and testing process was warranted for these patients. Given the scope and breadth of this operation, the public health agencies established a Unified Command under the Incident Command System to notify dental patients and recommend that they have their blood drawn for testing for hepatitis B, hepatitis C and HIV infection at free screening clinics established at THD, Oklahoma City-County Health Department and other county health departments in the state.

The respective communications personnel from the OSDH and THD established a Joint Information System (JIS) to plan the public release of information regarding the public health response including regular postings to each agency's website and the issuance of situation updates to news media as needed.

### Methodology

In the first week of Unified Command, daily teleconferences were held between the two agencies to move the investigation forward and determine appropriate media messaging. A call from the media investigating rumors of a Tulsa dentist under investigation prompted the release of a brief statement to the media on March 21, 2013.

Additional calls made by the media followed and the first major assignment for the JIS was the organization of a news conference to announce the initial findings of the investigation of the Harrington practice and plans for the public health response.

On March 28, 2013, a joint news conference at THD featured THD Director Dr. Bruce Dart, State Epidemiologist Dr. Kristy Bradley, and Oklahoma Board of Dentistry Executive Director Susan Rogers. A news release was provided to media attending the news conference with concurrent electronic release to more than 500 media outlets statewide. In the days following the news conference, THD set up its first screening venue for current and former Harrington patients, which prompted extensive national/state/local media attention and requests for interviews with THD personnel.

Local, state, and national media representatives arrived in Tulsa and requested on-camera interviews with THD staff and tours of the testing facility. An off-site media staging area was established for clinic operations on March 30, 2013, the first day of testing. The media staging

area was across the street from the clinic testing facility to ensure patient privacy and ample room for parking.

As the investigation and response progressed, JIS staff spoke at least daily to confer on the interviews each had conducted and agreement on issues for consistent messaging. Consultation was also sought with CDC's Division of Healthcare Quality Promotion. JIS staff used CDC's draft *Patient Notification Toolkit* and drew upon CDC's summary of lessons learned from previous investigations of dental practices in other states. Early on, the JIS issued twice-weekly situation updates, and then scaled back to weekly updates, which were jointly released to statewide media outlets. All Situation Updates and other publically released material are archived on the "Public Health Investigation of Tulsa Dental Practice" OSDH webpage accessible at: <a href="http://www.ok.gov/health/Organization/Office of Communications/News Releases/2013">http://www.ok.gov/health/Organization/Office of Communications/News Releases/2013</a>

Media monitoring was conducted through each agency's online media subscription services, including TVEyes Media Monitoring Suite and Meltwater News Report.

Media announcements, public information and directional advisories were posted regularly on THD and OSDH websites devoted specifically to the Harrington public health response. These websites featured "Frequently Asked Questions" (FAQ), fact sheets on hepatitis B and C and HIV, and instructions on the screening and testing process. Updates were also provided on THD and OSDH social media pages.

## Hotline

THD has an on-site call center which consists of six telephone workstations. This center is activated, as needed, to provide information to the public regarding an incident. THD established a 24-hour Public Information Hotline (918-595-4500) to provide the public with access to public health professionals who were able to answer questions and provide more detailed information. The hotline was opened on March 28, 2013, immediately following the initial press conference.

Call center staff received standardized "just in time training" to ensure the accuracy and consistency of information provided to callers. The call center was managed by the Phone Bank Unit Leader under the Operations Section Chief.

Upon connecting to the call center, a pre-recorded message was played for callers providing the recent information regarding the investigation. The message was developed and updated by the JIS and approved through ICS. Callers were given touch key options to speak to a public health professional in English or Spanish from 7 am to 7 pm on weekdays, and shortened hours on the first two Saturdays. The hours of the call center were adjusted throughout the duration of the investigation to reflect the changing demand for information from the public. The call center was demobilized on April 12, 2013.

Call center operators utilized FAQ documents to facilitate and answer questions from the public, patients of Dr. Harrington, concerned medical facility personnel, and insurance companies. FAQ documents included information about HBV, HCV, and HIV, as well as answers

specific to the Dental Public Health Investigation. Communication flow between Phone Bank Unit Leaders and the JIS was smooth, utilizing email and phone to discuss updates for phone bank operators, the pre-written and recorded main message, and/or public information.

### Summary

The public health investigation of the Harrington oral surgical practice and resulting public health response garnered international, national, state and local media attention. The JIS worked exceedingly well in helping each agency "be first, be right, be credible" in its crisis communications response.

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## **Results at a Glance**

23: Situation Updates released by the JIS from March 29, 2013, to Oct. 17, 2013

**3,467:** Phone bank calls received from March 28, 2013, through April 12, 2013, while phone bank was fully staffed. An unknown number of calls were received after this date by THD switchboard operators who routed callers to appropriate Dental HAI Investigation and Response staff. The heaviest volume was the day after the initial press conference with 1,005 calls.

**9,129:** International/national/state/local news stories on this public health response documented by TVEyes Media Monitoring Suite and Meltwater News Report media subscription services.

**39:** Number of countries outside the United States that documented news coverage of this event.

## Other media of note, not inclusive:

### Wire Services:

Associated Press UPI Reuters

### **National Print Media:**

Washington Post LA Times Detroit Free Press Huffington Post Bloomberg Business News

### National Broadcast Media:

CNN (News, Situation Room with Wolf Blitzer)

NBC News (NBC Nightly News with Brian Williams, TODAY Show) CBS News (CBS Evening News, CBS This Morning) ABC News (ABC World News, Good Morning America) MSNBC News HLN FOX News WNBC-New York Inside Edition

### **Oklahoma Print Media:**

The Tulsa World The Oklahoman Journal Record Oklahoma Gazette Norman Transcript Bartlesville Examiner-Enterprise Muskogee Phoenix Enid News

### **Oklahoma Broadcast Media:**

KRJH-TV, Tulsa (NBC affiliate) KTUL-TV, Tulsa (ABC affiliate) KOTV, Tulsa, (CBS affiliate) KOKI-TV, Tulsa (FOX affiliate) KFOR-TV, Oklahoma City (NBC affiliate) KOCO-TV, Oklahoma City (ABC affiliate) KWTV, Oklahoma City (CBS affiliate) KOKH-TV, Oklahoma City (FOX affiliate) OETA, Oklahoma City/Tulsa (Public TV affiliate) KRMG Radio, Tulsa KTOK Radio, Oklahoma City KOSU Radio, Stillwater (NPR) KGOU Radio, Norman (NPR)

### **Dental Organizations/Association Journals & Online Blogs:**

American Dental Association Oklahoma Dental Association Dr. Bicuspid.com Dentistry Log Blog Dentistry IQ

### **Other Websites:**

Insurance Journal One and Only Campaign Oklahoma Policy Institute Decoded Science About Lawsuits.com

## **SECTION 11**

## Epidemiologic Study of a Subset of Dental Patients to Determine Risk Factors for Hepatitis C: Record Abstraction

The OSDH attempted to collect basic demographic and medical information from all individuals who sought testing for HIV, HBV, and HCV as part of the dental patient notification effort. An objective of the epidemiologic investigation was to determine any risk factors for oral healthcare-associated transmission of hepatitis C, such as receipt of certain injectable medications, having a certain procedure performed, or having certain personnel assist with treatment. To conduct a risk factor study, the OSDH required access to dental medical records and a patient database that contained information on appointment dates and times, reason for patient visit, and care provided during each visit. A patient scheduler containing this basic level of data was only available for patients who were seen at the Harrington oral surgical clinic from March 1, 2012 through March 20, 2013 ("scheduler period"). The patient scheduler was received by the OSDH from Dr. W. Scott Harrington's office. In addition to appointment dates and times, the scheduler contained information on patient age and sex, phone number, insurance type, date of last visit, prior medications prescribed by Dr. Harrington, operatory room (chair) number, and amount paid at visit. A total of 1,021 patients were seen by Dr. Harrington for consultations, procedures, or observations during the scheduler period; some patients had more than one visit during this period.

### **Dental Medical Record Abstraction**

Patient medical records were confiscated by the Oklahoma Board of Dentistry and maintained in their possession throughout the public health investigation. A dental record abstraction form [Appendix A, 11-1] was created and piloted by OSDH HIV/STD Service staff. To assist with abstracting over 1,000 patient records, OSDH employees with prior knowledge and experience with medical chart review were recruited from other Service areas to assist with the study. These staff received training in use of the abstraction tool prior to beginning record abstraction which occurred on-site at the office of the Oklahoma Board of Dentistry from July 19 through July 24, 2013. Records for 26 patients listed on the patient scheduler could not be located; chart abstraction forms were completed for 995 (97.5%) patients. Quality control measures were implemented during the record abstraction process, including a secondary review of the form following data entry into an electronic database to ensure accuracy and completeness. If any discrepancies or data entry errors were identified, the database was updated to include the correct information.

### **HCV Status Determination**

Data linkage between the OSDH Laboratory Information System and PHIDDO system with the scheduler patient database was performed to ascertain HCV testing status of the patients in the scheduler period. Of these 1,021 patients, 611 (59.8%) had a hepatitis C test result reported to OSDH, either through the free testing provided by the OSDH or through a private medical

facility. Some patients called, faxed, or mailed their laboratory test results to the OSDH in order to document their HCV and HIV status. Of those tested, 95.6% (n= 584) were non-reactive for HCV antibodies and 4.4% (n=27) were reactive (positive test result). Of those scheduler patients who tested HCV reactive, 33.3% (n=9) were defined as a newly diagnosed case of hepatitis C, and 66.7% (n=18) were defined as previously diagnosed based on the timing of their dental visit relative to their laboratory testing date. Newly identified is a patient who initially tested positive on or after March 20, 2013. A previously identified patient is one who tested positive for hepatitis C prior to his/her first visit to Dr. Harrington's office.

## **HCV Behavior Risk Categories for Scheduler Patients**

The nine newly identified HCV-positive patients with dental visits during the scheduler time period were further evaluated for risk factors and behaviors using information obtained during the patient interview. Essentially, these patients were placed into one of two risk groups: 1) no major risk factor for HCV exposure reported or disclosed, or 2) at least one major risk factor associated with HCV transmission reported. Patients in the no/low risk category were determined to have a higher likelihood of having a procedure at the oral surgical clinic as their source of hepatitis C infection although a self-report of another risk factor would not rule out the potential for acquiring an oral healthcare-related infection.

Major risk factors for HCV infection include recreational injection drug use; receipt of donated blood, blood products, or organs prior to 1992; and occupational needlestick injuries in health care settings. Although infrequent, HCV can be spread through sex with an HCV-infected person and sharing personal items contaminated with infectious blood (such as razors or toothbrushes)<sup>2</sup>. For this investigation, patients were categorized as high risk if they reported any of the following exposures: injection drug use, receipt of blood/blood products/organs prior to 1992, needlestick injury involving a known HCV-infected person, tattoos in an unlicensed or non-commercial facility (such as prison), or sexual/household contact to a person known to be chronically infected with HCV. Patients were placed in the no/low risk category if they denied all of the aforementioned major risk factors. Additionally, patients who reported working in a healthcare setting, but denied needlesticks or frequent blood contact were considered low risk. Of the nine newly identified HCV infections among scheduler patients, five (56%) were classified as having high risk exposures and four (44%) were classified as no/low risk.

A total of five specimens from HCV-infected patients who had dental procedures during the scheduler period were forwarded to the CDC for quasi-speciation analysis to determine genetic relatedness among infecting viruses (Section 8). Of these specimens, two were patients with newly diagnosed infections.

## **SECTION 12**

Epidemiologic Study of a Subset of Dental Patients to Determine Risk Factors for Hepatitis C: Data Analysis, Results and Limitations

### Methodology

The data analyzed for this epidemiologic study was obtained from five different datasets: dental record abstraction (Section 11); patient scheduler for the period of March 1, 2012 through March 20, 2013; Public Health Laboratory Information System; the DHAI Investigation database; and the PHIDDO case report. All information was merged by name and date of birth using Statistical Analysis System (SAS) software before being analyzed. A summary of the data variables used for statistical analyses are located in Appendix A, 12-1.

