

**ACUTE COMMUNICABLE DISEASE CONTROL PROGRAM
LOS ANGELES COUNTY DEPARTMENT OF PUBLIC HEALTH
2010 PAIN CLINIC HEPATITIS INVESTIGATION REPORT - OB 2010164**

BACKGROUND

On July 16, 2010, the Acute Communicable Disease Control Program (ACDC) of the Los Angeles County (LAC) Department of Public Health (DPH) received a report of a patient with acute hepatitis C infection whose symptoms started in May 2010. When interviewed by staff at ACDC, the patient (case #1) reported no other standard risk factors for acute hepatitis C during the incubation period for hepatitis C except four epidural injections with intravenous (IV) sedation at Advanced Pain Treatment Medical Center (APTMC) during January - April 2010. Since receiving injections for pain management has been implicated in hepatitis C transmission,¹ ACDC staff undertook an investigation of APTMC to determine if it was the source of hepatitis C infection in case #1; identify other possible cases; and, if needed, control spread of hepatitis C or other bloodborne pathogens. The investigation was undertaken with the authority of the local health officer ("upon receiving a report made pursuant to reportable diseases or notification by laboratories, the local health officer shall take whatever steps deemed necessary for the investigation and control of the disease, condition or outbreak reported").² The investigation consisted of the following components: case finding, site visits with observation of procedures, chart review, interviews with staff, laboratory investigation, and a review of policies and procedures.

INVESTIGATION

Case Definition

A case patient was defined as having acute hepatitis B or C if they met the Council of State and Territorial Epidemiologists' definitions of acute hepatitis B or C.³ A case patient was defined as having chronic hepatitis C if they had ever had a positive test for hepatitis C. A case patient was defined as having chronic hepatitis B if they had a positive serum test for HBsAg or HBV DNA but failed to meet the definition of an acute case.

Case/Source Identification

To identify possible source patients for case #1, ACDC investigators obtained the names and birthdates (if available) of patients who attended APTMC on the same or adjoining days as case #1. The names were checked against the ACDC electronic hepatitis registry and the LACDPH human immunodeficiency virus (HIV) registry. ACDC investigators also checked the hepatitis registry for the names and birthdates (if available) of patients who attended APTMC on the same day as any additional cases of acute viral hepatitis identified during the investigation. ACDC investigators submitted the list of patients who attended the clinic on the same days as any acute case of viral hepatitis to the California Department of Public Health (CDPH) for cross checking against its statewide hepatitis registry.

Case #1 had a total of 4 procedures on 4 separate days during January - April 2010. A total of 40 unique names of patients who attended APTMC on the same or adjoining days were

¹ Williams IT, Perz JF, Bell BP. Viral hepatitis transmission in ambulatory health care settings. *Clinical Infect Dis* 2004; 38 (11): 1592-8.

² Reportable Disease and Conditions, Title 17, California Code of Regulations, Section 2501

³ <http://www.cste.org/dnn/Default.aspx>

checked in the LAC hepatitis registry: 3 additional patients with chronic hepatitis C and one case of acute hepatitis B were identified (case #2). No cases of HIV were reported in these 40 patients.

Case #2, identified in the ACDC electronic hepatitis registry by review of patients who had procedures on the same or adjoining days as case #1, had a total of 8 procedures from July 2009 - January 2010. The names of ~120 patients who also attended the clinic on those 8 days were checked in the ACDC electronic hepatitis registry. No additional cases of hepatitis B or C were identified from that group.

The CDPH hepatitis registry did not identify additional cases of acute or chronic hepatitis.

Overview of APTMC

Two site visits at APTMC were conducted. On August 18, 2010, a site visit, including facility walk-through, was conducted by ACDC investigators Elizabeth Bancroft, M.D., S.M., Susan Hathaway, R.N., M.P.H., Clara Tyson, R.N., B.S.N., P.H.N. and Heidi Lee, R.N., M.P.H. On September 2, 2010, Bancroft, Hathaway, and Lee were accompanied by ACDC investigator Rosie Vasquez, R.N., B.S.N., P.H.N. Both site visits included interviews with APTMC staff; observation of the insertion of heparin locks and administration of IV sedation medication; observation of epidural and other neuraxial procedures; and review of patient charts.

