

June 5, 2008

Hepatitis C Investigation Update #2

Current situation

The Southern Nevada Health District SNHD has concluded its investigation into the acute case of hepatitis C associated with the Desert Shadow Endoscopy Center, 4725 Burnham Avenue. Based on the information and records that are currently available, it has been determined this acute case is linked to the center. However, there is not sufficient information at this time to determine the likely source of disease transmission.

SNHD is encouraging patients of the Desert Shadow clinic to discuss their risk for disease exposure with their physician and to pursue testing for hepatitis C, hepatitis B and HIV if they are concerned. The health district has obtained a list of patients from this clinic location and, while there is no way of determining the completeness of the list at this time, a letter outlining the investigation findings and current recommendations will be sent to the available list of patients.

The SNHD is unable to make a specific recommendation based on documented unsafe injection practices, such as those that occurred at the Desert Shadow Endoscopy Center of Southern Nevada. However, the health district is stressing that it is important for patients to know their infection status and work proactively with their physicians to manage their health. The SNHD estimates that approximately 13,000 patients were treated at the Desert Shadow clinic since it opened two years ago.

Investigation findings include the following: a clinic staff person was observed reusing single use vials of propofol on more than one patient at this facility during an inspection by the State Health Division Bureau of Licensure and Certification. A review of propofol logs provided further documentation the bottles of anesthesia were reused on multiple patients. However, staff has not been able to observe the reuse of syringes because this clinic location was closed prior to the identification of the associated acute case.

The acute case of hepatitis C that lead to further investigation of the Burnham clinic was self-reported to the health district by the patient in March 2008. Laboratory tests documented this person tested negative for hepatitis C days prior to undergoing a procedure at the Desert Shadow Endoscopy Center and later developed an acute infection.

Hepatitis C Exposure Registry

SNHD will be implementing a Hepatitis C Exposure Registry in order to gather additional information related to patients of both the Southern Nevada Endoscopy Center and the Desert Shadow Endoscopy Center. The registry was developed to assist in tracking patients with known disease who had procedures at the clinics, and will allow patients the opportunity to learn their case classification. The registry will also include sections to allow patients to report on possible hepatitis B or HIV infections.

SNHD will be mailing enrollment forms to patients of both these clinics and encouraging patients to enroll in the registry. Registry information and enrollment forms are available on the health district's website, <u>www.SouthernNevadaHealthDistrict.org</u>. In addition, enrollment forms will be available at the health district's public health centers.

Since the initial notification seventy-seven additional cases of hepatitis C infection have been identified as potentially linked to the Endoscopy Center of Southern Nevada. Participation of clinic patients in the exposure registry will allow the health district to classify additional cases of infection that may be associated with these clinics.

Hepatitis C Testing

Testing remains the same as outlined in the technical bulletin distributed on February 27th, 2008 (http://www.southernnevadahealthdistrict.org/physic ian/download/tb-hepc-022708.pdf). The testing algorithm was recommended by the CDC and SNHD for investigational purposes in order to minimize the number of false positive test results and to allow laboratories to rapidly screen a large number of samples using an initial three (3) test panel. The testing algorithm is intended to identify persons who have been exposed to hepatitis B, hepatitis C and/or HIV. Persons with positive tests will need to follow-up with

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their primary care provider for any additional diagnostic testing needed. Hepatitis B & C Result Interpretations Additional information regarding interpretat

Test Ordering

Many physicians are following the recommended testing algorithm and ordering the custom panel of tests provided by LabCorp, Quest, or Clinical Pathology Laboratories. However, the laboratories have received significant numbers of test orders that do not follow the testing algorithm. While physicians may order other test combinations, there are drawbacks to deviating from the recommended algorithm:

- 1. Ordering acute or comprehensive hepatitis panels on asymptomatic persons slows down the testing process, is more expensive, and does not include the HIV test.
- Ordering individual tests on asymptomatic persons without custom coding or tests not in the algorithm may lead to false positive results or lack of reflex testing.

Table 1 lists the initial recommended testing panel, while Tables 2-4 list the corresponding LabCorp, Quest and Clinical Pathology Laboratories test codes.

