

Outbreak of Hepatitis C at Outpatient Surgical Centers

Public Health Investigation Report

December 2009

Southern Nevada Health District
Outbreak Investigation Team
Las Vegas, NV

This report represents the complete findings of the Southern Nevada Health District in the matter of the investigation an outbreak of hepatitis C infections from the Endoscopy Center of Southern Nevada and related clinics.

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Executive Summary

On January 2, 2008, through routine disease investigation and surveillance activities, the Southern Nevada Health District (SNHD) identified a cluster of persons who developed acute hepatitis C infection and who had reported undergoing procedures at the Endoscopy Center of Southern Nevada (ECSN) during the incubation periods of their illnesses. Of the three cases identified, one had a procedure on July 25, 2007 and two had procedures on September 21, 2007.

During an investigation conducted with the Centers for Disease Control and Prevention (CDC) and the Nevada State Health Division Bureau of Licensure and Certification (BLC), unsafe injection practices were identified that placed patients at risk for exposure to bloodborne pathogens. Disease transmission is believed to have occurred through a combination of unsafe injection practices that were reported by staff members, identified in clinic documentation, and observed by investigators. The reuse of syringes to access vials could have introduced the blood of patients (and any viruses therein) into vials of propofol, and the vials were then reused for subsequent patients, transmitting any contamination to those patients.

As a result of the investigation, on February 27, 2008, SNHD began the process of notifying approximately 50,000 clinic patients of the possible exposure, and recommended that all patients who received injected sedatives at ECSN from March of 2004 through January 11, 2008 be tested for infection with hepatitis C, hepatitis B, and the human immunodeficiency virus (HIV). Based on observations made by BLC and the identification of a previously-unreported acute case of hepatitis C infection, an additional 13,000 patients of a related clinic, the Desert Shadow Endoscopy Center (DSEC), were later notified and encouraged to contact their healthcare providers about testing.

Genetic testing performed at CDC revealed source patients for both days of known transmission at ECSN with the infection of one case-patient being linked to the source patient on July 25, 2007, and the infections of six case-patients being linked to the source patient on September 21, 2007. Two additional acute infections were identified, with one being linked to a procedure at DSEC.

Through the evaluation of laboratory results, patient interviews, and the development of an exposure registry, an additional 106 cases were identified that could be possibly linked to one of the clinics. For these patients, the clinic's role as the source of the patient's infection cannot be confirmed, as other sources of infection cannot be conclusively ruled out. Although these patients did not report any major risk factors for hepatitis C infection, minor or unknown risk factors may still be present and may be the actual source of the patient's infection.

Taking into account the cost of SNHD personnel working on the outbreak and response, the cost of patient testing and medical counseling, and the long-term cost of the treatment and management of identified infected patients, the total cost of this outbreak investigation, response, and testing to the community was estimated to be between \$16 million and \$21 million.

Each of the 63,000 possible patient exposures identified in this investigation were entirely preventable, and would not have occurred if clinic staff had adhered to well-established, safe, and common sense injection practices.

Part 1

Southern Nevada Health District Legal Authority

Disease Reporting and Investigation

The Southern Nevada Health District (SNHD) is the legally-recognized health authority for Clark County, Nevada per Nevada Revised Statutes (NRS).¹ Nevada Administrative Code (NAC) Chapter 441A.570 requires that health care providers report communicable diseases to the health authority, including cases of acute hepatitis C, within 24 hours of the identification of that case.²

SNHD is required to investigate reported cases of acute hepatitis C infection to confirm the diagnosis, identify disease carriers and additional cases, and to identify the source of infection.³ Investigation findings are evaluated to determine if the patient meets the national surveillance case definition for acute hepatitis C infection,⁴ and those meeting the definition are reported to the Nevada State Health Division (NSHD) as a confirmed case of acute hepatitis C viral infection through the National Electronic Telecommunications System for Surveillance.^{5,6} Non-acute hepatitis C infections are not reportable within the state of Nevada either by healthcare providers to the health authority or by the health authority to NSHD.⁷

Healthcare providers typically report by telephone or by faxing reporting forms to SNHD.⁸ Reports of acute hepatitis C made to SNHD are assigned to a Disease Investigation and Intervention Specialist (DIIS) in the Office of Epidemiology (OOE). The DIIS obtains information from the healthcare provider, laboratories that have performed testing for the patient, and directly from the patient as necessary. As part of the investigation of acute hepatitis C, consistent with national surveillance guidelines, the DIIS inquires about disease signs and symptoms, laboratory findings, and patient-reported risk factors.^{9,10,11} As part of the evaluation of risk factors, patients are asked about medical procedures they may have undergone during the incubation period for acute hepatitis C, including specific questions about endoscopic procedures.

Outbreak Investigation

As the health authority for Clark County, Nevada, SNHD has jurisdiction over all public health matters including outbreak investigation and response.¹² An outbreak is defined in both state administrative code and county regulations as “the occurrence of cases in a community, geographic region or particular population at a rate in excess of that which is normally expected in that community, geographic region or particular population”.^{13,14} Persons are required to cooperate during the investigation of and response to outbreaks upon request of the health authority.^{15,16}

For each outbreak, SNHD assembles a multi-disciplinary team to perform the investigation, including staff with skills in outbreak investigation, epidemiology, environmental health, risk communication,

laboratory sciences, clinical services, and any other skill sets determined to be beneficial to the investigation. The team may be expanded to include additional people with specific technical expertise, including individuals from other local, state, or federal agencies.

Licensing, Regulation, and Oversight

Ambulatory Surgical Centers (ASCs) are licensed and regulated by the Bureau of Health Care Quality and Compliance, formerly the Bureau of Licensure and Certification (BLC), within the Nevada State Health Division. Healthcare providers, such as physicians or nurses, are licensed by their respective professional licensing boards. Individual businesses are regulated by the business licensing department of the jurisdiction in which the business is located. The Southern Nevada Health District has not been granted the legal authority, nor given a legal mandate, for the licensing, regulation, or oversight of healthcare facilities or healthcare providers.

Confidentiality

Both state and federal laws provide protection for personal health information (PHI), while recognizing that the reporting of communicable diseases and outbreaks to the health authority is necessary for the protection of public health.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) provides for the protection of PHI, while allowing for legitimate uses of that information. Under HIPAA, PHI may only be released without the patient's consent for the treatment, payment or other healthcare operations directly related to the patient,¹⁷ or when required by law.¹⁸ HIPAA does not prohibit providers from reporting diseases to legally-recognized public health authorities such as SNHD.¹⁹

In addition to federal regulations, Nevada statutes also provide protection for PHI. Nevada statutes treat any information "of a personal nature about any person" collected as part of a disease report or investigation into such a report as confidential medical information and prohibits the release of that information "under any circumstances, including pursuant to any subpoena, search warrant or discovery proceeding" with a few specified exceptions.²⁰ In addition, SNHD is expressly prohibited from releasing "the name of, or other personal identifying information, about a person infected with a communicable disease who has been investigated by the health authority" without the consent of the person.²¹

Part 2

Investigation and Response Goals

Public Health Investigation

In general, the reason for investigating an outbreak of disease is to determine the source of the outbreak in order to prevent ongoing or future cases of disease.²² In the outbreak described herein, the goals of the public health investigation were to:

- Confirm the existence of an outbreak, including confirming reported cases
- Identify additional cases of disease
- Describe the outbreak epidemiologically
- Determine the cause of the outbreak by identifying and evaluating potential sources of infection
- Initiate an appropriate public health response

Although a number of agencies and individuals were conducting parallel (and often overlapping) investigations, the health district did not play a role in setting the focus or goals of any of these investigations.

Public Health Response

Based on the public health investigation, the goals of the public health response were to:

- Notify patients of their potential exposure and recommend testing for hepatitis C, hepatitis B and the human immunodeficiency virus (HIV)
- Ensure that potentially-exposed patients have access to testing
- Provide appropriate risk communication to the public
- Coordinate with partner agencies in areas of concurrent jurisdiction and in overlapping, parallel, but separate investigations

Part 3

Hepatitis C

Disease Overview

Organism

The hepatitis C virus (HCV) is a positive-sense, single-stranded, encapsulated, ribonucleic acid (RNA) virus, and a member of the genus *Hepacivirus* within the family *Flaviviridae*.²³ HCV has been grouped into six genotypes, numbered one through six,²⁴ through phylogenetic analysis of nonstructural protein 5B (NS5B). Within each genotype are a number of subtypes given a single-letter designation such as “1a”.²⁵

The genome for HCV is approximately 9.6 kilobases in length and codes for a single, 3,000 amino acid polyprotein which is cleaved by proteases into at least 11 distinct proteins.²⁶ The RNA polymerase found in HCV lacks a proofreading mechanism,²⁷ and as a result, HCV mutates at a rate approximately one million times faster than is observed in plants, animals, or bacteria, at approximately 10^{-3} nucleotide substitutions per site per year.^{28,29} The virus undergoes rapid replication, and it is estimated that over 10^{12} viral particles are produced in an infected individual each day.³⁰ These two factors combine to result in the relatively rapid accumulation of mutations within an infected host.³¹ At any given time, a number of different HCV variants, typically described as a “quasispecies” or “swarm”, can be identified within an infected individual.³² Due to immune pressure, the mutations are most frequently identified in hypervariable region one (HVR-1) of envelope protein two (E2).³³

The virus can survive in the environment on surfaces at room temperature from 16 to 96 hours.³⁴ The Environmental Protection Agency lists 111 products as registered as effective against the hepatitis C virus for environmental disinfection, including chlorine-, phenol-, peroxide- and alcohol-based products.³⁵ The Food and Drug Administration (FDA) has approved 26 products for use in equipment reprocessing, sterilization, and high-level disinfection, including glutaraldehyde-, peracetic acid-, hydrogen peroxide-, and *ortho*-phthaldehyde-based products.³⁶

Transmission

HCV is transmitted from person to person through direct blood-to-blood contact,³⁷ and is not spread through household or casual contact.³⁸ The risk of transmission from mother to child *in utero* is approximately 5%,³⁹ and is correlated with the viral load of the mother.⁴⁰ Although sexual transmission of HCV can occur, it appears to be an inefficient mode of transmission. The risk for sexual transmission of HCV from an infected partner to a non-infected partner within a monogamous relationship is estimated to be between 0% and 0.6% per year.⁴¹ Because of the low risk, barrier precautions for sexual contact within a monogamous relationship and routine screening

of pregnant women are not recommended, and there are no recommendations that HCV-infected women abstain from breastfeeding.⁴²

When compared to hepatitis B virus (HBV) and human immunodeficiency virus (HIV), HCV has a moderate risk of transmission. Studies of accidental needlesticks in healthcare settings indicate the risk of HCV transmission is about 3% per documented exposure, whereas the risk of HIV transmission is approximately 0.3% per exposure, and the risk of HBV transmission is approximately 30% per exposure.⁴³

Clinical Presentation

Acute hepatitis is characterized by the discrete onset of symptoms such as jaundice, anorexia, abdominal pain, nausea, vomiting, dark urine, and clay-colored stools, as well as elevated serum alanine aminotransferase (ALT) levels.^{44,45} In those who develop acute disease, symptoms appear between two weeks and six months after infection, averaging seven weeks,⁴⁶ and full recovery may take several months after the onset of symptoms.⁴⁷ Nationally in 2006, 41% of reported cases of acute HCV infection were hospitalized, with one death from acute infection among 450 reported cases.⁴⁸

Fewer than ten percent (10%) of persons infected with the virus develop acute disease.⁴⁹ Most new infections result in a subclinical presentation without apparent symptoms. After both acute and subclinical infection, between 50% and 85% of patients enter a long-term, chronic state of infection.⁵⁰ Of those with chronic infection, 20% will develop cirrhosis, with 2% developing hepatocellular carcinoma.⁵¹ Cirrhosis is more likely to develop in those who have been infected at an older age, persons with high levels of alcohol consumption, and those who are co-infected with hepatitis B.⁵²

HCV Diagnosis and Classification for Public Health Surveillance

Hepatitis C virus infection is detected through one of several blood tests. Most frequently, enzyme immunoassay (EIA) or enhanced chemiluminescence immunoassays (CIA) tests are used to detect anti-HCV antibodies in the blood of an infected person. EIA or CIA tests must be confirmed by a more specific test unless the signal-to-cut-off (s/co) is sufficiently high, in which case the result is considered self-confirmatory.⁵³ HCV Recombinant Immunoblot Assays (RIBA) are typically ordered as a confirmatory test for EIA or CIA positives, and a positive RIBA result is considered confirmatory with or without any other laboratory findings. HCV Nucleic Acid Tests (NAT) are typically ordered as part of the long-term management infection, although a positive NAT test such as an RNA viral load or viral genotyping result is considered confirmatory with or without any other laboratory findings.⁵⁴

Acute HCV infection is diagnosed by a combination of laboratory findings and clinical signs and symptoms. The national surveillance case definition for acute hepatitis C infection requires that the patient develops an illness with discreet onset of any sign or symptom consistent with acute viral hepatitis, have either jaundice or an ALT greater than 400 international units per liter (IU/L), and have a laboratory-confirmed HCV infection as described above. In addition, the identification of acute infection also requires ruling out acute hepatitis A and acute hepatitis B infections through a negative test for IgM antibody to hepatitis A and a negative test for IgM antibody for hepatitis B core antigen.⁵⁵

As most people infected with HCV have asymptomatic infections, a case definition has been developed for past or present infection with HCV (non-acute infections). To be considered a confirmed case of past or present HCV infection, the case definition requires that a person has a laboratory-confirmed HCV infection as described above but does not meet the case definition for acute hepatitis C. In addition, a probable classification exists for past or present infection, which requires that the patient have a positive EIA without confirmatory testing and ALT above the upper limit of normal.⁵⁶

Epidemiology

HCV infection is the most common bloodborne infection in the United States, with an estimated 3.2 million Americans currently infected.⁵⁷ Genotype 1a is the most prevalent HCV genotype in the United States, responsible for 58% of infections. Genotype 1b is responsible for 21% of infections, and genotype 2b is responsible for 13% of infections. The prevalence of these genotypes has been consistently reported throughout the country, and although local data are not available, it is likely that the prevalence of the genotypes in Southern Nevada is consistent with national data.⁵⁸

Approximately 4 million Americans (1.6%) show evidence of having ever being infected with HCV.⁵⁹ Since the peak in 1989 when an estimated 291,000 persons were newly infected with HCV nationwide, the number of new infections has decreased in each successive year.⁶⁰ In 2006, it was estimated that 19,000 people were newly infected with HCV nationwide, with 3,200 (16.8%) developing acute symptoms.⁶¹ In Clark County, Nevada, between 0 and 4 cases of acute HCV infection were reported each year between 2000 and 2006, with an annual average of 1.6 cases.

Males, non-Hispanic blacks, people below the poverty threshold, and those with a high school education or less are the demographic groups that have been historically more likely to have been infected with HCV, although these demographic differences have recently been changing.⁶² In 2006, acute HCV incidence was similar among all racial and ethnic groups, and the ratio of male to female cases was approximately 1.2, down from a peak of approximately 2.0 in 1989.⁶³

A history of intravenous drug use, receipt of blood transfusions prior to 1992, and a high number of lifetime sexual partners are all associated with an increased risk for HCV infection.⁶⁴ Additional significant risk factors include receipt of pooled clotting factors prior to 1987, organ transplant prior to 1992, and undergoing long-term hemodialysis.^{65,66,67} Less significant risk factors include occupational exposure to blood in medical or public safety occupations, tattooing, body piercing, dental work, medical procedures, and incarceration.⁶⁸

Nationally in 2006, the most commonly-reported risk factor for acute HCV infection was intravenous drug use, which was reported by 42% of identified acute cases. Other reported risk factors in 2006 included having more than one sex partner (36%), having sexual contact with a person known to be infected with HCV (10%), and having a needlestick exposure (10%). No cases were reported in persons who had undergone hemodialysis or blood transfusions. Multiple risk factors were reported by individual acute cases, but of all cases, 32% reported no risk factors.⁶⁹

Historical Evolution of Risk Factors

Although the genotypes of the virus evolved at least 500-2000 years ago,⁷⁰ the major modes of HCV transmission are the result of relatively recent inventions.⁷¹ Blood and plasma transfusions became more common starting around the time of World War II,^{72,73} glass syringes began to be produced on

a large scale in the 1920s,⁷⁴ and disposable syringes became mass-produced and widely available in the 1950s.⁷⁵

Prior to 1970, approximately one-third of persons who received a blood transfusion developed transfusion-associated hepatitis.⁷⁶ The identification of the hepatitis B virus (HBV) in 1967 led to the development of screening tests for HBV.⁷⁷ Studies using the screening test showed that of those who developed post-transfusion hepatitis, only 20% of infections were related to HBV.⁷⁸

The United States shifted to an all-volunteer blood donation program in 1970 after research identified that blood from volunteer donors resulted in lower rates of post-transfusion hepatitis than from compensated donors.⁷⁹⁻⁸⁰⁻⁸¹ Also in 1970, HBV screening tests were developed and implemented by blood banks.⁸² As a result, post-transfusion hepatitis incidence was lowered to approximately 10% of transfusion recipients.⁸³⁻⁸⁴

In 1973, hepatitis A virus (HAV) was identified by electron microscopy in stool samples.⁸⁵ Studies ruled out HAV as the etiologic agent responsible for the non-HBV transfusion-associated hepatitis.⁸⁶ As these post-transfusion hepatitis cases were not caused by HAV or HBV, they became known as “non-A, non-B” (NANB) hepatitis.

In 1985, pooled clotting factor concentrates, which came from large numbers of paid plasma donors, began being chemically treated to inactivate viruses.⁸⁷ Research showed that pooled clotting factor concentrates could be treated, preventing post-transfusion hepatitis and HIV infection while retaining their effectiveness.⁸⁸⁻⁸⁹

The virus responsible for NANB hepatitis was identified in 1989 and was named the “hepatitis C virus”.⁹⁰ In 1990, the first EIA tests for HCV were approved and used to screen the blood supply. These tests decreased the incidence of post-transfusion hepatitis to 1.1% of transfusion recipients, and second generation EIA tests introduced in 1992 essentially eliminated the risk of hepatitis C infection from blood transfusion.⁹¹ The Centers for Disease Control and Prevention (CDC) estimates that the current risk of HCV transmission through blood transfusion is currently about 1 in two million transfused units.⁹²

Part 4

Cluster Identification and Initial Response

On December 4, 2007, a case of acute hepatitis C infection in a hospitalized patient was reported to OOE by a healthcare provider. Upon interview, the patient denied all major risk factors for HCV infection, but did report having a dental procedure and having two procedures at the Endoscopy Center of Southern Nevada (ECSN): a colonoscopy on September 20, 2007 and an esophagogastroduodenoscopy (EGD) on September 21, 2007. The investigation was completed on December 26, 2007, and the patient was determined to have met the case definition for acute HCV infection.

On December 17, 2007, a second case of acute hepatitis C was reported to OOE by a different healthcare provider. Upon interview, the patient denied all major risk factors for HCV infection, but did report having a colonoscopy at ECSN on July 25, 2007. The investigation was completed on December 28, 2007, and the patient was determined to meet the case definition for acute HCV infection.

Upon completion of the second acute hepatitis C case investigation, a common association was identified between both cases and the Endoscopy Center of Southern Nevada. Neither patient could provide the exact procedure dates at the time of interview, but reported undergoing procedures in mid- to late-summer of 2007; the patients did not appear to have procedures on the same day. Upon identification of the initial cluster on December 28, 2007, the SNHD Chief Health Officer and the State Epidemiologist at NSHD were notified.

On January 2, 2008, the OOE contacted CDC for advice and to explore the possibility of requesting formal assistance from CDC. In addition, the NSHD Bureau of Licensure and Certification (BLC) was contacted to determine if BLC was responsible for the licensing and regulation of ECSN. Agency staff reported that ECSN was licensed by BLC as an ambulatory surgical center. As a result, staff from SNHD and BLC agreed to coordinate investigative efforts.

Also on January 2, 2008, a third case of acute hepatitis C was reported to OOE by a third healthcare provider. Upon interview, the case denied all major risk factors for HCV infection, but did report having a colonoscopy at ECSN on September 21, 2007.

Exact procedure dates were requested from the clinic, and based on the identification of a third case and a temporal clustering of two of the cases, SNHD requested formal assistance from the Centers for Disease Control and Prevention (CDC) through the state epidemiologist.

Two CDC Epidemic Intelligence Service officers arrived in Las Vegas, NV, on January 9, 2008, at which time SNHD convened a meeting with personnel from SNHD, CDC, and BLC in attendance.

The CDC assisted SNHD with the field portion of the investigation conducted from January 9, 2008 through January 18, 2009 through the temporary assignment of CDC staff, and provided ongoing technical assistance throughout the course of the investigation. The report of the field investigation conducted by CDC has been included as Appendix J.

An independent investigation of the clinics by BLC was conducted concurrently with the SNHD investigation; the reports of the field investigations conducted by BLC have been included as Appendix K and Appendix L.

Part 5

Clinic Organization and Operations

Methodology

The clinic organization, administration, and staffing was determined through review of the clinic website, business licenses, interviews with staff and administration, and review of clinic records and documentation.

ECSN Overview

The Endoscopy Center of Southern Nevada, located at 700 Shadow Lane, Suite 165-B, Las Vegas, NV, was an outpatient surgical center specializing in endoscopic procedures.⁹³ The clinic primarily performed esophagogastroduodenoscopies and colonoscopies, and occasionally placed gastrostomy tubes and esophageal pH probes. Staff reported that the center moved to the Shadow Lane location in 2002, and underwent significant remodeling to expand from one surgical suite to two surgical suites in March of 2004.

Clinic administration reported that the clinic was typically open from Monday through Friday, with the first procedures scheduled to begin at 7:00 am. Staff reported that the clinic would occasionally open on Saturday mornings to perform procedures, although this was a rare occurrence. The clinic reported performing procedures on 50 to 60 patients each day, with the last procedures of the day generally being completed in the late afternoon. Four or five patients were typically scheduled during the first time slot of the morning at 7:00am; subsequent patients were scheduled in 15-minute intervals, with two patients scheduled for most time slots throughout the day.

The clinic was issued a business license by the City of Las Vegas, Nevada, on October 9, 2002;⁹⁴ the business license was allowed to lapse on November 17, 2007.⁹⁵ It was also licensed as an ambulatory surgical center by the Bureau of Licensing and Certification of the Nevada State Health Division. Clinic staff reported that the facility was voluntarily accredited by the Accreditation Association for Ambulatory Health Care.

Affiliated Clinics

The Endoscopy Center of Southern Nevada was affiliated with several Gastroenterology Center of Nevada (GCN) clinics and two ASCs. Clinic management reported that each was operated as a separate business entity, although many of the group's administrative and management functions were centralized. A total of fourteen physicians were owners or employees within the group, with overlap between the ownership groups of each business.⁹⁶

In addition to ECSN, there were two additional ASCs in the group:

- Desert Shadow Endoscopy Center (DSEC), 4275 Burnham Avenue, Suite 101, Las Vegas
- Spanish Hills Surgery Center, 5915 South Rainbow Boulevard, Las Vegas

A total of six Gastroenterology Center of Nevada offices were part of the group.⁹⁷ These clinics did not perform outpatient surgical procedures and were located at:

- 700 Shadow Lane, Suite 165-A, Las Vegas
- 4275 Burnham Avenue, Suite 101-B, Las Vegas
- 3150 North Tenaya Way, Suite 225, Las Vegas
- 5380 Rainbow Boulevard, Suite 210, Las Vegas
- 1815 East Lake Mead Blvd, Suite 207, North Las Vegas
- 2610 West Horizon Ridge Parkway, Suite 105, Henderson

A centralized billing and administration office was located in the 700 Shadow Lane building.

Staffing

Employed ECSN staff at the time of investigation in January 2008 included 9 physicians, 4 certified registered nurse anesthetists (CRNA), 10 registered nurses (RN), 9 technicians and 2 licensed practical nurses (LPN), and additional front and back office staff. In January of 2008, the clinic's website listed a total of 14 physicians and 4 physician assistants (PA) as being employed by the group, although no PAs were observed to be working at ECSN.⁹⁸

The Spanish Hills Surgical Center and Gastroenterology Centers of Nevada were not investigated, thus information about staffing levels was not available. ECSN management reported common management between ECSN and DSEC, but that CRNAs or other staff generally did not rotate between the two facilities.

An investigation of DSEC practices was not initiated until after Clark County had placed a restriction on the DSEC business license, effectively closing the clinic, thus information about the staffing of DSEC was unavailable. ECSN, DSEC, and all related facilities were closed to patients as of April 2008, either voluntarily or by order of a government business licensing agency, preventing the initiation or continuation of any field investigations.⁹⁹⁻¹⁰⁰

Part 6

Field Investigation

Methodology

The field investigation began on January 9, 2008 and continued through January 16, 2008; several follow-up visits to the clinic were conducted through the end of January, 2008 to collect additional information. ECSN Clinic layout, operations, and procedures were evaluated by multiple days of observation, overviews provided by clinic management, interviews with current and former clinic staff, and reviews of clinic and other documents by investigators from SNHD and CDC.

Clinic Layout

Within the clinic suite, ECSN had three distinct areas: a patient waiting room, clinic offices, and a procedure area. Unless escorted or admitted by a staff member, patients had no access to areas other than the waiting room. The offices within the suite consisted of a reception area, medical records storage, small offices, and a staff break room.

The procedure area was divided into several rooms and general areas, including two procedure rooms, an IV preparation room, an equipment reprocessing room, an endoscope and equipment storage room, a patient changing area, and a large area divided by curtains into four patient bays. The general layout of the procedure area is presented in Figure 6-1. At the back of the suite, ECSN was connected to the affiliated GCN clinic, allowing staff to move between the two clinics.

In addition, the clinic had a small conference room and administrative and billing offices separate from the ECSN surgery suite.

General ECSN Clinic Operations

The clinic was observed to be clean and well-organized. Equipment appeared generally to be in good working order.

Each morning, an RN unlocked a medicine cabinet containing propofol, lidocaine, and saline which remained unlocked throughout the day. A CRNA checked out 30-milliliter (ml) lidocaine vials and vials of propofol (either 20ml or 50ml vials), then placed the vials in storage cabinets in both procedure rooms.

A lockbox containing fentanyl, meperidine, and midazolam was opened and counted each morning, but remained locked throughout the day. Staff reported that, if needed, narcotics were distributed to CRNAs just before sedation. Narcotics were described as being used only for patients who could not

tolerate propofol. Narcotics were not needed for patients observed during the investigation, thus the distribution or administration of narcotics could not be evaluated.

Patients initially reported to the clinic waiting room, filled out paperwork, and waited to be called into the procedure area. Patients disrobed, changed into gowns in changing rooms, and were escorted to the patient bay area. Patients were then called into an intravenous (IV) preparation room where a heparin lock was placed in the patient's arm by an RN. The patients then returned to one of four patient bays where they were placed on a gurney for transport into the procedure rooms. Clinic staff were not observed performing any pre-surgical testing, including finger stick glucose testing, and reported not to be authorized to do so.

The patient was transported into the procedure room and interviewed by the CRNA about the patient's allergies, medications taken, underlying health problems (including hepatitis), and previous reactions to anesthesia. The endoscope was prepared by a technician who brought a clean endoscope and disposable biopsy equipment into the procedure room from the clean storage room and attached the endoscope to the electronic system. Once the doctor entered the room, he donned a gown and gloves and spoke briefly with the patient. The patient was then sedated for the procedure.

Upon completion of the procedure, the patient was transported back to one of the patient bays by a technician for recovery and post-procedure assessment. IV fluids were available, but according to staff, rarely need to be administered after the procedure and were not observed to be administered.

There were several staff members directly involved with patient care during the procedure:

- A physician performed the procedure, and one physician was typically assigned to perform all procedures during a several hour block of time (e.g. from opening to mid-morning). The physician rotated between both procedure rooms during this block of time. If two physicians were scheduled for the same time block (as they were on the afternoons of July 25, 2007 and September 21, 2007) they generally each remained in one procedure room.
- A CRNA was responsible for sedation of the patient, and was typically assigned to a shift that lasted the entire day. The CRNA generally remained in one room for the day, unless they were covering for the CRNA assigned to the other room during that CRNA's lunch or break. A third CRNA was scheduled on some days to cover for breaks and the lunch period as needed in either procedure room.
- A technician was responsible for assisting in the procedure, setting up the equipment and generally positioning the patient prior to the procedure, and assisting the physician during the procedure. Technicians were observed to remain in one room for several consecutive patients, although clinic records from September 21, 2007 indicate that the some technicians would occasionally rotate between rooms along with the physician. On both July 25, 2007 and September 21, 2007, four technicians were listed in clinic records as assisting in procedures.
- Once the procedure was completed, the endoscope was passed to a different technician in the equipment room for reprocessing. The scheduling of the reprocessing technicians was not evaluated during the investigation.
- An RN was present in the room to generally chart the procedure, and was the only member of the team present in the room that was not assigned to any duties requiring direct contact with the patient. The nurse would remain in one room for several consecutive patients. On

both July 25, 2007 and September 21, 2007, five nurses were listed in clinic records as the nurse responsible for charting the procedures.

- Additional nurses were assigned to patient recover areas, intake, discharge, and IV placement. The scheduling of these nurses was not evaluated during the investigation.

Injection Practices: IV Placement

IV placements were typically done by RNs in the IV preparation room prior to the patient entering the procedure room. The RNs placing the IV lines were observed to wear gloves and cleanse the patient's skin with alcohol before placing the heparin lock. Once the heparin lock was placed, it was flushed with 1ml-2ml of saline from a multi-dose saline vial. The RNs were not observed flushing the heparin lock a second time and did not report doing so. In general, the RNs were observed to use a clean needle and syringe for each injection, but were not observed wiping the stopper of the saline vial with alcohol prior to accessing it with a needle.

Not all heparin locks were placed in the IV preparation room by an RN prior to the procedures. Some of the IVs were started by a CRNA, and staff reported that this generally occurred with the first few patients of the day or when the IV needed to be restarted. One CRNA was observed restarting an IV, and was not observed to flush the heparin lock with saline once it was placed, but immediately administering propofol.

Injection Practices: Sedation

Each morning, CRNAs would draw 1ml of lidocaine from a 30ml multi-dose vial into multiple clean 10ml syringes with clean needles and then recap the needles. The syringes were neither labeled as to their contents nor with the date. They were placed in a drawer with any unused syringes from previous days.

Each CRNA drew 9ml-10ml of propofol into a pre-filled lidocaine syringe to start the procedure, resulting in a mixture of lidocaine and propofol which was used for the initial injection. Observations and interviews identified that each CRNA had their own technique for the administration of propofol. The propofol vials were not labeled as to the date or time the vial was initially used.

CRNA 1 was observed placing a new needle on a syringe that had been used to initially administer propofol to a patient. The syringe was then used to draw additional propofol from an open vial for use on the same patient. Upon interview, the CRNA stated that he had been instructed to do this by clinic staff, and that it was his routine procedure for the administration of additional propofol to a patient. He also reported that at the end of the procedure, he would discard the needle and syringe and keep any remainder of the propofol in the vial for use on subsequent patients.

CRNA 2 was observed filling syringes, including full syringes and partially-drawn syringes, with propofol in advance to be used for patients who needed additional propofol after the initial dose.

Some syringes were drawn from new vials of propofol. Other syringes were drawn from vials with propofol remaining from previous patients, including syringes that were drawn from multiple vials. CRNA 2 was observed disposing partially used syringes after the procedure was completed. CRNA 2 reported being instructed to reuse syringes to provide additional propofol to patients but reported not doing so.

CRNA 3 was observed drawing doses of propofol with a new needle and syringe when needed, but did use the vials for multiple patients. CRNA 3 reported being instructed to reuse syringes to provide additional propofol to patients but reported not doing so.

CRNA 4 no longer worked at the clinic at the time of investigation and could not be observed. Through a telephone interview, CRNA 4 reported using the same practices as CRNA 1, changing the needle but reusing a syringe if additional doses of propofol were needed.

No CRNAs or RNs were observed using syringes or needles on multiple patients, and none reported either doing so or being instructed to do so.

Endoscope Reprocessing

Upon completion of the endoscopic procedure, the physician handed the scope to the assisting technician. The technician placed the end of the scope into a small container containing detergent and water. The solution was run through the scope until the exiting solution appeared clear.

The scope was then taken into the reprocessing room adjacent to the procedure rooms, where a second technician would continue the process. Both types of endoscopes used by the clinic were processed in the same manner, as the equipment used for reprocessing was compatible with either type of scope.

In the reprocessing room, a leak test was performed with a handheld manometer. During the period of observation, all scopes passed the leak test. The caps were then removed from the scope, and the scope and caps were submerged in one compartment of a two-compartment cleaning basin which contained an enzymatic detergent, EmPower™. The second compartment was filled with fresh tap water.