The APTMC opened in 2000 at the current site (1412 West 7th St., San Pedro, CA 90732). APTMC holds voluntary certification from the Accreditation Association for Ambulatory Health Care, Inc. The medical center staff includes a physician who is an anesthesiologist with a specialty in pain medicine, two registered nurses (RNs) and three medical assistants (MAs). According to the physician, RN #1 has worked at the site since January 2006 and RN #2 has worked at the site since it opened. At the time of the investigation, the physician had a current license to practice medicine in the State of California. Each RN also held a current Registered Nurse License issued by the California Board of Registered Nursing. None of the three MAs had current MA certification.

According to the physician, he performs lumbar, cervical, and thoracic epidural injections; nerve blocks; facet and joint injections; and miscellaneous other procedures. Most of the neuraxial procedures are performed under fluoroscopy. The physician estimated that he sees approximately 1,000 unique patients each year and performs approximately 3,000 procedures each year (most patients receive more than 1 procedure). At the time of the site visits, procedures were performed on Wednesday, Thursday and Friday. RN #1 typically worked on Wednesdays and Fridays assisting the physician with procedures and RN #2 worked on Thursdays. Approximately 10-20 procedures are performed on procedure days. Most patients who receive epidural or other para-vertebral injections also receive IV sedation with midazolam and/or fentanyl. Mondays and Tuesdays are reserved for new patient evaluations and follow-up visits and no invasive procedures are performed.

Chart Review

On August 18, 2010, ACDC investigators reviewed charts for patients who had procedures on the same day as case #1; on September 2, 2010, ACDC investigators reviewed charts of patients that had procedures on the same day as case #2. All charts were reviewed for type of procedure performed, the names of the physician and nurses involved in the procedure, time of procedure, and medications administered during the procedure.

The chart review revealed that a patient with chronic hepatitis C (who had been identified in the ACDC electronic hepatitis registry) had a procedure immediately preceding case #1 on the same day in April 2010. Both patients received IV sedation from RN #1 as documented by her initials in the charts. No cases of acute or chronic hepatitis B were identified among patients receiving care on the same days as case #2 was treated.

Patient Interviews

Investigators from ACDC interviewed case #1 and interviewed the spouse of case #2. Both denied standard risk factors for acquiring acute viral hepatitis (multiple sex partners, drug use, blood transfusions, and medical procedures other than at APTMC) during the incubation period before the onset of disease.⁴

Laboratory Investigation

Blood samples were obtained on September 9, 2010 from case #1 and the patient with chronic hepatitis C who had a procedure directly before case #1 in April 2010. The samples were sent to the Centers for Disease Control and Prevention (CDC) in Atlanta, GA, for genotype testing and species analysis (which helps to determine how closely related are samples of hepatitis C). According to the CDC, the tests revealed that “both specimens contain Hepatitis C virus variants that belong to genotype 2, subtype B. In addition, results from these specimens indicate the presence of several Hepatitis C virus variants that share identical and closely genetically related sequences of the analyzed viral genomic regions identified in both patients. The results are consistent with infection of both patients with same strain of Hepatitis C virus.” (See appendix A: case #1 is LACCB2 and patient with chronic hepatitis C is LACCB1.)

Infection Control Observations

The overall appearance and set up of the medical office was clean, and organized. There was a patient examining room, pre-procedure and post-procedure rest areas for patients, a procedure room, and a storage room. The procedure room was equipped with a fluoroscope, a portable blood pressure machine, a pulse oximeter, and an ECG machine. The latter two pieces of equipment were used for conscious sedation monitoring. Hand washing sinks were located in the patient pre-procedure and post-procedure areas and outside of the procedure room.

Administration supplies and non-narcotic medications used for IV sedation were stored inside a medication cart in the procedure room or in the storage room. The injection medications were prepared on top of this cart. Narcotic medications were stored in the procedure room. RN #1 and RN #2 were responsible for preparing the IV medication and documenting use of any narcotics. A sharps container and trash can were placed on the floor by the medication cart.