Extended Laboratory Hours

LabCorp will offer extended and weekend hours, through the month of June, at the Patient Service Center located at 2801 West Charleston Blvd, Suite #201. The facility will be open Monday-Friday from 7 am—9 pm; Saturday and Sunday from 7 am–4 pm.

Quest will offer extended and weekend hours beginning June 11 and continue as needed, at the following locations: Megacenter Patient Service Center located at 7460 W. Lake Mead, Suite 3 from 6:30 am— 9 pm and Legacy PSC at 1701 Green Valley Parkway from 6 am -9 pm.

Clinical Pathology Laboratories (CPL) provides multiple Patient Service Center locations with Monday-Friday hours.

Additional information regarding laboratory hours and locations is available on the health district website at <u>www.SouthernNevadaHealthDistrict.org</u>.

Hepatitis B & C Result Interpretations Additional information regarding interpretation of hepatitis B and C test results can be found on the SNHD website at: <u>http://</u>

www.southernnevadahealthdistrict.org/outbreaks/ download/hepc-bulletin_update1.pdf

Patient Resources

Individuals who have potentially been exposed as a result of the unsafe injection practices at the Endoscopy Center of Southern Nevada or the reuse of single use vials at the Burnham Center have many questions and needs that are outside the scope of the routine physician/patient relationship. To assist these residents, SNHD has developed a list of resources on the health district website at <u>http://</u>

www.southernnevadahealthdistrict.org/outbreaks/ hepc-patients.htm or call (702) 759-INFO (4636). Among the informational items included are clinical and laboratory services, support groups, fact sheets, and a form for requesting medical records from the Endoscopy Center through the Las Vegas Metropolitan Police Department.

Table 1 Initial and reflex laboratory testing

Test Name	Description	Synonyms	Reflex testing for positives
HBcAb, Total	Antibody to Hepatitis B core antigen, to- tal IgG and IgM. Nonspecific marker of acute, chronic, or resolved Hepatitis B infection. It is not a marker of vaccine induced immunity.	Hepatitis B Core Antibody, Total; Anti-HBc (total); HBV Core Total Antibody	Positives reflex to Hepatitis B core anti- body, IgM and Hepa- titis B surface anti- gen
HCV Ab	Antibody to Hepatitis C Virus. Screening immunoassay method with signal-to-cutoff ratio (s/co) reported	Hepatitis C Antibody; Anti-HCV; HCV; Hep C	Positives with low s/ co ratio reflex to RIBA, anti HCV
HIV 1 or HIV 1/2	Antibody to Human Immunodeficiency Virus. Immunoassay method with reflex to Western Blot for all positives	HIV 1/2 EIA Antibody Screen; HIV-1; HIV-1/O/2	Positives reflex to HIV-1 Western Blot

Table 2. Labcorp Test Codes

Order the panel below which will include both initial and reflex testing

Labcorp Panel code	Initial testing includes	Reflex testing
344053	Hepatitis B Core Antibody, total (006718) Hepatitis C Antibody (143991) HIV-1/O/2 (083824)	Reflex testing for positives will auto- matically occur based on the tests listed in Table 1

Table 3. Quest test codes

Order the individual Hepatitis custom codes and HIV test code listed below. The Hepatitis custom codes must be written on the test requisition form to ensure the appropriate reflex testing occurs

Quest			
test code	Description	Reflex testing	
7040E	Hepatitis B Core Antibody, Total	Reflex testing for positives will automatically occur	
1590E	Hepatitis C Antibody (HCV)	based on the tests listed in Table 1, only if custom test codes are ordered	
3200	HIV1/2 EIA Antibody Screen with re- flexes		

Table 4. Clinical Pathology Laboratories (CPL) Test Codes

CPL Panel code	Initial testing includes	Reflex testing
9327	Hepatitis B Core Antibody, total (2730) Hepatitis C Antibody (4647) HIV1 & 2 EIA Antibody Screen (3540)	Reflex testing for positives will auto- matically occur based on the tests listed in Table 1