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Technical Bulletin **Interim Report # 2** March 31, 2011

Investigation into Infection Control Breach at Physician's Office, Henderson, NV

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Investigation Update

The Nevada State Board of Medical Examiners (NSBME) suspended Dr Kaplan's medical license on March 14, 2011 and filed a formal complaint against Dr Kaplan on March 29, 2011. Dr Kaplan obtained new biopsy and treatment equipment for his Henderson office in mid-December 2010. Prior to obtaining this new equipment, Dr Kaplan used biopsy and treatment equipment for many years that included using stainless steel needle guides that were reused after cleaning and disinfection. Interviews with Dr Kaplan and his staff did not elicit information that cleaning and disinfection instructions were not followed properly. According to information from staff interviews, the new equipment began to be used in mid-December, 2010. The new equipment required using a different needle guide that was approved only for single patient use. Dr Kaplan and his staff said that they did not follow these requirements when they began using the new equipment, and they did reuse the new needle guides after cleaning and disinfecting them. Therefore, the investigation has focused on the period when the new equipment was used – December 9, 2010 through March 11, 2011.

The Southern Nevada Health District released a technical bulletin Friday, (3/18/11), summarizing the status of the ongoing investigation and providing recommendations for patients who had medical procedures at the office that might have exposed them to hepatitis B, hepatitis C, or HIV to be serologically tested.

The District sent a patient notification letter on Monday, 3/21/2011, to all patients identified up to that date by the ongoing Food and Drug Administration (FDA) and NSBME investigation as having had an implicated procedure. The District recommends that patients get tested now and then get tested again 6 months after the date of their medical procedure for hepatitis B, hepatitis C, and HIV.

The NSBME faxed to the SNHD a list of patients, including date of birth, who had implicated procedures at the physician's office that might have exposed them to blood borne pathogens. The SNHD cross matched this preliminary list of patients with the SNHD list of reported diseases to see if any of the patients from the physician's office had been reported to the district with hepatitis B, hepatitis C, or HIV. There were no cases of HIV or hepatitis C that matched. We identified 2 patients from the list provided to the SNHD by the NSBME who had been reported to the SNHD in 2008 as having hepatitis B. We are reviewing their medical records to obtain additional information, but their hepatitis B infections did not occur as a result of having procedures at Dr Kaplan's office. The NSBME notified the SNHD on Tuesday, March 29, 2011 that 15 additional patients who had implicated procedures have been identified. The SNHD will be sending patient notification letters to all of them as soon as possible and will also cross-match this additional list of patients with the SNHD list of reported diseases.

None of the patients who had medical procedures using the new needle guides at the office from December 20, 2010 to March 11, 2011 have been reported to the SNHD with any acute illness from a reportable infectious disease since December 1, 2010.

The SNHD has posted background information and "frequently asked questions" (FAQs) and responses on its website and has activated the SNHD HELP line (702) 759-INFO.

The FDA and NSBME are continuing their investigation of the urologist's office and practices. The SNHD has asked both agencies to address the question of the office's infection control practices prior to December 20, 2010. The SNHD is prepared to issue additional guidance, recommendations, and measures as necessary should the ongoing investigation uncover any suggestion of wider exposure.

Laboratory Testing

The initial testing algorithm outlined in the technical bulletin distributed on March 18 (http://www.southernnevadahealthdistrict.org/download/epi/tb-ic-breach-bulletin.pdf) was recommended by

CDC and SNHD to identify persons who may have been exposed to hepatitis B virus, hepatitis C virus and/or HIV. Persons with positive tests will need to follow up with their primary care provider for any additional diagnostic testing needed.

While physicians may order other test combinations, there are drawbacks to deviating from the recommended algorithm. 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 recommended initial and reflex testing algorithm. To assist with testing follow-up and to ensure appropriate reflex testing occurs, Quest (table 2) and LabCorp (table 3) will provide custom panels and tests for clients located in Nevada.