A bedside table was used to set-up the sterile field and to prepare injections (mainly contrast, saline, steroid, and anesthetic) administered by the physician. The physician used a separate sharps container, approximately 7 feet from his usual work space, to dispose of sharps used during procedures.

During the site visits, ACDC investigators observed both RNs start heparin locks, prepare and administer IV sedation, monitor vital signs of patients under sedation, and assist the physician with preparing injection medications. ACDC investigators observed the physician perform epidural and transforaminal injections.

⁴ The incubation period for acute hepatitis B is 6 weeks to 6 months; the incubation period for acute hepatitis C is 2 weeks to 6 months. <http://www.cdc.gov/hepatitis/index.htm>

During site visit #1 on August 18, 2010, the following breaches in infection control were observed by ACDC investigators⁵

- Entering a multi-dose vial with a syringe and needle that was previously used on a patient.
 - RN #1 injected IV sedation into a patient's heparin lock and then used the contaminated syringe and needle to enter a multi-dose vial of saline. She withdrew several CCs of saline and used this to flush the heparin lock. She then placed the multi-dose vial of saline back onto the medication cart where it could be used for subsequent patients. This practice was observed during procedures for two patients and was also observed when the nurse was asked to demonstrate her technique of administering medication and flushing heparin locks.
 - RN #1 stated she would use a single vial of normal saline for up to 4 different patients on the same day, then she would discard the last open vial of saline at the end of the day.
- Using single dose vials (SDV) of contrast (Omnipaque), lidocaine, and sodium bicarbonate for multiple patients.
- Not using aseptic technique to access medication vials (i.e., not cleaning the top of open vials with alcohol swabs before entry).
- Open dates were not written on some of the unsealed multi-dose vials already in the room.
 - RN #1 did not date multi-dose medication vials when she opened them.
- Medications, intended to be given to multiple patients by IV or injection, were prepared in patient care areas.
- No mask and head covering were worn by physician or RNs while performing neuraxial procedures.
- Inconsistent hand washing/hand hygiene between patients.
- Reuse of x-ray protective under-gloves between patients.
- Not using needleless devices or safety needles when possible.

On September 2, 2010, ACDC investigators made their second site visit to APTMC. Several of the identified infection control breaches identified during the first site visit were corrected, including:

- RN #2 did not enter a multidose vial of saline with a previously used needle and syringe.
- The physician stated that he no longer used contrast for routine procedures, thus eliminating the use of a single dose vial of Omnipaque for multiple patients.
- There was more consistent cleaning the top of multi-dose vials with alcohol swabs before entry.
- Both RN#2 and the physician used a mask and head covering while performing neuraxial procedures.
- There was more consistent hand washing between patients.

⁵ The practices observed at the APTMC were compared to the CDC recommendations for injection procedures found at: Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings. <http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf>

However, during the second site visit, ACDC investigators noted another deficiency; the physician used povidone-iodine from a single large bottle for skin preparation for neuraxial procedures, contrary to the American Society of Anesthesiologists recommendation to use single dose packets of chlorhexidine for neuraxial procedures.⁶

Review of Written Policies and Procedures

ACDC investigators requested copies of facility infection control policies; documentation of employee training on infection control; written duty statements for the MAs and RNs; written policies for procedures performed on site; documentation of hepatitis B vaccination and/or immunity of employees; policies and procedures related to infection control, environmental cleaning and disinfection; and medication preparation, storage and administration.

During the site visits ACDC investigators were able to view documents for infection control training, infection control policies, duty statements for RNs and MAs, and hepatitis B vaccination declarations. In addition, ACDC investigators received the following documents after the site visits:

- Plan for Cleaning (addressing environmental cleaning)
- Weekly Cleaning Schedule and Monthly Cleaning Schedule (addressing environmental cleaning)
- Bloodborne Pathogens Exposure Control Plan
- Infection Control for Ambulatory Care
- Bloodborne Pathogens for School Staff
- Poster Displaying Standard Infection Control Precautions
- Labeling and Discarding Multidose Vials
- IV Sedation Policy, and
- Time-Out Procedure.