The technician then cleaned the ports of the scope and the outside surface of the scope using a disposable brush. Technicians were observed discarding the brushes after use. Once the manual cleaning was completed, the scope was attached to a pump called a Scope Buddy™ which pumped the enzymatic detergent through the scope for a timed, one-minute cycle. The scope was then moved to the basin containing water, where the pump was again used to flush the scope with water for a timed, one-minute cycle.

The water and enzymatic cleaning baths were changed after every two scopes. The manufacturer's instructions stated that fresh detergent should be used for each endoscope or set of instruments, and that used detergent should be discarded after use.

Once the manual cleaning steps were completed, the scope and caps were transferred to an automated reprocessor for high-level disinfection. The clinic had two Medivators™ reprocessors, each of which could process two scopes simultaneously using Rapicide™, a glutaraldehyde solution maintained at 35 °C. Two scopes were attached to the reprocessor, and in an internally-timed 15-minute process, the glutaraldehyde solution was passed over and through the scope and caps.

When the disinfection cycle was completed, the reprocessor emitted an audible alarm to notify the technician to initiate the drying process. The technician then injected a syringe of 70% isopropyl

alcohol and a syringe of air. Once the automated process was completed, the scopes were removed from the reprocessor and the ports were further dried with compressed air. The scopes were then hung in a cabinet in a separate equipment room to air dry.

The entire cleaning process took approximately 25 to 30 minutes, with the automated step taking about 17 minutes.

Staff reported that each morning, routine testing was performed on the automated reprocessor to ensure that the machine was functional and that the glutaraldehyde was at the appropriate concentration. The functional evaluation involved checking the level and temperature of the disinfectant, which was maintained at 36 °C-37 °C in the reservoir to ensure that the 35 °C temperature was maintained during the disinfection process.

A colorimetric test strip was used to ensure that the glutaraldehyde solution met the minimum recommended concentration (MRC) of 1.5% glutaraldehyde. Although Rapicide™ is labeled for up to 28-day reuse, the solution must be replaced if it falls below the MRC. Clinic staff stated that the high volume of procedures often necessitated more frequent replacement of the solution. Clinic logs indicated that the tests were performed each day, and that the solution was changed on a regular basis.

As of August 2007, the clinic had two identical Medivators™ reprocessors. Prior to August 2007, the clinic had one Medivators™ and one Johnson & Johnson automated reprocessor. As the Johnson & Johnson reprocessor was no longer at the clinic at the time of the investigation, the use of the reprocessor (either through direct observation or review of maintenance logs) could not be evaluated. Maintenance records for one Medivators™ reprocessor were available for all of 2007, and records for the second Medivators™ were available from August 2007 through the time of the investigation.

Clinic staff gave conflicting information about the reasons for the removal of the Johnson & Johnson reprocessor. Staff members reported that maintenance issues, including a pump that had failed, that took the reprocessor out of service on multiple occasions. Clinic management stated that the machine was removed because it did not provide the projected savings expected. The nursing supervisor stated that the reprocessor did not fail, but that there was an internal limitation set on the number of times the solution could be reused despite the solution maintaining the MRC. Upon reaching that limit, users were locked out until the solution was changed or the counter was reset. Because of the high volume of scopes being reprocessed, the machine had to be reset frequently, taking it temporarily offline.

Noted in the equipment logs was that the Medivators™ reprocessor was out of service from March 24, 2007 to March 31, 2007. Clinic staff stated that there were manual high-level disinfection procedures which could be used when this happened, although these steps were not observed and could not be evaluated. In addition, the nursing supervisor stated that existing maintenance contracts provided for a temporary replacement which could be brought in within 24 hours. There were no entries for replacement or temporary machines in the clinic log book for this period, nor were there records of any manual reprocessing steps implemented.

Review of equipment logs demonstrated no problems on July 25, 2007 or on the two days prior. According to clinic records, the glutaraldehyde solution had been changed on July 2 and 30. As the

Johnson & Johnson machine was no longer at the clinic at the time of the investigation, the maintenance logs for the same time period were not available for review. Review of equipment logs demonstrated no problems on September 21, 2007 or in the two days prior. According to clinic records, the Rapicide solution had been changed on September 10, 17 and 25 in both reprocessors.

Technicians responsible for the reprocessing of endoscopes and maintenance of equipment were trained through an informal mentorship process. Technicians were trained by a staff member experienced in the process until it was felt that the trainee understood the steps and could correctly complete the process independently. A reference diagram on reprocessing was posted on the wall in the work area.

Infection Control

Sinks and hand sanitizers were located throughout the center and were readily available to staff members. However, staff members were observed not performing proper hand hygiene on multiple occasions before working with patients. Although staff generally wore gloves when working with patients, CRNA 2 was observed not wearing gloves or only wearing one glove during the administration of anesthesia.

Sharps containers were located in any area where needles were used. The containers were not observed to be full or overflowing and were disposed of in a utility area at the end of the day. Although staff generally used the sharps containers appropriately, one CRNA 2 was observed moving around the procedure room with a used uncapped needle, recapping a needle after it had been used on a patient, and uncapping a needle with their mouth prior to injecting the patient.

The clinic was observed to use disposable, single-use biopsy equipment and bite blocks. Several staff members expressed concern to investigators about the reuse of these items at the clinic. One staff member reported only being allowed to use four bite blocks per day per procedure room. Another staff member stated that the clinic staff were directed to use disposable items three times before discarding, with items being cleaned and reprocessed with the scopes. The staff member also reported that the reuse of biopsy equipment stopped after multiple staff members expressed their concerns to management. Clinic management denied the reuse of any single-use biopsy equipment or bite blocks, and no items were observed being reprocessed by clinic staff.

Purchasing records for bite blocks indicated that the clinic had purchased approximately 2,000 bite blocks in 2007, while procedure logs indicated that the clinic performed 5,800 EGDs. Purchasing records for biopsy equipment indicated that in 2007, clinic staff purchased 6,200 biopsy forceps and polyp removal wires, while procedure logs indicated that the clinic performed over 7,800 biopsies and polyp removals.

Procedure Documentation

An RN was stationed in each procedure room to record general findings and to organize the chart for the patient's procedure. Endoscopic findings were made by the physician through Provation® MD, an automated, menu-driven computer system; printouts of the findings were included in the patient's chart.¹⁰¹⁻¹⁰² The patient's preoperative evaluation, vital signs, and sedatives administered were recorded by the CRNA in an anesthesia record which was given to the RN at the end of the procedure for inclusion in the chart. A printout from the patient's vital sign monitors was made

upon completion of the procedure before the patient was moved to the recovery bay and was included in the chart as well. A printout from a second vital sign monitor, used in the recovery area, was also included in the chart.

A review of patient charts from the days of known disease transmission identified a number of problems with the clinic's documentation. First, the procedure room utilized for a patient was not recorded on the chart. A second problem identified in multiple instances was that the time-numberings recorded on the chart were often inconsistent, recorded in an illogical sequence, and/or overlapping (an example of this is presented in Figure 6-2). Times recorded on the charts were not based on a common time source, as a number of sources for the time were present in the procedure rooms, including wall clocks, computerized records, and timestamps on multiple electronic devices.

A former staff member reported that she was trained to record certain events in advance of the occurrence of the event. For example, the time a physician was at the patient's bedside was to be recorded before the patient left the procedure room, although staff reported that the physician did not typically visit the patient in the recovery area. A review of charts from the known days of transmission in 2007 identified that for 55% of patients, the physician was performing a different procedure at the time he was reported to have been at the patient's bedside, and the time at which the physician was present at the patient's bedside was consistently recorded on charts to have occurred seven minutes after the completion of the procedure.

Staff members reported that anesthesia times were intentionally recorded incorrectly for the purposes of obtaining additional reimbursement. The staff members reported that the anesthesia times for procedures shorter than 30 minutes in length were typically recorded as 31 or more minutes. A review of anesthesia times from procedures on July 25, 2007 and September 21, 2007 identified a total of 128 procedures for review. Of all procedures, 115 (90%) had reported anesthesia times of between 31 and 33 minutes, with a median of 32 minutes.

Graphical depictions of vital signs recorded in the anesthesia records were evaluated from some patients, and on multiple charts, the vital signs charted extended beyond both the time recorded for the administration of anesthesia and the time of the end time of the second vital sign monitor. In one chart from September 21, 2007, vital signs were recorded for 29 minutes after the second vital sign monitor report ended and 12 minutes after the recorded anesthesia end time.

An additional problem identified with the charts was in the recording of the scope numbers. Two successive patients from September 21, 2007 appeared to have had a procedure with the same scope. Clinic staff attributed this to a clerical error, and produced scope numbers from the automated system which identified that the patients had procedures performed with different scopes. The numbers from the automated system were in a different format than those recorded by the nurses.

Part 7

Cluster Investigation

Methodology

Endoscopy Center of Southern Nevada Patient charts from September 21, 2007 and July 25, 2007 were reviewed, and information related to patients, procedures, providers, anesthesia, and times was abstracted. Patient information was grouped by procedure room and put in sequential order using the start time recorded by the automated computer system used by the physicians during the procedure.

Five different sets of procedure times were abstracted from the patient charts:

- Anesthesia Time: the times recorded on the anesthesia log as the start and end time of the anesthesia administered for the procedure
- Nurse Log Time: the times recorded by the procedure room nurse as the start and end times of the procedure
- Vital Sign Monitor One Time: the first and last time recorded by the patient's vital sign monitor used in the procedure room
- Vital Sign Monitor Two Time: the first and last time recorded by the patient's vital sign monitor used in the recovery room
- Report Time: The time recorded as "note initiated" and the time recorded as "note signed" on the procedural chart produced by the computer system used by the physician to perform the procedure

Additional times were identified on the charts, including the time nursing notes were made, the time of discharge, and time at which the patients signed forms.

Procedure times were determined using the nurse log time start time as the beginning of the procedure and the earlier of the nurse log time end time and the report time end time as the end of the procedure.

Data were analyzed in Microsoft Excel 2007 (Redmond, WA) and Statcalc 6 (Centers for Disease Control and Prevention, Atlanta, GA).

September 21, 2007 Cluster Investigation Results

Although patient rooms were not recorded, it was possible to determine which patients likely had procedures in the same room on September 21, 2007 through a date error present in some procedure reports. For an undetermined reason, the date listed as "date signed" on roughly half the patient reports from September 21, 2007 was electronically recorded incorrectly as August 21, 2007;

the date listed under “date initiated” was correct on all patient charts. Patients who had procedures in which the date error was not present on the patient’s chart were designated as having a procedure in ECSN procedure room “A”, and patients who had procedures in which the date error was present on the patient’s chart were designated as having a procedure in ECSN procedure room “B”. Although these rooms could be differentiated, they could not be linked to a specific physical location

In order to verify that the date error was present at the time the procedure was performed, a procedure report submitted to the referring physician of a patient who had a procedure on September 21, 2007 was reviewed. The report reviewed was submitted to the referring physician within three days of the procedure, and the date error was present in the report, indicating that it was not introduced after the initiation of the investigation but was present at the time of the procedure.

There were other problems identified with the information recorded in patient charts. As described in Part 6 of this report, the duration of anesthesia times was incorrectly recorded, resulting in an incorrect end time. In addition, some anesthesia start times appear to be incorrect as well. For eight procedures on September 21, 2007, the anesthesia start times recorded were at least five minutes after the procedure had been initiated, with four procedures having a discrepancy of ten or more minutes; the largest discrepancy noted was 14 minutes. In one case, the anesthesia start time recorded was the same time as when the procedure was recorded to have been completed.

On September 21, 2007, a total of 64 procedures were performed on 63 patients (one patient underwent both an EGD and colonoscopy), including 33 procedures in room “A” and 31 procedures in room “B”. The first procedure started at 06:59 and the last procedure ended at 17:03.

Anesthesia times recorded for the patients ranged from 25 minutes to 41 minutes, with a mean and median time of 32 minutes (see Figure 7-1). Sixty-one of the 63 procedures (97%) had a recorded anesthesia time of between 30 and 34 minutes. The total amount of anesthesia time recorded was 33 hours, 25 minutes, a per-room average of 16 hours, 42 minutes.

The source patient underwent a procedure mid-morning, and all infected patients underwent procedures within about three hours and thirty minutes of the source patient’s procedure. The order of patients’ procedures grouped by CRNA is presented in Figure 7-2, and the order of patients’ procedures grouped by physician is presented in Figure 7-3.

A total of four physicians performed procedures on September 21, 2007, and two CRNAs administered anesthesia in the two procedure rooms. The IVs of the source patient and five of the case patients were started by RN 1, and the IVs of the other two case patients were started by RN 2. Case patients had procedures performed in both procedure rooms on that day, and the procedures were performed using several endoscopes. No case patients had a procedure performed with the same endoscope as was used on the source patient. Four of the case patients had biopsies performed during their procedures, and three did not.

None of the following placed the patients at a statistically significant increased risk for infection (calculated among patients who had procedures subsequent to the source patient’s procedure): having a biopsy, the physician performing the procedure, the CRNA administering the anesthesia, the technician assisting, the nurse starting the IV, the type of procedure, or the room in which the procedure was performed.

Clinic records indicate that, although the CRNAs generally remained in one room for the majority of the day, CRNAs performed procedures in both rooms. CRNA1 remained in room “A” for all procedures that occurred both before and after the time period displayed in Figure 7-2, and CRNA2 remained in room “B” for all procedures that occurred both before and after the time period displayed in Figure 7-2.

According to patient charts, CRNA 1 began administration of anesthesia to a patient in room “B” while still completing a procedure in room “A” approximately thirty minutes after the start of the source patient’s procedure. In addition, about two hours after the beginning of the source patient’s procedure, CRNA 1 administered anesthesia during multiple, overlapping procedures in both procedure rooms.

Both 20 milliliter (ml) / 200 milligram (mg) and 50ml/500mg propofol vials were checked out by CRNAs on September 21, 2007. According to the propofol daily sign out log, four 20ml vials were checked out and all four were returned. A total of twenty-four 50ml vials of propofol were used. Initially, eighteen 50ml vials were checked out and none were returned, then an additional twenty vials were checked out and fourteen were returned. In total, 1,200ml of propofol (12,000 mg) was checked out and not returned.

A total of 9,530mg of propofol was recorded to have been administered to the sixty-three patients, which would have required the use of at least twenty 500mg vials. Patients were injected with an average 151mg of propofol (range 50mg-300mg); four patients needed more than 200mg, and four patients needed less than 100mg.

Of forty-five ECSN patients from September 21, 2007 who had procedures after the source patient, six patients (13.3%) were infected with the hepatitis C virus and were genetically linked to a source patient. An additional patient has been classified as having a possibly-associated infection, as genetic testing could not be conducted on the patient’s specimen; this patient was not known to be infected with HCV prior to undergoing the procedure on September 21, 2007 . Patients having procedures on September 21, 2007 after the source case were over 31 million times more likely than non-clinic patients to develop an acute HCV infection (RR=31,702,375 [8,179,409; 122,876,729] $p<.0000001$).

The identified source patient was recorded to have received a total of 200mg of propofol, divided into four injections of 50mg, 50mg, 60mg, and 40mg. The case patients (numbered in descending order of the total amount of propofol administered) received injections of the following:

- Case patient 1: 170mg, divided into injections of 50mg, 50mg, 50mg, and 20mg
- Case patient 2: 160mg, divided into injections of 50mg, 50mg, 30mg, and 30mg
- Case patient 3: 150 mg, divided into injections of 50mg, 50mg, and 50mg
- Case patient 4: 150 mg, divided into injections of 100mg and 50mg
- Case patient 5: 150 mg, divided into injections of 100mg and 50mg
- Case patient 6: 130 mg, divided into injections of 50mg, 50mg, and 30mg
- Case patient 7: 50 mg given as a single injection

There was no indication on the anesthesia record as to the number of vials used or the amount of propofol drawn into a syringe at one time (*i.e.* if syringe was filled with 100mg and given as a single 100mg dose or two 50mg doses to the same patient).

July 25, 2007 Cluster Investigation Results

As with the September 21, 2007 records, procedure rooms were not recorded on the charts of patients from July 25, 2007. For this date, a date error was not reported, and it was not possible to identify the room in which procedures had occurred. A total of 67 procedures were conducted on 65 patients on July 25, 2007; two patients underwent both an EGD and colonoscopy.

The genetically- identified source patient was the first patient to have a procedure performed on July 25, 2007 by Physician B and CRNA 4. The procedure on the one newly-infected patient began 1 hour and 11 minutes after the source patient's procedure began, and was also performed by Physician B and CRNA 4. Three additional patients had procedures performed by physician B and CRNA 4 during the time between when procedures were performed on the source patient and the newly-infected patient. According to the records of the infected patient, the IV was started by CRNA 4.

Both 20ml (200mg) and 50ml (500mg) propofol vials were checked out by CRNAs on July 25, 2007. According to the propofol daily sign out log, twelve 20ml vials were checked out and ten were returned. Twenty 50ml vials of propofol were used on July 25, 2008; initially, five 50ml vials were checked out and none were returned, then an additional twenty vials were checked out and five were returned.

Part 8

Clinic Demographics

Methodology

Ages of patients at the time of procedure were calculated from dates of birth abstracted from the charts of patients who had procedures at ECSN from September 21, 2007 through September 24, 2007.

Estimates of the proportion of Clark County residents that were potentially exposed were determined using the total estimated potentially-exposed patients and the 2007 mid-year certified population estimate from the Nevada State Demographer.¹⁰³ The total number of persons exposed in each 5-year age group were estimated by applying the proportion of patients in each 5-year age group in the September 21, 2007 through September 24, 2007 ECSN sample to the total number of potentially-exposed patients. Age-specific rates were then calculated using the estimated total number of patients in each age group and age-specific 2007 population estimates from the Nevada State Demographer.¹⁰⁴ The percentage of households with an exposed patient was estimated using the total number of estimated potentially-exposed patients and the number of estimated Clark County households from the American Community Survey 3-Year Estimates of the number of households in Clark County.¹⁰⁵

Clinic patient volume was determined by abstracting information from two sets of log books maintained by the clinic, one for US Department of Veterans Affairs (VA) patients, and one for non-VA patients.

The age-adjusted prevalence of hepatitis B and hepatitis C was calculated using age-specific prevalence rates determined in the Third National Health and Nutrition Examination Study (NHANES III).¹⁰⁶⁻¹⁰⁷⁻¹⁰⁸ The age-adjusted prevalence of HIV infection including Acquired Immune Deficiency Syndrome (AIDS) was calculated using age-specific national estimates of persons living with HIV/AIDS in 2007 and the clinic age distribution.¹⁰⁹⁻¹¹⁰⁻¹¹¹ Nevada age- and race-stratified populations estimates made by the Nevada State Demographer for 2007 were used in the calculation of rates.¹¹²

Analysis of data was performed in Microsoft Excel (Redmond, WA) and Statcalc 6 (Centers for Disease Control and Prevention, Atlanta, GA).

Results

Data on 232 patients were available for analysis. The average age of clinic patients was 55.8, the median age was 57, and the range of ages was 17 to 83. The age distribution of clinic patients is presented in Figure 8-1.

As described in Part 11, it is estimated that 49,254 patients were potentially exposed at ECSN between March of 2004 and January 11, 2008, and 12,895 patients were exposed at DSEC (all dates), a total of 62,149 patients. The certified 2007 estimate of the Clark County population was 1,954,310, resulting in an estimated exposure of 3.2% of Southern Nevada residents. The age-specific potential-exposure rate ranged from 0.4% of Clark County residents age 15-19 to 14.2% of Clark County residents age 65 to 69. Of 662,025 households in Clark County, 9.4% had a member potentially exposed at ECSN or DSEC.

In 2007, ECSN performed 15,249 procedures on 253 business days, an average of 60.3 procedures per day (range: 25 to 76). Of the procedures performed in 2007, 34% were EGDs and 66% were colonoscopies.

Patient records were contained in two sets of clinic log books, one for VA patients, and one for all other patients. Nine percent (9%) of patients were recorded in ECSN log books for VA patients and 91% were recorded in the log books for other patients. Other than for VA patients, insurance provider information was not available for ECSN. For DSEC, 10.9% of all patients were insured by Medicare or Medicaid.

Biopsies were performed on 51% of patients, although statistically significant differences were noted between the two log books types in the biopsy rates. Non-VA patients were 21% more likely to have a biopsy than VA patients (RR=1.2 [1.13-1.28], $p<0.0000001$), as 52% of non-VA patients had a biopsy and 43% of VA patients had a biopsy. Other than recording VA patients in a separate log book, the clinic did not report using policies or procedures different from non-VA patients for VA patients.

Based on national age-specific seroprevalence and the age distribution of clinic patients, the background prevalence of past or present HCV infection in the sample clinic population was calculated to be between 1.5% and 3.3%.

Based on national age-specific seroprevalence and the age distribution of clinic patients, the background seroprevalence of HBV in clinic patients was calculated to be 6.9%. Based on the ratio of chronic to past hepatitis B infections determined by NHANES III, 0.6% of clinic patients were estimated to have a chronic hepatitis B infection.

Based on national age-specific seroprevalence and the age distribution of clinic patients, the background prevalence of HIV in clinic patients was estimated to be 0.4%.

Part 9

Staff and Cluster Laboratory Investigation

Collection Methodology

SNHD attempted to collect blood samples from all patients who had procedures on July 25, 2007 and September 21, 2007 to identify source patients and patients with asymptomatic infections. For patients who refused interview or who could not be located, commercial laboratories were contacted to determine if the patients had undergone testing and if so, to obtain laboratory results. Death certificates were obtained for patients who had died in Clark County, Nevada.

In addition, SNHD collected blood samples from ECSN employees with direct patient contact who were employed by the clinic at the time of the field investigation in early January, 2008.

All blood samples collected directly by SNHD were drawn by licensed laboratory personnel and were accessioned and handled through previously-established laboratory procedures. Prior to the blood draw, SNHD staff verified the patient's identity. For each patient, two tubes of blood were collected by SNHD staff.

SNPHL contacted local commercial laboratories to obtain any remaining specimens from testing performed as part of the patient's disease identification and management by the patient's provider. When available, frozen serum samples were submitted to the Southern Nevada Public Health Laboratory (SNPHL) by the commercial laboratories through previously-established sample submission procedures and were accessioned and handled through previously-established laboratory procedures.

Specimens were generally screened for evidence of infection with HCV, HBV, or HIV, and those specimens that screened positive for evidence of HCV infection underwent additional HCV genetic testing. The location of testing varied based on the group of persons being tested:

- For SNHD-collected specimens from clinic staff, one of the two tubes of blood was submitted to laboratories at the CDC for the initial HCV, HBV, and HIV screening. The second tube remained at SNPHL. In addition, lists maintained by SNHD of persons who had tested positive for HCV infection were reviewed for the names of current and former employees provided by the clinic, including those from whom specimens have been collected.
- For SNHD-collected specimens from clinic patients with acute disease who had procedures on July 25, 2007 and September 21, 2007, one of the two tubes of blood was submitted to CDC for the initial HCV, HBV, and HIV screening. For patients who had screened positive for HCV infection, the second tube was divided, with one portion being submitted to CDC laboratories for HCV genetic testing, and the other portion remaining at SNPHL.

- For commercial laboratory-collected specimens obtained by SNPHL, the entire frozen serum sample was submitted to CDC laboratories for HCV genetic testing.
- For SNHD-collected specimens from clinic patients without acute disease who had procedures on July 25, 2007 and September 21, 2007, one of the two tubes of blood was submitted to NSHL for the initial HCV, HBV, and HIV screening. For patients who had screened positive for HCV infection, the second tube was divided, with one portion being submitted to CDC laboratories for HCV genetic testing, and the other portion remaining at SNPHL.

Although SNHD made recommendations for the testing of potentially-exposed clinic patients, SNHD neither collected nor submitted specimens for testing other than from those patients described above. Specimens from the two patients with acute disease that had previously gone unreported in 2005 and 2007 (as described in Part 10 and Part 19, respectively) were not collected nor submitted to CDC for genetic testing as incomplete information provided by the clinic made it impossible to identify other patients who had procedures on the same dates as case-patients, and thus no comparisons could be made to identify a potential source patient or additional infected patients.

Screening Methodology

Patient specimens collected by SNHD as part of the cluster investigation were tested for HCV, HBV, and HIV infection as follows:

- HBV: total antibody to HBV core antigen with additional testing for IgM antibody to HBV core antigen (anti-HBc) and hepatitis B surface antigen on initial testing positives
- HCV: antibody to HCV (anti-HCV), with additional testing by RIBA to confirm a positive HCV antibody result with a low signal-to-cutoff ratio (a high S/CO is considered self-confirming)
- HIV: antibody to HIV, with HIV-1 western blot testing to confirm antibody positive results

This same testing schema was recommended to healthcare providers for use in the testing of potentially-exposed clinic patients.¹¹³ SNHD worked with commercial laboratories to develop testing panels to simplify the testing process for healthcare providers. However, there was no requirement to use the SNHD-recommended tests and healthcare providers had the option to use any FDA-approved diagnostic tests available at commercial laboratories. Laboratory diagnostic criteria from national case definitions for HCV infection, HBV infection, and HIV infection were utilized to interpret laboratory findings for July 25, 2007 and September 21, 2007 patients not tested by SNHD.

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Molecular Testing Methodology

Patient samples submitted to CDC for genetic testing were first genotyped by sequencing and analysis of a 300-nucleotide segment of the NS5B region.¹¹⁹ Each quasispecies was isolated from samples with a 95% or greater NS5B sequence homology to other submitted samples, and the HVR-1 region of NS5B of each viral isolate was sequenced using previously described methods.¹²⁰⁻¹²¹ Included in the phylogenetic analysis was a reference group of six randomly selected participants from NHANES III infected with HCV genotype 1a with a 95% or greater NS5B sequence homology to the suspected source patients.¹²²

Results

Samples were collected from the 36 employees (including physicians) who were currently working at the facility at the time of the investigation in mid-January, 2008, and were identified as having direct

patient contact. All samples submitted screened negative for evidence of infection with HCV, HBV, and HIV. No current or former clinic staff were identified in existing SNHD databases as having been infected with HCV.

SNHD identified a total of 126 patients who had procedures on July 25, 2007 and September 21, 2007. Four of the patients were known to be infected with HCV prior to their procedures (*i.e.* classified as unrelated infections). Of 122 potentially-exposed patients, 107 (88%) were screened for infection through SNHD or commercial laboratories.

Three patients had since died and were unable to be interviewed or tested. A review of death certificates indicated no evidence of hepatitis, HIV infection, evidence of liver disease, or death from hepatitis-related causes. Information on the infection status on the remaining twelve patients was unavailable, as either SNHD was unable to locate the patients or the patients declined testing through SNHD and laboratory testing results from commercial laboratories could not be identified.

Of all samples tested by SNHD and commercial laboratories from patients who had procedures on July 25, 2007 or September 21, 2007, none tested positive for infection with HIV. Five patients tested positive for evidence of past infection with HBV, although none showed evidence of chronic infection.

Molecular testing was performed on samples from ten patients who had screened positive for HCV infection: six patients with acute disease, two patients with non-acute disease, and two potential source patients. Despite repeated attempts, the sample from one non-acutely-infected patient was unable to be sequenced as a result of a low viral load. Samples from all six acute patients, one non-acute patient, and two potential source patients were determined to be of genotype 1a.

Phylogenetic analysis (Figure 9-1) identified two distinct clusters of related infections. One cluster consisted of patients who had procedures on July 25, 2007, and included one source patient and one patient who subsequently developed acute disease. The second cluster consisted of patients who had procedures on September 21, 2007, and included one source patient, five patients who subsequently developed acute disease, and one patient who was infected with HCV but did not develop acute disease. Both clusters were distinct from NHANES III patients tested.

The maximum genetic relatedness between the source patient and infected patient in the July 25, 2007 cluster was determined to be 98.6%. The maximum genetic relatedness between the source patient and infected patients in the September 21, 2007 cluster ranged from 99.3% to 100.0%. Two patients were a 99.3% match to the source patient, three patients were a 99.7% match to the source patient, and one patient was a 100.0% match to the source patient.

Part 10

Desert Shadow Endoscopy Center Investigation

In March 2008, SNHD was contacted by a former patient of the Desert Shadow Endoscopy Center who reported that they had developed acute hepatitis C after a procedure at DSEC on June 14, 2006. The patient reported that as part of a routine physical, he or she tested negative for HCV infection on June 12, 2006, and developed the symptoms of acute hepatitis approximately 6-7 weeks after the procedure. Upon interview, the case denied any other risk factors in the six months prior to the onset of symptoms, and based on laboratory and clinical findings, the patient was determined to have met the case definition for acute HCV infection. An investigation was initiated into the practices of DSEC, given the identification of the acute case in a DSEC patient and the association between DSEC and ECSN.

Methodology

Medical records of the patient were obtained from the physician who had ordered the routine physical and had diagnosed the patient with acute hepatitis C. The records were evaluated to determine if the patient met the case definition for acute hepatitis C infection and to identify if and when the case was reported. Health district records were evaluated to determine if the case had been reported at the time of diagnosis.

At the time of the SNHD investigation into the transmission of disease at the Desert Shadow Endoscopy Center, the clinic had been closed. In addition, all clinic documentation and files had been collected as part of a law enforcement investigation and were not available to SNHD investigators. Thus, no field investigation was conducted.

In order to investigate the risk of exposure to patients, the NSHD Bureau of Licensure and Certification Statement of Deficiency dated January 30, 2008 was reviewed (Available in Appendix L). Medical charts of the acute patient were reviewed and patient interviews were conducted in order to evaluate and classify potentially-infected patients (as described in Part 12 and Part 18).

Results

Physician records indicate an illness that met the case definition for acute hepatitis C. There was no indication in the chart of the disease being reported, and there were no reports received at SNHD. There was no evidence identified that, at the time of diagnosis in August of 2006, the case was reported to SNHD by the diagnosing physician in accordance with NAC 441A.

During the BLC clinic inspection on January 30, 2008, CRNA 5 reported the reuse of a single-use propofol vial for multiple patients to BLC inspectors.¹²³ This reuse occurred despite the existence of

formal policies and statements by the nurse manager and a physician that CRNAs had met with the physician director at which time they were informed of the new policies.^{124,125} The reuse of syringes at the clinic was not observed by BLC surveyors. ECSN management reported that the CRNAs that worked at ECSN did not generally work at DSEC.

No additional cases of acute HCV infection linked to DSEC were identified, and five infections possibly linked to DSEC were identified (as described in part 18).

Part 11

Investigation of Positive Laboratory Results, March and April, 2008

Methodology

Per NAC 441A.570, diagnostic laboratories and healthcare providers are required to notify the health authority upon the finding of evidence of infection with HCV in a patient or from a clinical specimen. Reports are submitted in several formats:

- Healthcare providers or laboratories may call OOE and make a verbal notification
- Commercial and hospital laboratories may call OOE or SNPHL and make a verbal notification
- Laboratories or providers may submit a report by fax, using a standardized reporting form
- Laboratories may submit reports electronically through previously-established daily electronic reporting procedures.

As part of the ongoing hepatitis C investigation, any patient reported to have developed acute hepatitis C disease was referred to a DIIS for investigation and follow-up using established previously-established, routine OOE protocols and procedures.

Lab results were matched to the list of clinic patients provided by ECSN by matching first and last names, and addresses or phone numbers when available on the provider report. The identities and contact information of reported patients who could be matched were entered into a Microsoft Access (Microsoft Corporation, Redmond, WA) database developed to manage the information and track attempts to contact the patients. When sufficient contact information was available, cases reported in March and early April of 2008 were interviewed through a call-center established at SNHD.

An outgoing call center was established to assist OOE in the investigation of these reported cases; this call center was separate from the call center established to handle incoming informational calls. The call center was staffed by SNHD employees and members of the Medical Reserve Corps of Southern Nevada. The Medical Reserve Core is a federal government program sponsored by the Office of the U.S. Surgeon General, and is designed to provide medical and public health surge capacity during times of emergency or when needed to support local public health initiatives. Local Medical Reserve Corps members with a nursing or medical background were utilized in the call center to make outgoing calls and interview patients.

Call center staff left messages for patients who were unavailable, and made up to two additional attempts to contact any patients who did not respond. Patients were questioned to confirm their identity, and to ensure that they had received their test results from their healthcare provider. If patients had not received their results, they were encouraged to contact SNHD once that had been accomplished. If patients' identities could be confirmed and they had received their laboratory results and consented to be interviewed, each patient was interviewed using a standardized questionnaire (see Appendix E). The questionnaire was implemented through an online survey tool, Survey Monkey. The questionnaire was terminated if the patient reported any symptoms of acute hepatitis, and the patient was transferred to DIIS staff for investigation and follow-up using established previously-established, routine OOE protocols and procedures.

When all surveys had been completed, results from the survey were exported from Survey Monkey to Microsoft Access, and were analyzed using Microsoft Excel. Cases were classified according to the classifications listed in Appendix B.