CDC and SNHD further recommend that persons with negative tests should get retested 6 months after the date of their medical procedure. Patients that test positive for antibody to hepatitis B surface antigen (anti-HBs) on the initial screening are immune to hepatitis B either by natural infection or hepatitis B vaccination. Those patients with initial hepatitis B surface antibody test positive will only need to have negative hepatitis C virus and HIV tests repeated at 6 months.

Table 1. Recommended Initial and reflex laboratory testing

Test Name	Description	Synonyms	Reflex testing for positives
Hepatitis B surface antigen	Serologic marker on the surface of Hepatitis B virus. Presence indicates person is infectious.	HBsAg; HBV surface antigen	No reflex for positive
Hepatitis B surface antibody, qualitative	Antibody to Hepatitis B surface antigen. Presence indicates recovery and immunity from Hepatitis B infection.	Anti-HBs; HBV surface antibody	No reflex for positive
Hepatitis B Core Antibody, Total	Antibody to Hepatitis B core antigen, total IgG and IgM. Nonspecific marker of acute, chronic, or resolved Hepatitis B infection. It is not a marker of vaccine induced immunity	Anti-HBc(total); HBV Core Total Antibody; HBcAb, Total	Request that positives reflex to Hepatitis B Core antibody, IgM
Hepatitis C Antibody	Antibody to Hepatitis C virus. Screening immunoassay method.	HCV Ab; Anti-HCV; HCV; Hep C	Request that positives reflex to HCV RNA. Depending on the testing laboratory, this may require recollection of an additional sample for HCV RNA testing.
HIV 1 or HIV 1/2	Antibody to Human Immunodeficiency virus. Immunoassay method with reflex to Western Blot for all positives	HIV1/2 EIA Antibody screen; HIV-1; HIV-1/O/2	Request that positives reflex to HIV-1 Western Blot

Table 2. Quest test codes

The Quest custom panel test code #9000E must be written on the test requisition form to ensure that the recommended initial and reflex testing is performed.

Quest panel test code	Test Name	Reflex testing
9000E	Hepatitis B surface antigen Hepatitis B surface antibody, qualitative Hepatitis B Core Antibody, Total Hepatitis C Antibody HIV 1/2 EIA Antibody Screen	Reflex testing for positives will automatically occur based on the tests listed in Table 1 if the panel test code is ordered initially. Follow up testing for HCV RNA will require recollection of an additional sample.

Table 3. LabCorp test codes

The LabCorp custom panel test code #367567 must be written on the test requisition form to ensure that the recommended initial and reflex testing is performed.

LabCorp panel test code	Test Name	Reflex testing
367567	Hepatitis B surface antigen Hepatitis B surface antibody, qualitative Hepatitis B Core Antibody, Total Hepatitis C Antibody HIV-1/O/2	Reflex testing for positives will automatically occur based on the tests listed in Table 1 if the panel is ordered initially. Follow up testing for HCV RNA does not require recollection of an additional sample

Hepatitis B Virus Serology Interpretations

Hepatitis B virus infection serologic testing involves measurement of several hepatitis B virus (HBV) specific antigens and antibodies. Different serologic "markers" or combinations of markers are used to identify different phases of HBV infection and to determine whether a patient has acute or chronic HBV infection, is immune to HBV as a result of prior infection or vaccination, or is susceptible to infection. Table 4 provides guidance for the interpretation of Hepatitis B panels. (http://www.cdc.gov/hepatitis/HBV/PDFs/SerologicChartv8.pdf)