The majority of the policies were dated 2000 or 2001 or had no date on them. Many of the policies were not developed specifically for outpatient practices. ACDC investigators noted several inconsistencies between what was written in the policies (e.g. use of safety needles, requirement to date multi-dose vials) and what actually occurred at APTMC. No written procedures for the preparation and administration of medication using aseptic technique were submitted by APTMC to ACDC investigators.

RECOMMENDATIONS MADE DURING THE INVESTIGATION

During site visit #1, ACDC investigators gave oral recommendations to the physician including:

- Stop all practice of re-entering multi-dose vials of medication with needles or syringes that had been in contact with patients.*
- Use single dose vials of medication as much as possible.
- Reserve use of single dose vials to one patient.
- Consider the use of masks when performing neuraxial procedures.

*The order to stop the practice of re-entering multi-dose vials with contaminated needles was reinforced with a letter sent by ACDC to the physician on August 25, 2010.

⁶ Stockhouse, R.A., *What's New in Infection Control: Practice Advisory for the Prevention, Diagnosis, and Management of Infectious Complications Associated with Neuraxial Techniques*. American Society of Anesthesiologists 2010; 74 (9): 46-47.

During site visit #2, ACDC provided oral recommendations to the physician including:

- Prepare epidural and injection medications in a clean room and transport them to the procedure room.
- Cease reusing brown undergloves when using fluoroscopy.
 - Identify a way to sterilize under-gloves or use new sterile under-gloves for each patient.
- Consider using single dose packets of chlorhexidine for skin disinfection.
- Consider hiring an infection control consultant to assess facility practices and provide further recommendations regarding infection control.

A letter was sent by ACDC to the physician on November 5, 2010, informing him of the findings of the investigation, the conclusion that on at least one occasion hepatitis C was transmitted between patients at the APTMC probably due to poor injection safety procedures, and written recommendations to improve infection control at the clinic. An overview of the investigation was attached to that letter along with references on how to improve infection control and injection safety at the clinic.

PATIENT NOTIFICATION

According to the CDC, patients at facilities where there has been a documented “Category A” infection control violation (including contaminating multi-dose vials with syringes/needles previously used on patients) should be notified of their risk of exposure to bloodborne pathogens.⁷ Notification is recommended even if no transmission has been documented. Based on the conclusion that there was transmission of hepatitis C from at least one patient to another at APTMC because of deficient infection control procedures, the decision was made to notify all patients who had had an invasive procedure at the APTMC under the care of RN #1 from the start of her employment (January 16, 2006) until the day investigators told RN #1 and the physician to cease accessing medication vials with contaminated syringes/needles (August 18, 2010).⁸ In the ACDC letter sent November 5, 2010, the physician was told that patients must be notified of their risk of having acquired a bloodborne pathogen due to having had a procedure at the APTMC. The physician chose to have LACDPH notify the patients directly and agreed to provide a database of patients who had injection related procedures from January 16, 2006 - August 18, 2010.

Based on the experience of other public health jurisdictions in the United States and on input from CDC, ACDC investigators drafted notification letters in English and Spanish. The letter provided an overview of the situation and encouraged patients to be tested for hepatitis B, hepatitis C, and human immunodeficiency virus (HIV). Included in the patient letter was a page that patients could bring to their physician(s) that provided an overview of the situation and recommended specific follow-up tests. Patients were encouraged to seek care with their usual physicians but the letter also included a list of low or no cost clinics, including LACDPH clinics, where patients could be tested.

In addition to developing notification letters, ACDC investigators also developed an extensive website on the investigation with an expanded Question and Answer section on hepatitis C

⁷ Patel P, Srinivasan A, Perz, J. Developing a broader approach to management of infection control breaches in healthcare settings. *Am J Infect Control* 2008; 36: 685-90
http://www.cdc.gov/ncidod/dhqp/pdf/bbp/Patel_breaches_AJIC_2008.pdf

⁸ Denise M. Dudzinski, Ph.D., Philip C. Hébert, M.D., Ph.D., Mary Beth Foglia, R.N., Ph.D., and Thomas H. Gallagher, M.D. The Disclosure Dilemma — large-scale adverse events. *N Engl J Med* 2010; 363: 978-986.