Results

A total of 1,110 calls (including initial contact attempts and follow-up attempts to contact patients for whom the initial contact attempt was unsuccessful) were made by the call center to 594 patients for whom positive laboratory results were reported, resulting in 422 patient contacts. Fifteen persons refused to speak with call center staff, including three who reported doing so on the advice of legal counsel. Of the 407 patients who spoke with staff, 203 were aware of their test results and were willing to answer the questions on the questionnaire. A total of 175 patients reported undergoing procedures at ECSN during the risk period and were further evaluated.

Of these patients, 77 were identified as having a possible clinic-associated infection, and 50 were identified as having been infected prior to the procedure (*i.e.* had an unrelated infection). The source of infection for 20 patients could not be determined because of the presence of other major risk factors, and 28 patients did not provide sufficient information to interviewers to make a determination about the possible source of their infection.

A complete breakdown of all calls made, including classification results, is presented in tables 11-1 and 11-2.

Part 12

Patient Notification

Patient Information Request

On February 7, 2008, SNHD requested a list of all patients who had procedures during the risk period at the clinic from clinic management. March 2004 was selected as the beginning of the risk period; clinic management reported that at that time, the clinic had undergone an expansion to a two-procedure room clinic and had implemented new protocols. January 11, 2008 was selected as the end date of the risk period. This date was the date in which unsafe injection practices were observed and clinic management was notified; the unsafe injection practices were observed to have been discontinued on the next day of operations. The health district requested an electronic file with information on each patient, including the patient's name, full address, date of birth, procedure date, phone number, and the name of the insurance company billed for the procedure.

On February 22, 2008, legal counsel for ECSN provided a compact disc to SNHD legal counsel containing one electronic file dated February 14, 2008. For each patient, the clinic provided the patient's name, full address, phone number, and system accession date. In addition, for some patients, the patient's employer name and work phone number were provided. The list did not include the patient's date of birth, procedure date, or insurance company billed. Patients who had undergone multiple procedures were only listed in the file one time.

The file was provided in electronic format, and consisted of a fixed-width system report printed to a file, with patient information spread over one or two lines of the printout. A Microsoft Access database was developed to import the file and convert it to a standard format. Once standardized, the data were exported to a Microsoft Excel file for analysis.

The patient notification letter (appendix D) and list of addresses was provided to a Las Vegas-based company specializing in printing and distribution of large-volume mailings. Prior to mailing the letters, the list was checked against the United States Postal Service's (USPS) National Change of Address (NCOA) database to identify bad addresses and update the address for people who have filed a change of address form with USPS.

Completeness and Accuracy

A total of 39,561 patient names were provided in the electronic file. Nearly 99% of clinic patients were from Nevada (94.6% of clinic patients lived in Southern Nevada), although there were patients from 38 states and 2 territories. Because procedure dates were not provided, it was not possible to determine the completeness of the list at the time it was provided to SNHD.

Prior to mailing, a total of 5,219 addresses (13.2%) were updated with current information from the NCOA, and 1,449 addresses (3.7%) were identified as being undeliverable. In the initial SNHD mailing, 38,112 letters were mailed to former ECSN patients. As the letters were sent as standard mail, letters that could not be delivered were not returned to SNHD, and it is not possible to determine what percent of letters were unable to be delivered.

Based on SNHD evaluations of clinic volume, it was estimated that the clinic performed over 50,000 procedures between March 2004 and January 11, 2008. In order to evaluate the completeness of the list, in April of 2008, a list was obtained from one insurance carrier of patients for whom claims were paid.

The completeness of the list was evaluated by comparing a list of insurance claims paid by a large insurer to the patient list provided by the clinic. Names from the insurer's list were compared by a computerized matching to the list provided by the clinic. Any names not found in the initial match were then manually evaluated and matched to the clinic list.

Of 1,621 names of patients for who claims paid by the insurer, 1,302 (80.3%) were found on the clinic list. Using this percentage and the number of patients on the list provided by the clinic, it was estimated that the clinic list should have included 49,254 patients, 9,693 more than provided in the clinic list. This is consistent with estimates made based on the analysis of clinic volume.

Second Mailing

A second mailing was conducted in June of 2008 to provide recommendations to patients of DSEC and to announce the SNHD Hepatitis C Exposure Registry. A process similar to that used in the first mailing was used in the second mailing, with the only notable difference being that the letters were mailed first class to ensure that undeliverable letters would be returned to SNHD. A list of DSEC patients was obtained, and the same address verification process was conducted as described for the first mailing. Enrollment forms, as well as follow-up letters to ECSN patients (appendix D) and notification letters to DSEC patients (appendix D) were mailed to 38,024 ECSN patients and 12,895 DSEC patients. A total of 3,012 letters from this mailing were returned to SNHD (5.9%), including 340 from people who were reported to be deceased.

Part 13

Commercial Laboratory Testing

Methodology

Existing SNHD datasets were analyzed for changes in hepatitis test result reporting, including raw lab reporting logs, compiled datasets of test results, and daily result tracking count logs. Also analyzed was a dataset provided by a commercial laboratory containing the number of relevant tests ordered between February 18, 2008 and May 20, 2008. The number of HIV reports reported by different commercial laboratories for the time period of January through March, 2009 was abstracted from the Evaluation HIV/AIDS Reporting System (the system used by SNHD for the investigation and surveillance of HIV and AIDS cases) to determine local commercial laboratory market share.

For datasets containing records with unique patient identifiers, records were de-duplicated using “The Link King” software (Camelot Consulting, Olympia, WA)¹²⁶ for SAS Version 9 (SAS Institute, Cary, NC).

Data analysis and visualization was performed in Microsoft Excel 2007 (Microsoft Corporation, Redmond, WA).

Daily counts of tests ordered were adjusted using the estimated market share of the commercial laboratory providing the data to determine estimated daily test counts.

Baseline numbers of expected tests ordered were calculated by averaging the daily total of tests ordered from February 18, 2008 through February 27, 2008. The total number of HCV tests ordered was calculated by combining EIA tests, comprehensive hepatitis panels, and acute hepatitis panels. The total number of HBV tests ordered was calculated by combining hepatitis core antibody tests, comprehensive hepatitis panels, and acute hepatitis panels.

Observed test counts and expected tests counts were adjusted by the laboratory’s market share to derive the total number of tests ordered.

Results

For the period of February 28, 2008 through May 20, 2008, in addition to tests that would have been routinely ordered for hepatitis or HIV (background), it is estimated that the following numbers of laboratory tests were ordered in southern Nevada:

- 57,047 tests for HCV infection
- 53,691 tests for HBV infection

- 53,507 tests for HIV infection

Through the period described above, the number of tests ordered continued to exceed the number of expected tests (see Figure 13-1).

For the period of February 28, 2008 through December 31, 2008, SNHD received 2,172 initial positive lab reports in excess of what was expected given the baseline calculated from calendar year 2007. These reports consist of the first time a patient infected with hepatitis C was reported to SNHD. In addition, 12,331 excess positive tests were reported to SNHD as follow-up tests for previously reported individuals. Through the end of 2008, the number of reports continued to exceed the number of expected reports (see Figure 13-2).

Part 14

Hepatitis C Exposure Registry

Methodology

Exposure registry enrollment forms (appendix F) were mailed to approximately 51,000 former patients of ECSN and DSEC. As correct contact information was not available for all clinic patients, registry enrollment forms were also available through the health district's website.

Data provided on exposure registry enrollment forms was entered into a Microsoft Access 2003 database (Microsoft Corp., Redmond, WA) developed for registry data management using a three-step process. First, demographic and risk factor data was entered as provided on the application. Second, procedure dates were entered for patients who submitted verification of their identity. Finally, testing and infection information were entered for all patients who were determined to have a procedure at DSEC or ECSN between March 2004 and January 11, 2008.

Procedure dates were entered using documents provided by the enrollee, clinic-provided patient lists, and lists of patients provided by insurance companies. Exact procedure dates were entered if they could be confirmed by one of the data sources. If the exact procedure date could not be confirmed, the clinic's accession date was entered as an approximate procedure date if it was included on one of the data sources. If the accession date was not available on the data source confirming the patient's procedure (such as the list of patients who had undergone procedures at ECSN, but did not include procedure or accession dates), the best available date from documentation provided by the patient was entered as an approximate procedure date. In situations where it could be verified that the patient had undergone a procedure at the clinic but no date information was available, the patient-reported procedure date was entered as an approximate procedure date.

Reports of the first dates of infection were verified using documents provided by the patient and existing SNHD data sources for hepatitis C infection.

Data for all forms were analyzed in Microsoft Excel 2003 (Microsoft Corp., Redmond, WA) and Statcalc (Centers for Disease Control and Prevention, Atlanta, GA).

Results

Through January 1, 2009, the enrollment form was downloaded 1,297 times from the website, of which 9% were the Spanish-language version of the form.

Through April 1, 2009, a total of 7,605 enrollment forms were submitted to the health district. Of the forms submitted, 5,628 (74.0%) provided documentation necessary to confirm the patient's identity, while 1,977 (26.0%) did not.

Of the patients whose identity could be confirmed, procedure dates were identified for 5,084 (90.3%). Of those with confirmed procedure dates, 3,898 enrollees (69.3%) were identified as having procedures at ECSN, 1,100 enrollees (19.6%) had procedures at DSEC, and 86 enrollees (1.5%) had procedures at both ECSN and DSEC. A graphic depiction of the process is presented in Figure 14-1.

Among patients whose identity could be confirmed, an estimated 8% of ECSN patients and 9% of DSEC patients enrolled in the registry.

All cases reporting infection were confirmed using the case definition as described in Appendix B. In addition to provided documentation, existing SNHD data sources were examined to identify the first date of infection. The first date of identification of infection was recorded as the earliest date on which a specimen was collected that resulted in a positive laboratory finding for HCV infection by any methodology. Unconfirmed infections were those that were reported by the patient without supporting documentation and for whom no existing SNHD documentation could be identified. The classification of these reported infections is presented in Table 14-1.

The average age of people who submitted enrollment forms was 64 (Range 19-97); for persons with verified identity, the average age was 63, and the average age for persons whose identity could not be confirmed was 66. About one-third of patients 70 years of age or older did not submit information that allowed for the verification of their identity, and were less likely to do so than patients under 70 (RR=1.45, [1.34-1.56], $p<.0000001$).

Over 46% of clinic patients with verified identities provided an email address, and were more likely to do so than patients whose identity could not be verified (RR=1.19, 1.16-1.22, $p<.0000001$). Former clinic patients under 70 years of age with verified identities were more likely to provide an email address than former patients 70 years of age and older (RR=1.72, [1.60, 1.85], $p<.0000001$).

Of the 7,605 forms submitted, 60 were submitted on behalf of a deceased patient, 36 of which had sufficient documentation to verify the identity of the submitter.

Enrollment forms were received from former patients living in 42 states, with Nevada residents comprising 94.8% of enrollees. Of all forms submitted, 89.9% were paper forms mailed out by the health district; the remaining 10.1% were forms that were either picked up at health district locations or were printed from the SNHD website.

Of 310 enrollees reporting having not undergone testing, 40.6% did not report a reason for not being tested. Of those who provided a reason, 32.1% reported not having been notified of their exposure, 15.8% reported that it was not necessary or that they did not feel ill, 11.4% reported cost as a barrier, and 11.4% reported that testing was scheduled but had not been completed (including patients in the window period).

Part 15

Call Center

Methodology

Inbound calls from the general public were transferred to a telephone number that had been previously reserved for public health information requests during events and emergencies. Calls to this number were routed to the Rocky Mountain Poison and Drug Center (RMPDC) in Denver, CO, which serves as the poison control center for the state of Nevada, as well as the states of Colorado, Idaho, Hawaii and Montana. RMPDC also provides call center services for events such as public health emergencies; call center staff have a medical or health background and go through a standardized training program to ensure the accuracy and consistency of information provided to callers.

Upon connecting to the call center, a pre-recorded message was played for callers providing answers to the questions most frequently asked by callers. This message was changed as the response progressed to reflect the most frequently asked questions by callers. This message was also played for persons calling outside the normal hours of call center operation which initially was available from 7:00am through midnight. The hours of the call center were adjusted throughout March, 2008 to reflect the changing demand for information from the public.

Information provided by the call center to the general public came from frequently asked questions (FAQs) developed by SNHD, NSHD and BLC for this event which were provided to RMPDC and entered into the commercial call center software. The FAQ library was updated as needed throughout the response, and the FAQ used by the call center can be found in Appendix G.

The software used to operate the call center tracked basic information about the call, including the date, time of the call, the zip code provided by the caller, and the specific FAQs used to answer questions from the caller. Other than the zip code of the caller, no identifying information was collected or recorded about each call unless the caller was self-reporting an infection. The contact information of persons self-reporting an infection was provided to SNHD on an ongoing basis, although the number of such reports made to SNHD by the call center was not tracked.

Standardized reports of call center activity, including call volume, locations of callers, and the frequency of individual FAQ usage were provided on an ongoing basis throughout the operations of the call center.

Call Center Results

From the activation of the call center at 1pm on February 27, 2008 through the end of October 2008, the call center received 35,391 calls (See Figure 15-1). Of these, 14,912 (42%) spoke with call center staff and 20,479 (58%) only accessed the prerecorded message. Of the callers who spoke with call center staff, 96.6% were from Clark County, 2.7% were from within Nevada but outside Clark County, and 0.6% were from outside Nevada.

Of all calls, 8,651 (24%) were received between the activation of the call center at 1pm on February 27, 2008 and midnight on Saturday, March 1, 2008. An hourly distribution of call volume over the 2-and-a-half days after the activation of the call center is presented in Figure 15-2. An additional 14,652 calls (41%) were received the following week, and over 75% of calls to the call center occurred within 17 days of the activation of the call center. The day with the greatest number of calls was Monday, March 3, 2008, when 4,221 calls were received. The greatest number of calls received in one hour occurred between 1pm and 2pm on Thursday, February 28, 2008, when 510 calls were received.

Anecdotally, call center management reported an increase in the average duration of the calls as the response progressed and that it was a result of callers shifting from mainly asking factual questions to requiring increased counseling and support.

The most frequently utilized FAQs included:

- Which clinic are we talking about? (17% of callers)
- Where can I get tested? (12% of callers)
- When were the known cases exposed? (5% of callers)
- Can you tell me if I'm on the list and should receive a letter? (5% of callers)
- I am uninsured. When can I get tested? (5% of callers)

Part 16

Southern Nevada Health District Outbreak Website

Methodology

Monthly summaries of web page views of the SNHD website were produced from web server logs using Advance Web Statistics 6.9 (Laurent Destailleur, Montigny-le-Bretonneux, France).¹²⁷ Individual files were selected for analysis from the directory on the website used for outbreak-related information and from other related files. Unique page views and the number of times a page or file was the web user's initial page viewed were extracted for the reports for analysis. Data analysis was performed in Microsoft Excel 2007 (Microsoft Inc., Redmond WA).

Internet searches were evaluated using the Google Insights for Search tool (Google Inc, Mountain View, CA)¹²⁸ and Microsoft Excel 2007 (Microsoft Inc., Redmond WA).

SNHD Website Results

From February through December of 2008, there were 116,149 unique views of outbreak-related pages on the SNHD website. The total unique views by month are presented in Figure 16-1.

Of all unique views, 88,344 (76.1%) were hypertext markup language (HTML) page views, and 25,471 (21.9%) were portable document file (PDF) views. Multimedia files accounted for 1,826 (1.6%) of unique page views, including 1,245 (1.1%) video file downloads, 163 (0.1%) audio file downloads. Also included in multimedia file downloads are 418 (0.4%) downloads of the graphic entitled "Unsafe Injection Practices and Disease Transmission" in Adobe Illustrator (AI) and Encapsulated PostScript (EPS) formats.

The most frequently viewed web pages, documents, and media files are listed in Tables 16-1, 16-2, and 16-3, respectively. The most frequently viewed Spanish-language items of all types are presented in Table 16-4.

Google Search Results

At the time of the public announcement, Google was the most popular search engine used on the internet, performing nearly 59% of all internet searches.¹²⁹ In March of 2008, Google identified a 200% increase in website searches for the term "hepatitis", making it the 5th most popular health search in Las Vegas, and a 160% increase in website searches for the term "endoscopy", making it the 7th most popular health search in Las Vegas.¹³⁰ In addition, Las Vegas website searches for "hepatitis C" increased 130%, and website searches for "endoscopy center" increased 90%.

Google health news search volume was above normal for Las Vegas from February 28, 2008 through mid-March, 2008 at a level not reached again through March of 2009. The most frequent health news search for that time period is “endoscopy”, with “endoscopy of Nevada” ranking 4th and “hepatitis” ranking 5th. The search frequency for each of these terms had increased over 4,000% from January of 2008.¹³¹

Part 17

Media

Methodology

SNHD-related media coverage is routinely tracked by the SNHD Public Information Office and generally included reports of local origination and those from national news outlets broadcast or distributed locally. Media coverage related to the investigation and response was identified through logs of interviews conducted with health district staff, stories directly identified in local media, and reports identified by an outside media tracking company. The log identified the date of the report and media outlet, and when appropriate, the times the report was aired. Repeat airings of the same report as part of the same newscast, such as in an early morning news television broadcast, were not individually counted.

Media coverage logs generally did not contain stories that originated locally but were broadcast elsewhere (*e.g.* wire stories), general discussions of the investigation or response (*e.g.* current events or interview shows), or broadcast reports in local markets outside Southern Nevada. Stories published on the websites of media outlets, blogs, or internet discussion forums were not counted for purposes of this report.

As part of the routine duties of the Public Information Office, stories were generally reviewed to evaluate content and accuracy, with staff responding as appropriate to inaccurate reports at the time the problems are identified. For analysis purposes, stories were not reviewed for placement, content, or general tone.

Daily totals of stories in newspapers, on radio, and on television were calculated from a review of routine monthly reports produced by the Public Information Office.

SNHD developed and issued media advisories and releases to local media outlets through fax and by email, as well as posted the releases and advisories on the SNHD website. A list of news releases and media advisories was compiled from the news release section of the SNHD website.¹³²

Results

A total of 2,125 stories were identified for the time period of February 27, 2008 through December 31, 2008. Of these, 474 (22%) were print stories and 1,651 (78%) were broadcast media reports. Monthly counts are reported in Table 17-1.

Print stories were identified in *El Mundo*, *Henderson Home News*, *In Business Las Vegas*, *Labontan Valley News*, *Las Vegas Business Press*, *Las Vegas Review-Journal*, *Las Vegas Sun*, *Los Angeles Times*, *Mojave Daily*

News, Nevada Appeal, New York Times, Reno Gazette-Journal, Summerlin Home News, Summerlin Southwest Home News, and USA Today.

Local broadcast reports were identified from LV1 (Cable Channel 1), KNTV (NBC – Channel 3), KVVU (FOX – Channel 5), KLAS (CBS – Channel 8), KVBC (ABC – Channel 13), KINC (Univision - Channel 15), KVCW (CW - Channel 33), KBLR (Telemundo - Channel 39), KAZA (Azteca América - Channel 63), KNUU (970 AM), KDWN (720 AM), KNPR (88.9 FM). The story was also aired locally as part of several national news programs, including reports on *ABC World News*, *CBS Evening News*, *FOX & Friends*, *All Things Considered* (NPR), and *ABC Radio*.

The greatest number of reports identified on a single day occurred on Friday, March 7, 2008, where 109 were aired or printed. From the day of the public announcement on February 27, 2008, at least one report appeared locally for 67 consecutive days, through May 3, 2008. Of all reports, 30% occurred within two weeks of the announcement, and 57% occurred within one month.

Media Releases

Over the course of the outbreak, SNHD issued eleven News Releases and one Media Advisory. Half of these releases were distributed within one month of the public announcement of the notification. The complete releases are provided in Appendix H.

Part 18

Cost

Methodology

Outbreak-related time expenditure was tracked by individual SNHD offices and submitted with payroll forms for the period of February 1, 2008 through May 9, 2008. Staff time expenditure for periods prior and after this period were estimated by staff members involved in the ongoing investigation and response. Costs include the base pay rate of staff members as well as indirect costs. Costs for non-personnel-related items and temporary staffing were determined from actual charges to SNHD.

The cost to the public health and medical system for the testing of exposed patients was calculated using the Medicare reimbursement rates for general medicine and family practice and the average costs of the specified laboratory testing panel in Southern Nevada. The cost to the public health and medical system for the management of those determined to be infected was calculated using cost estimates from published literature adjusted into 2008 dollars using the medical care component of the consumer price index.^{133,134}

Results

The total cost to SNHD for the outbreak investigation and response was determined to be \$828,369. This includes \$255,605 for staffing. The total breakdown of costs is presented in Table 18-1.

The market-share weighted cost average cost of laboratory testing was calculated to be \$232.79. Laboratory testing for all potentially-exposed patients was estimated to be \$13.8 million, including \$11.1 million for the testing of ECSN patients and \$2.7 million for the testing of DSEC patients.

Some insurance plans and clinics announced that they would not require a physician visit to order a lab test or obtain testing results.^{135,136} Complete information on the requirements for all providers and insurance companies was not available, thus it was not possible to calculate the percentage of patients who visited a doctor for either of these two purposes. The cost of physician office visits for laboratory testing referrals and result reporting was estimated to be approximately \$1 million for each 25% of the patient population who required such visits. If all patients were required to have these visits, the total costs would be approximately \$4 million.

As the decision to treat a person infected with HCV is one that is made on a case-by-case basis, it is not possible to estimate the percentage of patients infected or possibly infected that will undergo treatment. The treatment cost for one patient was estimated to be approximately \$30,000; this includes the direct costs for professional services, laboratory testing, and medications, but does not

include time spent by the patients, lost work, or quality of life issues. If all 115 identified infected patients were treated, the total cost would be approximately \$3.3 million.

Given an average patient age of 56, and a life expectancy at birth in 1950 of 68 years,¹³⁷ patients were assumed to be infected for a total of 12 years. The annual monitoring and management of the 115 HCV-infected patients for these 12 years is estimated to cost \$260,000. About twenty percent of patients are expected to develop cirrhosis, and in patients infected after age 50, cirrhosis develops about ten years after infection.¹³⁸ The treatment of cirrhosis is estimated to cost approximately \$110,000, and the treatment of the two expected cases of hepatocellular carcinoma is estimated to cost approximately \$100,000. The total cost of treatment of the 115 patients does not include complications from cirrhosis or liver transplants, and is estimated at \$460,000.

In total, the cost to the community for laboratory testing for exposed patients, treatment of infected patients, and the SNHD investigation ranged from \$16.3 million to \$21.9 million. These costs do not include costs to other investigating agencies, loss of earnings for those who were infected, or any other costs to the community.

Part 19

Summary of Identified Cases

Case Finding

Several approaches were taken to identify both potential source cases and additional clinic-associated cases of acute hepatitis C or infection with hepatitis C virus:

- Procedure charts from all patients who had procedures at ECSN on July 25, 2007, and September 19, 2007 through September 21, 2007 were reviewed for documentation or indication of prior infection with hepatitis C.
- Recent acute hepatitis C cases reported to OOE were reviewed for reports of endoscopic procedures at ECSN and matched to clinic logs.
- Individual positive laboratory results from commercial laboratories were submitted to SNHD per routine reporting protocols. When sufficient contact information was available, cases reported in March and early April of 2008 were interviewed through a call-center established at SNHD (as described in part 1).
- Names of patients on July 25, 2007 and September 19, 2007 through September 21, 2007 were matched to the OOE hepatitis C lab report registry. Patients with a first positive test result reported after September 2007 were investigated to identify evidence of acute infection.
- A patient exposure registry was developed to solicit information from former clinic patients (as described in part 13)
- Patient self-reports of acute hepatitis C infection made to SNHD were investigated to identify evidence of acute infection.
- ECSN staff were interviewed in regards to their medical history (including prior diagnosis with HCV infection), surgical history, and risk factors for hepatitis, and provided a blood sample for laboratory testing for bloodborne pathogens.

Names of acute hepatitis B cases who were identified in 2006 and 2007 by SNHD and were 50 years of age or older were cross-matched with clinic records.

Newly-identified persons infected with HIV, acute hepatitis B, or acute hepatitis C were questioned about procedures at ECSN or DSEC, as well as matched to the list of known clinic patients.

Names of clinic patients were cross-matched to the list of persons known to be infected with HIV. The records from all matching patients were evaluated for significant risk factors for HIV infection, and persons from whom those risk factors could not be identified were re-interviewed to identify potential sources of infection.

Results

No incident HIV infections could be linked to ECSN, as all patients evaluated either were infected prior to their procedures or reported other significant risk factors for infection.

One acute hepatitis B case was identified as having undergone a procedure prior to the onset of symptoms. The association with the clinic was coincidental, as the onset of symptoms was insufficiently long after the procedure date to be the result of a clinic-acquired infection. No other acute hepatitis B cases were identified to have undergone procedures at the clinic.

A total of eight cases could be directly linked to ECSN.

- One had a procedure on June 7, 2005 and developed acute hepatitis C. The case was not reported by the provider at the time of diagnosis, but was identified through a patient self-report to SNHD.
- One had a procedure on July 25, 2007, developed acute hepatitis C, and was genetically linked to a source patient on that day.
- Six had procedures on September 21, 2007:
 - Five developed acute hepatitis C and were genetically linked to a source patient on that day
 - One did not develop acute hepatitis C and was genetically linked to a source patient on that day

One case was linked to DSEC; the case had a procedure on June 14, 2006, developed acute hepatitis C approximately 6-7 weeks later, and reported no other risk factors

A total of 106 cases have been classified as possibly linked to the clinics, including 101 cases that were possibly linked to ECSN, and 5 cases that were possibly linked to DSEC.

There was insufficient information available to determine the source of infection for 32 patients, each of whom did not develop acute hepatitis C and reported one or more major risk factors for HCV infection.

A total of 130 people were identified who had been infected with HCV prior to their procedure or procedures at the clinic.

Through genetic testing, source patients were identified for patients infected on July 25, 2007 and September 21, 2007. Source patients were not identified for other linked or possibly-linked cases.

A summary of the identified cases is presented in Figure 19-1.

Part 20

Discussion

The 9 linked cases and 106 possibly-linked cases identified during the course of this investigation represent the largest reported outbreak of health care-associated hepatitis C infection in United States history.¹³⁹⁻¹⁴⁰ Of 33 health-care acquired hepatitis C and hepatitis B outbreaks reported between 1998 and 2008 identified in a CDC study,¹⁴¹ the outbreak related to ECSN and DSEC was not only the largest, but resulted in the possible exposure of more patients than the other 32 outbreaks combined. In all, approximately 63,000 patients were potentially exposed to the blood of other patients through unsafe injection practices, resulting in the largest public health notification of its kind in United States history. Based on direct costs to SNHD, estimates of the cost of testing and numbers of persons tested, and the cost of treating infected individuals, the total cost of this outbreak could be as high as between \$16.3 million and \$21.9 million.

Seven HCV infections were genetically linked to infections in two source patients who were infected prior to undergoing procedures at the clinic and reported such infections to ECSN staff in pre-procedural interviews. Despite the relatively high mutation rate of HCV, one case-patient isolate was an exact match to a viral isolate from one of the source patients, and isolates from each of the remaining six patients were at least a 98.6% match to that of the other source patient. Source- and case-patient isolates from both July 25, 2007 and September 21, 2007 formed clusters distinct from each other and distinct from NHANES III patient isolates, further indicating a high degree of relatedness between source and case patients. Given the facts that:

- There is a high degree of relatedness (in some cases an exact match) between viruses isolated from source patients and case patients, and
- The procedures performed on case patients occurred on the same day as the procedures of the source patient to whom the case patient was genetically matched, and
- For each genetically-linked infection, the initiation of the source patient's procedure preceded the initiation of the case patient's procedure, and
- All genetically-matched source and case patients were given injected sedatives, and
- There were no potential sources of infection or common exposures or behaviors identified between any of the source and case patients outside of undergoing procedures at ECSN,

it is evident that all genetically-linked infections occurred as a result of undergoing procedures at ECSN.

Transmission is believed to have occurred through a combination of unsafe injection practices. The reuse of syringes to access vials could have introduced the blood of patients (and any viruses therein) into vials of propofol (see Figure 19-1), and the vials were then reused for subsequent

patients, transmitting any contamination to those patients. The reuse of single-use vials of Propofol for multiple patients was identified through clinic documentation, and was documented to have occurred on the days of known transmission. It was also observed at the time of investigation in January 2008, and was reported by staff members as a common practice of the clinic. The reuse of syringes to access vials of Propofol was observed by investigators in January of 2008, and was described by staff members as a common practice of the clinic at the time of the identified disease transmission.

Transmission of hepatitis through the contamination of medications used for multiple patients has been identified in previous outbreaks and established as theoretically possible through laboratory experimentation.^{142,143,144,145} Experimental studies found that syringes frequently become contaminated with blood “even if only the needle had been in contact with blood”. That same study found that over one-third of the syringes tested became contaminated and concluded that “This high rate of contamination emphasizes the uselessness of [changing needles] to prevent syringe contamination.”¹⁴⁶

The mode of transmission identified in this outbreak has been identified in numerous other outbreaks both within the United States and internationally. A review of over 600 published outbreaks that have been investigated worldwide since 1992 identified unsafe injection practices as the vehicle of transmission in most of those outbreaks.¹⁴⁷ Even subsequent to the announcement of the exposure in Southern Nevada in February of 2008 and subsequent national media coverage, similar exposures continue to occur.^{148,149}

Safe injection practices have been well-established as well as widely publicized. CDC guidelines recommend the use of “a sterile, single-use, disposable needle and syringe for each injection given”.^{150,151} The American Society of Anesthesiologists recommends that “sterile needles and syringes should always be used to aspirate the contents of an ampoule or vial”¹⁵². Guidelines from the American Association of Nurse Anesthetists state “Do not reuse needles and syringes. Once used, all needles and syringes are contaminated. They are single-use items”.¹⁵³ In addition, these safe injection practices have been described as being common sense practices by CDC officials¹⁵⁴, politicians,¹⁵⁵ and in scientific publications.^{156,157,158} Propofol (marketed under the trade name Diprivan™) has been approved by the FDA, and is labeled for, single use. Although it can be argued that “single use” means used in one set time period (even for multiple patients) and not stored for later use, product labeling approved by the FDA in 2001 states that “Diprivan Injectable Emulsion should be prepared for single-patient use only. Any unused portions of Diprivan Injectable Emulsion... must be discarded at the end of the anesthetic procedure or at 6 hours, whichever occurs sooner.”¹⁵⁹ Thus, the product labeling clearly states that the vial is to be used for a single patient and that any leftover medication must be discarded and cannot be used for subsequent patients.

As the infections occurred in patients who had procedures in two procedure rooms, it was necessary for the contaminated propofol vial or syringe to move from the room where the contamination occurred to the second procedure room. Movement of the CRNAs between rooms provided ample opportunity for this to happen, as vials or pre-filled syringes could have moved between rooms. According to clinic documentation, there was movement of the CRNAs between the two rooms around the time of the source patient’s procedure and prior to the second group of patients becoming infected (starting about two hours after the source patient’s procedure).

As the minimum total amount of propofol needed to infect all patients was 280mg, it is possible that additional contaminated vials were unnecessary to transmit infection, and that each patient received an injection from the initially-contaminated 500mg vial.

In addition to infection from a single vial, the contamination could have been spread to other vials, which then could have been used to infect patients. If a syringe drawn from the initially-contaminated vial was reused to draw a second dose for a patient from a new vial, the contamination would have passed into the new vial. This process could have continued over the course of the day, contaminating multiple vials in succession (see Figure 19-2). Given the observed practices of pre-filling syringes and storing previously-used vials on the anesthesia table for later use, injections from this single vial could have been spread out over a several hour period. These practices also increased the likelihood of the contamination of additional vials, and may have resulted in the contamination of multiple vials directly from the initially-contaminated vial. The result of either method of contamination would have been the presence of multiple sources of contaminated propofol in the clinic.

Each contamination would have resulted in a dilution of the contamination and a decreased, but not eliminated, risk of infection given the same exposure. As the viral load of the source patients and the amount of blood resulting in the initial contamination are unknown, it is not possible to calculate the concentration of virus or the effect of the dilution.

The pre-filling of syringes and contamination of additional vials would have allowed the contamination to remain in the clinic for several hours; this would have been unnecessary for transmission to occur on July 25, 2007, as only one patient was infected, and infection was transmitted less than 90 minutes after the contamination occurred. Laboratory experiments have indicated that HCV can survive on environmental surfaces for at least 16 hours, and in propofol for at least two hours (the study did not test the viability of HCV for more than two hours), sufficiently long for transmission to occur in this setting.¹⁶⁰

The unsafe injection practices utilized in the clinic clearly allowed for the contamination of the propofol vials used in the clinic, and those same unsafe injection practices provided multiple opportunities to transmit the infection from contaminated vials to clinic patients.

Other possible modes of transmission were examined and ruled out, including the reprocessing or reuse of the endoscopes, the use or reuse of biopsy equipment, reuse of disposable equipment (such as bite blocks), staff-to-patient transmission, and the IV placement process (see Table 19-1).