### Data Coding

From review of the patient records, it was observed that four medications were frequently administered by IV injection to patients undergoing oral surgical procedures. These included propofol, ketamine, and Brevital<sup>®</sup> (brand name for methohexital) which are drugs commonly used to induce deep sedation or anesthesia for surgery and dental procedures; and Reglan<sup>®</sup> (brand name for metoclopramide) which may be used pre- or post-operatively to reduce nausea, vomiting, and stomach distention. Based on interviews with the dental assistants (Section 4), these medications were often drawn from multi-dose vials or single dose vials used for multiple patients. Therefore, patient receipt and dosage of these four commonly used drugs were analyzed as a potential risk factor for patient-to-patient transmission of HCV. After analyzing the distribution of medication dosages administered within the Harrington Oral Surgical Clinic, the data variable for medication dose per dental visit was coded according to the following categories:

- Propofol Administration
  - No medication or 0 mg = NO DOSE
  - 1 mg to 100 mg = LOW DOSE
  - 101 mg to 300 mg = MEDIUM DOSE
  - 301 mg to 1000 mg =HIGH DOSE
- Brevital Administration
  - No medication or 0 mg = NO DOSE
  - 1mg to 100 mg = LOW DOSE
  - 101 mg to 200 mg = MEDIUM DOSE
  - 201 mg to 1000 mg = HIGH DOSE
- Ketamine Administration
  - No medication or 0 mg = NO DOSE
  - 0.25 mg to 25 mg = LOW DOSE

- 26 mg to 100 mg = MEDIUM DOSE
- 101 mg to 625 mg = HIGH DOSE
- Reglan Administration
  - No Medication or 0mg = NO DOSE
  - 1mg to 5mg = LOW DOSE
  - 6mg to 10mg = MEDIUM DOSE
  - 11mg to 30mg = HIGH DOSE

For every scheduler patient who underwent a procedure, the maximum dose of each medication received was calculated. From the dental records, it could not be determined if dosages were divided, and if so, how many divided dosages were administered to attain the maximum dose administered. The maximum dose of the medications of interest received per patient during one dental procedure were: propofol = 410 mg, ketamine = 625 mg, Brevital = 400 mg, and Reglan 20 mg.

Data was abstracted from the dental records to document which assistant provided services to a patient during any dental procedure, as well as if the assistant was indicated as the lead (or first) assistant during a dental procedure. It was assumed that the lead assistant administered most of the injectable medications during the procedure; however, patients may have received care from more than one assistant during a dental procedure.

### Statistical Analysis

Descriptive statistics were calculated for the demographic and clinical measures, including counts and percentages for categorical measures, and means and standard deviations, or medians and interquartile ranges, for continuous measures. Comparisons of the distribution of demographic and clinical measures were made between newly-identified HCV case-patients and HCV-negative patients using Fisher's exact test for categorical measures and the Wilcoxon rank sum test for continuous measures. The exact form of the Cochrane-Armitage test for trend was used to compare the distribution of ordered categorical variables, such as medication usage classified as 0 times, 1 time, or 2 or more times/patient visits, between newly-identified HCV cases and HCV-negative patients. Exact and non-parametric tests were chosen due to the small number of patients who were newly-identified HCV cases. Only patients with a dental procedure within the scheduler period were included in the statistical analyses.

Patients with previously-identified HCV infection and patients with missing information were excluded from analyses aimed to identify potential risk factors associated with newly-identified (incident) HCV cases.

### Results

### Summary of Missing Data

During the study period of March 1, 2012 through March 20, 2013, a total of 1,021 patients were seen by Dr. Harrington. Among these, clinical records were available for 995 (97.5%) patients. Age and sex were available for most of the patients who visited Dr. Harrington's clinic during the scheduler period. Date of birth for three patients and sex for seven patients were

missing. Hepatitis C status was unknown for 40% (410/1021) of all patients. Of those 966 patients who underwent a procedure during the study period, 57.7% had a known HCV status (556/966). Persons with unknown HCV status and who had a procedure were slightly younger, although not significantly, than those with known HCV status (Table 1). Among patients with unknown HCV status and who had an oral surgical procedure, 45.7% were between the ages of 0-29 years, compared to 41.5% of those with known HCV status. Among patients with known HCV status, 35.7% were over the ages of 49 years, compared to 31.4% of those with unknown HCV status. The proportion of patients in the age grouping of 30-49 years was the same in both HCV status groups, 22.8%. There was no significant difference of sex distribution between the known HCV status groups.

Medication use information was incomplete in many of the patient records; all of the medications of interest had patients with missing/unknown information about whether they received the drug during an oral surgical procedure. The medication with the highest number of patients with unknown exposure was Brevital<sup>®</sup> (513, 53%) followed by ketamine (183, 19%), propofol (132, 14%) and Reglan<sup>®</sup> (124, 13%). These percentages were calculated among all 966 patients who underwent a surgical procedure, regardless of HCV status.

## Summary of Demographic and Clinical Data

The 410 patients with unknown HCV status were excluded from further analysis. Among the patients with known HCV status, 18 (3%) had previously-identified HCV, 9 (1.5%) had newly-identified HCV, and 584 (96%) had negative HCV testing. For the risk factor analyses, only the newly-identified HCV infections (incident cases) were compared to those who tested negative for hepatitis C. Of these 593 patients, 538 (90.7%) had a procedure requiring injectable medications during the study time period and were retained for the analysis cohort. Among the 538 patients with procedures, 8 (1.5%) were newly-identified cases of hepatitis C and 530 (98.5%) had a negative hepatitis C test.

Demographic and clinical characteristics by hepatitis C status are summarized in Table 2 for the patients who underwent an oral surgical procedure. Overall, based on patients with available anesthesia information, propofol and ketamine were commonly used. The probability of exposure to Assistant X as the lead assistant (36%) was nearly 10% higher than the probability of exposure to Assistant Y as the lead assistant (27%), but was similar to exposure to Assistant Z as the lead assistant (35%).

### Evaluation of Potential Exposure Risk Factors Associated with Newly-identified HCV Cases

The estimated percentage of patients with incident HCV infection within each selected patient variable subgroup is summarized in Table 3. There were no significant associations found with age or sex. Newly-identified HCV infection was more common among patients who received higher doses of propofol (<5% for None, Low, and Medium dose groups versus 15.4% in High dose group), but this difference was just above statistical significance (p=0.059). Reglan administration was also associated with newly-identified hepatitis C with 9% of these patients receiving Reglan 2-3 times compared to those receiving Reglan only a single time (2%) or not at all (0%) (p=0.027). Similarly, newly-identified HCV infection was more common among patients treated with high maximum doses of Brevital (<0.5% for None or Low Dose compared to 5.3%

within the Medium Dose group and 11.1% in the High Dose group) (p=0.016). For all other variable subgroups, no associations with an increased probability of newly-identified HCV infection were observed.

### Limitations

### Missing data

Results of the analyses of the risk factor data should be interpreted cautiously because of the large percentage (40%) of dental patients for whom we did not have HCV status information. The observed sample may have had exposures that differed from the patients that did not opt for testing or did not receive the patient notification and recommendation for laboratory testing. The analyses may also have been biased if medication information was systematically omitted or recorded illegibly in the patient charts regarding type or dosage of medication administered.

### Misclassification of HCV status

The effect of misclassification between those with previously-identified HCV and newlyidentified HCV was not accounted for in the analysis. Due to the small number of newlyidentified HCV cases, even a misclassification and reduction of one newly-identified HCV case would have a large impact on the estimates.

## Interpretation of Anesthetic Drug Administration Frequency

Inferences regarding an association between the likelihood of having an incident HCV infection and receipt of a particular drug multiple times cannot be drawn due to the limitations of medical recordkeeping. This association would have the greatest strength if it were clear that a patient received the same drug in multiple, divided doses during a singular patient visit. However, this level of detail was not available in the medical record or anesthetic drug log. The coding for receipt of a drug more than one time may have referred to receipt of multiple doses during the same patient visit, or receipt during more than one patient visit on different dates.

# Table 1. Comparison of patient sex and age distribution by availability of hepatitisC status among those who underwent an oral surgical procedure (n=966); March1, 2012 – March 20, 2013

Variable	HCV S	Status	HCV State	us Missing	p-value
	(n=556)		(n=	410)	
	Count	%	Count	%	
Age (years)					0.2708
0-19	110	19%	73	18%	
20-29	121	22%	113	28%	
30-39	78	14%	53	13%	
40-49	49	9%	40	10%	
50-59	67	12%	51	13%	
60-69	69	12%	39	10%	
70-79	41	7%	21	5%	
80-89	17	3%	12	3%	
90+	4	1%	5	1%	
Female	303	55%	222	55%	0.9461
Male	253	45%	188	45%	

	Newly-id	dentified	Previously	-identified	Non-re	eactive
Categorical Variable	(n:	=8)	(n=	:18)	(n=	530)
	Count	%	Count	%	Count	%
Age (years)						
0-29	2	25%	1	6%	228	43%
30-59	3	38%	12	67%	179	34%
60+	3	38%	5	28%	123	23%
Female	2	25%	10	56%	291	55%
Male	6	75%	8	44%	239	45%
Propofol Exposure (n=522)						
None	2	25%	0	0%	42	8%
1 Visit	5	63%	12	86%	444	89%
2+ Visits	1	13%	2	14%	14	3%
Propofol Maximum Dose						
None	2	25%	0	0%	42	8%
Low	0	0%	3	21%	56	11%
Medium	4	50%	11	79%	391	78%
High	2	25%	0	0%	11	2%
Ketamine Exposure						
None	0	0%	1	6%	46	9%
1 Visit	5	63%	14	78%	414	78%
2+ Visits	1	13%	1	6%	8	2%
Ketamine Maximum Dose						
None	0	0%	1	6%	46	9%
Low	2	25%	6	33%	167	32%
Medium	4	50%	9	50%	240	45%
High	0	0%	0	0%	10	2%
Reglan Exposure (n=524)						
None	0	0%	3	19%	158	32%
1 Visit	7	88%	12	75%	332	66%
2+ Visits	1	13%	1	6%	10	2%
Brevital Exposure (n=285)						
None	1	33%	5	63%	232	85%
1 Visit	2	67%	3	38%	42	15%
2+ Visits	0	0%	0	0%	0	0%
Brevital Maximum Dose						
None	1	33%	5	63%	233	85%
Low	0	0%	0	0%	15	5%
Medium	1	33%	3	38%	18	7%
High	1	33%	0	0%	8	3%
Ever Had X as Lead Assistant (n=556)	0	0%	5	28%	146	28%

# Table 2. Summary of patient clinical and demographic information for patients who underwent a procedure during the study time period by HCV status.

Ever Had Y as Lead Assistant (n=555)	5	63%	6	33%	186	35%
Ever Had Z as Lead Assistant (n=555)	3	38%	7	39%	186	35%

Continuous Variable <sup>1</sup>	Newly-identified (n=8)			Previously-identified (n=18)			Non-reactive (n=530)		e
	Median	Low Quartile	Upper Quartile	Median	Low Quartile	Upper Quartile	Median	Low Quartile	Upper Quartile
Maximum Propofol Dose (mg)	225	200	350	200	120	200	200	180	250
Maximum Ketamine Dose (mg)	75	25	100	37.5	12.5	50	50	25	50
Maximum Brevital Dose (mg)	250	200	300	200	200	200	200	100	200

<sup>1</sup>Data summaries for all maximum dose variables were calculated among patients who had non-zero values for the dose.

