Memo

To: Lawrence Sands, DO, MPH

From: Southern Nevada Health District Outbreak Investigation Team

Date: 3/28/2008

Re: Interim report on the Endoscopy Center of Southern Nevada Hepatitis C Investigation

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This provisional document has been developed as an interim report on the investigation into acute hepatitis C cases reported in patients of the Endoscopy Center of Southern Nevada. A final report will be issued when the epidemiological investigation is completed, which will document the complete and final findings of the Southern Nevada Health District Outbreak Investigation Team.

Investigation Timeline

As the local health authority, the Southern Nevada Health District (SNHD) has the statutory responsibility for most public health activities, including disease surveillance and investigation, outbreak investigation, and the implementation of the public health interventions. On January 2, 2008, through routine disease investigation and surveillance activities, the Southern Nevada Health District identified a cluster of two cases of acute hepatitis C who had both reported undergoing procedures at the Endoscopy Center of Southern Nevada.

The Nevada State Epidemiologist was notified of the cluster upon discovery of the relationship between the two initial cases. The health district contacted the Centers for Disease Control and Prevention (CDC) for technical assistance on January 2, 2008. In addition, the health district notified the State Bureau of Licensure and Certification (BLC), as it is the agency responsible for the licensure of the facility. On January 2, 2008, a third case of acute hepatitis C with history of endoscopic procedures at the same facility was identified. A formal request for epidemiologic assistance was then made through the Nevada State Epidemiologist to the CDC on January 4, 2008, with CDC staff arriving in Las Vegas, NV on January 9, 2008.

The SNHD Outbreak Investigation Team (OIT) led the investigation, with technical assistance provided by the CDC. The BLC conducted a parallel investigation in response to a complaint made by the health district about the outbreak. On the afternoon of January 9, 2008, OIT members met with clinic management and were provided a basic overview of clinic operations. On January 10, OIT members began reviewing clinic records and patient charts, which began with a review of incident cases. Observations of clinic operations and procedures began on January 11, 2008. The initial field investigation continued through January 17, 2008, with additional visits to the clinic to review records and interviews with current and former staff members continuing over the following two weeks.

During the investigation, the health district identified unsafe injection practices which placed patients at risk for exposure to bloodborne pathogens. The identification of these practices alone was sufficient to warrant the notification of patients of their risk. After consultation with the CDC and the Nevada State Epidemiologist, the health district made the decision to notify patients of their risk and recommend that they be tested for bloodborne pathogens, including hepatitis C, hepatitis B, and HIV. This decision was based on the identification of the unsafe injection practices, and the determination that these practices had been the standard practices of the clinic since a remodeling in March of 2004.

On February 7, 2008, the health district requested that clinic management provide a list of all clinic patients from March of 2004 through January 11, 2008, which included patient contact information, date of birth, procedure date, and insurance company billed. On February 22, 2008, the clinic management provided a CD to the health district with a file dated February 14, 2008. The file included patient name, address, phone number, and accession date. In addition, the name and phone number of the employer were provided for some cases.

A total of 39,562 patient names were provided in the electronic file. The clinic's plan of correction filed with BLC stated that "Because all patients who could potentially be at risk can be identified through the facility's records, direct mail notification is likely to be most effective". The completeness of the list could not be ascertained at the time the list was provided, as the information provided by the clinic did not include the procedure date. Use of the post office's change of address database to verify the list identified over 1,400 patients with addresses determined to be undeliverable. As a result, it was necessary to notify patients through the media in addition to direct mail notification. Subsequent to the patient notification, the health district began receiving reports from former patients who were not on the list, indicating that the list was not complete. In order to create a more complete list, or at the very least determine how many people were left off the list, the health district is working with law enforcement to obtain access to additional clinic records and with insurance companies who may have paid claims to the clinic.