Although a problem of the reuse of detergent in the reprocessing of endoscopes was identified, this problem was not thought to pose a risk for disease transmission between patients; the endoscopes were cleaned with a brush, and the rest of the cleaning process was sufficient to sanitize the equipment.¹⁶¹ In addition, no infected patients had procedures performed with the same endoscope as the source patient.

Staff-to-patient transmission of hepatitis had been reported in previous outbreaks, although this type of transmissions has typically been the result of drug diversion by a staff member.¹⁶² Propofol abuse by healthcare professionals has been reported, although the phenomenon has not been as widely reported as narcotic abuse.¹⁶³⁻¹⁶⁴ In this outbreak, staff-to-patient transmission was ruled out, as no

staff members were identified as being infected with HCV, and genetic testing identified that the case patients were infected with the same virus as the source patient on both July 25, 2007 and September 21, 2007.

The placement of IVs was considered as a possible mode of transmission, as injection practices in general were considered possible sources of disease transmission during the field investigation. In addition, contamination of multi-dose saline vials had been identified in previous outbreaks.¹⁶⁵

Disease transmission through the contamination of multi-dose saline vials in the clinic is not consistent with investigative findings, including reports by staff members and clinic documentation. In the IV preparation room, clinic staff were observed (and reported as common practice) to flush the IV a single time after placement. As the saline vial would not have been accessed a second time, the vial would not have been contaminated through the reuse of a syringe to access the saline.

In addition, disease transmission through contaminated multi-dose saline vials in the IV preparation room could be ruled out for the patient infected on July 25, 2007. The source patient on July 25, 2007 was the first patient of the day, and had an IV placed by CRNA 4 in the procedure room. Clinic staff stated that CRNAs frequently placed IVs for the first patient of the day in the procedure rooms. The infected patient had an IV placed by RN 1, which would have occurred prior to the procedure in the IV placement room. As the source patient on July 25, 2007 did not have an IV placed in the IV preparation room, contamination of the multi-dose saline vial in the IV preparation room could not have occurred, and disease transmission could not have been the result of this contamination.

In contrast, CRNAs admitted to using unsafe injection practices, reported being instructed to use such practices, and were observed doing so. During the investigation, CRNA 1 was observed performing injections in an unsafe manner, and CRNA 4 reported using similar practices to investigators. These CRNAs were the same CRNAs that were working at the clinic on September 21, 2007, the day on which the largest cluster of cases had procedures. In addition, CRNA 4 performed the procedures on both the source patient and the infected patient on July 25, 2007.

The decision to notify patients was based on the identification of unsafe injection practices at ECSN. The identification of the outbreak at ECSN led to the discovery of the unsafe injection practices, and confirmed that the practices were considered a “Category A” infection control breach.¹⁶⁶ A “Category A” infection control breach is defined by CDC as “gross mistakes in infection control practices, typically with identifiable risk”, which includes “reuse of contaminated syringes to access multi-dose medication vials or intravenous fluid bags”. For “Category A” infection control breaches, CDC advises that “patient notification and testing is warranted” and that “an identifiable or significant risk of bloodborne pathogen transmission exists and should be considered to outweigh the potential harms of patient notification and testing”.¹⁶⁷

In this situation, early medical treatment and management is known to provide significant survival benefit to persons infected with HIV and HCV.¹⁶⁸⁻¹⁶⁹ As most hepatitis C infections transmitted in this setting were expected to be asymptomatic, laboratory screening was necessary to identify infected patients. This screening could only be achieved through notification and subsequent laboratory testing of the exposed patients.

The time period chosen for notification corresponded to the time period for which the practices were known to be occurring. The unsafe injection practices were identified by investigators and

reported to the clinic on Friday, January 11, 2008, with the clinic's corrective actions that day marking the end of the exposure period for patients. Numerous clinic staff and administrators repeatedly stated that clinic procedures had not significantly changed since March of 2004, when the clinic underwent a remodeling and expansion. Although the unsafe injection practices may have occurred prior to this date, it was not possible to make this determination based on the clinic records.

The preferred approach to patient notification was a direct, individual notification of former clinic patients through letters mailed directly to each patient. However, a complete individual notification through mailed letters was not possible because of an incomplete patient list provided by the clinic. Because of missing data elements in the list provided by the clinic, the completeness and accuracy of the list could not be determined at the time the list was provided to SNHD, although initial estimates that approximately 10,000 patients were left off the list of ECSN patients were later confirmed.

Prior to mailing, addresses were updated to include any changes of address in the National Change of Address database maintained by the United States Postal Service. Through this system, a number of addresses on the list were determined to be undeliverable, further emphasizing the need for an announcement through the media.

Given the incompleteness of the list and that many addresses were found to be undeliverable, it became necessary to use the media to reach patients who could not be contacted by direct mail in order to encourage those patients to undergo laboratory testing. SNHD disagreed with the clinic management's assessment 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 and should be preferred rather than general public media notification."¹⁷⁰

A news conference was held concurrently with the mailing of letters as a means of contacting patients for whom home address information was not available, providing additional information to the public and emphasizing the importance of testing for those who had received letters. It was also expected that a mailing of this size would be quickly reported to the media, and a news conference allowed for better management of the resulting media inquiries.

Media coverage of the event was significant in southern Nevada; stories related to the outbreak and subsequent events received ongoing media coverage through May, 2009.¹⁷¹ The hepatitis C outbreak was named the top story of 2008 by the *Las Vegas Review-Journal*, ahead of the economy, the presidential election, and O.J. Simpson's trial.¹⁷² This sustained level of media attention represents the highest possible level of success in using the media to deliver testing recommendations to exposed individuals for whom contact information was not available, and for emphasizing the importance of testing for all clinic patients. In addition to media coverage, widespread television advertising by attorneys brought additional attention to the event.¹⁷³

The level of media coverage, however, does not necessarily correlate with the level of interest on the part of the public and the success of SNHD in contacting exposed individuals. Analysis of internet and news searches through Google for disease- and outbreak-related information increased, indicating an increased level of interest on the part of the public. Data provided by Google are only provided as relative changes, not absolute searches, making it impossible to determine numbers of persons that searched for outbreak-related information.

The SNHD website developed for this event received over 115,000 page views. Although the page viewed most frequently on the SNHD website related to the outbreak was the main outbreak page, roughly half the SNHD website page views were for pages with specialized content. The graphic developed to explain the transmission of disease was the second most viewed item on the SNHD website, with over 6,000 views. The graphic developed by SNHD was based on a graphic produced by the New York Times to describe an outbreak in Nassau County, NY,¹⁷⁴ and has been used in a number of publications and presentations by numerous groups and government agencies outside SNHD to explain the mode of transmission.¹⁷⁵⁻¹⁷⁶⁻¹⁷⁷⁻¹⁷⁸⁻¹⁷⁹⁻¹⁸⁰⁻¹⁸¹⁻¹⁸²

Similar to data collected for the website, the total number of calls to the call center does not represent individuals; one person may have made multiple calls to the call center, and no information was routinely collected that would allow for the identification of individual callers. The number of calls received was much greater than expected based on the experience of other jurisdictions that had made similar announcements. Other jurisdictions reported receiving roughly one call per six exposed patients; in Southern Nevada, the call center received over one call per two exposed patients.

In speaking with the public and the media about the prevalence of HCV infection in the community, the high end estimate of 3.3% was rounded up to 4%. As many of the patients referred to ECSN came from GCN, and GCN was a group of clinics specializing in gastrointestinal disease such as hepatitis C, the use of this slightly-higher estimate was utilized to account for this potential referral bias, as well as to emphasize the frequency with which this disease is identified in the community.

The goal of the notification was to ensure that former clinic patients be tested for HIV, HBV, and HCV. Nevada disease reporting requirements do not require the reporting of negative test results for hepatitis or HIV, and thus a list of all persons tested could not be developed.¹⁸³⁻¹⁸⁴ Because the list of patients provided by the clinic was incomplete, and the date of birth was not provided for any of the patients on the list (which was necessary to match lab results to the patient list), it would not be possible to determine the testing rate among clinic patients if negative results were provided to SNHD.

Information provided by commercial laboratories allowed for the estimation of the total number of tests performed in Southern Nevada. However, the number of tests ordered cannot be used to determine the testing rate among former clinic patients as it is not limited to clinic patients and may include multiple tests performed on an individual. The group of patients being tested was known to include clinic patients, family members or spouses of clinic patients, and persons with chronic hepatitis C being tested as part of their disease management, and likely included the “worried well” and persons who had other (unrelated) risk factors for hepatitis infection.

Barriers to testing were identified through the patient exposure registry, although the proportion of barriers reported by registry enrollees may not be representative of the overall clinic population. However, the reasons given for not being tested are likely to encompass the reasons given by the clinic population as a whole.

Given the number of letters sent, the media coverage in the community, internet traffic, and the number of laboratory tests conducted in Southern Nevada, the public notification is considered to be largely successful in attaining the goal of ensuring that former clinic patients were screened for hepatitis and HIV infections.

Although cost was cited as a barrier to testing, it is unclear if the cost of testing was an actual barrier to testing or a perceived barrier to testing. A number of community resources were made available to patients to ensure that cost was not a barrier to testing, including free testing offered by one commercial laboratory,¹⁸⁵ free testing offered by a community health center,¹⁸⁶ and streamlining the referral and testing process or the waiving of fees for insured patients.¹⁸⁷⁻¹⁸⁸⁻¹⁸⁹⁻¹⁹⁰ A foundation announced by the Endoscopy Center of Southern Nevada to cover the cost of testing for the uninsured never materialized,¹⁹¹ although a portion of fines paid by the clinic to the City of Las Vegas were used to support long-term testing and treatment of infected clinic patients.¹⁹²

A total of 9 linked cases and 106 possibly-linked cases have been associated with procedures at ECSN and DSEC, including seven infections that were genetically linked to source patients and two additional acute infections. For the 106 patients classified as having a possibly-linked infection, the clinic's role as the source of the patient's infection cannot be confirmed, as other sources of infection cannot be conclusively ruled out. Although these patients did not report any major risk factors for hepatitis C infection, minor or unknown risk factors may still be present and may be the actual source of the patient's infection.

A total of 130 unrelated HCV infections (*i.e.* persons who were infected prior to their procedures at the clinic) were identified in clinic patients. An additional 32 patients were identified as having been infected, although given self-reported risk factors for hepatitis C infection, the source of their infections could not be determined.

Given the estimated background prevalence of hepatitis C in the clinic population, and the number of patients who had procedures at the clinics, between 945 and 2,079 background (*i.e.* not outbreak-acquired) infections were expected in the patient population. The number of identified cases was significantly less than the expected cases for several reasons. First, although additional positive laboratory findings may have been reported to SNHD, problems with the list provided by the clinic (described in Part 12) limited the ability of investigators to identify former clinic patients. Second, persons with known chronic hepatitis C infection would have been less likely to be tested for hepatitis C infection than hepatitis B or HIV infection, as they were already known to be positive. Some attorneys were advising their clients (including those who would be classified as unrelated cases) not to cooperate with the health district.¹⁹³ Finally, fewer than 15% of former clinic patients enrolled in the exposure registry, and as such, the infection status of the majority of former clinic patients is unknown.

The identification of infected patients was largely based on attempted follow-up of positive laboratory results reported to SNHD, patient self-reports, and evaluation of patients' self-reported risk factors. The limitations with the list provided by the clinic described previously in this section limited the ability of investigators to identify and contact former clinic patients, as the date of birth could not be used to cross-match information sources. Given that the names of 10,000 patients were not on the list provided by the clinic, it is likely that hepatitis C positive laboratory results were received by SNHD but were not identified as occurring in clinic patients. As a result, follow-up on positive laboratory results underestimated the true number of infected patients.

The evaluation of patient risk factors was necessary for the differentiation of patients who likely acquired their disease while undergoing procedures at ECSN or DSEC from those who were likely

infected elsewhere. For patients with acute disease, a six-month period prior to the onset of symptoms (the maximum incubation period) could be evaluated. However, given that an infection may have remained undetected for decades, it was necessary to evaluate lifetime risk factors for HCV infection for non-acutely-infected patients. Some non-acutely-ill patients were identified as having been infected prior to undergoing procedures at the clinic, and thus their infections could be clearly identified as being unrelated to the clinic. Non-acutely-ill patients without evidence of infection prior to their procedures who reported risk factors were classified as having an HCV infection of indeterminate origin, and were classified as such because infection from another source at some point in the patient's life could not be ruled out. However, for cases classified as being of indeterminate origin, the presence of other risk factors did not rule out the possibility of acquiring an infection during the procedure, but the relatedness of their infection to procedures at the clinic could not be determined because of the presence of these risk factors.

Self-underreporting and self-overreporting of sexual behaviors and drug use has been a limitation identified in numerous studies, although the degree to which this occurs varies widely by situation.^{194,195} The degree to which this occurred in the clinic population in this outbreak cannot be determined as there was no mechanism of validating self-reports. Recall bias may also be a factor in registry enrollees who received blood transfusion or clotting factors decades earlier, leading to an underreporting of these factors. In addition, it was assumed that risk factors would generally be under-reported in the registry enrollee population because of potential civil litigation against the clinic. The likely result of the bias in self-reporting would be a possible misclassification of patient infections.

Enrollment in the SNHD patient exposure registry was voluntary, and it was expected that infected patients would be more likely to enroll than non-infected patients, resulting in an over-reporting of cases but a better enumeration of those who were infected. As some attorneys involved in civil litigation encouraged their clients not to respond to SNHD, patients who were potentially infected during procedures at ECSN and DSEC did not enroll in the registry, and thus are unknown to SNHD.¹⁹⁶ As a result, infected patients, including those with infections prior to procedures and those with other significant risk factors, were underrepresented in registry enrollees, resulting in the underreporting of cases to SNHD.

Given the registry response rate, challenges in identifying clinic patients who had tested positive, and the effect of bias on the classification of cases, the 115 cases identified in this outbreak most likely represent an underestimation of the true number of persons infected during procedures at ECSN or DSEC.

Several items were identified during the course of the investigation that could not be explained by investigators, although finding a reason or cause for these issues was not a focus of the public health investigation. These issues include:

- A statistically-significant lower rate of biopsy in patients referred to the clinic by the US Department of Veterans Affairs that cannot be explained by differences in the protocols or procedures used by the clinic
- Inconsistencies between the number of pieces of disposable biopsy equipment ordered and the number of biopsies that were performed in 2007, despite administration denying the reuse of biopsy equipment and staff members reporting that the clinic had discontinued the reuse of some disposable equipment in early- or mid- 2007

- Inconsistent times recorded throughout the chart, including internal inconsistencies between data points collected by an individual staff member during the procedure
- Incorrect dates on the automated system for September 21, 2007 but not for July 25, 2007
- Documentation created by the CRNAs indicating that CRNAs were performing two procedures simultaneously on September 21, 2007

Additionally, a number of colonoscopies were reported to have been of a short duration, including total procedure times (insertion and withdrawal of the endoscope) recorded on September 21, 2007 of three and four minutes. Given the underlying data quality issues for times recorded on the patient charts, it is not possible to verify the exact duration of procedures. However, the use of times recorded in multiple places on the patient's chart to determine procedure duration, including times recorded by the automated system, appears to be sufficient to provide an approximate total procedure duration and to identify that some colonoscopies were of less than five minutes in duration.

The American Society for Gastrointestinal Endoscopy/American College of Gastroenterology Taskforce on Quality in Endoscopy recommends that the once the endoscope has been inserted to the cecum, the mean time for withdrawal should be at least six minutes, and found that “longer withdrawal times have been demonstrated to improve polyp detection rates, and conversely, rapid withdrawal may miss lesions and reduce the effectiveness of colon cancer prevention by colonoscopy.”¹⁹⁷ This six-minute recommendation is in addition to the insertion time of the colonoscope, which, in a 2006 study was found to average 7.2 ± 4.4 minutes.¹⁹⁸ As it was not the focus of the investigation, patient charts were not systematically reviewed to evaluate the duration or quality of colonoscopies, and the magnitude of this problem or the risk to the health of the public could not be determined. The identification of apparent short-duration procedures raises public health concerns that some procedures may have been insufficient to identify colon cancer in patients undergoing screening.

Conclusion

The prevention of healthcare-acquired infections requires a multi-faceted approach, including training and competency in infection control and safe injection practices, regulation and oversight of outpatient surgical centers, and engineering controls that would provide barriers to unsafe practices.¹⁹⁹⁻²⁰⁰⁻²⁰¹⁻²⁰²⁻²⁰³ Each of the clinic-acquired infections identified in this investigation and 63,000 possible patient exposures were entirely preventable, and would not have occurred if clinic staff had adhered to well-established, safe, and common sense injection practices.

Appendix A

Tables and Figures

Figure 6-1. Procedure Area Layout

Not to scale, not all areas shown

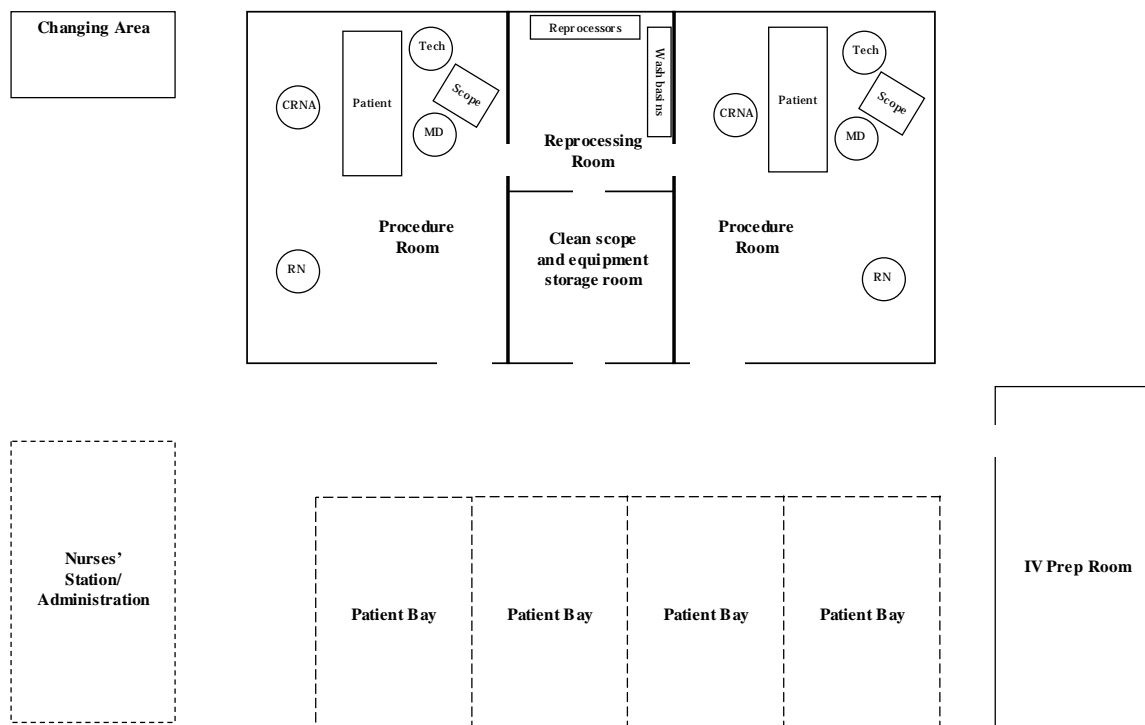


Figure 6-2. Example of Times Recorded on Procedure Charts

All times abstracted from those recorded on procedure charts by ECSN staff or on monitoring equipment for one patient from September 21, 2007

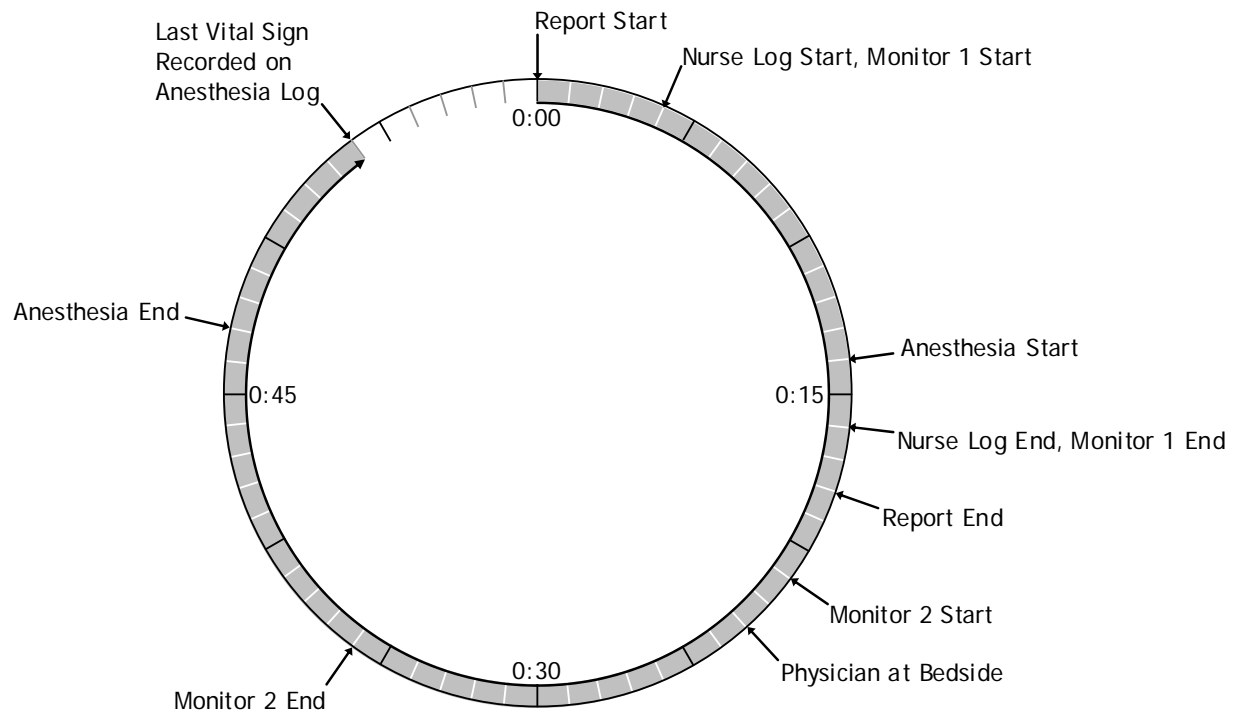


Figure 7-1. September 21, 2007 Recorded Anesthesia Times
All patients, n=63

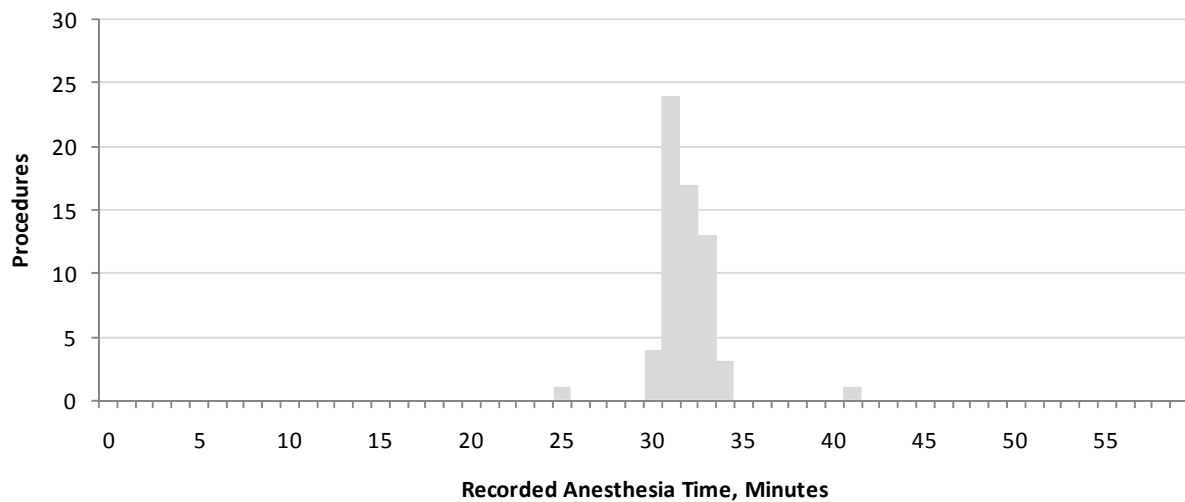


Figure 7-2. September 21, 2007 Procedures by CRNA and Room
All patients, time offset from the beginning of the source patient's procedure

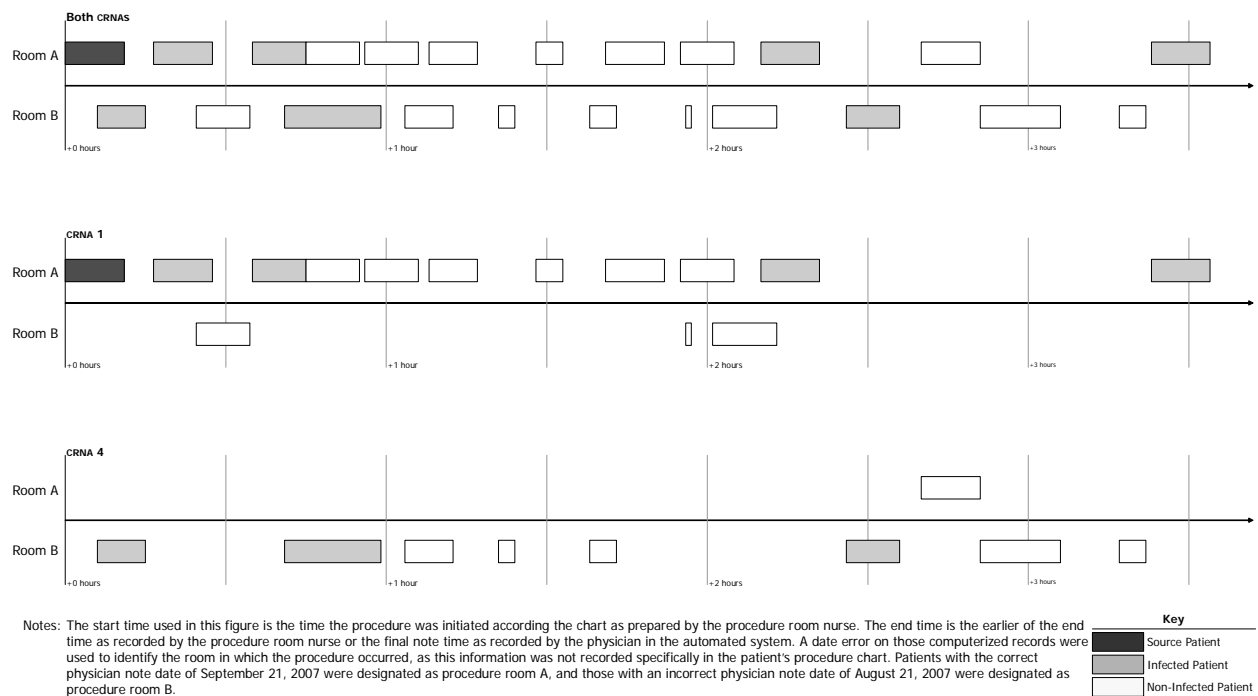


Figure 7-3. September 21, 2007 Procedures by Physician and Room
All patients, time offset from the beginning of the source patient's procedure

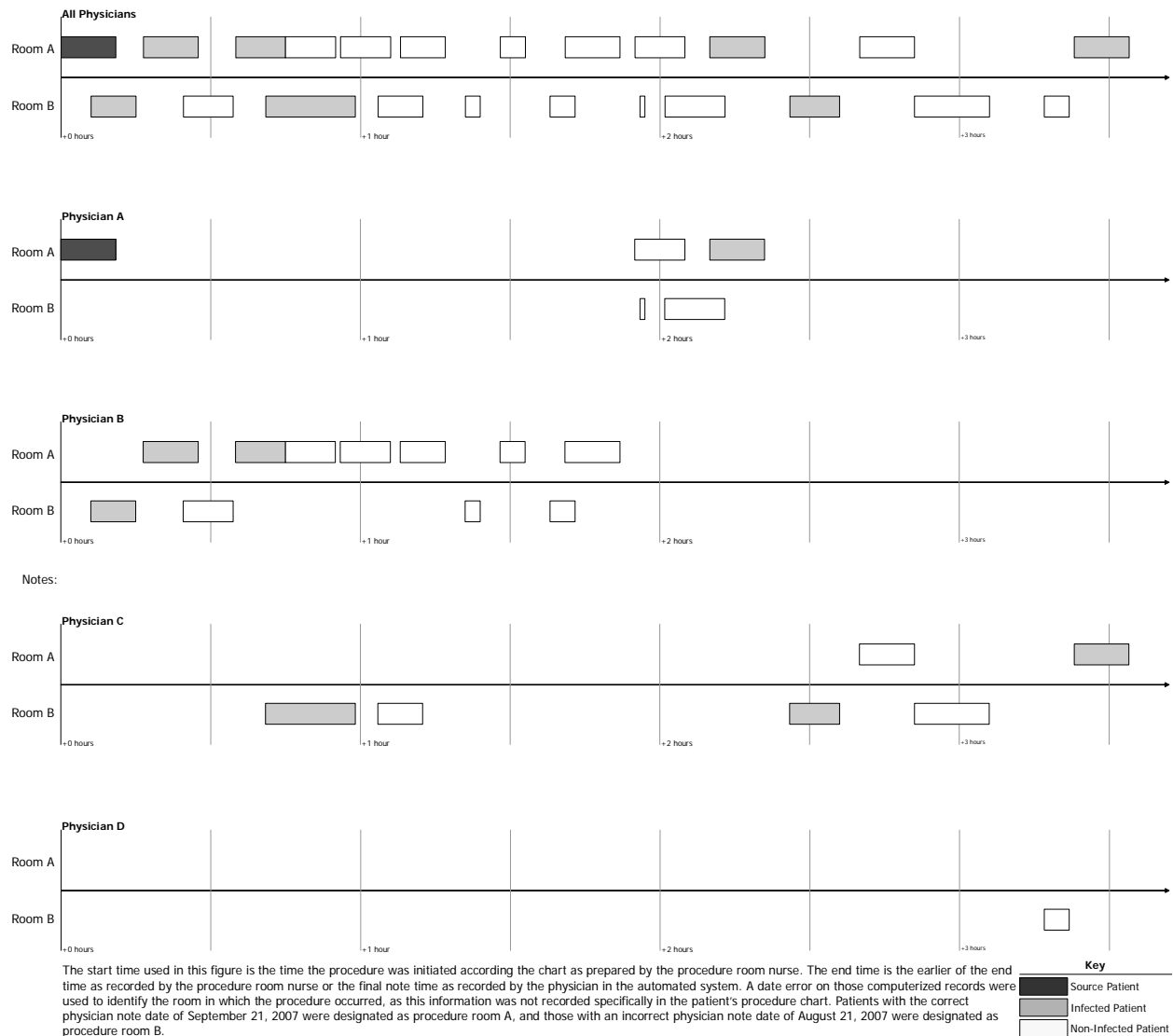


Figure 8-1. Clinic Patient Age Distribution

Based on clinic patients from September 21, 2007, and September 24, 2007 (n=232)

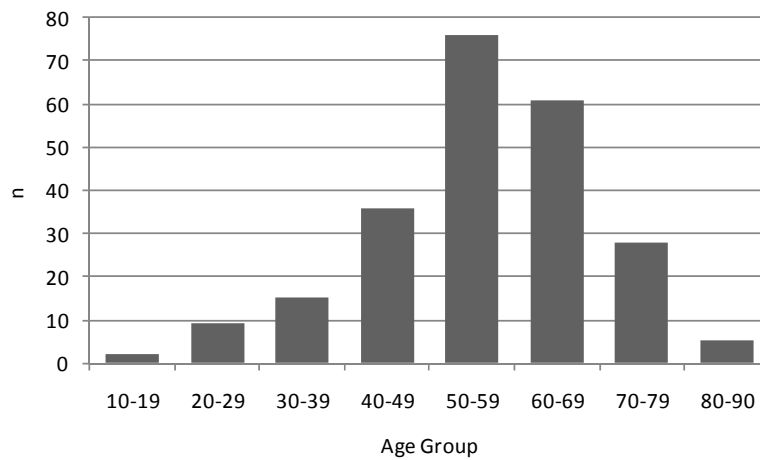


Figure 9-1. Phylogentic Tree, Quasispecies Analysis of Infected Cases

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

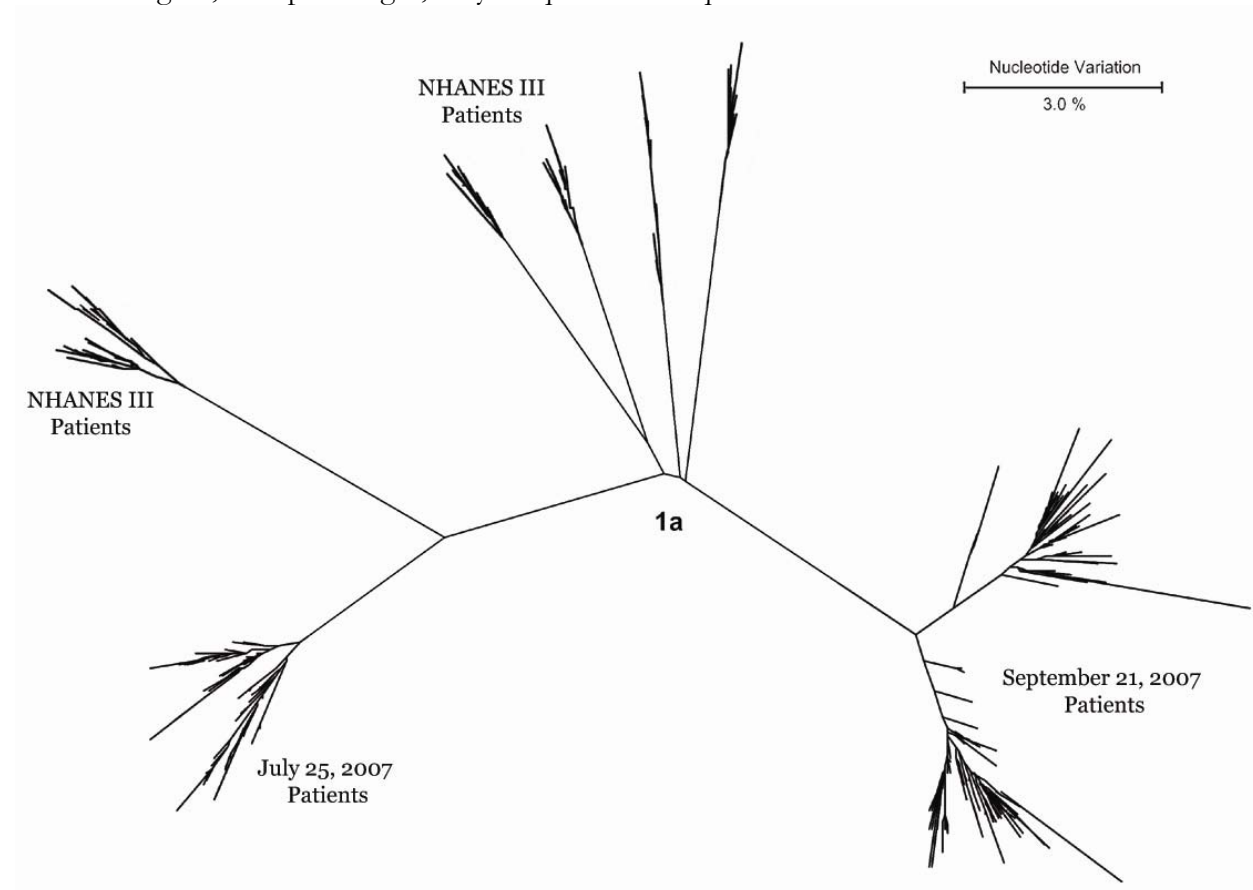


Table 11-1. Outcome of All Calls Made by SNHD Outgoing Call Center

| Category | n |
|--|-------|
| Total calls made | 1,110 |
| Messages left | 404 |
| Patients identified as deceased | 1 |
| Refused interview | 15 |
| Refused interview on advice of counsel | 3 |
| Unsuccessful contacts | 283 |
| Patient contacts | 407 |
| Identity confirmed | 387 |
| Had received results from physician | 342 |
| Were told they were positive | 214 |
| Willing to complete questionnaire | 203 |
| Had procedures at ECSN | 199 |
| Had procedures during the risk period | 178 |

Table 11-2. Classification of Cases Identified by the SNHD Outgoing Call Center

Cases are classified as described in Appendix B

| Category | n |
|--|----|
| Clinic-associated infections | 0 |
| Possible clinic-associated infections | 77 |
| Unrelated infections | 53 |
| Infections of indeterminate origin | 20 |
| Could not be evaluated because of incomplete information | 28 |

Figure 13-1. Laboratory Test Performed: Ratio of Actual Orders to Background Expected, February 24, 2008 Through May 20, 2008

One commercial laboratory, 7-day average of ordered tests vs. background average from February 18, 2008 through February 27, 2008.