Table 3. Association of newly-identified HCV infection with selected demographic and medication exposure variables among dental patients with known HCV status who underwent procedures during the scheduler time period (N=538\*)

Variable	Newly-identifie	ed HCV	p-value
	Count / Row Total	Row %	
Age (years)			0.269
0-29	2/230	0.9%	
30-59	3/182	1.6%	
60+	3/126	2.4%	
Sex			0.15
Male	6/244	2.5%	
Female	2/293	0.7%	
Propofol			0.15
Received	6/464	1.3%	
Did not receive	2/44	4.5%	
			0.50
Propotol Frequency	2/11		0.56
None	2/44	4.5%	
1 visit	5/449	1.1%	
2-3 visits	1/15	6.7%	
Propofol Maximum Dose	- 1		0.059
None	2/44	4.5%	
Low	0/56	0%	
Medium	4/395	1.0%	
High	2/13	15.4%	
Reglan Exposure			0.063
Received	8/350	2.3%	
Did not receive	0/158	0%	
Reglan Frequency			0.027
None	0/158	0%	
1 visit	7/339	2.1%	
2-3 visits	1/11	9.1%	
Ketamine Exposure			
Received	6/428	1.4%	1.000
Did not receive	0/46	0%	
Ketamine Maximum Dose			0.909
None	0/46	0%	
Low	2/169	1.2%	
Medium	4/244	1.6%	
High	0/10	0%	
Brevital Exposure			0.065

Variable	Newly-identif	ied HCV	p-value
	Count / Row Total	Row %	
Received	2/43	4.7%	
Did not receive	1/234	0.4%	
Brevital Frequency			0.067
None	1/234	0.4%	
1 visit	2/43	4.7%	
2-3 visits	N/A	N/A	
Brevital Maximum Dose			0.016
None	1/234	0.4%	
Low	0/15	0%	
Medium	1/19	5.3%	
High	1/9	11.1%	
Ever Had X as Lead Assistant			0.12
Yes	0/146	0%	
No	8/391	2.0%	
Ever Had Y as Lead Assistant			0.14
Yes	5/191	2.6%	
No	3/346	0.9%	
Ever Had Z as Lead Assistant			1.0
Yes	3/189	1.6%	
No	5/348	1.4%	

\* Information unavailable for some variables, so not all variable denominators will total 538.

## **SECTION 13**

## **Discussion and Conclusions**

### Discussion

This joint public health investigation conducted by OSDH and THD identified the first confirmed healthcare-associated transmission of HCV in a U.S. dental setting. Documentation of bloodborne virus transmission in oral healthcare facilities is exceedingly rare with only two recognized occurrences of hepatitis B virus transmission: one in a private dental clinic in New Mexico in 2001,<sup>3</sup> and one HBV outbreak associated with a West Virginia community charity dental clinic in 2009.<sup>4</sup> Before the advent of universal precautions, there was a dentist-to-patient transmission event of HIV in Florida during 1991.<sup>5</sup>

Laboratory confirmation of patient-to-patient transmission of HCV attributable to a significant breach in injection safety or infection control at the Harrington oral surgical clinic was obtained through quasispecies analysis at CDC. The hepatitis C viruses isolated from both of these patient specimens were an exact genetic match. Other supportive evidence of patient-to-patient transmission is:

- The oral surgical procedures performed on both patients occurred on the same day and the patient known to be chronically infected with HCV preceded the acutely-infected patient;
- Both patients received similar intravenously injected sedation drugs; and
- There were no common exposures identified for the source patient and the index patient other than both having a dental procedure at the same clinic.

The mode of transmission between the source case and the index case was not elucidated, but multiple infection control violations were observed at the dental practice which could have resulted in exposing patients to HCV. We think it is most likely that HCV transmission occurred through a combination of unsafe injection practices, which has been documented in previous HAI investigations of HBV and HCV.<sup>6-9</sup> Safe injection practices, such as never using the same syringe to administer medications to more than one patient, never reusing the contents from a medication bag or vial that has already been used, and never using single-dose or single-use medications for more than one patient, are considered standards of practice in dental clinics.<sup>10</sup>

During the clinic site visit, staff members readily shared that it was a customary practice to use multi-dose vials of injectable medications on multiple patients. Transmission of hepatitis through the contamination of medications used for multiple patients has been identified in several healthcare-associated hepatitis outbreaks. Studies have found that syringes frequently become contaminated with blood even if only the needle had been in contact with a patient's blood. Even though the field investigation team was unable to observe patient procedures being performed at the Harrington Oral Surgical Clinic, it is conceivable that needles and/or

syringes may have been reused on some occasions to re-enter medication vials leading to contamination of that vial or fluid bag.

Particular focus was paid to the possibility of contaminated propofol as the transmission vehicle between the source case and the index case. Propofol emulsions have been described to support the growth of certain microorganisms, and patient-to-patient transmission of HCV has previously been documented involving propofol used for anesthesia during arthroscopy and colonoscopy.<sup>11,12</sup> From the findings of our risk factor epidemiologic study, a possible association of having a newly identified HCV infection and receiving higher doses of propofol was observed despite not reaching statistical significance. Our investigation revealed that the source patient received a total dose of 300 mg of propofol and the index case received 400 mg of propofol during their respective dental procedures; these ranked among the highest dosages of propofol administered during the study period. Assuming a propofol vial was contaminated with the blood of the source patient, the higher dosage of propofol administered to the index case could have led to greater amounts of injected bloodborne material in the anesthetic medication, resulting in patient-to-patient HCV transmission. Also, the higher dosages could be indicative of having to give additional escalating doses of propofol from the same vial, increasing the likelihood of cross-contamination of the vial from the patient's syringe used to administer propofol. While other intravenous medications were administered to both patients, ketamine has never been reported as a vehicle for bloodborne diseases, and dexamethasone appears to have been given in a single fixed dose which decreases the likelihood of cross-contamination. Our analysis also demonstrated that higher dosages of, or repeated exposures to Brevital<sup>®</sup> were associated with a higher probability of newly identified HCV infection, although the association was not statistically significant.

Propofol is marketed under the trade name Diprivan<sup>™</sup>. Product labeling approved by the U.S. Food and Drug Administration in 2008 states that "Diprivan Injectable Emulsion should be prepared for single patient use only. Any unused portions of Diprivan Injectable Emulsion...must be discarded at the end of the anesthetic procedure or at 12 hours, whichever occurs sooner."<sup>13</sup> Thus, healthcare providers who are using propofol for patient sedation should be adhering to the product labeling and only use the vial contents for single patient use.

Other possible routes of transmission included improperly sterilized dental equipment or environmental contamination. Because of the shorter length of survivability of HCV on inanimate surfaces as compared to HBV, indirect transmission of HCV is considered less likely to have occurred because no transmission events of HBV were identified during our investigation. Staff-to-patient transmission has been reported in previous healthcare-associated outbreaks of viral hepatitis; however, staff-to-patient transmission was ruled out as all staff members complied with hepatitis and HIV testing and tested negative for all viruses.

The decision by OSDH and THD to notify dental patients was based on the identification of longstanding, unsafe infection control practices and inappropriate handling of controlled injectable drugs at the Harrington oral surgical clinic. As most patients who contract hepatitis or HIV infections in a healthcare setting remain asymptomatic for a lengthy period, laboratory screening was necessary to identify infected patients and quantify the extent of the problem.

This broad screening could only be achieved through a large scale patient notification effort and providing easily accessible diagnostic testing for potentially exposed patients. Additionally, early medical treatment and management is known to provide significant survival benefit to persons infected with HIV and HCV.

Through our patient notification effort and enhanced surveillance during the public health response, 96 persons were identified with hepatitis C, six with hepatitis B, and four with HIV infection. Of the 90 dental patients who tested positive for hepatitis C, 63 (70%) had a diagnosis after their first visit or procedure at the Harrington Oral Surgical Clinic. Nearly half of the newlyidentified HCV infections did not report any high risk behaviors or exposures for HCV. Therefore, it is possible that more patients acquired hepatitis C from exposure during an oral surgical procedure, but we had insufficient information to identify these cases. Among dental patients who had the most recent encounters (March 1, 2012 – March 20, 2013), the hepatitis and HIV status was unknown for 40% of the patients. There are a number of reasons for the missing status information: 1) Patient had moved and did not receive notification; 2) Patient received notification, but was fearful of being tested or knowing their infection status; 3) Patient was already aware they had hepatitis or HIV and did not want to share that information with public health officials; or 4) Patient elected to be tested through their private healthcare provider, but test results were not forwarded to the OSDH. It is conceivable that additional clusters or epidemiologic links between cases may have escaped detection due to the high percentage of patients with unknown status. Also, genotype information is essential for identifying transmission clusters and this information was not available for 56% of the HCVpositive cases. The investigation team performed additional outreach to obtain genotype information on several cases of particular interest, but genotype was not available because the patient could not be reached by phone, the patient declined to provide a specimen for additional testing, or the viral load was insufficient for genotyping.

### Conclusion

This report documents the first person-to-person HCV transmission event in a dental setting. Contaminated medication vials used on more than one patient was the likely mode of transmission, possibly involving propofol suspensions. Broadening state-level HCV surveillance programs, recognizing dental encounters as a risk for HCV transmission, and increased state and federal oversight of outpatient oral surgical practices are future steps to consider to reduce the risk of HCV transmission events in oral healthcare settings.

## **SECTION 14**

## Costs of Public Health Response

Expenses related to the Dental HAI Investigation and Response were tracked by the OSDH and the THD for the period of March 24 through June 30, 2013. Costs included the base pay and associated benefits of employees directly involved with the response, including command and general staff, laboratory personnel, epidemiologists, public health nurses, and other clinic support staff. OSDH personnel whose work duties were directly related to the Dental HAI event entered program code 911, task code 923 into the agency's Time & Effort system for validation. Similarly, THD personnel tracked their time through the THD Time & Effort system program code 304, activity code EHE. Costs for non-personnel related items were determined from actual charges. Costs incurred by the two public health departments totaled \$681,859.01. Personnel costs comprised 60% of those costs and were largely attributed to clinical personnel at the THD and laboratory personnel at the OSDH.

Personnel and associated benefits	\$ 430,068.18
Employee travel costs	\$ 4,647.87
Supplies	\$ 140,922.11
Contracted services	\$ 12,403.05
Indirect costs	\$ 67,231.13
Other	\$ 26,586.67
Total	\$ 681,859.01

### Table 1: OSDH and THD Expenses

Based on the treatment costs for hepatitis C, it is estimated there is a cost savings of \$30,000 -\$40,000 in associated healthcare costs for every HCV infection that is prevented. Through screening that occurred among dental patients, at least 61 new infections of HCV were identified. A vital element in control of viral hepatitis is recognizing one's infection status, seeking treatment to reduce the level of infection, and becoming educated on how to reduce the risk of transmission to others. Thus, \$1,830,000 - \$2,440,000 might have been saved in future medical costs assuming one new case of HCV infection was averted for every newly identified case of hepatitis С in this public health response.

## **SECTION 15**

## Subsequent Activities and Policy Changes

This investigation reverberated throughout the Oklahoma dental community. In the months following the investigation, the state dental association created a video to reassure patients that by following infection prevention practices, dental offices are safe. Infection control and injection safety trainings were conducted at the Oklahoma Dental Association's annual meeting and at the University of Oklahoma College of Dentistry. It is expected that policy will be developed requiring continuing education on bloodborne pathogens and infection prevention for dental professionals. There remains a heightened awareness of the law, rules and regulations as they relate to the dental profession.

Through a collaborative effort, the Oklahoma Board of Dentistry, the Oklahoma Dental Association, the Oklahoma Association of Oral Maxillofacial Surgeons and the Oklahoma Dental Hygiene Association developed a bill revising the Oklahoma Dental Practice Act that passed into law effective July 1, 2013. Included in the law are changes in the Dental Practice Act intended to increase patient safety by addressing some of the factors that likely contributed to HCV transmission in the oral surgical clinic:

- 1. Creation of a new level of Dental Assistant, the Oral Maxillofacial Surgery Assistant;
- 2. Requirement of permits for all Dental Assistants;
- Increase in the maximum number of full-time-equivalent employees at the Board of Dentistry agency from five to ten – this will include more dental investigators;
- 4. Addition of language that constitutes grounds for penalties: practicing dentistry in an unsafe or unsanitary manner or place, including but not limited to repeated failures to follow CDC or Occupational Safety and Health Administration (OSHA) guidelines.

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## **Appendix A: Report Attachments**

Appendix A, Figure 2-1

Oklahoma State Department of Health Creating a State of Health
March 22, 2013
All OSDH Personnel
Terry Cline, Ph.D. MSN 3,22,13 Commissioner Secretary of Health and Human Services
Delegation of Authority

Effective today I have activated the agency's Incident Command System (ICS) to coordinate the Dental Healthcare-Associated Infection (HAI) Investigation and Response. Dr. Kristy Bradley is assigned to serve as Incident Commander (IC) for this response.

The IC has full authority and responsibility for managing resources, requesting assets, assigning tasks, establishing an incident command structure, and establishing the incident action plan. The IC's primary responsibility is to organize, obtain and direct necessary resources related to the Oklahoma public health and medical system infrastructure's support to this 2013 Dental HAI Investigation and Response pursuant to official requests.