Table 4: Interpretation of the Hepatitis B virus infection

Tests	Results	Interpretation	Action
HBsAg anti-HBc anti-HBs	negative negative negative	Not infected – Susceptible	Retest in 6 months, if still negative at second round of testing: no action
HBsAg anti-HBc anti-HBs	negative positive positive	Immune due to natural infection	No action
HBsAg anti-HBc anti-HBs	negative negative positive	Immune due to hepatitis B vaccination	No action
HBsAg anti-HBc IgM anti-HBc anti-HBs	positive positive positive negative	Acute infection	Report to SNHD Evaluation and follow up
HBsAg anti-HBc IgM anti-HBc anti-HBs	positive positive negative negative	Chronic infection	Report to SNHD Evaluation and follow up
HBsAg anti-HBc anti-HBs	negative positive negative	Interpretation unclear; four possibilities; 1. Resolved infection (most common) 2. False-positive anti-HBc, thus susceptible 3. "Low level" chronic infection 4. Resolving acute infection	Evaluation and follow up

Definitions:

Hepatitis B Surface Antigen (HBsAg): A protein on the surface of hepatitis B virus; it can be detected in high levels in serum during acute or chronic hepatitis B virus infection. The presence of HBsAg indicates that the person is infectious.

Hepatitis B Surface Antibody (anti-HBs): The presence of anti-HBs is generally interpreted as indicating recovery and immunity from hepatitis B virus infection. Anti-HBs also develops in a person who has been successfully vaccinated against hepatitis B.

***Total Hepatitis B Core Antibody (anti-HBc)*:** Appears at the onset of symptoms in acute hepatitis B and persists for life. The presence of anti-HBc indicates previous or ongoing infection with hepatitis B virus in an undefined time frame.

IgM Antibody to hepatitis B Core Antigen (IgM anti-HBc): Positivity indicates recent infection with hepatitis B virus ($\leq$6 mos). Its presence indicates acute infection.

Hepatitis C virus infection Serology Interpretations

CDC has recommended that a person be considered to have serologic evidence of HCV infection only after an antibody to hepatitis C (anti-HCV) screening test positive result has been verified by a more specific serologic testing (e.g., RIBA) or a nucleic acid test (NAT). This more specific, supplemental testing is necessary, particularly in populations with a lower prevalence of disease, to identify and exclude false positive screening test results. (http://www.cdc.gov/hepatitis/HCV/LabTesting.htm)

While supplemental testing after an anti-HCV screening test positive result is recommended, use of signal-to-cut-off (s/co) ratios of screening test positive results can serve as an alternative to a supplemental test in some circumstances, minimizing the number of specimens that require supplemental testing and providing a result that has a high probability of reflecting the person's true antibody status. For example, screening-test-positive samples with high s/co ratios can be interpreted as anti-HCV-positive without supplemental testing; however, providers must be aware that if supplemental serologic testing is not performed results might represent a false positive (typically <5%). Further, for the purposes of clinical management, anti-HCV screening-test-positive patients will likely require additional testing (e.g., quantitative HCV RNA assay, genotype, liver function tests).

Screening-test-positive samples without high s/co ratios should have reflex supplemental testing performed either by RIBA or NAT. RIBA testing is currently not available due to a reagent shortage. Therefore, NAT testing is the only option for supplemental testing. If NAT testing is negative, the patient's HCV infection status should be considered indeterminate and providers should repeat the anti-HCV testing algorithm on a follow-up specimen collected ≥1 month after the current specimen's date of collection. This is because HCV RNA may not be initially detectable in certain persons during the acute phase of their hepatitis C virus infection.

CDC has developed a reference guide for interpretation of HCV test results. The guide is available at http://www.cdc.gov/hepatitis/HCV/PDFs/hcv_graph.pdf

Links

SNHD Info Page: http://www.southernnevadahealthdistrict.org/icb/index.php
Nevada State Needle Guide Technical Bulletin: http://health.nv.gov/Epidemiology/2011-03_NeedleGuideTechnicalBulletin.pdf
One & Only Campaign: http://www.oneandonlycampaign.org/media/default.aspx
CDC Healthcare Associated Infections website: http://www.cdc.gov/hai/
Article on Needle Guides: http://www.ncbi.nlm.nih.gov/puNSBMEd/18400273