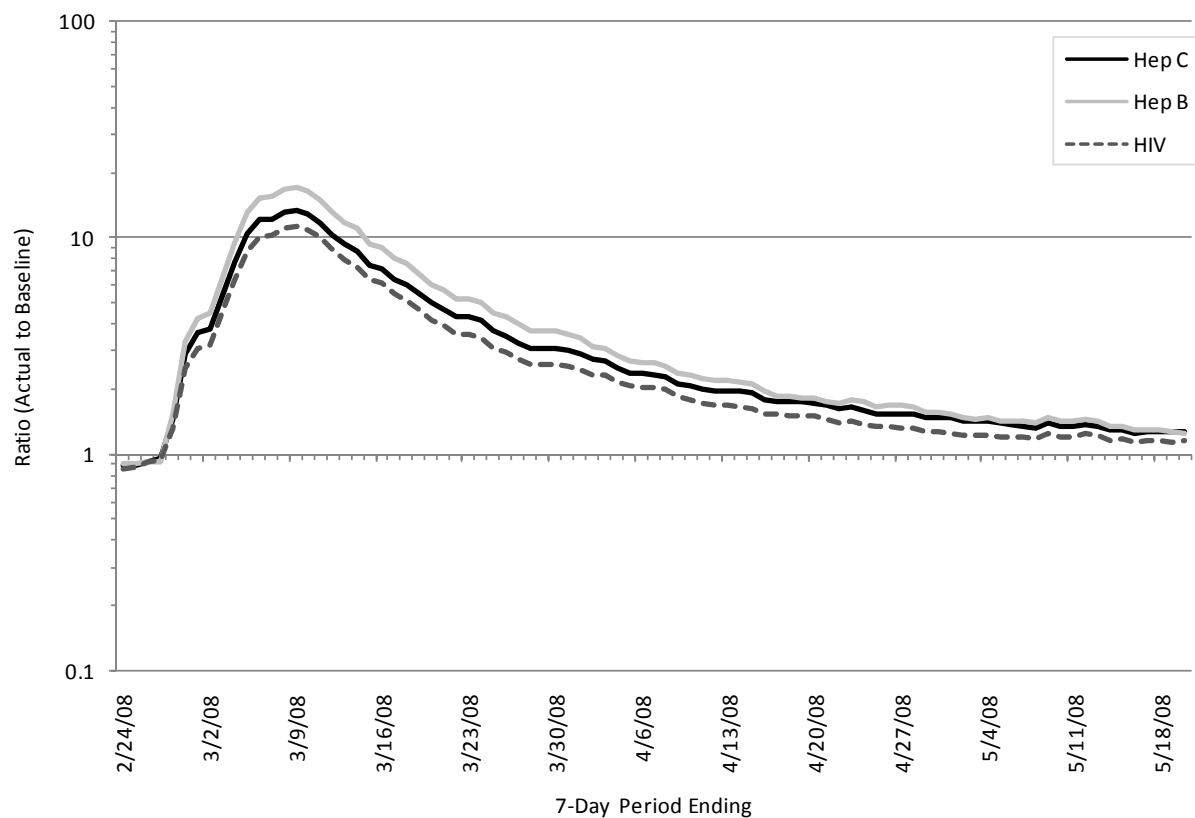


Figure 13-2. Laboratory Positives: Ratio of All Positives to Background Expected, 2007-2008
 All reporting sources, 7-day average of positives reported vs. background average from 2007

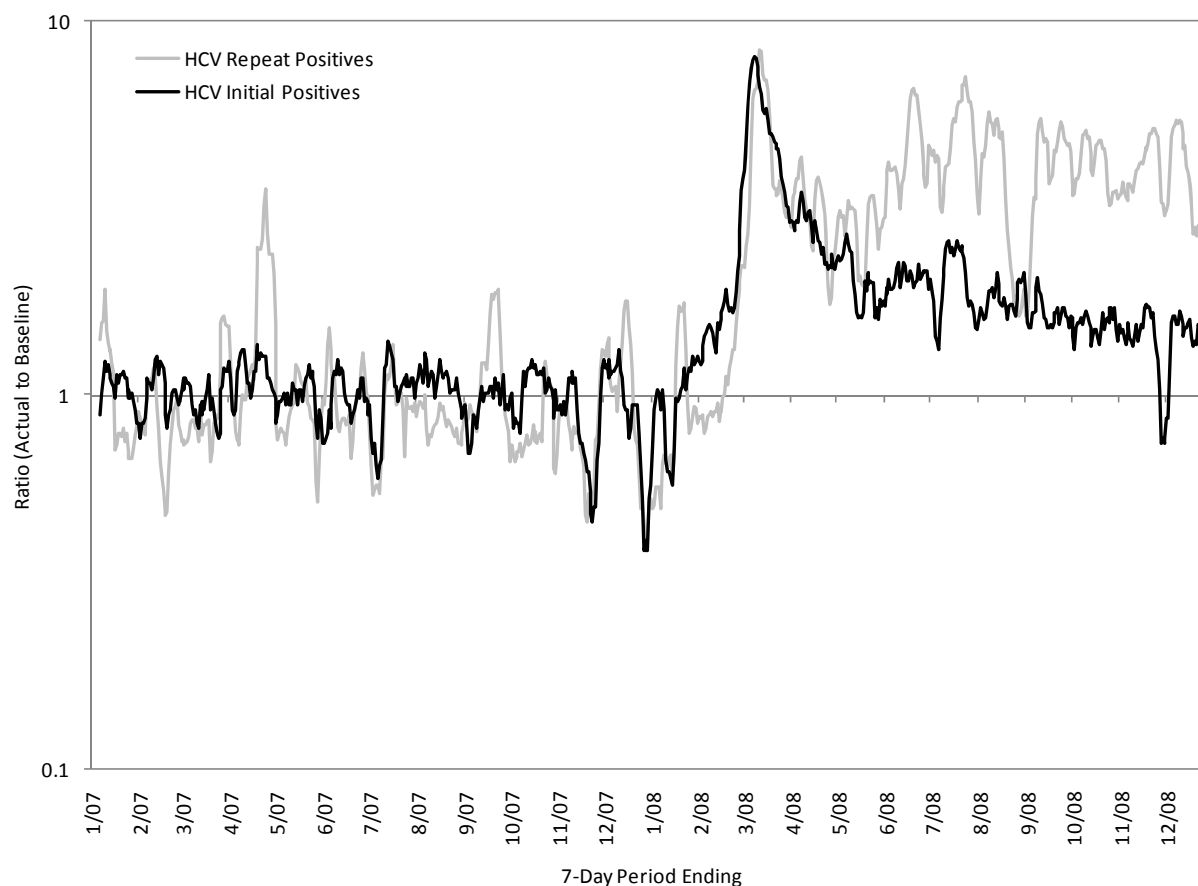


Figure 14-1. Verification of Hepatitis C Exposure Registry Enrollment Forms
Includes all forms submitted prior to April 1, 2009

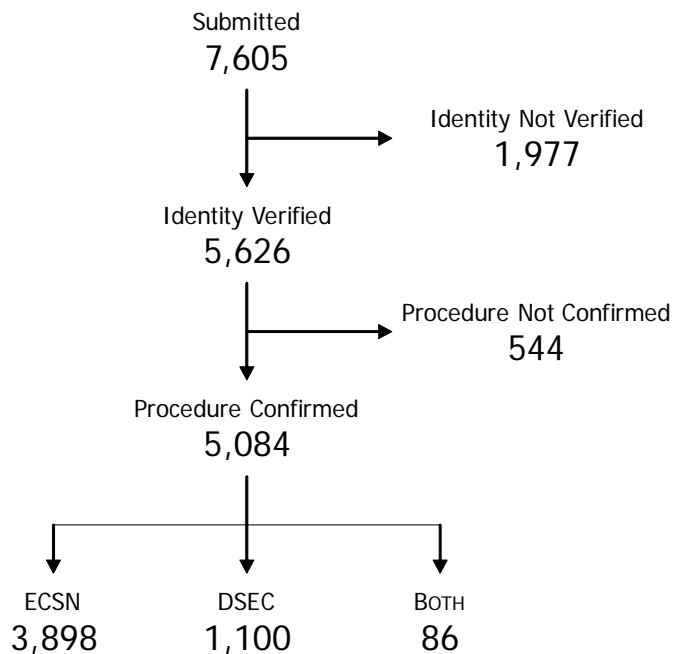


Table 14-1. Classification of Persons Reporting Infection to the Hepatitis C Exposure Registry

Cases are classified as described in Appendix B, with the exception of unconfirmed infection. Unconfirmed infections were those that were reported by the patient without supporting documentation and for whom no existing SNHD documentation could be identified.

| Classification | ECSN | DSEC | Both clinics | Total |
|------------------|------|------|--------------|-------|
| Related | 2 | 0 | 0 | 2 |
| Possibly Related | 31 | 6 | 0 | 37 |
| Unrelated | 24 | 5 | 3 | 32 |
| Indeterminate | 11 | 0 | 0 | 11 |
| Unconfirmed | 20 | 4 | 1 | 25 |

Figure 15-1. Daily Calls to the Call Center, February 24, 2008 through May 10, 2008

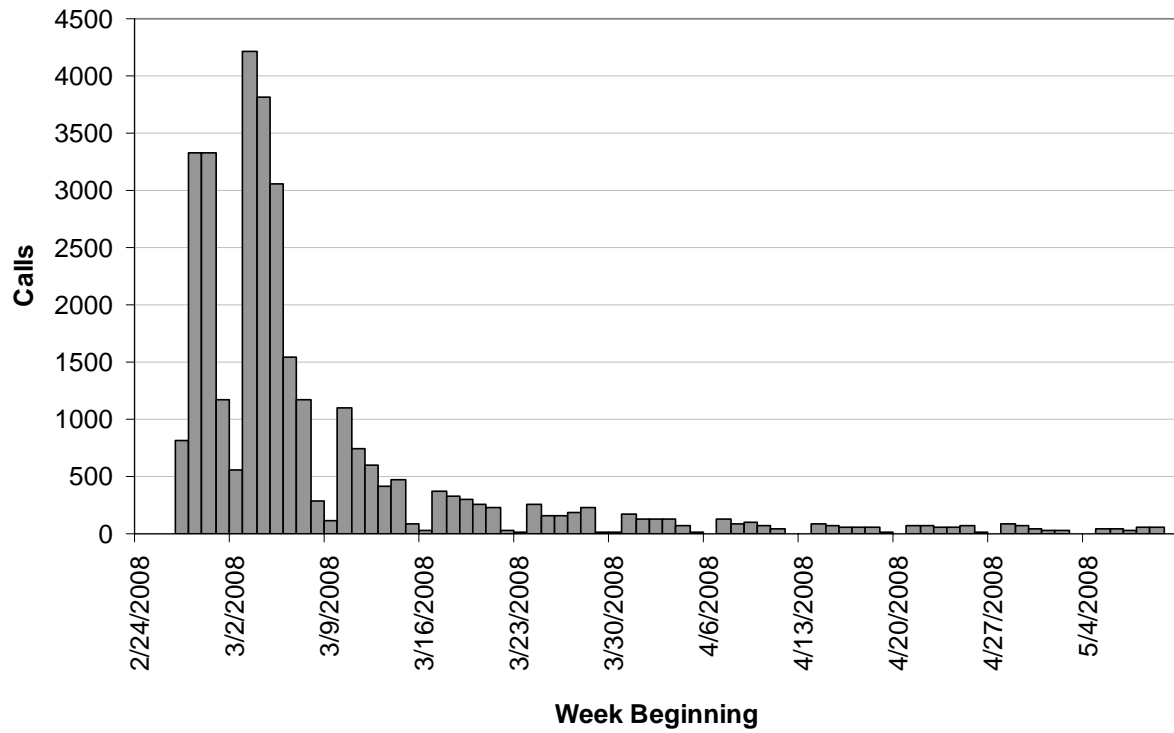


Figure 15-2. Hourly Calls to the Call Center, 14:00 February 27, 2008 through 0:00 March 1, 2008

Times of local television news broadcasts are shaded in the background

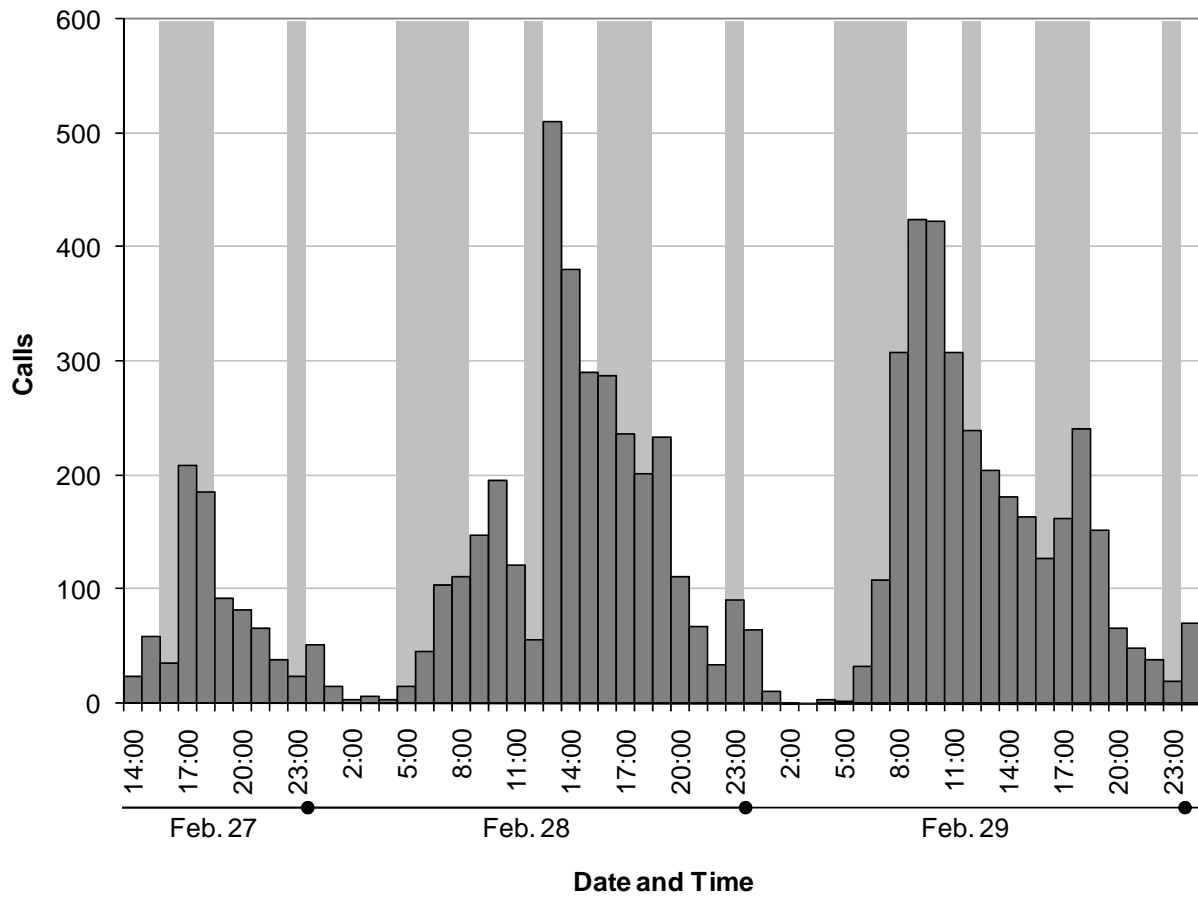


Figure 16-1. Hepatitis C Website Page Views by Month, 2008

Includes all views of SNHD outbreak-related pages.

* Outbreak-related information was only publicly-available for the last 3 days of February

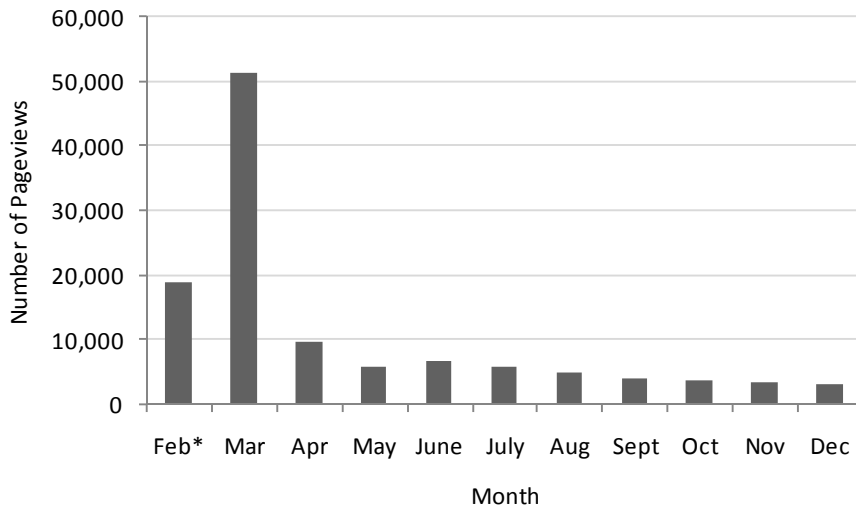


Table 16-1. Hepatitis C Investigation and Response Most Viewed Web Pages

Includes all SNHD outbreak-related web pages, percentage of total page views, and percentage of specific page views for which the page was the viewer's initial page

| Web page | Total Views n (%) | Initial Page n (%) |
|---|----------------------|-----------------------|
| Hepatitis C Investigation Main Page | 57,204 (49.2) | 26,257 (45.9) |
| Hepatitis C Investigation Patient Resources | 6,056 (5.2) | 1,434 (23.7) |
| Hepatitis C Investigation Patient Resources & Clinics | 3,884 (3.3) | 1,489 (38.4) |
| Hepatitis C Factsheet | 3,868 (3.3) | 460 (11.9) |
| Hepatitis C Investigation for Health Care Providers | 3,336 (2.9) | 268 (8.0) |

Table 16-2. Hepatitis C Investigation and Response Most Viewed Documents

Includes all SNHD outbreak-related web pages, percentage of total page views, and percentage of specific page views for which the page was the viewer's initial page

| Document | n (%) | Initial Page n (%) |
|--|-------------|-----------------------|
| Graphics - Unsafe Injection Practices and Disease Transmission | 6,464 (5.6) | 2,420 (37.4) |
| Interim Investigation Report | 2,501 (2.2) | 266 (10.6) |
| Letter to Patients | 2,089 (1.8) | 160 (7.7) |
| Law Enforcement Records Request Form | 2,083 (1.8) | 450 (21.6) |
| February 27, 2008 Physician Technical Bulletin | 1,443 (1.2) | 267 (18.5) |

Table 16-3. Hepatitis C Investigation and Response Most Requested Media Files

Includes all SNHD outbreak-related web pages, percentage of total page views, and percentage of specific page views for which the page was the viewer's initial page

| Document | n (%) | Initial Page n (%) |
|---|-----------|-----------------------|
| Hepatitis C Exposure at a Medical Clinic (Video - English) | 530 (0.5) | 25 (4.7) |
| Hepatitis C Exposure at a Medical Clinic (Video - Spanish) | 97 (0.1) | 2 (2.0) |
| Hepatitis C Exposure at a Medical Clinic (Audio - English) | 89 (0.1) | 21 (23.6) |
| Hepatitis C Exposure at a Medical Clinic (Audio - Spanish) | 74 (0.1) | 14 (18.9) |
| Robert Gish, MD: Overview of Hepatitis C (Video – English) | 76 (0.1) | 7 (10.5) |

Table 16-4. Hepatitis C Investigation and Response Most Viewed Spanish-Language Pages, Documents, and Media Files

Includes all SNHD outbreak-related web pages, percentage of total page views, and percentage of specific page views for which the page was the viewer's initial page

| Document | n (%) | Initial Page n (%) |
|--|-------------|-----------------------|
| Hepatitis B Factsheet | 1,273 (1.1) | 915 (71.9) |
| Hepatitis C Factsheet | 292 (0.3) | 75 (25.7) |
| Patient Letter | 208 (0.2) | 17 (8.2) |
| Exposure Registry Enrollment Form | 115 (0.1) | 54 (47.0) |
| Hepatitis C Exposure at a Medical Clinic Video | 97 (0.1) | 2 (2.0) |

Figure 16-2. Las Vegas Google Health News Search Volume, February-March 2008

Data source: Google Insights for Search

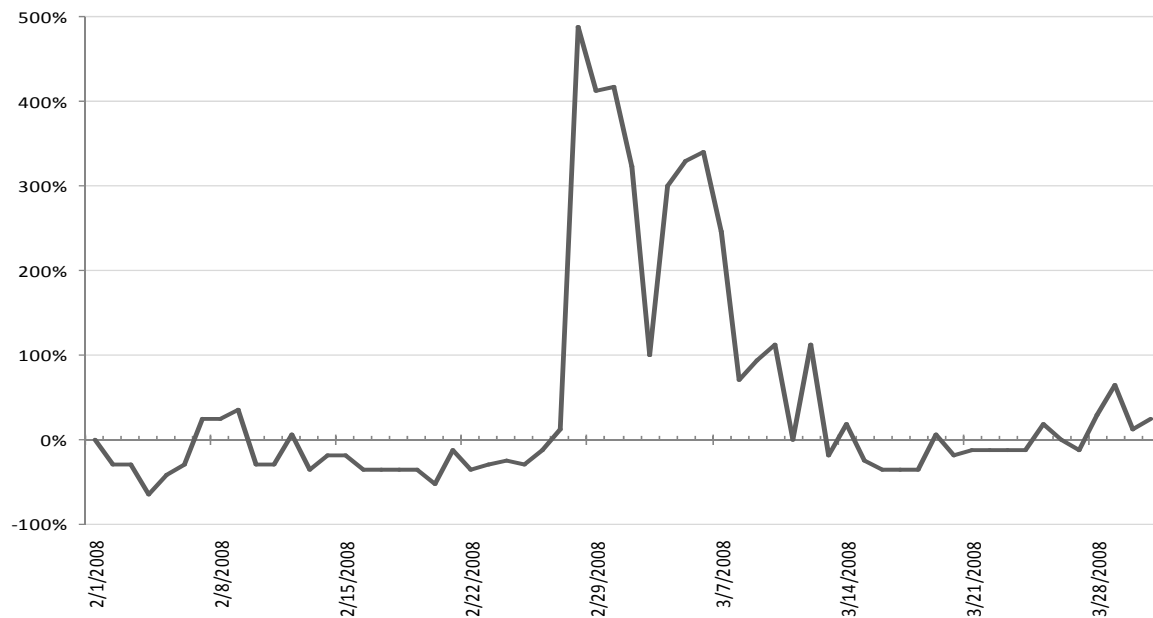


Table 17-1. Hepatitis C Investigation and Response Media Coverage and News Releases by Month, 2008

Includes locally-published or aired stories, national stories aired locally, and news releases issued by the health district

| Month | Stories |
|-----------|---------|
| February | 116 |
| March | 1159 |
| April | 342 |
| May | 172 |
| June | 89 |
| July | 119 |
| August | 20 |
| September | 33 |
| October | 31 |
| November | 7 |
| December | 37 |
| Total | 2125 |

Table 18-1. SNHD Hepatitis C Outbreak Investigation and Response Costs

Actual and estimated costs for all SNHD investigation and response activities, January 2008 through May 2009

| Category | Cost, \$ |
|----------------------------|----------|
| Personnel Regular Time | 215,863 |
| Personnel Overtime | 39,742 |
| Temporary Staffing | 9,324 |
| Printing | 13,355 |
| Postage | 39,767 |
| Laboratory Services | 1,934 |
| Help Line (Call Center) | 253,599 |
| Patient Records Management | 100,000 |
| Legal Services | 154,812 |
| Total | 828,369 |

Table 19-1. Summary of Identified Cases

Includes cases identified by SNHD by all reporting source and systems

| Category | n |
|---|------------|
| Clinic-Associated HCV Infection, Genetically-Linked, ECSN | 7 |
| Clinic-Associated HCV Infection, Not Genetically-Linked, ECSN | 1 |
| Clinic-Associated HCV Infection, Not Genetically-Linked, DSEC | 1 |
| Possible Clinic-Associated HCV Infection, ECSN | 101 |
| Possible Clinic-Associated HCV Infection, DSEC | 5 |
| Total infections linked to procedures at ECSN or DSEC | 115 |
| Unrelated HCV Infection | 130 |
| Indeterminate Infection | 32 |
| Source Patients | 2 |
| ECSN- or DSEC-related HIV Cases | 0 |
| ECSN- or DSEC-related Acute HBV Cases | 0 |

Figure 20-1. Graphical Depiction of the Mode of Contamination

Based on clinic observations and staff interviews. Shading indicates contamination.

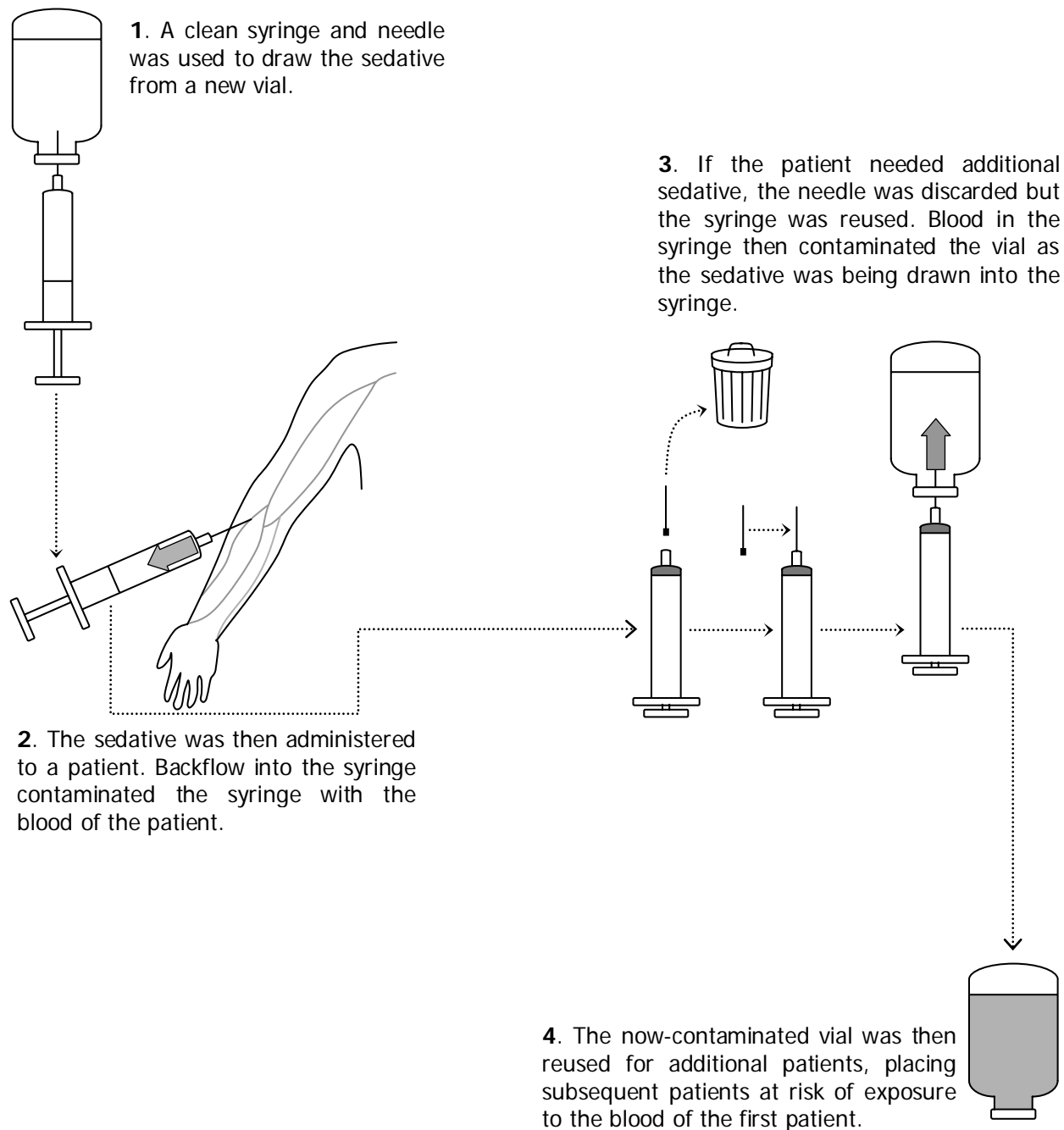
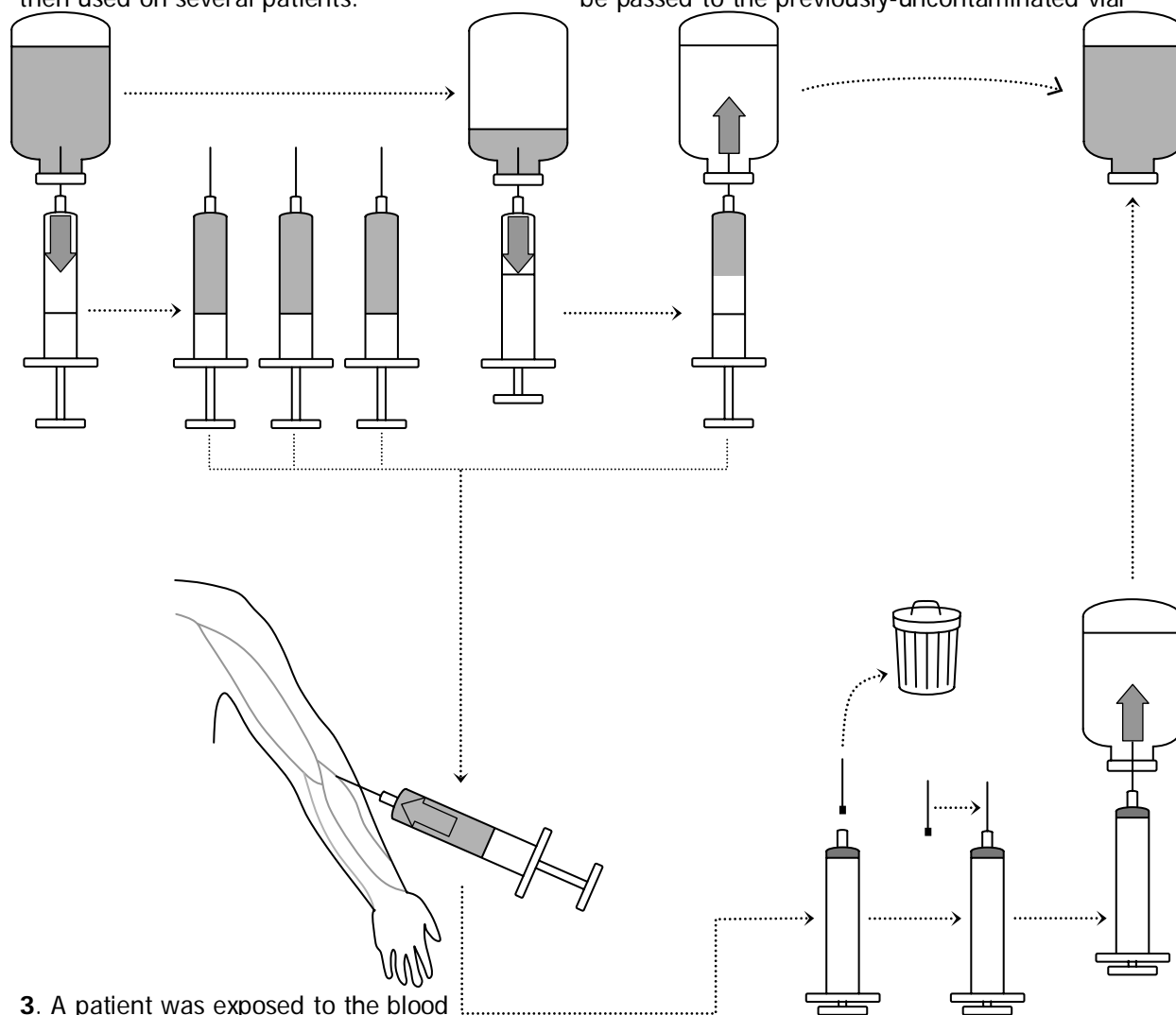


Figure 20-2. Graphical Depiction of the Possible Modes of Patient Exposure and Vial Contamination

Based on clinic observations, staff interviews, and clinic records review. Shading indicates contamination.