The IC has responsibility for all response activities within the framework of law. established response plans, agency policy and direction provided by me (or my designee). The IC is accountable to me (or my designee). The IC may delegate duties by establishing an incident command organizational structure and job action sheets.

This delegation is effective for the duration of the 2013 Dental HAI Investigation and Response effort.

Terry L Cline, PhD Commissioner of Health Secretary of Health and Human Services

Board of Health R Murali Krishna, MD, President

Jenny Alexopulos, DO

Terry R Gerard, DO

Ronald Woodson, MD, Vice President Martha A Burger, MBA, Secretary-Treasurer Cris Hart-Wolfe

Barry L Smith, JD Timothy E Starkey, MBA

1000 NE 10TH Street Oklahoma City, OK 73117-1299 www.health.ok.gov An Equal Opportunity Employer



### ADDRESS REVIEW PROTOCOL FOR MAILING LETTERS BY FIRST CLASS MAIL DENTAL HAI INVESTIGATION AND RESPONSE – 2013

The Unified Command for the ICS for the Dental HAI Investigation and Response, 2013 hereby approves the following protocol for the verification of address for first class letters to be sent to patients of W. Scott Harrington, DMD to be notified of the potential exposure to a contagious disease and the availability of testing. This protocol follows the protocol terms used by the Oklahoma State Department of Health (OSDH) in notifying individuals during a HIPAA Breach that occurred in 2011. The terms of the OSDH HIPAA Breach protocol were submitted to the DHHS Office of Civil Rights, who had the opportunity to review. The OSDH did not receive any negative comments concerning the use of the protocol or the terms of the protocol.

### Terms of the Protocol:

- 1. The OSDH has received a list of 6000+ names from the Offices of Dr. Harrington, identifying his patients over the past seven (7) years. The information includes addresses and phone numbers for the patients as well as the date the patient was last seen by Dr. Harrington.
- 2. The list will be reviewed by the OSDH, Division of Vital Records, Death Registry to identify and remove those names of patents that are already deceased.
- 3. The list will be divided into years based on the date the patient was last seen by Dr. Harrington. Five to ten names will be chosen at random and the information contained in the list reviewed through an on-line data base, CLEAR (Consolidated Lead Evaluation and Reporting) to identify current addresses. This program is supported by Thomson-Reuters and is an investigative platform and the OSDH currently has access to the data base through a subscription.
- 4. If any year falls below a 45% match between the address contained in the list provided by the Offices of Dr. Harrington and the information provided by CLEAR, an additional 25 names will be added to the list and reviewed.
- 5. If after the adding of 25 names finds the match below 15%, then the mailing will not occur and the notice contained in the press conference will be considered sufficient. In any year wherein the match falls below 15%, it is deemed to be unlikely that the letter will reach the recipients using the mail.
- 6. The United States Postal Service (USPS) maintains change-of-address forms for 18 months. The USPS will forward any mail to a new address if the form has been on file for 12 months or less. For forms on file from 12-18 months, the letter is sent back to the sender with a new address. For forms older than 18 months, the letter is just returned to the sender. A request for change-of-address information will be requested in the mailing.

Dated: March 28, 2013: [Approved electronically]

Priscilla Haynes, Incident Commander Tulsa Health Department Dr. Kristy Bradley, Incident Commander OSDH





March 29, 2013

### Dear Patient,

The Tulsa Health Department (THD), the Oklahoma State Department of Health (OSDH), and the Oklahoma Board of Dentistry are in the process of conducting a public health investigation of Dr. W. Scott Harrington's dental practice. Through the investigation, practices were discovered which may have exposed patients to infectious material. You are receiving this letter because you had a dental procedure at Dr. W. Scott Harrington's office located at 2111 S. Atlanta Place in Tulsa or at 12806 E. 86<sup>th</sup> Place N. in Owasso.

Although we do not know whether you were personally exposed to blood-borne viruses, there is a possibility that you may have been exposed to infectious material. As a precaution, we are recommending that you get tested for hepatitis C virus, hepatitis B virus, and human immunodeficiency virus (HIV). All testing done through the Tulsa Health Department will be free of charge. Laboratory analysis for HIV, hepatitis B, and hepatitis C will be conducted by the OSDH Public Health Laboratory.

The Tulsa Health Department has set up a clinic to draw your blood for the tests at the **North Regional Health and Wellness Center (NRHC)** located at **5635 N. Martin Luther King Jr. Blvd.** Services will be provided on a walk-in basis starting on Monday, April 1<sup>st</sup> from 8:00 AM to 6:00 PM. **Please bring this letter with you to the clinic.** Your test results will be directly shared with you in a timely manner and will be kept confidential.

We understand that this news may be alarming and frightening to you, and that you may have additional questions or concerns. To assist you, we have established a dedicated hotline at (918) 595-4500. The hotline hours of operation are between 8:00 AM and 5:00 PM, Monday through Friday. You may also obtain information from these websites: <u>http://www.tulsa-health.org</u> or <u>www.health.ok.gov</u>.

Sincerely,

Kointy X. Bradley

Kristy Bradley, DVM, MPH State Epidemiologist Oklahoma State Department of Health

Since Dant

Bruce Dart, Ph.D., Director, Tulsa Health Department





April 4, 2013

Dear \_\_\_\_\_

Recently, you received testing for hepatitis B, hepatitis C and HIV as a part of a public health investigation involving Dr. W. Scott Harrington's dental practice. Your test results were negative for these blood borne viruses.

Our records indicate that your last dental visit to Dr. Harrington's occurred sometime between September 20, 2012 and March 20, 2013; therefore, it is possible that you may be in an early infection stage that is not yet detected by the tests that were performed. The Tulsa Health Department and the Oklahoma State Department of Health recommends follow up testing to ensure that you have these tests repeated at least 6 months past your last dental clinic date at Dr. Harrington's practice. Please contact the public health department where you had your blood drawn for the HIV and viral hepatitis testing to schedule your follow up and repeat testing visit.

We understand that you may have additional questions or concerns. The Tulsa Health Department has set up a Patient Information Hotline at 918- 595-4500 to address your questions about this letter, or other aspects about the public health investigation.

In addition, both the Tulsa Health Department and the Oklahoma State Department of Health will continue to provide information and regular updates on their websites at <u>www.health.ok.gov</u> and <u>www.tulsa-health.org</u>.

Sincerely,

Kristy K. Bradley

Kristy Bradley, DVM, MPH State Epidemiologist Oklahoma State Department of Health

ny Dat

Bruce Dart, Ph.D., Director, Tulsa Health Department





Date

Dear \_\_\_\_\_,

Recently, you received testing for hepatitis B, hepatitis C and HIV as a part of a public health investigation involving Dr. W. Scott Harrington's dental practice. Your test results were negative for these blood borne viruses.

Our records indicate that your last dental visit to Dr. Harrington's occurred <u>before</u> September 19, 2012; therefore, no additional testing or follow up is recommended as part of this investigation. If our information about the date of your last dental procedure is incorrect, please contact the public health department where you had your blood drawn for the HIV and viral hepatitis testing.

We understand that you may have additional questions or concerns. The Tulsa Health Department has set up a Patient Information Hotline at 918-595-4500 to address your questions about this letter, or other aspects about the public health investigation.

In addition, both the Tulsa Health Department and the Oklahoma State Department of Health will continue to provide information and regular updates on their websites at <u>www.health.ok.gov</u> and <u>www.tulsa-health.org</u>.

Sincerely,

Kristy K. Bradley

Kristy Bradley, DVM, MPH State Epidemiologist Oklahoma State Department of Health

Since Dart

Bruce Dart, Ph.D., Director, Tulsa Health Department



DATA COLLEC	TION FORM
Today's Date:// Form Completed By:	Patient's ID#:
PATIENT INFO	DRMATION
Last Name: First Name:	Middle Name/Initial:
DOB:// Parent/Guardian Name (if min	nor child):
Street Address:	
City:	State:Zip:
Phone Number://	Other Phone Number:///
Please Check One:	
Sex: 🗆 Male 🗆 Female 🗆 Unknown	Pregnant: □ Yes □ No □Unknown
Race (Check all that apply): <ul> <li>White</li> <li>Black</li> <li>Asian</li> <li>Hawaiian/Pacific Island</li> </ul>	ler 🛛 American Indian/Alaska Native 🗆 Unknown
Ethnicity: 🗆 Hispanic 🗆 Non-Hispanic 🗆 Unknown	
How Was Initial Contact Made?: Received telephone call fr Heard about it from friend patient of Dr. Harring Heard about testing on the Other:	l om THD or OSDH  /relative/acquaintance who knew he/she was a ton's e news 
DENTAL H	ISTORY
Please list: Number of Dental Clinic Visits (to Dr. Harrington only): Dental Clinic Visits (dates, if known, can be approximate):	

DENTAL HEALTHCARE-ASSOCIATED INFECTION INVESTIGATION

Clinic Times (if known – list approximate time of day for most appointments):

Updated 03/27/2013

### Dental Procedures and Dates at Dr. Harrington's Office:

Procedure	Date	Procedure	Date
□Extractions		□Implant placement	
□Alveoplasty (Smoothing of the		□Cosmetic injections	
bone)			
□Bone Graft		□Cosmetic surgery/eyelids, etc.	
□Apicoectomy (Removal of tooth		□Expose and bracket (for	
root)		Orthodontia)	
□Suture removal/postop		□Observation	
□X-rays		□Consultation	
□Biopsy/Pre-biopsy consult		🗆 Other:	

Did you receive medications at Dr. Harrington's Office? □Yes □No □Can't Remember

### Medications Received at Dental Clinic (Please List):

Med	Date of Medication (Can Be Approximate)	Type of Drug or Names if Known	Route of Administration (IM, IV, oral, other)
1			
2			
3			
4			
5			

Do you remember if Dr. Harrington or a dental assistant gave you your medications? □Yes □No □Can't Remember

If by a dental assistant, do you remember his/her name?: \_\_\_\_

Did you receive an IV at Dr. Harrington's Office? 

Yes 
No 
Can't Remember

Did you have an IV placed for your dental procedure? 
□Yes □No □Can't Remember

If you received an IV, did you observe staff open a new saline bag?: □Yes □No □Didn't see a bag of fluids on a pole by my chair or in the procedure room.

Did you observe dental staff opening a new package of tubing? 
□Yes □No □Can't Remember

Do you recall anything that happened during any of your dental visits to Dr. Harrington's office that seemed unusual to you or worried you?:

Other Comments:

Updated 03/27/2013

CLINICAL/LABORATORY INFORMATION
Driar HIV History
File HV history.
Tes, has previously tested positive
$\Box$ No, has previously tested negative
□ If negative, date of last negative test: :/ (month/year)
□Unsure, has never been tested for HIV
Prior Hepatitis B Diagnosis:
□Yes, has previously tested positive
□If positive, diagnosis date:/(month/year)
□No, has previously tested pegative
In the processing estate of last negative test: / (month/year)
□Unsure, has never been tested for Hepatitis B
Previously received Henatitis B vaccinations?
The but doesn't think be/she completed series
$\square$ No has not been vaccinated against HBV
Prior Hepatitis C Diagnosis:
□Yes, has previously tested positive
□If positive, diagnosis date:/ (month/year)
□Elevated liver enzymes □Yes □No □Unknown
□Highest ALT (Number, if known)
□High ALT Date (if known) / /
□Possible Infection Date (if known) / /
$\Box$ laundice: $\Box$ Yes $\Box$ No $\Box$ Unknown)
$\Box Onset Date of laundice: (if known) : (month/year)$
□No, has previously tested negative
If negative, date of last negative test: :/ (month/year)
□Unsure, has never been tested for Hepatitis C

### CURRENT TEST INFORMATION

Was a testing specimen collected?:  $\Box$  Yes  $\Box$  No

If yes, the specimen was collected for which tests?  $\hfill\square$  HIV  $\hfill\square$  Hepatitis B  $\hfill\blacksquare$  Hepatitis C

Date of Collection for these tests: \_\_\_/\_\_\_/\_\_\_\_

Updated 03/27/2013

### **Dental HAI Investigation Laboratory Protocol**

### For Use by County Health Departments

A total of three serum separator tubes are required for testing:

- one for HIV testing
- one for hepatitis testing
- one for potential re-testing

See instructions below for labeling each tube. After collection of blood (3 full-tubes), let the tubes sit for 30 minutes to 1 hour at room temperature to clot, then centrifuge (10 minutes at about X1000g) to separate serum. A delay in centrifugation may have a detrimental effect on the sample quality and may result in inaccurate results. Avoid hemolysis.