Outbreak Investigation Findings

To date, a total of six cases of acute hepatitis C have been identified among clinic patients. One of the cases had a procedure on July 25, 2007, and five had procedures on September 21, 2007. Patients who had procedures at the Endoscopy Center of Southern Nevada on September 21, 2007 were nearly 28 million times more likely ($p<0.00000001$) than non-patients to develop acute hepatitis C. Genetic testing completed on the viruses from four of the patients on September 21 identified that the infections had come from a common source (one result is still pending). Genetic testing on the case from July 25 identified that the infection had come from a different source than the cases from September 21.

A number of possible sources of exposure leading to the outbreak were investigated during the initial field investigation, including:

Reprocessing of Endoscopes

- Review of automated reprocessor logs for the month of July identified no problems in the two days immediately before and after one of the case patients received their procedure (July 25). Review of the daily logs for September 2007, indicated there

were no problems reported for either automated reprocessor within the two days before and after the case patients underwent their procedures.
- Disinfecting solution in the automated reprocessors appeared to be changed at a frequency consistent with the manufacturer's recommendations.
- Detergent labeled for use on one scope was observed to be used on the processing of two scopes. This step was one of many in the reprocessing of the scopes, and the reuse of the detergent would not likely result in a significantly decreased efficacy. As a result, the detergent reuse was not determined to be a significant public health risk.
- Initial review of patient charts identified that two patients potentially had procedures performed with the same scope, although this was attributed by the clinic to a clerical error. Verification through the computer system used with the scopes during the procedures identified that different scopes had been used on these two patients.
- Case patients had received either upper or lower endoscopies requiring different types of scopes.
- As a result, problems with endoscope reprocessing or use were ruled out as the likely source of the outbreak.

Biopsy and Other Equipment

- Several staff members reported that biopsy equipment labeled for use on a single patient had been reused for multiple patients after disinfection. One staff member stated that the rule was to reuse single-use equipment three times if possible. Clinic management denied the reuse of the biopsy forceps. As a result, steps used in the reprocessing and disinfection of this equipment could not be evaluated for their efficacy.
- Review of clinic purchase records identified irregularities in the purchasing patterns of biopsy forceps; over 7,800 biopsies or polyp removals were performed in 2007, but a total of 6,200 biopsy forceps or polyp removal wires were purchased. In addition, no purchases were made in 2007 prior to March 20, although over 1,500 biopsies or polyp removals were performed in this time period.
- Clinic staff reported the reuse of bite blocks (devices placed in the mouth during upper endoscopies) on multiple patients. One staff member reported that they were only allowed to use 4 bite blocks per day per procedure room (approximately 2080 bite blocks per year) despite the number of procedures performed. Review of purchasing records identified that the clinic purchased approximately 2,000 bite blocks in 2007, while reviews of procedure logs identified that the clinic had performed approximately 5,800 upper endoscopy procedures. The reuse of bite blocks is not thought to pose a significant risk to patients.
- Although there is a risk posed by the improper reuse of the equipment, not all patients had biopsies or upper endoscopies performed. Disposable equipment reuse was ruled out as the likely source of the outbreak, although risk from biopsy equipment for individual patients could not be determined.

Staff to Patient Transmission

- Outbreaks resulting from staff-to-patient transmission have previously been reported in the literature. Typically, these outbreaks are a result of a staff member with a chemical dependency contaminating medication vials intended for patients through injection drug practices. Although Propofol abuse has been reported, these outbreaks are typically related to narcotics such as fentanyl.

- Narcotic administration at the clinic was rare, and narcotics were only given to patients with previous adverse reactions to Propofol. No narcotics were administered on either of the days with known acute infections. Use of narcotics was also tightly controlled by the clinic.
- All current staff members with direct patient contact, including physicians, were tested for infection with hepatitis C virus. No infections were identified among staff members tested.
- The hepatitis C registry was searched for former staff members involved in the procedures of the known case patients, and no infections were identified.
- Genetic testing on the patient from July 25, 2007 identified a different virus than that of the patients tested from September 21, 2007, indicating that patients infected on the different days were not infected from the same source.
- The identification of different strains transmitted on different days, as well as not identifying a staff member infected with hepatitis C, rules out staff-to-patient transmission as the source of infection.