1. Several syringes of sedative could be drawn from a vial that had been contaminated and then used on several patients.

2. If a syringe of sedative was pooled from both a contaminated vial and an uncontaminated vial before being administered to a patient, contamination could be passed to the previously-uncontaminated vial



3. A patient was exposed to the blood of another patient during the injection of the contaminated sedative.

4. Syringe reuse (as during the initial contamination) could also pass the contamination to additional vials of sedative.

Table 20-1. Modes of Transmission and Sources of Infection Considered

Patients who were infected on September 21, 2007

| Transmission Mode/Source | Result | Rationale |
|------------------------------|---------------|--|
| Staff-to-Patient | Ruled Out | No staff members were positive for HCV infection, and source patient was identified through genetic testing |
| Provider: Physician | Ruled Out | Patients were treated by three physicians, none of which placed the patient at a statistically significant increased risk of infection |
| Provider: CRNA | Ruled Out | Patients were treated by both CRNAs, neither of which placed the patient at a statistically significant increased risk of infection |
| Provider: Technician | Ruled Out | Several technicians assisted on the procedures, none of which placed the patient at a statistically significant increased risk of infection |
| Biopsy Equipment | Ruled Out | Not all infected patients had a biopsy, and those who had a biopsy were not at a statistically significant increased risk of infection |
| Endoscope | Ruled Out | Five different scopes were used on the infected patients, none of which was the same as the source patient. |
| Procedure Type | Ruled Out | Infected patients had both colonoscopies and EGDs, neither of which placed the patient at a statistically significant increased risk of infection |
| Reuse of Bite Blocks | Ruled Out | Infected patients had both colonoscopies and EGDs (which require bite blocks), and the use of a bite block for a patient did not result in a statistically significant increased risk of infection |
| IV Placement | Ruled Out | Staff were not observed to re-flush heparin-locks, and none reported doing so. Clean needles and syringes were observed to be used for each flush |
| Sedation Injection Practices | Not Ruled Out | CRNAs were observed reusing syringes on one patient, reusing propofol vials for multiple patients, reported being directed to do so, and reported routinely doing so. CRNAs observed or reporting such practices were the same CRNAs responsible for administering anesthesia on September 21, 2007. |

Appendix B

Case Definitions and Case Classification

Over the course of the outbreak, National Notifiable Diseases Surveillance System (NNDSS) case definitions were used to determine the case status of potentially-infected individuals. In addition, a classification scheme was used to evaluate the relatedness of confirmed cases to procedures at the clinic. The definitions described herein are the final definitions used to evaluate the relatedness of identified cases.

Acute Hepatitis C Virus Infection

This case definition for acute hepatitis C virus infection was taken from the NNDSS case definition used in 2008, and is the confirmed case definition for “Hepatitis C Virus Infection, Acute,” last modified in 2007.²⁰⁴

Clinical Case Definition

An acute illness with a discrete onset of any sign or symptom consistent with acute viral hepatitis (e.g., anorexia, abdominal discomfort, nausea, vomiting), *AND EITHER*

- a) jaundice, OR
- b) serum alanine aminotransferase (ALT) levels >400 IU/L

Laboratory Criteria for Diagnosis

One or more of the following three criteria:

1. Antibodies to hepatitis C virus (anti-HCV) screening-test-positive with a signal to cut-off ratio predictive of a true positive as determined for the particular assay as defined by CDC, OR
2. Hepatitis C Virus Recombinant Immunoblot Assay (HCV RIBA) positive, OR
3. Nucleic Acid Test (NAT) for HCV RNA positive

AND, meets the following two criteria:

1. IgM antibody to hepatitis A virus (IgM anti-HAV) negative, *AND*
2. IgM antibody to hepatitis B core antigen (IgM anti-HBc) negative

Confirmed Case Classification

A case that meets the clinical case definition, is laboratory confirmed, and is not known to have chronic hepatitis C

Hepatitis C Virus Infection, Past or Present

This case definition for hepatitis C virus infection, past or present comes from the NNDSS case definition used in 2008, and is the confirmed case definition for “Hepatitis C Virus Infection, Past or Present,” last modified in 2005.²⁰⁵

Laboratory Criteria for Diagnosis

- Anti-HCV positive (repeat reactive) by EIA, verified by an additional more specific assay (e.g. RIBA for anti-HCV or nucleic acid testing for HCV RNA), OR
- HCV RIBA positive, OR
- Nucleic acid test for HCV RNA positive, OR
- Report of HCV genotype, OR
- Anti-HCV screening-test-positive with a signal to cut-off ratio predictive of a true positive as determined for the particular assay as determined and posted by CDC

Confirmed Case Classification

A case that is laboratory confirmed and that does not meet the case definition for acute hepatitis C infection.

Case Classification

Several case classifications were developed to categorize the likelihood of a patient’s infection being acquired at the clinic. The classifications include:

- *Unrelated HCV infection*: a patient who was infected prior to a procedure at the clinic, and therefore was not infected during procedures at the clinic
- *Clinic-associated HCV infection (genetically linked or not genetically-linked)*: a patient who was infected during their procedure at the clinic
- *Possible clinic-associated HCV infection*: a patient who was possibly infected during their procedure at the clinic. Although other major risk factors have been ruled out for patients in this classification, the possibility of an infection from a source other than the clinic cannot be ruled out.
- *Indeterminate infection*: a patient whose source of infection could not be classified

These classifications were restricted to use on patients who were determined to be placed at risk during their procedures based on date on which the procedure was performed. An at-risk patient is one who was potentially exposed to the blood of other patients while undergoing a procedure.

An at-risk patient is defined as a patient who was injected with a sedative during a procedure at:

- The Endoscopy Center of Southern Nevada from March 1, 2004 through January 11, 2008, OR
- The Desert Shadow Endoscopy Center at any time prior to January 30, 2008

For some classifications, a patient’s self-reported risk factors were utilized in the classification process. Significant risk factors are those which pose the greatest risk at the population level of exposure to hepatitis C, including:

- The use of injection drugs not prescribed by a doctor
- The receipt of a blood transfusion before 1992
- The receipt of an organ transplant before 1992

- The receipt of pooled clotting factors before 1987
- Undergoing long-term hemodialysis at any point in the patient's life
- Sexual contact with a person known or suspected to be infected with HCV

Case Classification

Unrelated HCV Infection

An HCV infection in a patient who:

- Meets the criteria for being an at-risk patient, *AND*
- Tested positive for infection with the hepatitis C virus by any testing methodology prior to the date of the procedure which placed the patient at risk

Clinic-Associated HCV Infection, Genetically-Linked

An HCV infection in a patient who:

- Meets the criteria of being an at-risk patient, *AND*
- Is infected with a virus that has been determined to be 95% or greater match through HVR1 sequencing (as described in Part 9) to a virus identified in a patient who:
 - Is classified as having an unrelated infection, *AND*
 - Had a procedure on the same day as the infected patient that started prior to that of the infected patient

Clinic-Associated HCV Infection, Not Genetically-Linked

An HCV infection in a patient who:

- Meets the criteria of being an at-risk patient, *AND*
- Meets the confirmed case definition for acute hepatitis C virus infection, *AND*
- Had the onset of symptoms within six months after the date of the procedure which placed the patient at risk, *AND*
- Reports no significant HCV risk factors in the six months prior to the onset of symptoms, *AND*
- Has not had HVR1 sequencing performed on a viral isolate

Possible Clinic-Associated HCV Infection

An HCV infection in a patient who:

- Meets the criteria of being an at-risk patient, *AND*
- Meets the confirmed case definition for hepatitis C virus infection, past or present, *AND*
- Was not known to be infected with HCV prior to the date of the procedure, *AND*
- Reports no significant risk factors at any point in the patient's life prior to the procedure which placed the patient at risk, *AND*
- Has not had HVR1 sequencing performed on a viral isolate

Indeterminate Infection

An HCV infection in a patient who:

- Meets the criteria of being an at-risk patient, *AND*
- Meets the confirmed case definition for hepatitis C virus infection, past or present, *AND*
- Was not known to be infected with HCV prior to the date of the procedure, *AND*

- Reports no significant risk factors at any point in the patient's life prior to the procedure which placed the patient at risk, *AND*
- Has not had HVR1 sequencing performed on a viral isolate

Appendix C

Acronyms

| | |
|----------|---|
| AI | Adobe Illustrator file |
| AIDS | Acquired Immune Deficiency Syndrome |
| ALT | alanine aminotransferase |
| ANTI-HAV | IgM antibody to hepatitis A virus |
| ANTI-HBc | IgM antibody to hepatitis B core |
| ANTI-HCV | antibody to hepatitis C virus |
| ASC | ambulatory surgical center |
| BLC | Bureau of Licensure and Certification (of the Nevada State Health Division) |
| CDC | Centers for Disease Control and Prevention |
| CFR | Code of Federal Regulations |
| CRNA | Certified Registered Nurse Anesthetist |
| CIA | chemiluminescence immunoassay |
| DIIS | disease investigation and intervention specialist |
| DSEC | Desert Shadow Endoscopy Center |
| ECSN | Endoscopy Center of Southern Nevada |
| EGD | esophagogastroduodenoscopy |
| EIA | enzyme immunoassay |
| E2 | envelope protein 2 (of the hepatitis C virus) |
| EPS | encapsulated PostScript file |
| FAQ | Frequently Asked Questions |
| FDA | Food and Drug Administration |
| GCN | Gastroenterology Center of Nevada |
| HIPAA | Health Insurance Accountability and Portability Act |
| HAV | hepatitis A virus |
| HBV | hepatitis B virus |
| HCV | hepatitis C virus |
| HIV | human immunodeficiency virus |
| HTML | hypertext markup language |
| HVR-1 | hypervariable region one (of the hepatitis C virus envelope protein 2) |
| IgM | immunoglobulin M |
| IU/L | international units per liter |
| IV | intravenous |
| LPN | Licensed Practical Nurse |
| mg | milligrams |

| | |
|------------|--|
| ml | milliliters |
| MRC | minimum recommended concentration |
| NAC | Nevada Administrative Code |
| NANB | non-A, non-B hepatitis |
| NAT | nucleic acid test |
| NCOA | National Change of Address Database |
| NHANES III | Third National Health and Nutrition Examination Survey |
| NNDSS | National Notifiable Diseases Surveillance System |
| NRS | Nevada Revised Statutes |
| NS5B | nonstructural protein 5B (of the hepatitis C virus) |
| NSHD | Nevada State Health Division |
| OOE | Office of Epidemiology |
| PA | Physician Assistant |
| PHI | personal health information |
| RN | Registered Nurse |
| PDF | portable document file |
| RIBA | recombinant immunoblot assays |
| RMPDC | Rocky Mountain Poison and Drug Center |
| RNA | ribonucleic acid |
| RR | relative risk |
| S/CO | signal-to-cutoff ratio |
| SNHD | Southern Nevada Health District |
| USPS | United States Postal Service |
| VA | United States Department of Veterans Affairs |

Appendix D

Patient Notification Letters



SAMPLE

February 27, 2008

Dear Sir or Madam,

In January of 2008, the Southern Nevada Health District began investigating reports of recent hepatitis C infection among several people who had undergone procedures at the Endoscopy Center of Southern Nevada, located at 700 Shadow Lane, Las Vegas. Through the investigation, we identified the use of unsafe injection practices which may have exposed patients to the blood of other clinic patients.

This letter serves as notification that you have been identified in clinic records as a former patient of the clinic who was placed at risk for possible exposure to bloodborne pathogens. As a precaution, and in order to take appropriate steps to protect your health, we recommend you get tested for hepatitis C, hepatitis B, and HIV.

It is not possible to determine specifically which people were exposed, but all patients who received injected anesthesia at the center have been placed at increased risk for exposure. As a result, we are notifying all people who received injected anesthesia medications between March 2004 and January 11, 2008. Our investigation has identified that the infections were associated with the unsafe injection practices and not with the procedures themselves.

People infected with viruses such as hepatitis C and HIV typically do not have symptoms for many years, so you may have been infected and not know it. Even though you may not feel ill or remember getting sick, you should get tested in order to safeguard your health. Although testing cannot determine if you were infected at the clinic or by another source, knowing that you are infected is important, as there are treatment options available if you do test positive.

We recommend that you be tested at your own doctor's office, as he or she will be able to best advise you on what to do if you test positive. If you do not have a regular doctor, a list of resources is available on the health district website at <http://www.southernnevadahealthdistrict.org>. Wherever you choose to be tested, be sure to bring this letter with you and give it to your doctor. Information for your doctor is printed at the end of this letter.

We understand that you and your family may have many more questions or concerns with the information you have received. To help answer them, we have established a hotline at (702) 759-

P.O. Box 3902 | Las Vegas, NV 89127
702.759.1000 | www.southernnevadahealthdistrict.org

INFO (4636). The hotline will be available starting Wednesday, February 27, 2008. You may also obtain additional information on the health district website at <http://www.southernnevadahealthdistrict.org>.

NOTA: Para obtener esta información en español llame al (702) 759-4636 o visite el sitio web www.southernnevadahealthdistrict.org

Sincerely,

Lawrence Sands, DO, MPH
Chief Health Officer

To Health Care Providers: The patient to whom this letter was addressed has possibly been exposed to bloodborne pathogens during a medical procedure. The Southern Nevada Health District is recommending that this patient be tested for hepatitis B, hepatitis C, and HIV. To simplify testing, the health district has arranged for the appropriate tests to be available as a panel from major commercial laboratories. For information on testing, please see the technical bulletin entitled "Hepatitis C Exposure at a Medical Clinic" available on the "Hepatitis C Investigation" section of the health district website at <http://www.southernnevadahealthdistrict.org>. It is also available by fax on demand by dialing 759-1499 and requesting document #90802.



June 9, 2008

Dear Sir or Madam:

As a former patient of the Endoscopy Center of Southern Nevada you should have received a letter earlier this year from the Southern Nevada Health District advising you of your risk of exposure to bloodborne illnesses due to unsafe injection practices at the clinic. It is very important for you to know your infection status and I hope you have followed our recommendation to get tested for hepatitis C, hepatitis B and HIV.

While I can only imagine the stress and frustration you and your family must feel in response to this situation, I want to assure you the health district is committed to working with our community partners to ensure patients are safe when seeking medical care. To this end, the health district is continuing our investigation into the outbreak to better understand the events that lead to patients being infected with hepatitis C and to continue to provide appropriate recommendations and information to those affected.

In order to complete a more thorough investigation of the cases of hepatitis C at both the Endoscopy Center of Southern Nevada and the Desert Shadow Endoscopy Center, we have developed a Hepatitis C Exposure Registry. As a patient of the Endoscopy Center of Southern Nevada we are asking for your assistance in order to gather more information and continue our investigation.

Enclosed with this letter is an enrollment form for the exposure registry. We ask that you complete this form and return it to the health district. The registry was developed to assist in the identification of patients who had procedures at the clinics, including those who are infected with the hepatitis C virus, and will allow patients who have tested positive 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.

The registry information and enrollment forms are also available on the health district's website, www.SouthernNevadaHealthDistrict.org. In addition, enrollment forms will be available at the health district's public health centers or patients can contact the hepatitis C helpline at (702) 759-4636 (INFO) to request a form.

NOTA: Para obtener esta información en español llame al (702) 759-4636 o visite el sitio web www.southernnevadahealthdistrict.org.

Thank you again for your assistance and cooperation.

Sincerely,

Lawrence Sands, DO, MPH
Chief Health Officer



June 9, 2008

Dear Sir or Madam:

As a former patient of the Desert Shadow Endoscopy Center, formerly located at 4275 Burnham Avenue, Suite 101, you are receiving this letter to inform you that based on the information and records currently available the Southern Nevada Health District has concluded its investigation into an acute case of hepatitis C associated with this clinic.

The acute case of hepatitis C that lead to this investigation was self-reported to the health district by a patient in March of 2008. Laboratory tests document this person tested negative for hepatitis C days prior to undergoing a procedure at this clinic and later developed an acute infection. Seven additional cases are associated with the Endoscopy Center of Southern Nevada. This clinic was the subject of a prior notification to more than 40,000 patients of their potential exposure to bloodborne pathogens.

While it has been determined this acute case is linked to the center there is not sufficient information at this time to determine the likely source of disease transmission. Unfortunately, this case was reported to the health district after the clinic location was closed and staff was not available for interviews with the health district and investigation team members were unable to further observe the clinic practices.

Due to the lack of documentation, the health district is encouraging you to discuss your risk for disease transmission with your physician and to pursue testing for hepatitis C, hepatitis B and HIV if you are concerned. While we cannot make a recommendation to get tested based on evidence of unsafe injection practices which may have exposed patients to the blood of other clinic patients, it is important for potentially affected patients to know their infection status.

It is unfortunate we have not been able to conclusively identify the practices that lead to a patient at this clinic being infected with hepatitis C. We do know a clinic staff person was observed reusing vials of anesthesia medication at this facility during an inspection by the Nevada State Health Division Bureau of Licensure and Certification in January 2008, and clinic records support the finding that vials of anesthesia were reused on multiple patients. However, the reuse of syringes cannot be documented at this time.

The health district is committed to continuing its efforts to further investigate this case as well as the cases associated with the Endoscopy Center of Southern Nevada, where the outbreak was first identified.

In order to complete a more thorough investigation into the events that lead to patients being infected with hepatitis C at both the Endoscopy Center of Southern Nevada and the Desert Shadow Endoscopy Center, we have developed a Hepatitis C Exposure Registry. As a patient of the Desert Shadow Endoscopy Center we are asking for your assistance in gathering more information in order to continue our investigation.

Enclosed with this letter is an enrollment form for the exposure registry. We ask that you complete this form and return it to the health district. The registry was developed to assist in the identification of patients who had procedures at the clinics, including those who are infected with the hepatitis C virus, and will allow patients who have tested positive 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.

The registry information and enrollment forms are also available on the health district's website, www.SouthernNevadaHealthDistrict.org. In addition, enrollment forms will be available at the health district's public health centers or patients can contact the hepatitis C helpline at (702) 759-4636 (INFO) to request a form.

We understand that you and your family may have many more questions or concerns with the information you have received. For additional information, please contact the hepatitis C helpline listed above. You may also find additional information on the health district website at <http://www.southernnevadahealthdistrict.org>.

NOTA: Para obtener esta información en español llame al (702) 759-4636 o visite el sitio web www.southernnevadahealthdistrict.org.

Thank you again for your assistance and cooperation.

Sincerely,

Lawrence Sands, DO, MPH
Chief Health Officer

Appendix E

Standardized Questionnaire

Introductions For the Interviewer

Thank you for your assistance in administering this survey. You will be calling a person who has recently tested positive for hepatitis C and asking them about their possible risk factors for infection. As different questions in the survey are asked based on the answers given, you may ask different questions each time you speak with a different patient.

Questions marked with an asterisk (*) require an answer to proceed.

Questions or information for the interviewer, not the patient, are written in green and are prefaced with "For the interviewer:".

Questions or introductory statements to be read to the patient are written in blue and prefaced with "Read to patient:".

Provided Patient Information

* For the Interviewer: What is the ID Number assigned to this person?

* For the Interviewer: What is the name of this person?

Contact Attempt

To the interviewer: attempt to contact the patient at the number provided. If the person answering asks what it is in regards to, Read to patient: "It is personal medical information and I must speak directly to (patient name)"

LINE BUSY, NO ANSWER, NO VOICEMAIL OR ANSWERING MACHINE, OR FULL VOICEMAILBOX
Choose "Unsuccessful Contact" below.

VOICEMAIL OR ANSWERING MACHINE

Read to patient: "Hello, I am calling from the Southern Nevada Health District for (patient name). Please call 759-xxxx Monday through Friday between the hours of 9:00 am and 4:00 pm. Thank you."

For the interviewer: Then, choose "Left Message" below.

PERSON ANSWERS

Read to patient: "Hello, is (patient name) available?"

YES - For the interviewer: choose "Spoke With Patient" below.

NO – Read to patient: I am calling from the Southern Nevada Health District. Please have (patient name) call 759-xxxx Monday through Friday between the hours of 9:00 am and 4:00 pm. Thank you."

For the interviewer: Then choose "Left Message" below.

★ For the Interviewer: What was the result of the contact attempt?

- ☐ Unsuccessful Contact
- ☐ Left Message
- ☐ Spoke With Patient
- ☐ Refused Interview
- ☐ Refused Interview on the Advice of Lawyer
- ☐ Patient is deceased

Confirmation of Recent Testing

★ Read to patient: "This is (interviewer first name) from the Southern Nevada Health District. I am calling in regard to our Hepatitis C investigation. Have you recently been tested for hepatitis C?"

- ☐ Yes
- ☐ No
- ☐ Refused
- ☐ Doesn't Know

Completion of Interview

Read to patient: This investigation is focusing on people who have recently tested positive for hepatitis C. As you have not been recently tested, this ends the survey. Thank you for your time.

★ For the interviewer: Complete interview

- ☐ Complete Interview (For the interviewer: do not read this choice, just select it to complete the survey).

Receipt of Results

★ Read to patient: "Have you received the results of your test?"

- ☐ Yes
- ☐ No

Physician Information

For the interviewer: If the patient does not know the name of the doctor, record the name of the clinic, otherwise record "Unknown" in the field.

★ Read to patient: Which doctor ordered your laboratory testing?

Doctor name (or clinic
name):


Doctor phone:

Does Not Know Results

Read to patient: This survey is focusing on people who have recently tested positive for hepatitis C. Please contact your physician to obtain the results of your test.

If your physician tells you that you have tested positive, please contact us at 759-xxxx from 9am to 4pm, Monday through Friday to complete the survey. Thank you for your time.

★ For the interviewer: Complete interview


 Complete Interview (For the interviewer: do not read this choice, just select it to complete the survey).

Discussed Results with Physician

★ Read to patient: "What did your doctor tell you about your hepatitis C test results? Were you:"

 Positive


 Negative

 Given some other result

Patient States Results Were Negative

Read to patient: This investigation is focusing on people who have recently tested positive for hepatitis C. As your test was negative, this ends the survey. Thank you for your time.

★ For the interviewer: Complete interview

 Complete Interview (For the interviewer: do not read this choice, just select it to complete the survey).

Introduction

Read to patient: "I would like to ask you some questions that will help us in our investigation. Do you have a few minutes to answer some questions?"

 Yes

 No

Survey Overview

Read to patient: I am going to be asking the questions as they appear on my computer screen. I have to put down an answer to each one before moving on to the next question. If we need to stop the survey at some point, we cannot come back to your answers at a later time and will have to start over

from the beginning when you call back.

Confirmation of Date of Birth

For the interviewer: In order to confirm the identity of the person with whom you are speaking, you will ask the patient to confirm information from their laboratory report. This will vary depending on the information you have available on the lab report.

Read to patient: "Could you please verify your date of birth."

- * For the Interviewer: Were you able to confirm the date of birth of the person with whom you are speaking?

jn Yes

jn No

Confirmation of Address

Read to patient: "Could you please verify your address."

- * For the Interviewer: Were you able to confirm the identity of the person with whom you are speaking?

jn Yes

jn No

Confirmation of Last Name

Read to patient: "Could you please verify the spelling of your last name."

- * Were you able to confirm the spelling of the last name of the person with whom you are speaking?

jn Yes

jn No

Introduction and Confidentiality

Read to patient: This survey will include questions about you, your health, your laboratory testing, and your risk factors for infection with hepatitis C.

I want to assure you that any information you provide will be kept strictly confidential in accordance with federal and state medical privacy laws.

If you have questions about your specific laboratory results, these would best be addressed by your healthcare provider. If you have other questions, I will be able to assist you with those at the end of the survey.

Patient Name

Read to patient: I'd like to begin by making sure that I have your name spelled correctly.

For the interviewer: If the patient does not have a middle initial, please leave blank.

* Read to patient: What is the correct spelling of your first name?

* Read to patient: What is the correct spelling of your last name?

Read to patient: What is your middle initial?

Clinic Visit: Endoscopy Center of Southern Nevada

Read to patient: I am going to begin by asking you about visits you may have made to certain medical clinics.

* Read to patient: Were you ever a patient at the Endoscopy Center of Southern Nevada, located at 700 Shadow Lane, Suite 165?

☐ Yes

☐ No

☐ Doesn't Remember or Know

☐ Refused to Answer

Endoscopy Center of Southern Nevada Procedure 1

Read to patient: I am now going to ask you about each visit you have had at the Endoscopy Center of Southern Nevada. In order to collect this information, I would like to ask you about each visit individually.

For the interviewer: if the patient does not know the exact date of the procedure, enter the year or month and year, or "Unknown" if the patient cannot provide any information.

* Read to patient: On which date did you have the first procedure at the Endoscopy Center of Southern Nevada?

Endoscopy Center of Southern Nevada Procedure Type 1

★ Read to patient: during that visit, what type of procedure did you have performed?

☐ Colonoscopy

☐ Upper Endoscopy (EGD)

☐ Colonoscopy and Upper Endoscopy (EGD)

☐ Flexible Sigmoidoscopy

☐ Other Procedure

☐ Doesn't Remember

☐ Refused to Answer

If other, please specify

Endoscopy Center of Southern Nevada Injection 1

★ Read to patient: During that visit, were you given an injection of anesthesia medicine?

☐ Yes

☐ No

☐ Doesn't Remember or Know

☐ Refused to Answer

Endoscopy Center of Southern Nevada Continue 1

★ Read to patient: Did you have another procedure at the Endoscopy Center of Southern Nevada?

☐ Yes

☐ No

☐ Doesn't Remember

☐ Refused

Endoscopy Center of Southern Nevada Procedure 2

For the interviewer: if the patient does not know the exact date of the procedure, enter the year or month and year, or "Unknown" if the patient cannot provide any information.

★ Read to patient: On which date did you have the second procedure at the Endoscopy Center of Southern Nevada?

Endoscopy Center of Southern Nevada Procedure Type 2

* Read to patient: during that visit, what type of procedure did you have performed?

☐ Colonoscopy

☐ Upper Endoscopy (EGD)

☐ Colonoscopy and Upper Endoscopy (EGD)

☐ Flexible Sigmoidoscopy

☐ Other Procedure

☐ Doesn't Remember

☐ Refused to Answer

If other, please specify

Endoscopy Center of Southern Nevada Injection 2

* Read to patient: During that visit, were you given an injection of anesthesia medicine?

☐ Yes

☐ No

☐ Doesn't Remember or Know

☐ Refused to Answer

Endoscopy Center of Southern Nevada Continue 2

* Read to patient: Did you have another procedure at the Endoscopy Center of Southern Nevada?

☐ Yes

☐ No

☐ Doesn't Remember

☐ Refused

Endoscopy Center of Southern Nevada Procedure 3

For the interviewer: if the patient does not know the exact date of the procedure, enter the year or month and year, or "Unknown" if the patient cannot provide any information.

* Read to patient: On which date did you have the third procedure at the Endoscopy Center of Southern Nevada?

Endoscopy Center of Southern Nevada Procedure Type 3

* Read to patient: during that visit, what type of procedure did you have performed?

☐ Colonoscopy

☐ Upper Endoscopy (EGD)

☐ Colonoscopy and Upper Endoscopy (EGD)

☐ Flexible Sigmoidoscopy

☐ Other Procedure

☐ Doesn't Remember

☐ Refused to Answer

If other, please specify

Endoscopy Center of Southern Nevada Injection 3

* Read to patient: During that visit, were you given an injection of anesthesia medicine?

☐ Yes

☐ No

☐ Doesn't Remember or Know

☐ Refused to Answer

Endoscopy Center of Southern Nevada Continue 3

* Read to patient: Did you have another procedure at the Endoscopy Center of Southern Nevada?

☐ Yes

☐ No

☐ Doesn't Remember

☐ Refused

Endoscopy Center of Southern Nevada Procedure 4

For the interviewer: if the patient does not know the exact date of the procedure, enter the year or month and year, or "Unknown" if the patient cannot provide any information.

- * Read to patient: On which date did you have the fourth procedure at the Endoscopy Center of Southern Nevada?

Endoscopy Center of Southern Nevada Procedure Type 4

- * Read to patient: during that visit, what type of procedure did you have performed?

☐ Colonoscopy

☐ Upper Endoscopy (EGD)

☐ Colonoscopy and Upper Endoscopy (EGD)

☐ Flexible Sigmoidoscopy

☐ Other Procedure

☐ Doesn't Remember

☐ Refused to Answer

If other, please specify

Endoscopy Center of Southern Nevada Injection 4

- * Read to patient: During that visit, were you given an injection of anesthesia medicine?

☐ Yes

☐ No

☐ Doesn't Remember or Know

☐ Refused to Answer

Clinic Visit: Desert Shadow Endoscopy Center

- * Read to patient: Were you ever a patient at the Desert Shadow Endoscopy Center, located 4275 S. Burnham Avenue?

☐ Yes

☐ No

☐ Unknown

☐ Refused

Desert Shadow Endoscopy Center Procedure 1

Read to patient: I am now going to ask you about each visit you have had at the Desert Shadow Endoscopy Center. In order to collect this information, I would like to ask you about each visit individually.

For the interviewer: if the patient does not know the exact date of the procedure, enter the year or month and year, or "Unknown" if the patient cannot provide any information.

- * Read to patient: On which date did you have the first procedure at the Desert Shadow Endoscopy Center?

Desert Shadow Endoscopy Center Procedure Type 1

- * Read to patient: during that visit, what type of procedure did you have performed?

☐ Colonoscopy

☐ Upper Endoscopy (EGD)

☐ Colonoscopy and Upper Endoscopy (EGD)

☐ Flexible Sigmoidoscopy

☐ Other Procedure

☐ Doesn't Remember

☐ Refused to Answer

If other, please specify

Desert Shadow Endoscopy Center Injection 1

- * Read to patient: During that visit, were you given an injection of anesthesia medicine?