Refrigerate spun tubes @  $2 - 8^{\circ}$ C prior to and during transportation. Samples must be tested within 7 days of collection.

If collecting samples from multiple clients, please place all HIV tubes/requisitions in one biohazard bag with pouch, all Hepatitis tubes/requisitions in another biohazard bag with pouch and all supplemental tubes in a third biohazard bag with pouch labeled "Supplemental ". ONLY include patient samples for this Dental HAI Investigation. If collecting sample from a single client, please place all tubes/requisition in one biohazard bag with pouch. (Do not include other regularly scheduled specimens).

Transport refrigerated to the OSDH Public Health Laboratory through the courier system. Normal working hours for the PHL are Monday through Friday 8:00 am to 4:30 pm.

Reports will be available on PHOCIS once tests are completed (see turn-around times for testing below).

### HIV test:

- 1. Requires one serum separator tube
- 2. Submit requisition (Form ODH 419)
  - a. Request test through PHIDDO
  - b. Use program code 911"Communicable Disease" when requesting test
  - c. Use printed barcode to label serum separator tube
- 3. Negative results will be reported within 48 hours (2 work-days) of receipt of sample
- 4. If confirmatory Western Blot testing is required, specimens are run *en batch* on Thursday of each week and reported the next day.

### Hepatitis B surface antigen and Hepatitis C virus antibody tests:

- 1. Requires one serum separator tube (for both tests)
- 2. Submit requisition (Form ODH 419)
  - a. Request tests through PHIDDO; request both tests on the same requisition
  - b. Use program code "Communicable Disease" when requesting test
  - c. Use printed barcode to label serum separator tube
- 3. Results of both tests will be reported within 48 hours (2 work-days) of <u>receipt</u> of sample, except in cases with a positive hepatitis B surface Ag test, where a confirmatory test will be performed and reported the following day (total of 3 work-days from receipt).

### Supplemental SST tube:

1. <u>One</u> supplemental serum separator tube will be drawn and labeled with one of the remaining labels from the printing of the HIV or Hepatitis requisition.

Updated 3/28/2013

### Dental Healthcare-Associated Infections (HAI) Investigation Specimen Submission Protocol for Oklahoma Physicians

The Oklahoma State Department of Health (OSDH) and the Tulsa Health Department have recommended that persons who were dental patients of W. Scott Harrington, DMD receive testing for HIV, hepatitis C, and hepatitis B (refer to attached Oklahoma Health Alert Network Advisory). These patients are being directed to county health departments for specimen collection and administration of a supplemental epidemiological questionnaire. Laboratory testing is being provided free of charge through the OSDH Public Health Laboratory. This protocol is intended for use by healthcare providers assisting patients who have a strong preference to access the testing through their personal physician rather than access testing through their respective county health department.

### Specimens:

A total of three serum separator tubes are required for testing by the OSDH Public Health Laboratory:

- one for HIV testing
- one for hepatitis B and C testing
- one for potential re-testing.
- 1. Label each tube with name of patient and DOB.
- After collection of blood (3 full-tubes), let the tubes sit for 30 minutes to 1 hour at room temperature to clot then centrifuge (10 minutes at about X1000g) to separate serum. A delay in centrifugation may have a detrimental effect on the sample quality and may result in inaccurate results. Avoid hemolysis.
- Refrigerate spun tubes @ <u>2 8°C prior to transportation to the OSDH PHL</u>. Samples must be tested within 7 days of collection.

### **Requisitions:**

There are two options to request tests:

- 1. If you are a user of the Public Health Investigation & Disease Detection of Oklahoma (PHIDDO) system, request tests through PHIDDO:
  - a. Fill out forms on-line
    - use one requisition to order HIV test
    - use another form to order hepatitis B and C tests
  - b. Use program code "Communicable Disease"
  - c. Print requisition forms
- 2. Alternatively, use the OSDH Public Health Laboratory requisition form (located at

http://www.ok.gov/health2/documents/Lab%20Requisition%203-5-2013.pdf ):

- Fill out form on-line use one requisition to order all tests (fields marked with an asterisk \* are required)
- b. Print requisition form and write "Communicable Disease" on the form
- c. If you require faxed reports, write your fax number on the form

#### Transport of Specimens to the OSDH Public Health Laboratory:

- 1. Place tubes and requisitions in one biohazard bag with pouch.
- 2. Call the OSDH Public Health Laboratory (PHL) @ 405-271-5070 for pick-up by courier. Normal working hours for the PHL are Monday through Friday, 8 am to 4:30 pm.
#### Reports of Test Results:

- 1. Results will normally be available within 48 hours (2 work-days) of <u>receipt</u> of sample; however, delayed reporting will occur when confirmatory testing is required:
  - a. confirmatory Western Blot testing for HIV-positive screens is performed on Thursday of each week and reported the next day
  - b. confirmatory testing for hepatitis B surface Ag-positive specimens is performed and reported the following day (i.e., total of 3 work-days from receipt)
- 2. Reports will be <u>mailed</u> to the physician's address provided on the requisition. Reports <u>can be faxed</u> to the submitter when a fax number is provided on the requisition form (fax verification will be required prior to sending results electronically). Results will <u>not</u> be provided verbally by telephone.

Physician Protocol – Page 2 of 2 Updated 3/29/13

#### Dental Healthcare-Associated Infections (HAI) Investigation in Oklahoma Specimen Submission Protocol for Out-of-State Sites

The Oklahoma State Department of Health (OSDH) and the Tulsa Health Department have recommended that persons who were former dental patients of W. Scott Harrington, DMD (dental surgical practice locations in Tulsa and Owasso, Oklahoma) receive testing for HIV, hepatitis C, and hepatitis B. In Oklahoma, these patients are being directed to county health departments for specimen collection and administration of a supplemental epidemiological questionnaire if the patient's last dental encounter occurred within the past year. Laboratory testing is being provided free-of-charge through the OSDH Public Health Laboratory (PHL). This protocol is intended for use by public health departments and healthcare providers assisting these former dental patients who have moved out-of-state and wish to access the free testing available through the OSDH PHL. Please note that the OSDH cannot reimburse for services associated with specimen collection, processing, or shipping. Also, be advised that the OSDH PHL cannot test samples drawn on patients within the states of New York, Rhode Island, Florida, California, and Maryland. For samples originating from these states, please contact Jan Fox, Chief of the OSDH HIV/STD Service, at janf@health.ok.gov or 405-271-4636, for further guidance related to this investigation.

#### Specimens:

A total of three serum separator tubes are required for testing by the OSDH Public Health Laboratory:

- one for HIV testing
- one for hepatitis B and C testing
- one for potential re-testing or virus genotyping
- 1. Label each tube with name of patient and DOB.
- After collection of blood (3 full tubes), let the tubes sit for 30 minutes to 1 hour at room temperature to clot, then centrifuge (10 minutes at about X1000g) to separate serum. A delay in centrifugation may have a detrimental effect on the sample quality and may result in inaccurate results. Avoid hemolysis.
- 3. Refrigerate spun tubes @ <u>2 8°C prior to transportation to the OSDH PHL</u>. Samples must be tested within 7 days of collection.

<u>Alternatively</u>, collect one red-stopper tube of blood, gently invert 3 to 5 times, let sit for 10 minutes at room temperature to clot, then centrifuge (10 minutes at about X1000g) to separate serum. Pipette serum into polypropylene tube with no additives (preferably screw-cap; if snap-cap, seal top with Parafilm). Refrigerate tube @  $2 - 8^{\circ}$ C prior to transportation to the OSDH PHL. Samples must be tested within 7 days of collection.

#### Requisitions:

To request tests, use the OSDH Public Health Laboratory requisition form located at <a href="http://www.ok.gov/health2/documents/Lab%20Requisition%204">http://www.ok.gov/health2/documents/Lab%20Requisition%204</a> 1 13.pdf

- Fill out form on-line. Use one requisition to order all tests (fields marked with an asterisk \* are required).
- b. Print requisition form and write "Communicable Disease" on the form.
- c. If you require faxed reports, write your fax number on the form.



Updated 4/3/2013

#### Transport of Specimens to the OSDH PHL:

- 1. Place tubes and requisition in one biohazard bag with pouch.
- Place in appropriate shipping container; mark on outside "Biological Substance, Category B". More information on packaging and shipping of clinical specimens can be found at <u>http://www.ok.gov/health2/documents/Transporting\_Infectious\_Substances\_brochure%202-15-13.pdf</u>
- Ship tubes on cold packs (at 2-8°C) to OSDH Public Health Laboratory at: Oklahoma State Department of Health Public Health Laboratory 1000 N.E. 10th Street Oklahoma City, Oklahoma 73117-1299

Normal working hours for the PHL are Monday through Friday, 8 am to 4:30 pm.

#### Testing:

The following testing will be performed at the OSDH PHL:

- HIV antibody screen using enzyme-linked immunosorbent assay (ELISA);
- HIV antibody screen-positive confirmation using Western blot;
- Hepatitis B surface antigen (HBsAg) screen using enzyme immunoassay (EIA);
- HBsAg screen-positive confirmation using a HBsAg antibody neutralization procedure;
- Hepatitis C antibody screen using ELISA.

#### Reports:

1. Results will normally be available within 48 hours (2 working days) of <u>receipt</u> of sample; however, delayed reporting will occur when confirmatory testing is required:

- a. confirmatory Western Blot testing for HIV-positive screens is performed on Thursday of each week and reported the next day
- b. confirmatory testing for HBsAg-positive specimens is performed and reported the following day (i.e., total of 3 work-days from receipt)
- Reports will be <u>mailed</u> to the physician's or health department address provided on the requisition. Reports <u>can be faxed</u> to the submitter when a fax number is provided on the requisition form (fax verification will be required prior to sending results electronically). Results will <u>not</u> be provided verbally by telephone.

If you have any questions regarding specimen draw or referral of specimens, call the OSDH Public Health Laboratory at 405-271-5070.

2 | Page

Updated 4/3/2013

Appendix A, Figure 8-1

Appendix 8-1. Distribution of Dental Patients Testing Positive for Hepatitis C by Date of Dental Visits, Hepatitis C Virus Genotype, and Timing of Hepatitis C Diagnosis Relative to First Dental Visit, March 1, 2012 – March 20, 2013







C13OK E1-HVR1 Quasispecies Analysis

#### Appendix A, Figure 11-1

Please complete a new f	orm for each procedure and number t	he form in the right hand corner.	
erson Completing Form:		Date Form Completed:	
atient name	name:		
	rauent Ag		
urgery/Consultation Record			
. Dental Assistant at Procedure: 1 <sup>st</sup> A	ssistant 2'	<sup>nd</sup> Assistant	
. Consultation Date(s):			
Observation Date(s):			
Date of Dental Procedure (MM-DD-	-YYYY):		
Procedure (Check all that apply):			
□Alveoplasty (Smoothing of th	e DApicoectomy (Removal of		
bone)	tooth root)	Biopsy/Pre-biopsy consult	
□Bone Graft	□Cosmetic injections	□Cosmetic surgery/eyelids, etc.	
□Expose and bracket (for	□ Extractions	□Implant placement	
Orthodontia)			
□X-rays	🗆 Other:		
Time of Dental Provedures, Class	The The T		
I lime of Dental Procedure: Start II	me Stop Time	e Lime was blank	
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1

# Appendix A, Figure 12-1 Alphabetic List of Variables Used for Dental HAI Risk Factor Analyses of Dental Patients with Procedures March 1, 2012 – March 20, 2013