(<http://publichealth.lacounty.gov/acd/HepInfo.htm>) with resources for both patients and clinicians. Employees of the Los Angeles County help line “211” were also provided with information about the situation to answer patients’ questions, while physicians were referred to the main ACDC telephone number for assistance.

On December 10, 2010, the physician provided an electronic Microsoft Excel file of 2,508 patients with the following information: patient name, date of birth, address, city, state, zip code, referring provider, date of last visit and procedure codes. All of these patients had at least one procedure between January 16, 2006 and August 18, 2010. Of the 2,508 patients, the physician identified 174 who had no IV sedation or exposure to unsafe practices and an additional 41 who had been screened for bloodborne pathogens since August 18, 2010. Therefore, there were a total of 2,293 patients who were thought to be at risk for bloodborne pathogens and who did not know of their risk.

On January 7, 2011, letters were sent to 2,293 individual patients notifying them of their potential risk of bloodborne pathogens. Of the 2,293 letters which were sent to individual patients, 190 (8.3%) were returned to DPH. Of the 190, 40 were identified as having died, 120 had letters re-sent based on up to date addresses, and 30 were unable to locate.

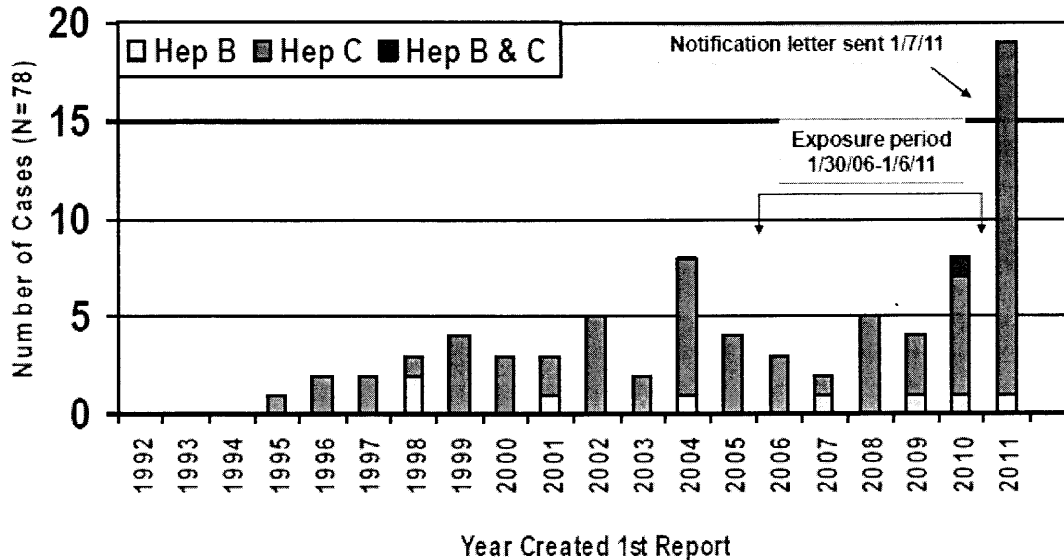
ACDC web statistics for the first month after the letters were released revealed that hepatitis was the most commonly searched for disease and that the web page dedicated to the outbreak was the 3rd most viewed web page. Requests for the outbreak webpage continued through May of 2011. There were a total of 84 calls made to ACDC and 2 calls made to the “211 LA County” hotline in the first week after the letter was released.

EPIDEMIOLOGIC ANALYSIS

ACDC investigators used the electronic hepatitis registry to identify previously reported cases of hepatitis B or C in the cohort of 2,293 patients. Prior to the patient notification in January 2011, there were a total of 59 patients with reports of hepatitis B, C, or both, in the electronic registry for a total prevalence of 2.6%. The majority of the cases were classified as chronic hepatitis C. The cases were first reported at a fairly regular rate from 1995-2010 (1-8 cases/year). After the patient notification on January 7, 2011, 19 additional cases were reported to DPH during January 10, 2011 - February 28, 2011. Of note, only one of the new reports was for chronic hepatitis B, the rest were all chronic hepatitis C reports. See Figure 1.