☐ Yes

☐ No

☐ Doesn't Remember or Know

☐ Refused to Answer

Desert Shadow Endoscopy Center Continue 1

* Read to patient: Did you have another procedure at the Desert Shadow Endoscopy Center?

☐ Yes

☐ No

☐ Doesn't Remember

☐ Refused

Desert Shadow Endoscopy Center Procedure 2

For the interviewer: if the patient does not know the exact date of the procedure, enter the year or month and year, or "Unknown" if the patient cannot provide any information.

* Read to patient: To the patient: On which date did you have the second procedure at the Desert Shadow Endoscopy Center?

Desert Shadow Endoscopy Center Procedure Type 2

* Read to patient: during that visit, what type of procedure did you have performed?

☐ Colonoscopy

☐ Upper Endoscopy (EGD)

☐ Colonoscopy and Upper Endoscopy (EGD)

☐ Flexible Sigmoidoscopy

☐ Other Procedure

☐ Doesn't Remember

☐ Refused to Answer

If other, please specify

Desert Shadow Endoscopy Center Injection 2

* Read to patient: During that visit, were you given an injection of anesthesia medicine?

☐ Yes

☐ No

☐ Doesn't Remember or Know

☐ Refused to Answer

Desert Shadow Endoscopy Center Continue 2

* Read to patient: Did you have another procedure at the Desert Shadow Endoscopy Center?

☐ Yes

☐ No

☐ Doesn't Remember

☐ Refused

Desert Shadow Endoscopy Center Procedure 3

For the interviewer: if the patient does not know the exact date of the procedure, enter the year or month and year, or "Unknown" if the patient cannot provide any information.

* Read to patient: To the patient: On which date did you have the third procedure at the Desert Shadow Endoscopy Center?

Desert Shadow Endoscopy Center Procedure Type 3

* Read to patient: during that visit, what type of procedure did you have performed?

☐ Colonoscopy

☐ Upper Endoscopy (EGD)

☐ Colonoscopy and Upper Endoscopy (EGD)

☐ Flexible Sigmoidoscopy

☐ Other Procedure

☐ Doesn't Remember

☐ Refused to Answer

If other, please specify

Desert Shadow Endoscopy Center Injection 3

★ Read to patient: During that visit, were you given an injection of anesthesia medicine?

☐ Yes

☐ No

☐ Doesn't Remember or Know

☐ Refused to Answer

Desert Shadow Endoscopy Center Continue 3

★ Read to patient: Did you have another procedure at the Desert Shadow Endoscopy Center?

☐ Yes

☐ No

☐ Doesn't Remember

☐ Refused

Desert Shadow Endoscopy Center Procedure 4

For the interviewer: if the patient does not know the exact date of the procedure, enter the year or month and year, or "Unknown" if the patient cannot provide any information.

★ Read to patient: To the patient: On which date did you have the fourth procedure at the Desert Shadow Endoscopy Center?

Desert Shadow Endoscopy Center Procedure Type 4

★ Read to patient: during that visit, what type of procedure did you have performed?

☐ Colonoscopy

☐ Upper Endoscopy (EGD)

☐ Colonoscopy and Upper Endoscopy (EGD)

☐ Flexible Sigmoidoscopy

☐ Other Procedure

☐ Doesn't Remember

☐ Refused to Answer

If other, please specify

Desert Shadow Endoscopy Center Injection 4

* Read to patient: During that visit, were you given an injection of anesthesia medicine?

☐ Yes

☐ No

☐ Doesn't Remember or Know

☐ Refused to Answer

Reason For Testing

Read to patient: I am now going to ask you some questions about laboratory testing you may have had for hepatitis C.

For the interviewer: read the reasons for testing in order. If a patient answer that they were tested for that reason, do not continue asking about other reasons and move to the next page.

* Read to patient: I would like find out why you were tested for hepatitis C.
Was it:

☐ Because you were previously diagnosed with hepatitis C, and this was part of your disease management?

☐ Because you were a patient of the Endoscopy Center of Southern Nevada?

☐ Because you were a patient of the Desert Shadow Endoscopy Center?

☐ Because you were a patient of an another endoscopy or gastroenterology center?

☐ Because a family member or friend was diagnosed with hepatitis C?

☐ Part of a diagnosis because you were ill?

☐ Because your doctor recommended it?

☐ For some other reason?

If some other reason, To the patient: please describe this reason?

Prior Testing

★ Read to patient: prior to your recent blood test, had you ever been tested for infection with hepatitis C?

☐ Yes

☐ No

☐ Doesn't Remember or Know

☐ Refused to Answer

Prior Negatives

★ Read to patient: Before this recent positive test, had you ever tested negative for infection with the hepatitis C virus?

☐ Yes

☐ No

☐ Unknown

☐ Refused

Negative Tests

For the interviewer: If the patient does not know the exact date, record the month and year or year.

Read to patient: When did you test negative for hepatitis C infection?

Date One

Date Two

Date Three

Date Four

Date Five

Prior Positives

★ Read to patient: Before this recent test, had you ever tested positive for infection with the hepatitis C virus?

☐ Yes

☐ No

☐ Does Not Know

☐ Refused to Answer

First Positive

* Read to patient: When did you first test positive for infection with the hepatitis C virus?

Prior Blood Donation

* Read to patient: If you have given blood since 1992, your blood was tested for hepatitis C. Information about blood donation may allow us to identify prior testing for hepatitis C. Have you donated blood since 1992?

☐ Yes

☐ No

☐ Does not know

☐ Refused

Blood Donation Dates

For the interviewer: If the patient cannot remember exactly when the blood was donated, get as much information as possible (e.g "Early 2005" or "August of 2004")

Read to patient: When did you donate blood (1992 or later)?

| | |
|----------------|----------------------|
| Donation One | <input type="text"/> |
| Donation Two | <input type="text"/> |
| Donation Three | <input type="text"/> |
| Donation Four | <input type="text"/> |
| Donation Five | <input type="text"/> |
| Donation Six | <input type="text"/> |
| Donation Seven | <input type="text"/> |
| Donation Eight | <input type="text"/> |
| Donation Nine | <input type="text"/> |
| Donation Ten | <input type="text"/> |

Prior Acute Illness

★ Read to patient: In the month prior to the first time you ever tested positive for hepatitis C, were you sick with an illness that lasted several weeks and included jaundice (a yellowing of the skin or whites of the eyes), abdominal pain, nausea, and fatigue?

☐ Yes

☐ No

☐ Does Not Know

☐ Refused to Answer

Provider During Illness

For the interviewer: for each medical provider, collect the phone number. If the patient does not know, record "Unknown" in the field.

★ Read to patient: Which doctor or doctors did you visit when you became ill?

Doctor one name:

Doctor one location:

Doctor one phone:

Doctor two name:

Doctor two location:

Doctor two phone:

Doctor three name:

Doctor three location:

Doctor three phone:

Completion of Interview

Read to patient: Because you reported having an illness, I would like to forward your information to the Office of Epidemiology, who will conduct a more in-depth interview with you. Someone will be contacting you soon to ask you some additional questions. Thank you for your time.

★ For the interviewer: Complete interview

☐ Complete Interview (For the interviewer: do not read this choice, just select it to complete the survey).

Chronic Risk Introduction

Read to patient: I am now going to ask you a few questions about your risk factors for infection with hepatitis C.

General Risk: Hemodialysis

★ Read to patient: Have you ever been on long-term dialysis?

☐ Yes

☐ No

☐ Doesn't Know or Can't Remember

☐ Refused to Answer

General Risk: Blood Transfusion pre-1992

★ Read to patient: Did you have a blood transfusion prior to 1992?

☐ Yes

☐ No

☐ Doesn't Know or Can't Remember

☐ Refused to Answer

General Risk: Organ Transplant

★ Read to patient: Did you have an organ transplant before 1992?

☐ Yes

☐ No

☐ Doesn't Know or Can't Remember

☐ Refused to Answer

General Risk: Clotting Factor

★ Read to patient: Did you ever receive clotting factor concentrates, blood products used to treat hemophilia, prior to 1987?

☐ Yes

☐ No

☐ Doesn't Know or Can't Remember

☐ Refused to Answer

General Risk: IVDU

★ Read to patient: Have you ever injected drugs not prescribed by a doctor, even if only once or a few times?

☐ Yes

☐ No

☐ Doesn't Know or Can't Remember

☐ Refused to Answer

General Risk: Hepatitis C Sexual Contacts

★ Read to patient: have you ever had sexual contact with a person with confirmed or suspected hepatitis C virus infection?

☐ Yes

☐ No

☐ Doesn't Know or Can't Remember

☐ Refused to Answer

Patient Address

For the interviewer: if the patient does not want to give an address, record "Refused" in the boxes below.

Read to patient: Finally, I want to collect your contact information and some basic demographic information.

★ Read to patient: What is your street address?

★ Read to patient: In which city do you live?

★ Read to patient: In which state do you live?

★ Read to patient: What is your zipcode?

Patient Phone

For the interviewer: if the patient does not want to give a phone number, record "Refused" in the box below.

★ Read to patient: what is the best phone number to reach you?

Race

* Read to patient: What is your race?

- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Black or African American
- ☐ Native Hawaiian or Pacific Islander
- ☐ White
- ☐ Other
- ☐ Refused to Answer

Ethnicity

* Read to patient: What is your ethnicity?

- ☐ Hispanic
- ☐ Non-Hispanic
- ☐ Refused to Answer

Country of Birth

For the interviewer: If the patient refuses to provide the country of birth, record "Refused" in the country of birth field.

* Read to patient: In what country were you born?

Date of Birth

For the interviewer: If the patient refuses to provide the date of birth, ask for the year of birth. If the patient still refuses to provide the information, record "Refused" in the date of birth field.

* Read to patient: What is your date of birth?

* For the interviewer: If you are a surveyor from Nellis Air Force Base, choose "Nellis Air Force Base" below for a few additional questions, otherwise choose "Complete Interview".

- ☐ Nellis Air Force Base
- ☐ Complete Interview (For the interviewer: do not read this choice, just select it to complete the survey).

US Military Status

* Read to patient: What is your current affiliation with the US Military?

☐ Currently Serving (Active Duty or Reserves)

☐ Formerly Served / Retired

☐ Current US Military Dependent

☐ Former US Military Dependent

Military Retirement

* In what year did you leave the service or retire?

Military Addresses

* Read to patient: Please provide addresses since your retirement

| | |
|------------------|----------------------|
| Address One | <input type="text"/> |
| City One | <input type="text"/> |
| State One | <input type="text"/> |
| Zip One | <input type="text"/> |
| Country One | <input type="text"/> |
| Years Lived One | <input type="text"/> |
| Address Two | <input type="text"/> |
| City Two | <input type="text"/> |
| State Two | <input type="text"/> |
| Zip Two | <input type="text"/> |
| Country Two | <input type="text"/> |
| Years Lived Two | <input type="text"/> |
| Address Three | <input type="text"/> |
| City Three | <input type="text"/> |
| State Three | <input type="text"/> |
| Zip Three | <input type="text"/> |
| Country Three | <input type="text"/> |
| Years Lived | <input type="text"/> |
| Three | |
| Address Four | <input type="text"/> |
| City Four | <input type="text"/> |
| State Four | <input type="text"/> |
| Zip Four | <input type="text"/> |
| Country Four | <input type="text"/> |
| Years Lived Four | <input type="text"/> |
| Address Five | <input type="text"/> |
| City Five | <input type="text"/> |
| State Five | <input type="text"/> |
| Zip Five | <input type="text"/> |
| Country Five | <input type="text"/> |
| Years Lived Five | <input type="text"/> |

Military Service Branch

* Read to patient: in which branch did you or your sponsor serve?

☐ Air Force

☐ Army

☐ Coast Guard

☐ Marine Corp

☐ Navy

Military Service Years

* How many years of service do/did you or your sponsor have?

Military Occupation

* Read to patient: What was your occupation in the US Military, or your occupation if you are a US Military Dependant?

Military Hepatitis B Vaccination

* Read to patient: Have you ever been vaccinated for hepatitis B?

☐ Yes

☐ No

☐ Doesn't Know or Can't Remember

☐ Refused to Answer

Military Duty Stations

* Read to patient: Please provide all your previous duty stations (location and year)

| | |
|------------------------|----------------------|
| Station One | <input type="text"/> |
| Station One Years | <input type="text"/> |
| Station Two | <input type="text"/> |
| Station Two Years | <input type="text"/> |
| Station Three | <input type="text"/> |
| Station Three Years | <input type="text"/> |
| Station Four | <input type="text"/> |
| Station Four Years | <input type="text"/> |
| Station Five | <input type="text"/> |
| Station Five Years | <input type="text"/> |
| Station Six | <input type="text"/> |
| Station Six Years | <input type="text"/> |
| Station Seven | <input type="text"/> |
| Station Seven Years | <input type="text"/> |
| Station Eight | <input type="text"/> |
| Station Eight Years | <input type="text"/> |
| Station Nine | <input type="text"/> |
| Station Nine Years | <input type="text"/> |
| Station Ten | <input type="text"/> |
| Station Ten Years | <input type="text"/> |

Military Deployments

★ Read to patient: Please provide your deployment history (location and year)


| | |
|------------------|----------------------|
| Deployment One | <input type="text"/> |
| Deployment One | <input type="text"/> |
| Years | |
| Deployment Two | <input type="text"/> |
| Deployment Two | <input type="text"/> |
| Years | |
| Deployment Three | <input type="text"/> |
| Deployment Three | <input type="text"/> |
| Years | |
| Deployment Four | <input type="text"/> |
| Deployment Four | <input type="text"/> |
| Years | |
| Deployment Five | <input type="text"/> |
| Deployment Five | <input type="text"/> |
| Years | |
| Deployment Six | <input type="text"/> |
| Deployment Six | <input type="text"/> |
| Years | |
| Deployment Seven | <input type="text"/> |
| Deployment Seven | <input type="text"/> |
| Years | |
| Deployment Eight | <input type="text"/> |
| Deployment Eight | <input type="text"/> |
| Years | |
| Deployment Nine | <input type="text"/> |
| Deployment Nine | <input type="text"/> |
| Years | |
| Deployment Ten | <input type="text"/> |
| Deployment Ten | <input type="text"/> |
| Years | |

Military Primary Care Provider

★ Read to patient: Who is your primary care provider?

| | |
|----------|----------------------|
| Provider | <input type="text"/> |
| Location | <input type="text"/> |

★ For the interviewer: Choose "Complete Interview".

 Complete Interview (For the interviewer: do not read this choice, just select it to complete the survey).

Deceased Patient

Read to Patient: I am very sorry for your loss, and sorry to be calling you at a time like this. If it is possible that (patient name) passed away from hepatitis C, our staff would like to ask you a few questions, if you have the time and feel comfortable speaking with us.


Would it be alright if one of our disease investigators contacted you to find out some additional 115

information?

YES: - Read to Patient When is the best time for them to contact you? What is the best phone number for them to call? I will pass that information to the disease investigation staff so that they can contact you. Thank you very much for your time, and again, I am sorry for your loss For the investigator: Take phone number and provide to supervisor.

NO, or caller insists that patient died of another illness/condition - Read to Patient: "Thank you very much for your time, and again, I am sorry for your loss."

* Complete Interview

 Complete Interview (For the interviewer: do not read this choice, just select it to complete the survey).

Continue Later

* Read to patient: Would you be willing to call back at another time to complete the survey?


 Yes

 No: Read to patient: Thank you for your time.

Callback Number

Read to patient: Good. Please call us back at 759-xxxx. We will be available Monday-Friday from 9:00 am – 4:00 pm.

* For the interviewer: Complete Survey.

 Complete Interview (For the interviewer: do not read this choice, just select it to complete the survey).

Clinic Visit: Desert Shadow Endoscopy Center

* Read to patient: Were you ever a patient at the Desert Shadow Endoscopy Center, located 4275 S. Burnham Avenue?

 Yes


 No

 Unknown

 Refused

No Clinic Visits


* Read to patient: This investigation is focusing on exposures that have occurred during medical procedures at specific clinics. Because you have not visited either of the clinics in question, this concludes the survey. Thank you for your time.

 Complete Interview (For the interviewer: do not read this choice, just select it to complete the survey).

Refused on Advice of A Lawyer

Read to patient: What is the name of your lawyer?


* Read to patient: Thank you for your time.

 Complete Interview (For the interviewer: do not read this choice, just select it to complete the survey).

Unverified Person

Read to patient: "Please have (patient name) call 759-xxxx Monday through Friday between the hours of 9:00 am and 4:00 pm. Thank you."


* For the interviewer: Complete interview

 Complete Interview (For the interviewer: do not read this choice, just select it to complete the survey).

Refused

Read to patient: "Thank you for your time."

* For the interviewer: Complete interview

 Complete Interview (For the interviewer: do not read this choice, just select it to complete the survey).

Informational Meeting

Read to patient: That is the end of my questions. I do want to let you know that on April 19th the health district will be hosting a hepatitis C informational event, which will be held at the main health district building at 625 Shadow Lane from 8:30am – 3:30pm. Information on this event is on the health district website at www.SouthernNevadaHealthDistrict.org.

Wrapup

* Read to patient: We have an information line available to answer any questions you may have about hepatitis C or the investigation. Would you like to speak with someone from our information line?

jn Yes: Read to patient: This completes the survey. Thank you for your time. I appreciate your willingness to answer my questions and to help the health district with their investigation. For the interviewer: forward the call to 759-xxxx.

jn No: Read to patient: If you do have questions, you can reach the information line at 759-xxxx (xxxx). This completes the survey. Thank you for your time. I appreciate your willingness to answer my questions and to help the health district with their investigation.

Completion

For the interviewer: This completes the survey for this person.

* For the interviewer: What is your name?

* For the interviewer: What is your interviewer number?

Appendix F

Registry Enrollment Form

Patient Enrollment Form Hepatitis C Exposure Registry



The Southern Nevada Health District (SNHD) Hepatitis C Exposure Registry has been developed to identify patients who have had medical procedures at specific clinics which may have exposed them to bloodborne pathogens. Information provided in this enrollment form and information related to the evaluation and processing of this form may be used by the Southern Nevada Health District or its agent in the investigation of clinic-related exposures, long-term effects of exposure or disease, or in the management of disease cases. Unless allowed by law, information provided cannot be disclosed to any person without your written consent, including "pursuant to any subpoena, search warrant or discovery proceeding" ([Nevada Revised Statute 441A.220](#)).

Mail completed enrollment forms to:

Southern Nevada Health District, Hepatitis C Exposure Registry, PO Box 3902, Las Vegas, NV 89127

Enrollee Information

Items marked with an asterisk (*) are required.

*Last Name

*First Name

Middle Name

Suffix

*Date of Birth

If Deceased, Date of Death

Contact Information

Items marked with an asterisk (*) are required.

*Current Address

*City

*State

*Zip Code

Phone Number

Email address

You must provide at least one procedure date from either the Endoscopy Center of Southern Nevada or the Desert Shadow Endoscopy Center. If you are unsure of the procedure date, provide the most accurate information possible (for example "September of 2006").

Endoscopy Center of Southern Nevada (700 Shadow Lane) Procedure Dates

Procedure Date

Procedure Date

Procedure Date

Procedure Date

Procedure Date

Procedure Date

Desert Shadow Endoscopy Center (4275 Burnham Ave) Procedure Dates

Procedure Date

Procedure Date

Procedure Date

Procedure Date

Procedure Date

Procedure Date

**Patient Enrollment Form
Hepatitis C Exposure Registry**



Recent Testing

Yes No

☐ ☐

Since your procedure, have you been tested for infection with hepatitis or HIV?

If no, why not? _____

Hepatitis C Laboratory Testing and Illness

Yes No

☐ ☐

Have you ever tested *positive* for infection with the hepatitis C virus?

If yes, on which date did you first test positive? _____

Yes No

☐ ☐

Have you ever tested *negative* for infection with the hepatitis C virus?

If yes, when was your most recent negative test? _____

Yes No

☐ ☐

Have you ever been diagnosed by a physician with *acute* hepatitis C or acute non-A, non-B hepatitis?

If yes, which physician made the diagnosis? _____

Hepatitis B Laboratory Testing and Illness

Yes No

☐ ☐

Have you ever been vaccinated against the hepatitis B virus?

Yes No

☐ ☐

Have you ever tested *positive* for infection with the hepatitis B virus?

If yes, on which date did you first test positive? _____

Yes No

☐ ☐

Have you ever tested *negative* for infection with the hepatitis B virus?

If yes, when was your most recent negative test? _____

Yes No

☐ ☐

Have you ever been diagnosed by a physician with *acute* hepatitis B?

If yes, which physician made the diagnosis? _____

Human Immunodeficiency Virus (HIV) Testing

Yes No

☐ ☐

Have you ever tested *positive* for infection with the human immunodeficiency virus (HIV)?

If yes, on which date did you first test positive? _____

Yes No

☐ ☐

Have you ever tested *negative* for infection with the human immunodeficiency virus (HIV)?

If yes, when was your most recent negative test? _____

Patient Enrollment Form Hepatitis C Exposure Registry



Risk Factors

If you tested positive for hepatitis C after your clinic procedures, items marked with an asterisk (*) are required for the determination of the relatedness of your infection to procedures at the clinic.

Yes No

- | | | |
|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | Have you ever been on long-term dialysis?* |
| <input type="checkbox"/> | <input type="checkbox"/> | Did you receive a blood transfusion prior to 1992?* |
| <input type="checkbox"/> | <input type="checkbox"/> | Did you receive an organ transplant prior to 1992?* |
| <input type="checkbox"/> | <input type="checkbox"/> | Did you receive clotting factor concentrates prior to 1987?* |
| <input type="checkbox"/> | <input type="checkbox"/> | Have you ever injected drugs not prescribed by a doctor, even if only once or a few times?* |
| <input type="checkbox"/> | <input type="checkbox"/> | Have you ever had sexual contact with a person with confirmed or suspected hepatitis C virus infection?* |

Additional Documentation

Many information sources are available to the Southern Nevada Health District which may provide documentation of procedure dates or laboratory testing, but these sources are not complete. Any additional documentation provided may simplify the processing of your enrollment forms.

Indicate which of the following documents is/are attached to your enrollment form (do not submit original documents, only copies):

- ☐ Bills from the clinic (showing your procedure date)
- ☐ Forms signed while at the clinic (showing your procedure date)
- ☐ Post-procedure reports provided by the clinic (showing your procedure date)
- ☐ Discharge instructions provided by the clinic (showing your procedure date)
- ☐ Laboratory testing results (positive or negative)
- ☐ Written documentation of a physician diagnosis of acute disease or illness
- ☐ Hepatitis B vaccination records
- ☐ A death certificate listing hepatitis C infection as a cause of death
- ☐ Some other type of documentation

Describe _____

Patient Enrollment Form Hepatitis C Exposure Registry



Authorizations to Release Information

Authorizing the release of your information to a third party is optional and will not affect your enrollment in the registry. You may revoke, change, or add to any or all of your authorization(s) at any time by making such revocation, change, or addition in writing and delivering it to the Southern Nevada Health District.

Release of Information to Other Persons

I authorize SNHD to release my information provided to the registry and any information about me collected during the health district's investigative process to the following person or persons upon request.

Name of Person

Relationship

Name of Person

Relationship

Signature

Date

Release of Information to Law Enforcement

I authorize SNHD to release my information provided to the registry and any information about me collected during the health district's investigative process to any law enforcement or government regulatory agency involved in any investigation in its jurisdiction, including the prosecution of a crime or crimes, related to the medical, business, or other practices of the Endoscopy Center of Southern Nevada, the Desert Shadow Endoscopy Center, affiliated medical or surgical centers, and affiliated physicians, employees, or other parties upon request.

Signature

Date

Verification of Identify and Certification of Information

To be enrolled, you *must* verify your identity, certify the information provided, and sign and date this form. Check the box that applies (you must check one):

- ☐ I am the enrollee, and I am providing a copy of my government-issued photo identification document. I have examined this application and accompanying documentation and statements, and to the best of my knowledge and belief, certify they are true, correct, and complete.
- ☐ I am the surviving spouse of a deceased enrollee, and I am providing a copy of government-issued photo identification document and a copy of the enrollee's death certificate. I have examined this application and accompanying documentation and statements, and to the best of my knowledge and belief, certify they are true, correct, and complete.
- ☐ I am a deceased enrollee's authorized personal representative, and I am providing a copy of government-issued photo identification document, a copy of letters or order of appointment of personal representative, and a copy of the enrollee's death certificate. I have examined this application and accompanying documentation and statements, and to the best of my knowledge and belief, certify they are true, correct, and complete.

Signature

Date

Appendix G

Frequently Asked Questions Used by the Call Center

This appendix contains a list of the questions and answers provided to the call center for use with the public. Phone numbers and references to non-governmental agencies providing patient assistance have been redacted from this appendix. Questions on obtaining medical records have been removed, as frequent changes in the process resulting in these specific answers evolving over the course of the response.

Hepatitis C Disease Questions

What is hepatitis C?

- Hepatitis C is a disease caused by the hepatitis C virus that results in infection of the liver.
- Hepatitis C is the most common (but not the only) cause of post-blood transfusion hepatitis in the United States.

Who gets hepatitis C?

- Anyone can get hepatitis C, but IV drug users, people who received blood transfusions or organ transplants prior to 1992, and dialysis patients are at high risk of getting the infection. Infants born to infected mothers are also at risk.

How is the hepatitis C virus spread?

- The hepatitis C virus is primarily spread by direct contact with contaminated blood or plasma.
- Contaminated needles and syringes are a source of spread among IV drug users.
- The role of person-to-person contact and sexual activity in the spread of this disease is unclear.
- Hepatitis C virus is not spread through casual contact or in typical school, office, or food service settings.
- It is not spread through the aerosol route, e.g., an infected person coughing or sneezing.
- The virus cannot be acquired by drinking out of a glass used by a person infected with hepatitis C.

What are the symptoms of Hepatitis C?

- 80% of persons may have no signs or symptoms.
- Symptoms develop slowly and may include:
 - Loss of appetite
 - Stomach pain
 - Nausea
 - Vomiting
 - Jaundice (yellowing of the skin or whites of the eyes)
- Although the initial infection may be asymptomatic or mild, a high percentage of infected people will develop chronic infection.
- This infection may persist for many years without symptoms, before cirrhosis (liver disease) develops.

How soon do symptoms of hepatitis C appear?

- Symptoms may appear within 6 to 9 weeks after exposure. However, they can also occur as soon as 2 weeks and as long as 6 months later.

How long can an infected person spread the virus?

- Infected people may spread the virus indefinitely even if they do not experience symptoms.

Is there a treatment for chronic hepatitis C?

- There is a treatment available for hepatitis C, although it does not work for everyone.
- The effectiveness of the treatment varies depending on the strain of the virus with which you are infected. In the strain most common in the United States, it is effective in about 50% of people.
- Your doctor will be able to discuss treatment options with you based on your individual test results.

How is hepatitis C diagnosed?

- There are several blood tests that can be done to determine if an individual is infected with the hepatitis C virus. These tests cannot determine whether the infection is new (acute) or chronic.

How good is the blood test used by blood donation centers?

- The hepatitis C test used by blood donation centers is only a screening test to eliminate hepatitis C virus from the nation's blood and plasma supply. Individuals who test positive on the hepatitis C virus antibody test should consult a physician and be retested using other types of blood tests.

How can the spread of hepatitis C be stopped?

- There is no vaccine for hepatitis C
- If you are a health care or public safety worker, always follow routine barrier precautions and safely handle needles and other sharps
- Individuals who shoot drugs should stop and get into a treatment program; those who cannot stop should never share needles, syringes, water, or "works".
- Syringes, tattooing needles and acupuncture needles should not be shared or reused
- Personal items such as toothbrushes and razors should not be shared.
- People who have multiple sexual partners should use condoms each time they have intercourse.
- Individuals that are HCV positive should not donate blood, organs, or tissue.

Is there a vaccine for the prevention of hepatitis C?

- No, there is no vaccine for hepatitis C.

Hepatitis B and HIV Questions

What is hepatitis B?

- Hepatitis B is a disease caused by the hepatitis B virus that results in infection of the liver.

Who gets hepatitis B?

- Anyone can get hepatitis B. However, certain groups have a greater chance of becoming infected. These include:
 - Infants born to an infected mother
 - IV drug users
 - Sexual partners of infected people
 - People with many heterosexual, homosexual or bisexual partners
 - Certain populations with high rates of hepatitis B infection
 - Health care workers exposed to blood and body fluids
 - Public safety workers
 - Anyone who has frequent contact with blood
 - Housemates of chronically infected people are at higher risk than the general population, but lower risk than those listed above

How is the hepatitis B virus spread?

- Through sexual activity
- From exposure to contaminated blood and blood products
- From close household contact with infected individuals
- From infected mothers to their infants at birth
- Through the sharing of drugs, needles or other paraphernalia (works) while "shooting drugs".

What are the symptoms of Hepatitis B?

- Symptoms develop slowly and may include:
 - Loss of appetite
 - Stomach pain
 - Nausea
 - Vomiting
 - Jaundice (yellowing of the skin or whites of the eyes)

How soon do symptoms of hepatitis B appear?

- Symptoms develop slowly and may take as long as 45-180 days (average is 60-90 days) to appear after exposure to the virus.

How long can an infected person spread the virus?

- An infected person can spread the virus for several weeks before symptoms appear and as long as the person is ill.
- Persons who develop lifelong infection may spread the virus for their entire lives.

Is there a treatment for chronic hepatitis B?

- There is no specific treatment for acute or chronic hepatitis B

How is hepatitis B diagnosed?

- There are several blood tests that can be done to determine if an individual is infected with the hepatitis B virus, and to determine if the infection is newly-acquired or chronic.

How can the spread of hepatitis B be stopped?

- Vaccination is highly protective against the hepatitis B virus.
- Testing all pregnant women is recommended to prevent spread from infected mothers to their infants.
- Donated blood is tested for hepatitis B as well as other hepatitis C and other diseases. Individuals who test positive are rejected as donors.
- Syringes, needles used for injection and acupuncture and tattooing needles should never be shared or reused.
- Personal items such as toothbrushes and razors that could have blood on them should not be shared.
- Latex condoms should be used regularly if you have more than one sexual partner.

Is there a vaccine for the prevention of hepatitis B?

- A vaccine is available and is recommended for all infants at birth as well as for persons at high risk of being infected with hepatitis B.
- The vaccine is safe for most people and the most common complaint is soreness at the injection site.

What is HIV?

- HIV stands for human immunodeficiency virus. It is the virus that causes AIDS.

What is AIDS?

- AIDS stands for acquired immune deficiency syndrome.
- AIDS is the final stage of HIV infection. It can take years for a person infected with HIV, even without treatment to reach this stage.
- Having AIDS means that the virus has weakened the immune system to the point at which the body has a difficult time fighting infections.

How is HIV spread?

- Unprotected sexual activity
- Sharing needles or syringes used for injecting drugs, medicines, tattooing or body piercing with someone who has HIV
- From infected mothers to their infants at birth or from breast milk after the child is born
- From exposure to open wounds or sores, including those related to a sexually transmitted disease such as syphilis.

Can I get HIV through casual contact?

- HIV is not transmitted by casual contact including:
 - Touching, talking, or sharing a home with a person who is HIV positive or has AIDS
 - Sharing utensils, such as forks, knives, or spoons
 - Using swimming pools, hot tubs, drinking fountains, toilet seats, tanning beds, doorknobs, gym equipment, or telephones used by people with HIV/AIDS
 - Having someone with HIV/AIDS hug, kiss, sneeze, cough, breathe, sweat, or cry on you
 - Being bitten by mosquitoes
 - Donating blood

Is there is a treatment for HIV?

- There is no cure for AIDS. There are only medications that can slow down the progress of the HIV virus and the damage to the immune system.
- HIV medications are more effective in some people, but may not work for all.
- If you are HIV positive, check with your health care provider to see if these medications are appropriate for you.

How will I know if am infected with HIV?

- It is recommended that everyone know their HIV status testing options include:
 - Getting tested for HIV at the Southern Nevada Health District (Free)
 - Getting tested and one of the local community HIV testing centers listed in the phonebook
 - Asking your doctor about testing options

Resources

Where can I get more information about HIV?

- The Southern Nevada Health District web site under Office of AIDS
 - http://www.southernnevadahealthdistrict.org/hiv_aids/aids_prevention.htm
- CDC's web site under HIV/AIDS
 - <http://www.cdc.gov/hiv/>
- Contact The Southern Nevada Health District' HIV Testing center Annex A xxx-xxxx
- Ask your Doctor

Where can I get more information about Hepatitis?