#	Variable	Variable	Variable	#	V
		туре	Length		
1	Alveoplasty1	Character	20	26	A
2	Alveoplasty2	Character	20	27	A
3	Alveoplasty3	Character	20	28	A
4	Alveoplasty4	Character	20	29	A
5	Anesthesia_start_time1	Character	50	30	A
6	Anesthesia_start_time2	Character	50	31	A
7	Anesthesia_start_time3	Character	50	32	A
8	Anesthesia_start_time4	Character	50	33	В
9	Anesthesia_stop_time1	Character	50	34	В
10	Anesthesia_stop_time2	Character	50	35	В
11	Anesthesia_stop_time3	Character	50	36	В
12	Anesthesia_stop_time4	Character	50	37	В
13	Apicoectomy1	Character	20	38	В
14	Apicoectomy2	Character	20	39	В
15	Apicoectomy3	Character	20	40	В
16	Apicoectomy4	Character	20	41	В
17	Appointment_date1	Numeric	8	42	В
18	Appointment_date2	Numeric	8	43	В
19	Appointment_date3	Numeric	8	44	В
20	Appointment_date4	Numeric	8	45	В
21	Appointment_time1	Numeric	8	46	В
22	Appointment_time2	Numeric	8	47	В
23	Appointment_time3	Numeric	8	48	В
24	Appointment_time4	Numeric	8	49	В
25	Atropine_amount1	Character	20	50	В
L	1	l	1	J L	I

#	Variable	Variable	Variable
		туре	Length
26	Atropine_amount2	Character	20
27	Atropine_amount3	Character	20
28	Atropine_amount4	Character	20
29	Atropine1	Character	20
30	Atropine2	Character	20
31	Atropine3	Character	20
32	Atropine4	Character	20
33	Biopsy_Pre_biopsy1	Character	20
34	Biopsy_Pre_biopsy2	Character	20
35	Biopsy_Pre_biopsy3	Character	20
36	Biopsy_Pre_biopsy4	Character	20
37	Bleeding	Character	20
38	Bone_graft1	Character	20
39	Bone_graft2	Character	20
40	Bone_graft3	Character	20
41	Bone_graft4	Character	20
42	BREVITAL_amount_All	Numeric	8
43	BREVITAL_Amount_All_new	Numeric	8
44	Brevital_amount1	Character	20
45	Brevital_amount1_Numeric	Numeric	8
46	Brevital_amount2	Character	20
47	Brevital_amount2_Numeric	Numeric	8
48	Brevital_amount3	Character	20
49	Brevital_amount3_Numeric	Numeric	8
50	Brevital_amount4	Character	20

		Туре	
			Length
51	Brevital_amount4_numeric	Numeric	8
52	Brevital1	Character	20
53	Brevital2	Character	20
54	Brevital3	Character	20
55	Brevital4	Character	20
56	Chair1	Numeric	8
57	Chair2	Numeric	8
58	Chair3	Numeric	8
59	Chair4	Numeric	8
60	Comments	Character	510
61	Con_only	Character	3
62	Consultation_dates	Character	50
63	Cosmetic_injections1	Character	20
64	Cosmetic_injections2	Character	20
65	Cosmetic_injections3	Character	20
66	Cosmetic_injections4	Character	20
67	Cosmetic_surgery1	Character	20
68	Cosmetic_surgery2	Character	20
69	Cosmetic_surgery3	Character	20
70	Cosmetic_surgery4	Character	20
71	Current_age	Numeric	8
72	Current_agecat	Character	10
73	Current_agecat2	Character	10
74	Date_form_completed	Numeric	8
75	Date_health_history	Numeric	8
76	Date_of_collection	Character	10
77	Date_of_Procedure1	Numeric	8
78	Date_of_Procedure2	Numeric	8

#	Variable	Variable	Variable
		Туре	Length
79	Date_of_Procedure3	Numeric	8
80	Date_of_Procedure4	Numeric	8
81	Days	Numeric	8
82	Decadron_amount1	Character	20
83	Decadron_amount2	Character	20
84	Decadron_amount3	Character	20
85	Decadron_amount4	Character	20
86	Decadron1	Character	20
87	Decadron2	Character	20
88	Decadron3	Character	20
89	Decadron4	Character	20
90	Dob	Numeric	8
91	Drugs	Character	20
92	Ever_had_W_assistant	Character	3
93	Ever_had_X_assistant	Character	3
94	Ever_had_Y_assistant	Character	3
95	Ever_had_Z_assistant	Character	3
96	Expose_and_Bracket1	Character	20
97	Expose_and_Bracket2	Character	20
98	Expose_and_Bracket3	Character	20
99	Expose_and_Bracket4	Character	20
100	Extractions1	Character	20
101	Extractions2	Character	20
102	Extractions3	Character	20
103	Extractions4	Character	20
104	First_asst_ever_W	Character	3
105	First_asst_Ever_X	Character	3
106	First_asst_Ever_Y	Character	3

#	Variable	Variable	Variable
		Туре	Length
107	First_asst_Ever_Z	Character	3
108	First_asst1	Character	20
109	First_asst2	Character	20
110	First_asst3	Character	20
111	First_asst4	Character	20
112	Genotype	Character	8
113	Had_alveoplasty	Character	3
114	Had_apicoectomy	Character	3
115	Had_Biopsy_Pre_biopsy	Character	3
116	Had_bone_graft	Character	3
117	Had_Expose_and_bracket	Character	3
118	Had_extractions	Character	3
119	Had_implant_placement	Character	3
120	HCV_new	Character	3
121	HCV_status	Character	35
122	Hcv_status_final	Character	4
123	HCV_status2	Character	10
124	HCV_statusrisk	Character	35
125	Hep_b_result	Character	37
126	Hep_c_result	Character	37
127	Hepchistorycd	Character	20
128	Hiv_result	Character	68
129	Immune	Character	20
130	Implant_placement1	Character	20
131	Implant_placement2	Character	20
132	Implant_placement3	Character	20
133	Implant_placement4	Character	20
134	lv_catheter1	Character	50

#	Variable	Variable	Variable
		Туре	Length
135	lv_catheter2	Character	50
136	lv_catheter3	Character	50
137	lv_catheter4	Character	50
138	Ketamine_amount1	Character	20
139	Ketamine_amount2	Character	20
140	Ketamine_amount3	Character	20
141	Ketamine_amount4	Character	20
142	Ketamine1	Character	20
143	Ketamine2	Character	20
144	Ketamine3	Character	20
145	Ketamine4	Character	20
146	Liver	Character	20
147	Local1	Character	20
148	Local2	Character	20
149	Local3	Character	20
150	Local4	Character	20
151	Morphine_amount1	Character	20
152	Morphine_amount2	Character	20
153	Morphine_amount3	Character	20
154	Morphine_amount4	Character	20
155	Morphine1	Character	20
156	Morphine2	Character	20
157	Morphine3	Character	20
158	Morphine4	Character	20
159	Nick_name	Character	50
160	Nitrous1	Character	20
161	Nitrous2	Character	20
162	Nitrous3	Character	20
		l	

Image: series of the series	#	Variable	Variable	Variable
163Nitrous4Character20164Obs_onlyCharacter3165Observation_datesCharacter50166Other_med_1_amount1Character50167Other_med_1_amount2Character50168Other_med_11Character50169Other_med_12Character50170Other_med_12Character50171Other_med_2_amount1Character50173Other_med_2_amount2Character50174Other_med_2_amount2Character50175Other_med_21Character50176Other_med_2Character50177Other_med_3_amount2Character50177Other_med_3_amount3Character50179Other_med_3_amount3Character50181Other_med_33Character50183Other_med_33Character50184Other_procedure1Character50185Other_procedure2Character205186Other_procedure3Character205189Oxygen3Character20189Oxygen4Character20			Туре	Length
164Obs_onlyCharacter3165Observation_datesCharacter50166Other_med_1_amount1Character50167Other_med_1_amount2Character50168Other_med_1_amount3Character50169Other_med_11Character50170Other_med_12Character50171Other_med_13Character50172Other_med_2_amount1Character50173Other_med_2_amount2Character50174Other_med_21Character50175Other_med_21Character50176Other_med_23Character50177Other_med_3_amount1Character50178Other_med_3_amount2Character50180Other_med_3aCharacter50181Other_med_33Character50183Other_procedure1Character50184Other_procedure2Character205185Other_procedure3Character20189Oxygen3Character20189Oxygen4Character20	163	Nitrous4	Character	20
165Observation_datesCharacter50166Other_med_1_amount1Character50167Other_med_1_amount2Character50168Other_med_1_amount3Character50169Other_med_11Character50170Other_med_12Character50171Other_med_2_amount1Character50172Other_med_2_amount2Character50173Other_med_2_amount2Character50174Other_med_2_amount3Character50175Other_med_21Character50176Other_med_23Character50177Other_med_3_amount1Character50178Other_med_3_amount2Character50180Other_med_3_amount3Character50181Other_med_31Character50182Other_med_33Character50184Other_procedure1Character255186Other_procedure3Character20189Oxygen4Character20	164	Obs_only	Character	3
166Other_med_1_amount1Character50167Other_med_1_amount2Character50168Other_med_1_amount3Character50169Other_med_11Character50170Other_med_12Character50171Other_med_2_amount1Character50173Other_med_2_amount2Character50174Other_med_2_amount3Character50175Other_med_21Character50176Other_med_22Character50177Other_med_3Character50178Other_med_3_amount1Character50180Other_med_3_amount2Character50181Other_med_3Character50182Other_med_33Character50183Other_med_33Character50184Other_procedure1Character255186Other_procedure2Character255186Other_procedure3Character20189Oxygen3Character20190Oxygen4Character20	165	Observation_dates	Character	50
167Other_med_1_amount2Character50168Other_med_1_amount3Character50169Other_med_11Character50170Other_med_12Character50171Other_med_13Character50172Other_med_2_amount1Character50173Other_med_2_amount2Character50174Other_med_2_amount3Character50175Other_med_2_amount3Character50176Other_med_22Character50177Other_med_3_amount1Character50178Other_med_3_amount2Character50180Other_med_3_amount3Character50181Other_med_3_amount3Character50182Other_med_31Character50183Other_med_33Character50184Other_procedure1Character255186Other_procedure3Character20188Oxygen1Character20189Oxygen3Character20190Oxygen4Character20	166	Other_med_1_amount1	Character	50
168Other_med_1_amount3Character50169Other_med_11Character50170Other_med_12Character50171Other_med_13Character50172Other_med_2_amount1Character50173Other_med_2_amount2Character50174Other_med_2_amount3Character50175Other_med_21Character50176Other_med_23Character50177Other_med_3_amount1Character50178Other_med_3_amount2Character50179Other_med_3_amount2Character50180Other_med_31Character50181Other_med_33Character50183Other_procedure1Character50184Other_procedure2Character255185Other_procedure3Character20188Oxygen1Character20189Oxygen3Character20190Oxygen4Character20	167	Other_med_1_amount2	Character	50
169Other_med_11Character50170Other_med_12Character50171Other_med_13Character50172Other_med_2_amount1Character50173Other_med_2_amount2Character50174Other_med_2_amount3Character50175Other_med_21Character50176Other_med_22Character50177Other_med_23Character50178Other_med_3_amount1Character50179Other_med_3_amount2Character50180Other_med_31Character50181Other_med_33Character50182Other_med_33Character50183Other_procedure1Character255185Other_procedure2Character255186Other_procedure3Character20188Oxygen1Character20189Oxygen3Character20190Oxygen4Character20	168	Other_med_1_amount3	Character	50
170Other_med_12Character50171Other_med_13Character50172Other_med_2_amount1Character50173Other_med_2_amount2Character50174Other_med_2_amount3Character50175Other_med_21Character50176Other_med_22Character50177Other_med_23Character50178Other_med_3_amount1Character50179Other_med_3_amount2Character50180Other_med_31Character50181Other_med_32Character50183Other_med_33Character50184Other_procedure1Character255185Other_procedure3Character20188Oxygen1Character20189Oxygen4Character20	169	Other_med_11	Character	50
171Other_med_13Character50172Other_med_2_amount1Character50173Other_med_2_amount2Character50174Other_med_2_amount3Character50175Other_med_21Character50176Other_med_22Character50177Other_med_23Character50178Other_med_3_amount1Character50179Other_med_3_amount2Character50180Other_med_3_amount3Character50181Other_med_31Character50182Other_med_33Character50183Other_procedure1Character50184Other_procedure2Character255185Other_procedure3Character20188Oxygen1Character20189Oxygen4Character20	170	Other_med_12	Character	50
172Other_med_2_amount1Character50173Other_med_2_amount2Character50174Other_med_2_amount3Character50175Other_med_21Character50176Other_med_22Character50177Other_med_23Character50178Other_med_3_amount1Character50179Other_med_3_amount2Character50180Other_med_3_amount3Character50181Other_med_31Character50182Other_med_33Character50183Other_procedure1Character50184Other_procedure2Character255185Other_procedure3Character20188Oxygen1Character20189Oxygen3Character20190Oxygen4Character20	171	Other_med_13	Character	50
173Other_med_2_amount2Character50174Other_med_2_amount3Character50175Other_med_21Character50176Other_med_22Character50177Other_med_23Character50178Other_med_3_amount1Character50179Other_med_3_amount2Character50180Other_med_3_amount3Character50181Other_med_31Character50182Other_med_32Character50183Other_med_33Character50184Other_procedure1Character255185Other_procedure2Character255186Other_procedure3Character20188Oxygen1Character20189Oxygen3Character20190Oxygen4Character20	172	Other_med_2_amount1	Character	50
174Other_med_2_amount3Character50175Other_med_21Character50176Other_med_22Character50177Other_med_23Character50178Other_med_3_amount1Character50179Other_med_3_amount2Character50180Other_med_3_amount3Character50181Other_med_3_amount3Character50182Other_med_32Character50183Other_med_33Character50184Other_procedure1Character255186Other_procedure3Character20188Oxygen1Character20189Oxygen3Character20190Oxygen4Character20	173	Other_med_2_amount2	Character	50
175Other_med_21Character50176Other_med_22Character50177Other_med_23Character50178Other_med_3_amount1Character50179Other_med_3_amount2Character50180Other_med_3_amount3Character50181Other_med_31Character50182Other_med_32Character50183Other_med_33Character50184Other_procedure1Character255185Other_procedure2Character255186Other_procedure3Character20188Oxygen1Character20189Oxygen3Character20190Oxygen4Character20	174	Other_med_2_amount3	Character	50
176Other_med_22Character50177Other_med_23Character50178Other_med_3_amount1Character50179Other_med_3_amount2Character50180Other_med_3_amount3Character50181Other_med_31Character50182Other_med_32Character50183Other_med_33Character50184Other_procedure1Character255185Other_procedure2Character255186Other_procedure3Character20188Oxygen1Character20189Oxygen3Character20190Oxygen4Character20	175	Other_med_21	Character	50
177Other_med_23Character50178Other_med_3_amount1Character50179Other_med_3_amount2Character50180Other_med_3_amount3Character50181Other_med_31Character50182Other_med_32Character50183Other_med_33Character50184Other_procedure1Character255185Other_procedure2Character255186Other_procedure3Character20188Oxygen1Character20189Oxygen4Character20	176	Other_med_22	Character	50
178Other_med_3_amount1Character50179Other_med_3_amount2Character50180Other_med_3_amount3Character50181Other_med_31Character50182Other_med_32Character50183Other_med_33Character50184Other_procedure1Character255185Other_procedure2Character255186Other_procedure3Character20188Oxygen1Character20189Oxygen4Character20	177	Other_med_23	Character	50
179Other_med_3_amount2Character50180Other_med_3_amount3Character50181Other_med_31Character50182Other_med_32Character50183Other_med_33Character50184Other_procedure1Character255185Other_procedure2Character255186Other_procedure3Character20188Oxygen1Character20189Oxygen4Character20	178	Other_med_3_amount1	Character	50
180Other_med_3_amount3Character50181Other_med_31Character50182Other_med_32Character50183Other_med_33Character50184Other_procedure1Character255185Other_procedure2Character255186Other_procedure3Character20188Oxygen1Character20189Oxygen3Character20190Oxygen4Character20	179	Other_med_3_amount2	Character	50
181Other_med_31Character50182Other_med_32Character50183Other_med_33Character50184Other_procedure1Character255185Other_procedure2Character255186Other_procedure3Character255187Oxygen1Character20188Oxygen2Character20189Oxygen4Character20	180	Other_med_3_amount3	Character	50
182Other_med_32Character50183Other_med_33Character50184Other_procedure1Character255185Other_procedure2Character255186Other_procedure3Character255187Oxygen1Character20188Oxygen2Character20189Oxygen4Character20	181	Other_med_31	Character	50
183Other_med_33Character50184Other_procedure1Character255185Other_procedure2Character255186Other_procedure3Character255187Oxygen1Character20188Oxygen2Character20189Oxygen4Character20	182	Other_med_32	Character	50
184Other_procedure1Character255185Other_procedure2Character255186Other_procedure3Character255187Oxygen1Character20188Oxygen2Character20189Oxygen3Character20190Oxygen4Character20	183	Other_med_33	Character	50
185Other_procedure2Character255186Other_procedure3Character255187Oxygen1Character20188Oxygen2Character20189Oxygen3Character20190Oxygen4Character20	184	Other_procedure1	Character	255
186Other_procedure3Character255187Oxygen1Character20188Oxygen2Character20189Oxygen3Character20190Oxygen4Character20	185	Other_procedure2	Character	255
187Oxygen1Character20188Oxygen2Character20189Oxygen3Character20190Oxygen4Character20	186	Other_procedure3	Character	255
188Oxygen2Character20189Oxygen3Character20190Oxygen4Character20	187	Oxygen1	Character	20
189Oxygen3Character20190Oxygen4Character20	188	Oxygen2	Character	20
190 Oxygen4 Character 20	189	Oxygen3	Character	20
	190	Oxygen4	Character	20