Individual Practitioners

- Cases were evaluated for their exposure to common staff members. No common staff member was identified among any of the cases, including those who had procedures on the same day.

Injection practices

- OIT Investigators observed (as did BLC surveyors) the reuse of "single use" Propofol vials for multiple patients on January 11, 2008.
- OIT investigators examined the Propofol check-out logs and identified that they were reusing vials, as evidenced by fewer vials being checked out each day than patients that were seen. The clinic could not provide the logs from 2005 and 2006, but the reuse was identified in 2004, 2007, and early 2008.
- OIT investigators conducted interviews with current staff members who reported that they were directed to reuse syringes, although staff were unwilling to elaborate on who told them to reuse syringes as interviews were conducted in the clinic. The majority of interviews with current staff members took place on January 11, 2008.
- A CRNA formerly employed by the clinic reported regularly reusing syringes.
- An RN reported that he had observed the practice on multiple occasions and complained to management about it. The same RN reported that Dr. A had directed them to reuse the syringes and other equipment. He stated that the standard practice was to reuse single-use items such as biopsy forceps three times. He stated that he had complained to Dr. B, supervisor C and administrator D about the practice.
- A third staff member reported quitting after one day of work because of concerns about equipment reuse and being told to document things that did not happen (e.g. record that the doctor checked in on a patient at a certain number of minutes after the procedure even if he had not). When complaints were voiced to other staff members about this practice, a CRNA told her that it was "how things were done there." She reported that she had complained to supervisor E, and did not return to work.
- During initial conversations with clinic management (on January 9, 2008) about the outbreak, several senior clinic staff members stated that nothing had changed in the

way they had done business since the remodeling in 2004, and that their practices were consistent over that time period.
- A CRNA was observed to reuse a syringe during a procedure on January 11, 2008. The syringes were reused to re-dose a patient, but were not used on multiple patients.
- Through the combination of observation, interviews, and evaluation of records, it was determined that the reuse of syringes to re-dose a patient, combined with the reuse of single use vials for multiple patients was the most likely source of transmission during the outbreak. The continuation of this practice over the course of a day could have serially contaminated vials. See the attached figure for a graphical depiction of how patients would have been infected.

Next Steps

As of March 27, 2008, the health district is continuing the outbreak investigation, focusing on the events of July 25, 2007 and September 21, 2007. Health district staff have been interviewing clinic patients and arranging for blood draws in order to better elucidate the timeline of events on those two days. Viral isolates from any patients on the two days of interest determined to be infected with the hepatitis C virus are being sent to CDC for genetic sequencing to identify a source as well as incident cases.

In addition, the health district will be interviewing patients with positive hepatitis C test results to evaluate their risk factors for infection. A case classification schema is under development which will allow investigators to make assessments about the likelihood of infection for an individual clinic patient.

Investigative Challenges

The information contained in clinic records from the Endoscopy Center of Southern Nevada has hampered the ability of investigators to accurately reconstruct the events on the days of known transmission. Specifically:

- The clinic did not record the room in which the procedure took place. Repeated requests for this information could not be fulfilled by the clinic administration.
- According to procedure times recorded on patient charts, on four separate occasions on September 21, 2007, an individual doctor was performing two procedures at the same time.
- One colonoscopy lasting two minutes and two colonoscopies lasting three minutes were identified through reviewing procedure times on September 21, 2007. The short duration of these procedures makes it difficult to put the sequence of procedures in order.
- Multiple clinic staff members reported that anesthesia times were incorrectly recorded to make it seem as if anesthesia had been given for a longer period of time, and allowing for additional billing. Review of several patient records seemed to confirm this report, making it impossible to use the anesthesia times in reconstructing the events of the day.