Figure 1

First Hepatitis B and/or C Report in Pain Clinic Patients Reported to vCMR, 1992-Feb. 28, 2011, LAC



None of the additional 19 cases can be specifically linked to the APTMC. The notification letter may have prompted patients who were at risk for acquiring chronic hepatitis for other reasons to be tested and reported for the first time.

Assuming a background prevalence of 2.6% for chronic hepatitis in this patient population, the 19 new cases represent ~730 people tested for hepatitis B and/or C after the notification letters were sent. These estimates are likely to be underestimates of the prevalence of hepatitis B or C in this population because 1) not all laboratories regularly report hepatitis B or C results despite legal mandates and 2) not all of the 2,293 patients are LAC residents and DPH only receives positive test results on LAC residents.

The list of the 2,293 patients was compared to the LACDPH HIV registry: no cases of HIV were identified in these patients. The list of 2,293 patients was also compared to the electronic death registry system. Four patients that matched by last name, first name, address, and date of birth had some form of liver disease in at least one of the following fields: immediate cause of death, consequence 1, 2, 3, or other significant conditions. Only one of those patients had been previously reported to LACDPH with a positive test for hepatitis C.

NOTIFICATION OF LICENSING BOARDS

Both the Medical Board of California and the California Board of Registered Nursing were notified of the situation. At this time, DPH is not involved in any investigation in conjunction with these Boards.

CONCLUSIONS

Hepatitis B and C viruses can be transmitted easily if infection control procedures are not meticulously followed. Based on multiple lines of evidence (chart review, laboratory results, and observation of infection control deficiencies), we conclude that case #1 acquired acute hepatitis C while being treated at APTMC in April 2010. This was most likely due to the cross contamination of a multi-dose vial of saline that was first used for a patient with chronic hepatitis C and then used again for case #1. This practice has been associated with the transmission of viral hepatitis in other settings.⁹ Though we did not find a source patient for case #2, we believe, given the lack of other risk factors for the acquisition of hepatitis B in this case-patient and the demonstrated transmission of viral hepatitis at APTMC, that the most likely source of infection for case #2 was also receiving treatment at APTMC. Because of the intermittent nature of the exposure and the lengthy incubation and asymptomatic period associated with both hepatitis B and hepatitis C, it is not possible to identify the source of infection for any individual patient who had a procedure at APTMC except for case #1.

We documented multiple infection control deficiencies during two site visits at APTMC that could have resulted in the transmission of bloodborne pathogens or the acquisition of bacterial infections in patients. According to the 2007 Healthcare Infection Control Practices Advisory Committee guidelines,¹⁰ healthcare workers should use single-dose vials of medications whenever possible; use aseptic technique when accessing medication vials; use a surgical mask when performing neuraxial procedures such as epidural injections; and perform hand hygiene (hand washing or use of alcohol based hand hygiene) before and after every patient encounter. Furthermore, healthcare workers should not administer medications from single-dose vials to multiple patients; should not keep multidose vials in the actual patient treatment area; and should not use a contaminated syringe to access medication that might be used for subsequent patients. All of these guidelines were not followed during our site visits.



The infection control deficiencies we identified could have resulted in the transmission of bloodborne pathogens, the development of bacterial infections, and danger to workers at APTMC. Therefore, patients were notified of their increased risk of bloodborne pathogens so that they could seek medical advice and treatment should they test positive.

⁹ Centers for Disease Control, Acute Hepatitis C Virus infection attributed to unsafe injection practices at and endoscopy clinic-Nevada, 2007. MMWR 2008; 57 (19): 513-517.
<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5719a2.htm>

¹⁰ Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings. <http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf>

LACCB HVR1 Quasispecies Analysis

(E1-HVR1 region, 291 bp in length, only unique clonal sequences are shown)

-  LACCB Hepatitis C Case-Patients
-  Unrelated HCV Infected Individuals

Maximum nucleotide identity between
case-patient LACCB1 & 2 : 99%