#	Variable	Variable	Variable
		Туре	Length
191	Pat_first_name	Character	50
192	Pat_last_name	Character	50
193	Pat_middle_name	Character	50
194	Patient_Age_at_Visit1	Character	20
195	Patient_Age_at_Visit2	Character	20
196	Patient_Age_at_Visit3	Character	20
197	Patient_Age_at_Visit4	Character	20
198	Person_completing_Form	Character	100
199	Person_UID	Numeric	8
200	Phiddo_id	Character	16
201	Previous_HBV_positive	Character	3
202	Previous_HCV_positive	Character	3
203	Procedure_detail1	Character	217
204	Procedure_detail2	Character	217
205	Procedure_detail3	Character	217
206	Procedure_detail4	Character	217
207	Propofol_amount_all	Numeric	8
208	Propofol_amount1	Character	20
209	Propofol_amount1_Numeric	Numeric	8
210	Propofol_amount2	Character	20
211	Propofol_amount2_Numeric	Numeric	8
212	Propofol_amount3	Character	20
213	Propofol_amount3_Numeric	Numeric	8
214	Propofol_amount4	Character	20
215	Propofol_amount4_numeric	Numeric	8
216	Propofol1	Character	20
217	Propofol2	Character	20
218	Propofol3	Character	20
		1	

Ŧ	Variable	Variable	Variable
		Туре	Length
219	Propofol4	Character	20
220	Receive_anesthesia1	Character	50
221	Receive_anesthesia2	Character	50
222	Receive_anesthesia3	Character	50
223	Receive_anesthesia4	Character	50
224	Received_atropine	Character	7
225	Received_brevital	Character	7
226	Received_decadron	Character	7
227	Received_general_anesthesia	Character	3
228	Received_iv_catheter	Character	3
229	Received_ketamine	Character	7
230	Received_morphine	Character	7
231	Received_propofol	Character	7
232	Received_reglan	Character	7
233	RECEIVED_sockit_wound	Character	3
234	Received_valium	Character	7
235	Received_versed	Character	7
236	Recurrent	Character	20
237	Reglan_amount_all	Numeric	8
238	Reglan_amount1	Character	20
239	Reglan_amount1_Numeric	Numeric	8
240	Reglan_amount2	Character	20
241	Reglan_amount2_Numeric	Numeric	8
242	Reglan_amount3	Character	20
243	Reglan_amount3_Numeric	Numeric	8
244	Reglan_amount4	Character	20
245	Reglan_amount4_numeric	Numeric	8
246	Reglan1	Character	20

#	Variable	Variable	Variable
		Туре	Length
247	Reglan2	Character	20
248	Reglan3	Character	20
249	Reglan4	Character	20
250	Second_asst1	Character	20
251	Second_asst2	Character	20
252	Second_asst3	Character	20
253	Second_asst4	Character	20
254	Sex	Character	1
255	Sockit_dental1	Character	20
256	Sockit_dental2	Character	20
257	Sockit_dental3	Character	20
258	Sockit_dental4	Character	20
259	Sockit_home1	Character	20
260	Sockit_home2	Character	20
261	Sockit_home3	Character	20
262	Sockit_home4	Character	20
263	Sockit_wound1	Character	20
264	Sockit_wound2	Character	20
265	Sockit_wound3	Character	20
266	Sockit_wound4	Character	20
267	Source1	Character	19
268	Source2	Character	19
269	Source3	Character	19
270	Source4	Character	19
271	Ssn	Character	12
272	Start_time1	Character	50
273	Start_time2	Character	50
274	Start_time3	Character	50

#	Variable	Variable	Variable
		Туре	Length
275	Start_time4	Character	50
276	Stop_time1	Character	50
277	Stop_time2	Character	50
278	Stop_time3	Character	50
279	Stop_time4	Character	50
280	Submitter	Character	50
281	Sutures_a1	Character	20
282	Sutures_a2	Character	20
283	Sutures_a3	Character	20
284	Sutures_a4	Character	20
285	Sutures1	Character	20
286	Sutures2	Character	20
287	Sutures3	Character	20
288	Sutures4	Character	20
289	Third_asst1	Character	20
290	Third_asst2	Character	20
291	Third_asst3	Character	20
292	Third_asst4	Character	20
293	Times_brevital_received	Numeric	8
294	Times_propofol_received	Numeric	8
295	Times_reglan_received	Numeric	8
296	Today	Numeric	8
297	Total_brevital_amount	Numeric	8
298	Total_propofol_amount	Numeric	8
299	Total_reglan_amount	Numeric	8
300	Valium_amount1	Character	20
301	Valium_amount2	Character	20
302	Valium_amount3	Character	20
		1	

#	Variable	Variable	Variable
		туре	Length
303	Valium_amount4	Character	20
304	Valium1	Character	20
305	Valium2	Character	20
306	Valium3	Character	20
307	Valium4	Character	20
308	Versed_amount1	Character	20
309	Versed_amount2	Character	20
310	Versed_amount3	Character	20
311	Versed_amount4	Character	20
312	Versed1	Character	20
313	Versed2	Character	20
314	Versed3	Character	20
315	Versed4	Character	20
316	Xrays1	Character	20
317	Xrays2	Character	20
318	Xrays3	Character	20
319	Xrays4	Character	20

# **Appendix B: Fact Sheets**

Appendix B-1



### **Frequently Asked Questions About the Dental Public Health Investigation**

How could I have been exposed to Hepatitis B (HBV), Hepatitis C (HCV), or Human Immunodeficiency Virus (HIV) in a dentist's office?

When dentists and other healthcare professionals do not follow proper infection control procedures, patients can be at risk to acquire these diseases. Proper infection control techniques include thorough disinfection and sterilization of instruments, proper disposal of sharp objects, use of single dose medication vials or proper handling and administering of multi-dose vial medications when used in the facility, and never reusing items such as needles and syringes between patients.

Does this happen very often in other dentist's offices?

No, most dentists practice proper infection control procedures.

#### Has HBV, HCV, or HIV transmission ever occurred before in a dental setting?

Very rarely, HIV and HBV have been known to be transmitted in the dental setting. HCV transmission has not been documented in the dental setting.

What do dentists do to protect their patients from being exposed to these bloodborne viruses?

Dentists, like other healthcare professionals, are trained to utilize what is known as Standard/Universal Precautions to protect themselves and their patients. Standard/Universal Precautions require that the blood and other body fluids of all patients be handled as if they contain viruses or other microorganisms in the blood that can cause human disease. Appropriate use of hand washing, protective barriers such as gloves, injection safety including proper medication preparation and administration, and care in the use and disposal of needles and other sharp instruments are also important components of observing Standard/Universal Precautions.

#### How will I be notified of today's test results? How long will it take to get results?

Most persons will be notified of their test results within 1 to 2 weeks. If you have negative test results and give the health department permission to mail negative test results to your home, you will be notified in this manner. Anyone who has a positive test result will be personally notified by a professional from the health department to provide more information about the test results and provide recommendations for follow up and care.



