

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

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Investigation Update

In mid-March the Southern Nevada Health District was notified of an investigation conducted by the Nevada State Board of Medical Examiners (NSBME) and the U.S. Food and Drug Administration (FDA) Office of Criminal Investigation that found a local urologist reused endocavity needle guides that were single-use only medical devices while performing prostate biopsies and treatments. Staff began using new equipment with the single-use only guides in mid-December 2010, and there have been no reports of infection control breaches occurring before that time.

As a result of this investigation the health district notified patients who underwent prostate biopsies, procedures for Visicoil™ implantable markers, or gold seed radiation implants that required use of a needle guide between Dec. 20, 2010 and March 11, 2011. The letter recommended that patients who underwent these procedures within the identified time-frame contact their physicians in order to be tested for hepatitis B, hepatitis C and HIV now and again 6 months after the date of their medical procedure. It was recommended that patients see their personal physician for testing in order to ensure they receive appropriate care and follow-up information.

Since the original notification a second urologist self-reported to the Board of Medical Examiners that the same single-use needle guides were being reused in his practice. The physician voluntarily notified his patients and recommended the appropriate testing. The Nevada Board of Medical Examiners and the Food and Drug Administration have been conducting an investigation of this physician's practice.

As part of the public health response, the Southern Nevada Health District enhanced surveillance to try to identify any cases of disease transmission among exposed patients. The NSBME faxed to the SNHD the lists of patients who had implicated procedures that might have exposed them to blood borne pathogens. The SNHD cross matched the lists from each of the urologists with the lists of reported diseases to see if any of the patients had been reported to the

district with hepatitis B, hepatitis C, or HIV.

The NSBME provided a list of 101 patients from the first urologist to the SNHD. Of the 101 patients, there were no cases of HIV or hepatitis C that cross matched, and there were 2 patients who had been reported with hepatitis B prior to the dates of their procedures.

The NSBME provided a list of 176 patients from the second urologist to the SNHD. Of the 176 patients, there were no cases of HIV, there were 2 patients who had been reported with hepatitis C, and there were 12 patients who had been reported with hepatitis B. Of the 14 patients who did cross match, 11 patients had a positive blood test prior to the date of their medical procedure. One patient had a positive hepatitis B after his medical prostate procedure, but his primary physician had diagnosed the patient as having chronic hepatitis B.

Of the 277 patients, to date, no cases of acute infection have been reported to the health district as a result of these two incidents. The FDA and NSBME are continuing their investigations of the urologist's offices and practices. The SNHD is prepared to issue additional guidance, recommendations, and measures if necessary in the future based on the findings of these investigations.

Discussion

Responding to reports of infection control breaches in the absence of known disease transmission is challenging and complicated. National guidelines and standards are not well developed and are evolving as more evidence and experience is gained. Our community has been traumatized and sensitized because of the widespread impact of the cluster of hepatitis C cases associated with the endoscopy center in 2008. The response to the endoscopy event was very different than the current investigation of the misuse of the needle guides, because no disease transmission from these infection control breaches has been identified. Based on other investigations of misuse of prostate needle guides, the risk of disease transmis-

sion in these recent cases is believed to be very low.

The SNHD has been consulting with the National Centers for Disease Control and Prevention, the New York State Health Department, and the Nevada State Health Division to share information and to develop procedures to guide future investigations. The Council of State and Territorial Epidemiologists (CSTE) is planning a workshop to discuss guidelines and policies during its annual meeting in June 2011 in Pittsburgh, PA. Some of the areas for discussion are included in Appendix 1, attached to this report.

Appendix 1

Procedures for Investigating Reported Infection Control Breaches – No Identified Disease Transmission. (for discussion, Council of State and Territorial Epidemiologists, Annual Meeting, 2011)

1. Determine if type of Infection Control Breach (ICB) places the patient at high or low risk of disease transmission
 - a. What was the ICB?
 - b. How likely was it that significant exposure might have occurred?
 - c. What are the infectious agents of concern?
2. Establish jurisdictional authority and the lead agency
 - a. If no disease transmission identified, the professional (medical) licensing board
 - b. If a medical device involved, Food and Drug Administration
 - c. If disease transmission identified, then public health agency in lead for epidemiologic investigation and licensing authorities conduct their own investigations.
3. Establish clear goals for interventions
 - a. Stop any continuing exposure/improper practices
 - b. Determine if sanctions/discipline appropriate (licensing authority/FDA)
 - c. Determine if epidemiology investigation should be done to try to document disease transmission from ICB
4. Determine if it is possible to identify patients who were exposed from patients who might have been exposed
5. Determine if the ICB warrants notification of patients who were exposed/who might have been exposed
6. Determine if notification of the patient should include a recommendation to:
 - a. Inform patient to report the diagnosis of hepatitis B, C, or HIV (or potentially other identified infectious diseases) to the health department or board of medical examiners if the diagnosis of acute infection occurred after the exposure
 - b. Recommend that the patient be serologically tested for hepatitis B, C, and HIV or tested for other infectious diseases/agents
 - c. Determine if the testing should be centralized by the health department or other agency and if the results of the testing should be sent to the health department or other agency
7. Establish who will notify patients, who will pay for any recommended testing, and who will be responsible for interpreting any test results.
8. Determine if there is any purpose in cross matching patients who were/might have been exposed with reported disease lists.
 - a. How to interpret results?
 - i. Will patients exposed need to be contacted?
 - ii. What information will need to be collected?
 - iii. Will information have to be obtained from patient's physicians?
 - b. How useful are the results?
 - c. Will results affect public health action or assist in patient care and management?

Conclusion

- Most reported infection control breaches in circumstances where no disease transmission is known to have occurred can be expected to fall into a low risk category. Low risk category breaches should be handled by the licensing agency and not involve look backs, cross-matching, or serologic testing.
- If the infection control breach involves a high risk situation, then patient notification, enlisting patients to self-identify to the health authority any acute illness diagnosis after exposure, serologic testing with reporting of results to the investigating agency, and cross-matching against reported disease databases should be done and centrally coordinated, evaluated, and results reported.