#### What happens if I test positive for HBV, HCV, or HIV?

If any of your test results are positive, you will be contacted by a professional from the health department for an interview. You will be provided with information specific to the disease for which you test positive and will be referred to your private physician for further evaluation.

#### Where will I go for treatment and care if I don't have insurance?

If your test result is positive, a counselor will address your follow-up needs. A health department professional will provide you with information regarding resources that are available in your area in the event that you do not have insurance or a private physician.

# Should my family members get tested, too, even though they did not have dental surgery at the practice of concern?

No, at this time, only persons who had the dental procedures are considered to be at risk of exposure to the bloodborne viruses and are recommended to obtain testing. Testing of family members may be advised if one of your tests is positive. Those recommendations will be made at the appropriate time.

#### What else is the health department doing to ensure this doesn't happen again?

The health department is actively investigating this situation to determine if diseases were transmitted and why. Once this is better understood, the health department can take steps to ensure that this doesn't occur again.

#### Is every patient of Dr. Harrington's being notified?

Every known patient of Dr. Harrington's is being notified of the need to be screened for HBV, HCV, and HIV. Patient information was only available from the past seven years, therefore, we do not have the ability to notify patients who had procedures many years ago. A press release from the health department is expected to inform others who may not be included in the available patient listing.

#### When was the problem identified?

The problem was identified on March 12, 2013 following a public health site investigation to Dr. Harrington's clinic.

#### Are any patients known to have been infected?

At this time, we do not know if any patients were infected due to exposures at the dental surgical clinic. We hope that our investigation will determine if the improper practices led to infection of some dental patients. Right now, we just want to inform persons that may have been at risk of exposure and provide testing, so they know their infection status.



#### Is the problem still going on?

No, once the improper practices were identified, the dental practice ceased patient care.

Who is performing the public health investigation?

The public health investigation is being conducted by both the Oklahoma State Department of Health and the Tulsa County Health Department.

When will the investigation be complete?

It is not possible to say how long the investigation will take. Investigations of this nature require extensive laboratory testing and follow up.

Who is responsible for making sure that dentists are following proper procedures?

This is a question for the Oklahoma Board of Dentistry. They can be contacted at 405-524-9037.

<u>I was a patient there many years ago. Should I be tested, even though I did not receive a notification?</u>

We do not know how long these improper practices have been occurring, so we recommend that all patients of Dr. Harrington's be tested for Hepatitis B, Hepatitis C, and HIV.

#### Is it too late to be tested?

No, if you have been infected, testing will always be positive, even years after infection.

#### How soon can I be tested?

The tests used to identify Hepatitis B, Hepatitis C, and HIV are based on your body's immune response to infection, which can take week to months to develop. If you are infected, people will begin to test positive within weeks, with almost all testing positive within 6 months. If you are tested prior to 6 months after your exposure and are found to be negative, it is recommended that you are tested again at 6 months after exposure to ensure that you are negative.

#### Where can I call if I have more questions?

Please call the Tulsa county health department at 918-595-4500.



#### What is Hepatitis C?

Hepatitis C is a liver disease that ranges in severity from a mild illness lasting a few weeks to a serious, lifelong illness that attacks the liver. It results from infection with the Hepatitis C virus (HCV), which is spread primarily through contact with the blood of an infected person. Hepatitis C can be either "acute" or "chronic."

#### How is Hepatitis C Spread?

Hepatitis C can be spread in any one of the following ways:

- Blood to blood contact
- Exposure to contaminated needles, syringes, or other equipment. This may occur in healthcare settings or with recreational drug use.
- Sex with multiple partners or rough sex
- Delivery of a baby to a mother with hepatitis C
- Tattooed or pierced with non-sterile needles or equipment
- Accidental needle stick with a needle that was used on an infected person
- Using the same razor or toothbrush that an infected person used
- Hepatitis C virus is not spread by sharing eating utensils, breastfeeding, hugging, kissing, holding hands, coughing, or sneezing.

#### Is there a vaccine that can prevent Hepatitis C?

Not yet. Vaccines are available only for Hepatitis A and Hepatitis B.

#### What are the symptoms of acute Hepatitis C?

Approximately 70%–80% of people with acute Hepatitis C do not have any symptoms. Some people, however, can have mild to severe symptoms soon after being infected, including

- Fever
- Fatigue
- Loss of appetite
- Nausea
- Vomiting
- Abdominal pain
- Dark urine
- Clay-colored bowel movements
- Joint pain
- Jaundice (yellow color in the skin or eyes)



#### How soon after exposure to Hepatitis C do symptoms appear?

If symptoms occur, the average time is 6-7 weeks after exposure, but this can range from 2 weeks to 6 months. However, many people infected with the Hepatitis C virus do not develop symptoms. The truth is that some people will never be able to be sure how they were infected.

#### How do I find out if I have Hepatitis C?

You can find out if you have Hepatitis C by taking an antibody test. If this comes back positive, it means that you have been exposed to the virus at some time. If it is negative, then you may be required to have another test at a later time, depending on your date of possible exposure. If the antibody test is positive, then a further test to check for the active virus will be necessary.

#### What can a person with chronic Hepatitis C do to take care of his or her liver?

People with chronic Hepatitis C should be monitored regularly by an experienced doctor. They should avoid alcohol because it can cause additional liver damage. They also should check with a health professional before taking any prescription pills, supplements, or over-the-counter medications, as these can potentially damage the liver. If liver damage is present, a person should check with his or her doctor about getting vaccinated against Hepatitis A and Hepatitis B.

# Should a person infected with the Hepatitis C virus be restricted from working in certain jobs or settings?

CDC's recommendations for prevention and control of the Hepatitis C virus infection state that people should not be excluded from work, school, play, child care, or other settings because they have Hepatitis C. There is no evidence that people can get Hepatitis C from food handlers, teachers, or other service providers without blood-to-blood contact.

#### How is Hepatitis C treated?

Antiviral medication can be used to treat some people with chronic hepatitis C, although not everyone needs or can benefit from treatment. For many, treatment can be successful and results in the virus no longer being detected.



#### What is Hepatitis B?

Hepatitis B is a contagious liver disease that ranges in severity from a mild illness lasting a few weeks to a serious, lifelong illness. It results from infection with the Hepatitis B virus. Hepatitis B can be either "acute" or "chronic."

#### How is Hepatitis B spread?

Hepatitis B is spread when blood, semen, or other body fluid infected with the Hepatitis B virus enters the body of a person who is not infected. People can become infected with the virus during activities such as:

- Birth (spread from an infected mother to her baby during birth)
- Sex with an infected partner
- Sharing needles, syringes, or other drug-injection equipment
- Sharing items such as razors or toothbrushes with an infected person
- Direct contact with the blood or open sores of an infected person
- Exposure to blood from needlesticks or other sharp instruments
- Hepatitis B virus is not spread by sharing eating utensils, breastfeeding, hugging, kissing, holding hands, coughing, or sneezing.

#### What are the symptoms of acute Hepatitis B?

Symptoms of acute Hepatitis B, if they appear, can include:

- Fever
- Fatigue
- Loss of appetite
- Nausea
- Vomiting
- Abdominal pain
- Dark urine
- Clay-colored bowel movements
- Joint pain
- Jaundice (yellow color in the skin or the eyes)

#### How soon after exposure to Hepatitis B will symptoms appear?

Not everyone has symptoms with acute hepatitis B. On average, symptoms appear 90 days (or 3 months) after exposure, but they can appear any time between 6 weeks and 6 months after exposure.



#### Is there a vaccine that can prevent Hepatitis B?

Yes. The best way to prevent hepatitis B is by getting vaccinated. For adults, the hepatitis B vaccine is given as a series of 3 shots over a period of 6 months. The entire series is needed for long-term protection.

#### Are booster doses of Hepatitis B vaccine necessary?

It depends. A "booster" dose of Hepatitis B vaccine is a dose that increases or extends the effectiveness of the vaccine. Booster doses are recommended only for hemodialysis patients and can be considered for other people with a weakened immune system. Booster doses are not recommended for persons with normal immune status who have been fully vaccinated.

# Should a person infected with the Hepatitis B virus be restricted from working in certain jobs or settings?

People should not be excluded from work, school, play, child care, or other settings because they have Hepatitis B. There is no evidence that people can get Hepatitis B from food handlers, teachers, or other service providers without exposure to infected body fluids.

#### How is Hepatitis B treated?

Antiviral medication can be used to treat some people with chronic Hepatitis B, although not everyone needs or can benefit from treatment.



### **Frequently Asked Questions About HIV**

#### What is HIV?

HIV is the human immunodeficiency virus. It is the virus that can lead to acquired immune deficiency syndrome, or AIDS. HIV damages a person's body by destroying specific blood cells, called CD4+T cells, which are crucial to helping the body fight diseases.

#### How is HIV Transmitted?

HIV is transmitted (spread) through the blood, semen, genital fluids, or breast milk of a person infected with HIV. These specific fluids must come in contact with a mucous membrane or damaged tissue or be directly injected into the blood-stream (from a needle or syringe) for transmission to possibly occur. Having unprotected sex or sharing drug injection equipment (such as needles and syringes) with a person infected with HIV are the most common ways HIV is transmitted.

You can't get HIV by shaking hands, hugging, or closed-mouth kissing with a person who is infected with HIV. And you can't get HIV from contact with objects such as toilet seats, doorknobs, dishes, or drinking glasses used by a person infected with HIV.

#### What is AIDS?

AIDS: Acquired immunodeficiency syndrome. AIDS is the most advanced stage of HIV infection. AIDS is diagnosed when a person infected with HIV has a CD4 count of less than 200 cells/mm3 or has an AIDS-defining condition.

#### What is the treatment for HIV/AIDS?

Antiretroviral therapy (ART) is the recommended treatment for HIV infection. ART involves taking a combination (regimen) of three or more anti-HIV medications daily. ART prevents HIV from multiplying and destroying infection-fighting CD4 cells. This helps the body fight off life-threatening infections and cancer.

ART can't cure HIV, but anti-HIV medications help people infected with HIV live longer, healthier lives.

#### I may have been exposed to HIV. What should I do?

Get tested. The only way to know if you're infected with the virus is to get an HIV test.

Soon after infection with HIV, a person may have flu-like symptoms. But HIV infection isn't diagnosed on the basis of symptoms. <u>Getting tested is the only way to know if you're infected with HIV.</u>

#### Where can I get tested for HIV?

HIV counseling and testing is available at your private physician, county health departments, and at some community based organizations. To find a testing site near you dial 211, text your zip code to Knowlt (56698) or visit <u>www.health.ok.gov</u>

# **Appendix C: Glossary of Acronyms**

## Acronyms

ALT	alanine aminotransferase	
CDC	Centers for Disease Control and Prevention	
СОРНІ	case of public health importance	
CRHC	Central Regional Health Center	
EMSA	Emergency Medical Services Agency	
FAQ	Frequently Asked Questions	
HAI	Dental Healthcare-Associated Infection	
HBsAg	hepatitis B surface antigen	
HBV	hepatitis B virus	
HCV	hepatitis C virus	
HIPAA	Health Insurance Portability and Accountability Act of 1996	
HIV	human immunodeficiency virus	
IAP	Incident Action Plan	
IC	Incident Commander	
ICS	Incident Command System	
IT	information technology	
IV	intravenous	
JIS	Joint Information System	
LACF	left antecubital fossa	
MIPS	Mass Immunization/Prophylaxis Strategy	
NCOA	National Change of Address database	
NIMS	National Incident Management System	
NRHC	North Regional Health and Wellness Center	
O.S.	Oklahoma Statute	
OJA	Office of Juvenile Affairs	
OKMRC	Oklahoma Medical Reserve Corps	
OSDH	Oklahoma State Department of Health	
OSHA	Occupational Safety and Health Administration	
PCR	polymerase chain reaction	
PHIDDO	Public Health Investigation and Disease Detection of Oklahoma	

POD	Points of Dispensing
PPE	personal protective equipment
RMRS	Regional Medical Response System
SAS	Statistical Analysis Software
STD	Sexually Transmitted Disease
THD	Tulsa Health Department
USPS	United States Postal Service