- Hepatitis C
 - The Southern Nevada Health District web site
http://www.southernnevadahealthdistrict.org/disease_factsheets/hep_c.htm
 - Center for Disease Control website
<http://www.cdc.gov/NCIDOD/diseases/hepatitis/c/index.htm>
 - Ask your Doctor
- Hepatitis B
 - The Southern Nevada Health District web site
http://www.southernnevadahealthdistrict.org/disease_factsheets/hep_b.htm
 - Center for Disease Control website
<http://www.cdc.gov/NCIDOD/diseases/hepatitis/b/index.htm>
 - Ask your Doctor
- Hepatitis A
 - The Southern Nevada Health District web site
http://www.southernnevadahealthdistrict.org/disease_factsheets/hep_a.htm
 - Centers for Disease Control and Prevention website
<http://www.cdc.gov/NCIDOD/diseases/hepatitis/a/index.htm>
 - Ask your Doctor

I am scared or anxious about my exposure or results. Is there someone I can talk to?

- Contact Southern Nevada Adult Mental Health Services at xxx-xxxx

Are there any resources for me in the community if I've contracted hepatitis C and I have no insurance or a physician?

- A number of resources for people with hepatitis C are available on the health district website at www.SouthernNevadaHealthDistrict.org on the "Hepatitis C Investigation" section.

I have no insurance/I am underinsured

- Additional patient resources are available on the Southern Nevada Health District website, www.SouthernNevadaHealthDistrict.org.

Investigation - Event Specific Information

Why has this not come to the attention of the health district before?

- Disease transmission may have occurred in the past, but most people infected with Hepatitis C virus do not develop symptoms and do not know that they have been infected.
- As a result, these infections would not have been reported to the health district.
- An infection with hepatitis C resulting in the patient developing symptoms (acute disease) is rare, and it was an unusual occurrence that brought this problem to the attention of the health district.
- On average, two cases of acute hepatitis C are reported each year in Clark County. Six cases have been identified in relation to this investigation.

Is this an outbreak?

- An outbreak is defined by Nevada Law as an occurrence of cases of disease in a particular population in excess of that which is normally expected (Nevada Administrative Code Chapter 441A.130)
- On average, two cases of acute hepatitis C are reported each year in Clark County
- This is in excess of what is expected, so yes, it is considered an outbreak

Which clinic are we talking about?

- The Endoscopy Center of Southern Nevada, located at 700 Shadow Lane, Las Vegas.

How were the cases discovered?

- These cases were reported by physicians in the community to the health district.
- Nevada law requires that medical providers notify public health officials when they identify a number of different diseases, including hepatitis C.
- The common link between cases was identified through the routine investigation of the cases reported by medical providers, which includes an interview of the patient.

When was the problem identified?

- The cluster came to the attention of the health district in early January, 2008.

What did the physician or health care worker do that put patients at risk for exposure?

- A syringe (not a needle) that was used to administer medication to a patient was reused on the same patient to draw up additional medication.
- The process of redrawing medication using the same syringe could have contaminated the vial from which the medicine was drawn with the blood of the patient.
- The vial, which was not labeled for use on multiple patients, was then used for a second patient (with a clean needle and syringe).
- If that vial were contaminated with the blood of the first patient, any subsequent patients given medication from that vial could have been exposed to bloodborne pathogens.

How did so many people get infected at this facility?

- The exact details of disease transmission on the days in question are still not fully understood. The investigation is ongoing in an attempt to further address this question.

Is there one patient, physician or health care worker to blame for these infections?

- There was no one healthcare worker or piece of equipment identified as common to all known cases.
- The transmission occurred because of unsafe injection practices and used in the facility. These practices were not limited to a particular healthcare worker, but were found to be common practices throughout the clinic for an extended period of time. Once they were recognized and brought to the attention of the facility, they were immediately discontinued.

Can you actually link the cases together? Can you specifically link them to this situation?

- Of the six known cases, five had procedures on the same day.
- Genetic testing on four of the cases from the same day has identified that they likely came from a common source.
- A fourth case, who had a procedure on a different day, does not share a common source as the other three. This indicates that the problem that allowed disease transmission to occur was not a one-time event, but had recurred over an extended period of time.
- Investigation of the clinic practices identified common practices which would allow disease to be transmitted in this manner.

Is the problem still going on?

- The unsafe injection practices associated with the outbreak were first identified in mid-January as part of the investigation, and were immediately brought to the attention of the clinic.
- At that time, the clinic corrected these practices.
- Thus, the practices that lead to the exposure of patients have been corrected, so no new patient exposures should be occurring.
- As it can take several months for the symptoms of Hepatitis C to appear, additional cases may be identified despite no ongoing transmission of disease.

Who performed the investigation?

- The response was led by the Southern Nevada Health District, and the team included members of the Nevada State Bureau of Licensure and Certification and the Centers for Disease Control and Prevention.

How long have you known about these lapses in infection control?

- The unsafe injection practices were first identified in mid-January as part of the investigation, and were immediately brought to the attention of the clinic.
- At that time, the clinic corrected these practices.

How many people will be diagnosed with hepatitis C, B or HIV from this investigation?

- It is unknown how many people were infected at the clinic.
- The diseases of concern are routinely found in the population, and a significant number of people may have been infected with them prior to their procedure.
- It is estimated that about 1 in 25 people in the clinic population could be infected with hepatitis C prior to their procedure, with a significant number of these patients not knowing they are infected.
- It is estimated that about 1 in 200 people in the clinic population could be infected with hepatitis B prior to their procedure, with a significant number not knowing they are infected.
- It is estimated that about 1 in 250 people in the clinic population could be infected with HIV prior to their procedure, with one-third to one-half not knowing they are infected.
- Although testing can determine if a person is infected, it cannot determine the source of the infection.

Will people die from this illness?

- The diseases for which patients are recommended to be tested can result in a range of disease severity, and can eventually result in death.
- It is important that you speak with your physician if you have one of these diseases, as your physician will be able to address your specific risks for serious illness and develop a plan to monitor your health.

I heard testing was offered by the health district for free to a group of people. Is this true? How do I become part of that group?

- As part of the investigation, the health district is testing about 100 patients who were seen in the clinic on the days of other identified cases.
- This is being done for the purposes of better understanding the transmission of disease within the facility.
- Only patients who had procedures on the specific days of concern are eligible for this testing.

What are the names of the infected individuals?

- Because of medical confidentiality laws, we cannot provide the names of any of the patients.

How many cases like this do you see in a year?

- Most people who become infected with hepatitis C initially have mild or no symptoms and do not know that they have been infected unless they are tested by a doctor.
- Only a small percentage of people infected with hepatitis C develop acute disease and have any outward signs of infection.
- On average, two cases of acute hepatitis C are identified each year in Clark County.

How many people have hepatitis C?

- It is estimated that about 2% of the United States population is infected with hepatitis C.

I have a new device that can be used to diagnose or treat patients, or clean medical devices. Will you endorse it?

- No. The health district does not endorse any products.

How could you let this happen in our community?

- The Southern Nevada Health District is responsible for investigating reports of illness in our community. Our first concern is the health and well-being of the public. When this situation was brought to our attention we promptly began an investigation and worked with the appropriate agencies to address the issues and have made recommendations to help prevent this type of situation from occurring again.

Does everyone who visits a doctor or has some type of medical test have to be concerned about getting some terrible infection or chronic disease?

- All health care professionals and medical facilities should follow safe injection and appropriate infection control practices. Patients can and should ask their medical providers about the practices used in their facility.

Why did they do these practices?

- The health district cannot speculate as to the reason for the unsafe injection practices that lead to the identified infections.

Are you trying to protect the doctor or the facility?

- Our mission is to protect the health of the public, not medical providers or businesses.
- We worked quickly to identify the source of the outbreak and to notify patients who were placed at risk.
- We have been forthcoming with details about the investigation, including the name of the facility involved, the time period in question, and the findings of our investigation.

Why was I not notified sooner?

- In early February, the investigation identified the time span over which patients may have been placed at risk.
- At that time, a list of addresses for the at-risk patients was requested from the clinic.
- The address list was provided on February 22, 2008.
- Given the magnitude of the notification, patients were notified as quickly possible.

Isn't it overkill to notify this many patients?

- The practices that lead to the transmission of disease have been occurring at this clinic for several years.
- It is not possible to say which patients were exposed to bloodborne pathogens. Based on the practices of the clinic, it was determined that all patients who received injected anesthesia medication as part of their procedure had been put at risk for possible exposure.
- Many of the diseases transmitted through the practices of the clinic have no outward symptoms of disease for many years. Patients may have been infected but not know it, so it was determined that all patients should be notified so that they can take the appropriate steps to determine if they are infected and protect their own health.

When will the investigation be completed?

- It is not possible to say how long the investigation will take, although it is expected that completion of laboratory testing will take two to three months.

Did you close the other clinics?

- The Southern Nevada Health District does not have regulatory authority over medical facilities and does not have the authority to close these types of facilities. The various governmental agencies holding their business licenses made the decision to close them.

Are you sending letters to patients at the other clinic?

- The Southern Nevada Health District is still recommending testing for hepatitis C, hepatitis B, and HIV for patients who received injected anesthesia medication at the Endoscopy Center of Southern Nevada (700 Shadow Lane, Suite 165B) between March of 2004 and January 11, 2008. At this time, the health district is not recommending testing of patient who had procedures at other clinics.
- If you have any concerns, you should contact your primary care physician to discuss them.

Why were the clinics closed then?

- The business licenses were suspended by the county and/or the cities of Las Vegas and Henderson

I have a complaint regarding a local medical clinic or facility. Where should I send it or what number should I call?

- The Southern Nevada Health District as well as other local health districts in the state do not have oversight or regulatory authority over those types of facilities. If you have a concern or a complaint, contact the Nevada State Health Division's Bureau of Licensure and Certification at xxx-xxxx or from northern Nevada call xxx-xxxx.

Am I the source of the infection at the Endoscopy Center of Southern Nevada

- The health district's investigation has identified the two source patients who had procedures at the Endoscopy Center on either July 25 or Sept. 21. These are the dates that the health district has identified as dates of known disease transmission.
- If you are the source case, the health district will be contacting you directly.
- The health district is notifying the source patients and those who had procedures on those dates of this updated information.

Who are the source patients?

- The health district will not publicly release protected patient information.

I think that I am one of the 77 hepatitis C patients who you reported as "potentially clinic associated." Can you verify that?

- We are not able to verify information on the telephone. It is recommended that you enroll in the Hepatitis C Exposure Registry. This will provide information to the health district that could assist us to classify your infection.
- You can contact the health district's epidemiology department at xxx-xxxx if you have additional questions.

Why can't you say with real certainty that the 77 cases you previously reported are positively linked to clinic and the source patients?

- At this time, the health district can only determine that these 77 cases of hepatitis C infection are potentially associated with the clinic because we are unable to test these samples genetically. Because the procedure dates are different, we have no additional sources identified to test against.
- The health district did not receive a complete patient list from the Shadow Lane clinic so we are not certain who could be tested. Many former patients who were tested and whose results were submitted to the health district were not on the lists. We are not certain of their procedure dates or which clinic they visited.

Aren't you going to genetically test those 77 patients?

- We are not able to genetically test the samples of these 77 patients for several reasons. The hepatitis C virus mutates quickly and the virus in these patients could have changed significantly since their infection.
- We do not have a source patient that will allow us to compare genetic samples

What do I do if I am positive for hepatitis C and visited either clinic but my procedure was on a different date?

- The health district is still investigating the outbreak, however, at this time there are no other identified clusters of infection. We cannot determine if you were infected at the clinic or prior to your procedure.
- The health district recommends that you enroll in the Hepatitis C Exposure Registry. This will assist our investigation to determine if there are any additional clusters of transmission or illness related to the outbreak. The registry will also allow us to determine the case classification for your infection.
- If you are positive, it is also recommended that you develop a relationship with a physician who can manage your medical care.

How did you determine the source of these cases? Why can't you determine the source of the Burnham clinic?

- The two cases that are the source of infection for July 25 and Sept. 21 are two separate patients. We know that each had a procedure on one of the two dates. Through genetic testing, we are able to determine that the strains of the hepatitis C virus in the cluster of patients who had procedures on those two dates are the same or are a nearly identical match to make the connection.
- The Desert Shadow clinic was closed when the acute case was reported and the source of disease transmission cannot be determined. We were not able to observe unsafe practices to determine transmission, a source for infection or any additional dates of disease transmission.
- We are not certain if our list from the Burnham clinic is complete.
- If additional information becomes available, the health district will continue its investigation and revise recommendations to patients as appropriate.

Inspections and Regulations

Who is responsible for making sure the facility follows safe injection practices?

- The Nevada State Health Division, Bureau of Licensure and Certification licenses ambulatory surgical centers in Nevada. The Bureau conducts initial state licensure inspections, complaint investigations and other periodic inspections to determine compliance with state regulations.
- State regulations require an ambulatory surgery center to have systems in place to assure quality care. These regulations require that the healthcare practitioners in the facility participate in the development and application of criteria to evaluate the care provided at the facility, identify problems and formulate resolutions based on currently accepted practices.
- Ambulatory surgery centers may choose to participate in the Medicare program. Medicare certified surgical centers are also inspected by the Bureau of Licensure and Certification to see that they adhere to federal regulations. The federal regulations also require systems to assure quality. The Bureau conducts initial Medicare certification inspections, complaint investigations and other periodic inspections to determine compliance with federal regulations.
- Although there is licensure and certification oversight of ambulatory surgical centers, the ultimate responsibility of assuring safe injection practices falls to the facility operators and the healthcare practitioners working in the facility on a day to day basis.

When was the ambulatory surgery center last inspected?

- The last ambulatory surgery center inspection related to health issues was on 1/9/08. The ambulatory surgery center had other inspections related to health issues completed on 6/7/07, 7/23/04, 1/30/04, and 8/29/03.
- The ambulatory surgery center had a Medicare inspection in 1/2/96 and 12/5/01. The ambulatory surgery center had construction and life safety code inspection on 12/5/01 and 5/24/04.

Why was this ambulatory surgical center not recently inspected?

- The Nevada State Health Division, Bureau of Licensure and Certification conducts initial inspections of all ambulatory surgical centers before a center can see patients.
- After licensing the Bureau conducts complaint investigations and periodic inspections if concerns arise.
- There is no inspection schedule mandated in state or federal law for ambulatory surgical centers.

What did the most recent inspection find?

- The last inspection in January 2008 identified staff using single-use Propofol for multiple patients, not following manufacturer's directions for the cleaning detergent used to clean the endoscopes, and not updating the ambulatory surgery center's policies and procedures.

How can I obtain a copy of your inspection findings?

- The surgical center must submit a Plan of Correction within 10 days of receipt of the Statement of Deficiencies from the Bureau. At that time the document becomes public record.
- You can obtain a copy of the Statement of Deficiencies/Plan of Correction that includes the inspection findings and the surgical center's corrective action plan from the Bureau of Licensure and Certification. Contact the agency at XXX-XXXX to obtain an information request form. Staff can assist you properly completing the request form.

Has the ambulatory surgery center been sanctioned for these practices?

- The role of the Bureau of Licensure and Certification in regards the practice that placed the public at risk is to ensure that the practice is corrected.
- The ambulatory surgery center was directed to immediately discontinue the unsafe practice.
- A Statement of Deficiencies was issued and the ambulatory surgery center submitted a Plan of Correction which addressed what corrective actions would be taken to comply with the requirements to remain licensed and to participate in the Medicare program and how compliance would be maintained.
- Because of the scope and severity of the problem identified, the surgical center will be subject to state administrative sanctions, including monetary penalties.
- To ensure that the ambulatory surgery center can continue to participate in the Medicare program, the Bureau will conduct a follow-up visit to ensure that the unsafe practice has been permanently corrected. If not, the Bureau will recommend that the ambulatory surgery center no longer be allowed to participate in the Medicare program.

Why hasn't this ambulatory surgery center been closed down?

- Revocation or suspension of a license occurs when an operator is unable to comply with state regulations.
- In this case the surgical center took immediate steps to correct deficient practices as soon as investigators identified procedures that could result in the transmission of bloodborne pathogens.
- Follow up inspections will take place to verify the surgical center continues to meet regulations.
- On-going practices in the surgical center will then determine if further state licensing action will be taken, or if the surgical center will be terminated from Medicare participation.

Will the doctors or other workers from the ambulatory surgery center be punished?

- The licensed professionals identified in the deficient practice will be referred to their appropriate licensing boards.

How can you be sure that the problem is not ongoing?

- The Bureau of Licensure and Certification will conduct follow up inspections to assess that the ambulatory surgery center has implemented and maintained appropriate corrective actions.

Have you inspected their other location to ensure that this is not occurring?

- Yes. A full inspection for compliance with state licensure and federal Medicare certification regulations was conducted at Desert Shadow Endoscopy Center, a licensed ambulatory surgery center. Deficiencies were identified and immediately corrected. The deficient practices were not found to put patients at risk as at the other facility. A formal Statement of Deficiencies has been issued to the facility.
- Unannounced on-site inspections will be conducted at this facility to evaluate the on-going implementation of the facility's corrective action.

Did you find similar practices at the other ambulatory surgery center?

- Yes, it was determined the other ambulatory surgery center was administering single-use vials of Propofol to multiple patients.

Have you checked other ambulatory surgery centers to make sure that they aren't using the same practices that lead to this outbreak?

- Mass education of all licensed ambulatory surgery centers has already begun. The Nevada State Health Division, State Epidemiologist, has issued a Technical Bulletin to all licensed ambulatory surgery centers providing clear education on the appropriate techniques for medication vial use, and the one-time use and disposal of needles and syringes.
- There is a targeted education effort underway throughout the state to assure that practitioners are applying correct procedures and quality assurance systems. Patients are encouraged to ask their healthcare practitioner any and all questions they have concerning patient safety systems that are in place.
- Additionally the Bureau of Licensure and Certification is conducting inspections of other ambulatory surgery centers. Information will become available as these investigations are completed.

Will there be any changes, regulations or recommendations made so something like this doesn't happen again in our community?

- The Nevada State Health Division, State Epidemiologist is preparing a technical bulletin to be issued to all licensed ambulatory surgical centers throughout the state of Nevada. The technical bulletin will include detailed information about safe injection practices to prevent this or similar occurrences.
- The State Epidemiologist is also coordinating with professional licensing boards and local health authorities to distribute technical information to licensed health care professionals in other healthcare settings.

As a patient or employee, I observed similar practices at another ambulatory surgery center. How do I make a report?

- Contact the Bureau of Licensure and Certification complaint line at xxx-xxxx.
 - Be prepared to report the following information:
 - The ambulatory surgery center's name and location
 - If known, the name of the patient(s) involved
 - The date of the observation(s)
 - The person(s) observed involved in the unsafe practice
 - What exactly was observed
 - If you are an employee, what is the center's current written policy which addresses your concerns.

I am a healthcare provider and my boss told me to reuse syringes or reuse single-dose vials of medication. How do I report it?

- Contact the Bureau of Licensure and Certification complaint line at xxx-xxxx.
- Be prepared to report the following information:
 - The ambulatory surgery center's name and location
 - If known, the name of the patient(s) involved
 - The date(s) of the observations
 - The person(s) observed reusing syringes or single-dose medication vials
 - The person(s) directing the reuse of syringes or the reuse of or single-dose medication vials
 - What exactly was observed
 - The ambulatory surgery center's current written policy which addresses your concern

I am an employee/former employee of the ambulatory surgery center (the Endoscopy Center of Southern Nevada) and would like to provide additional information to the investigators. How do I get in touch with them?

- **FOR CURRENT AND FORMER ENDOSCOPY CENTER OF SOUTHERN NEVADA EMPLOYEES ONLY:** Contact the Southern Nevada Health District Office of Epidemiology at xxx-xxxx.
- For employees of other centers contact the Bureau of Licensure and Certification complaint line at xxx-xxxx.

I am scheduled to have a procedure at an ambulatory surgical center, should I be concerned about their safe injection practices?

- As a healthcare consumer you have the right to ask any questions related to the procedure you are undergoing and the practices the surgical center uses to assure your safety.
- You may want to find out the ambulatory surgery center's procedures related to infection control and safe injections, including but not limited to handwashing, needle and syringe use and disposal, which equipment used in your procedure is single-use or disposable, medication vial reuse and how it is protected from contamination.

What about the Gastroenterology Center of Nevada?

- The Gastroenterology Centers of Nevada are physician medical offices and are not required to be licensed by the Bureau. However, the physician's must be licensed by the Board of Medical Examiners and are required by local jurisdictions to have a local business license.

They are located as follows:

Gastroenterology Center of Nevada
4275 Burnham Avenue
Suite 101-B
Las Vegas, NV 89119-5488

Gastroenterology Center of Nevada
3150 N. Tenaya Way
Suite 225
Las Vegas NV 89128

Gastroenterology Center of Nevada
5915 S. Rainbow Blvd. Suite 105
Las Vegas NV 89118

Gastroenterology Center of Nevada
1815 East Lake Mead Blvd
Suite 207
North Las Vegas, NV 89030-7187

Gastroenterology Center of Nevada
700 Shadow Lane
Suite 165-A
Las Vegas, NV 89106-4126

Gastroenterology Center of Nevada
2610 West Horizon Ridge Parkway
Suite 105
Henderson, NV 89052-2869

Safety/Surgical Procedures

Are colonoscopies safe?

- In this case, the disease transmission was not related to the colonoscopy, but rather to the injection practices used to administer anesthesia to the patient.
- When proper injection practices and infection control procedures are followed, medical procedures, including colonoscopies, are generally safe.

Should I still get a colonoscopy?

- Colonoscopies are an important part of protecting yourself against the development of colorectal cancer.
- Although this investigation focused on a center that performed colonoscopies, and other similar procedures, the source of the exposure was the way that the anesthesia was administered.
- If recommended by your physician, there is no reason why you should avoid undergoing this procedure.

I have a procedure scheduled there next week. Should I cancel it?

- Your specific needs for this medical procedure should be discussed with your personal physician.

I have a small surgery scheduled for next week at a different center. As a patient, how can I protect myself?

- As the patient, you should feel empowered to discuss what steps are being taken taking to protect you with your healthcare provider.
- If you have concerns about specific issues, ask your healthcare provider about those issues.

Is this same practice occurring at other medical facilities or doctor's offices in the Valley?

- The Southern Nevada Health District has jurisdiction to investigate reports of illness in the community. It does not have information related to the practices at facilities not under investigation.

Exposure/Risks

How did so many people get exposed at this facility?

- The practices that could have led to disease transmission have been occurring for several years.
- These common practices, combined with the fact that this is a very busy clinic resulted in the potential for a large number of people to be exposed.

How do I know if I was exposed to the virus during my procedure at the center?

- There is no way of knowing which patients were exposed during their procedures at the clinic. This is why all clinic patients were notified, and why we are recommending that all patients be tested.

When were the known cases exposed?

- The identified cases had procedures in the summer of 2007.
- However, the practices that could have resulted in the transmission of disease from one patient to another have been reported to be common practices in the clinic since it opened in March of 2004.

What is the risk of disease?

- The actual risk of disease cannot be determined for an individual patient.
- As the risk is unknown, all clinic patients were notified, and we are recommending that all patients be tested.

If I had a procedure at one of the other facilities, should I get tested?

- The Southern Nevada Health District is still recommending testing for hepatitis C, hepatitis B, and HIV for patients who received injected anesthesia medication at the Endoscopy Center of Southern Nevada (700 Shadow Lane, Suite 165B) between March of 2004 and January 11, 2008. At this time, the health district is not recommending testing of patient who had procedures at other clinics.
- If you are still concerned or have additional questions you should consult with your physician.

I was a patient there 5 years ago (prior to the notification group). Should I be tested too?

- This investigation focused on the practices at this specific clinic since it opened in March of 2004 when a major remodeling of the clinic and change in practices and procedures occurred.
- As we could not investigate the practices of the clinic prior to that time, we cannot advise you of the practices or risks at that clinic prior to March 2004.
- If you are concerned for your health, consult your physician, who will be able to determine if testing is appropriate for you.

Am I at greater risk for infection with one virus over another?

- There is no way of knowing which viruses, if any, a person has been exposed to.
- It is not possible to determine an individual's risk for infection with a particular virus.
- It is important that you be tested for Hepatitis B, Hepatitis C, and HIV.

In taking so long to notify patients, were additional patients placed at risk?

- Any delays in the notification would not have placed additional patients at risk.
- During the investigation, practices were identified that could have led to the transmission of disease. Those practices were immediately brought to the attention of the clinic, and were corrected.

How many people were exposed?

- About 40,000 patients have been notified that they may be at risk for exposure to bloodborne pathogens.
- Being placed "at risk" does not mean that the patient definitely was exposed, but that they had an increased chance of being exposed.
- The true number of "exposed" people cannot be determined.

Exactly how many people are you notifying about this situation?

- A total of 39,561 letters were mailed to clinic patients.

Can you tell me if I'm on the list and if I should receive a letter?

- The list the Southern Nevada Health District received might not be complete and due to patient confidentiality issues, we are not able to tell you whether or not you are on the list. We recommend that you contact your physician. He or she should have information regarding the referral to the clinic.

I think I was at that clinic and didn't get my letter. What am I supposed to do?

- The health district has determined that the list of addresses provided by the clinic is not complete, and that correct addresses were not provided for all patients on the list. If you are unsure about the location or date of your procedure, contact your insurance carrier or physician for additional information. If you were a patient of the center between March of 2004 and January 11, 2008 and have not received a letter, you may download it from the health district website at www.southernnevadahealthdistrict.org.

Who will pay for my treatment?

- The decision to treat you will be made by you and your healthcare provider, and that discussion should include the cost and length of treatment.
- A number of resources for medical follow-up and treatment are available on the health district website at www.SouthernNevadaHealthDistrict.org on the "Hepatitis C Investigation" section.

Testing

If I test positive for hepatitis C, what does this mean for my friends and family members? Should they also be tested?

- Hepatitis C does not spread through casual contact, through the air, through food, or through touching.
- You should be careful not to expose family members to your blood.
- In fact, you come in contact with people that have Hepatitis C every day without knowing it, but are not at risk for disease transmission through casual contact.

How soon after I am infected with hepatitis C will I test positive if I have no symptoms?

- On average, infected individuals will test positive within 8-9 weeks after exposure.
- 80% of infected individuals will test positive within 15 weeks after exposure.
- >90% of infected individuals will test positive within 5 months after exposure.
- ≥97% of infected individuals will test positive within 6 months after exposure.

How soon after I am infected with hepatitis C will I test positive if I have symptoms?

- The tests routinely used to identify Hepatitis C are based on your body's reaction to the virus. This reaction takes time to develop.
- In persons who become acutely ill, 7 of 10 people test positive when symptoms begin, and 9 of 10 will test positive within three months.

Is it possible for my hepatitis C test result to be incorrect? For example is it possible for me to be infected with hepatitis C, but test negative? Is it possible for me to test positive, but not really infected with hepatitis C?

- There are a number of factors to consider in the evaluation of test results.
- If you are tested too soon after infection, your results may be negative despite being infected.
- Although rare, tests can give incorrect results.
- Your physician will be able to help interpret test results related to hepatitis C.

Your investigation was for Hepatitis C. Why should I be tested for Hepatitis B and HIV as well?

- The investigation revealed practices which could have exposed patients to the blood of another patient. Although Hepatitis C was the focus of the investigation, Hepatitis B and HIV can be transmitted in the same manner as Hepatitis C.

Should I go to the emergency room?

- No. Although you are concerned about your health, this exposure is not immediately life threatening, and does not require a visit to an emergency room.
- Emergency rooms should be used for immediate health emergencies only.

Is there more than one kind of test for hepatitis C?

- There are different tests that can be performed to identify Hepatitis C. Your healthcare provider will be able to order the appropriate test for you, as well as help with the interpretation of results.

Is it too late to be tested?

- No, if you have been infected, testing will always be positive, even years after infection.

How soon can I be tested?

- The tests used to identify Hepatitis C, Hepatitis B, and HIV are based on your body's immune response to infection, which can take weeks to months to develop.
- If they are infected, people will begin to test positive after about 12 weeks, with almost all testing positive within 6 months.
- If you are tested prior to 6 months after your exposure and are found to be negative, it is recommended that you are tested again at 6 months after exposure to ensure that you are negative.

Could you help interpret my test results?

- We advise you to consult your physician as we are unable to interpret individual test results.
- Your physician is best prepared to explain the results of your test and, if needed, advise you of an appropriate course of action that takes into account your personal health history.

If I have tested positive for hepatitis C since having my procedure, does that prove that I was infected at the center?

- No. Although medical tests can show that you have been infected, they cannot determine the source of the infection.

My blood test was positive for hepatitis C, but I feel fine. Do I still need treatment?

- Your physician will be able to advise an appropriate course of medical monitoring and/or treatment based on your individual test results.

What are people who test positive for hepatitis C, B or HIV supposed to do?

- Options for disease management and possible treatment options, as well as regular health monitoring, should be discussed with a physician, who can determine the appropriate next steps for the patient.

If I test positive, who will know about my results?

- In addition to your doctor and the laboratory that performed the test, by Nevada law all positive tests must be reported to the Southern Nevada Health District.
- Medical privacy laws prohibit any of these individuals from releasing information about you or your test results to people other than the public health authority without your consent.

Are the symptoms that I am currently experiencing hepatitis C/hepatitis B/HIV?

- We cannot diagnose any disease over the telephone. If you believe that you are currently ill, you should seek medical attention.

Can you recommend a physician?

- No. We cannot endorse or recommend the services of any physician.
- A number of resources are available on the health district website at www.SouthernNevadaHealthDistrict.org for people with limited ability to pay.

What should I do to protect others while I am awaiting my test results?

- Do not donate blood or plasma.
- Avoid sharing items which may be contaminated with your blood, such as toothbrushes, nail clippers or razors.
- Abstain from sexual intercourse or use a latex condom.

Where can I get tested?

- Speak with your healthcare provider, as they will be able to refer you for testing as well as provide you with your results.

I am uninsured. Where can I get tested?

- A number of resources for testing and medical follow-up are available on the health district website at www.SouthernNevadaHealthDistrict.org on the “Hepatitis C Investigation” section.

Who is paying for all this?

- At this point, the primary concern of the health district is for the health of the people who have been exposed.
- Resources are available on the health district website for those who do not have the ability to pay at www.SouthernNevadaHealthDistrict.org.

How many cases has the health district linked to the Endoscopy Center?

- The Southern Nevada Health District has identified eight acute cases of hepatitis C, and seven of these can be linked to the Endoscopy Center of Southern Nevada on Shadow Lane. The eighth case can be linked to an affiliated clinic. The health district has identified 77 cases they are classifying as potentially linked to the clinic. These patients have tested positive for the virus, but have not developed an acute case of the disease.

How many of the 40,000 people you notified have been tested?

- Since the February 27 notification, about 50,000 test panels have been ordered through local laboratories. These do not necessarily represent the number of patients, just the number of test panels. The health district cannot say for certain that the number of test panes ordered represents everyone who has been notified.

The HD said that about 4 % of people will test positive, that number is much lower.

- The investigation is going to take many months to complete and the health district anticipates that there will be more positive test results. As part of the investigation, investigators are sorting through positive results to determine which patients received procedures at the clinic, their risk factors to determine their potential exposure. Hepatitis C infection is common in the community and many patients would have been positive prior to their procedures.

I received a positive test result, how come I haven't heard from the health district?

- The health district continues to receive reports of positive test results and is sorting through them to determine patients who were part of the notification. Our initial process included interviews with patients who received positive results and we are matching them to the list we received from the clinic, which we know is not complete. If you were a patient at the clinic between March 2004 and January 11 and received a positive result, please contact the health district's epidemiology department at xxx-xxxx. Or I can take your name and phone number and send a notification to the Health District for you.

I had a procedure at the Desert Shadow Endoscopy Center/Burnham, do I need to be tested?

- The health district continues to advise patients who are concerned about their health to speak with their physicians or healthcare providers about your risk of exposure and testing. Your physician will be able to advise you and will be able to manage your health care needs.

Why aren't you specifically recommending testing for patients of the Desert Shadow Endoscopy Center.

- At this time, the health district is not able to make specific recommendations due to incomplete information. The clinic was closed when the acute case was reported and the health district was not able to interview staff or observe clinic practices.
- Due to the lack of documentation, the health district encourages patients to discuss their concerns and risk of disease with their physician or healthcare provider and to pursue testing for hepatitis C, B and HIV if they are concerned. A source of disease transmission has not been determined.

Why aren't you specifically recommending testing for patient?

- Prior to making a decision regarding a patient recommendation or notification, it is important that the health district have all of the necessary information.
- Thousands of boxes of clinic files were collected by the Metropolitan Police Department and information only became properly sorted out and available to both Metro and the health district recently.
- At this time, the health district is not able to make specific recommendations based on incomplete information. The clinic was closed when the acute case was reported and the health district was not able to observe unsafe practices, such as the reuse of syringes, and the source of disease transmission cannot be determined.
- If additional information becomes available, the health district will continue its investigation and revise recommendations to patients as appropriate.
- The health district is encouraging patients of the Desert Shadow clinic to speak with their physicians or health care provider about their concerns and their risk of exposure.

If you knew one person got sick, how come you are not advising they get tested?

- At this time, the health district is not able to make specific recommendations based on incomplete information. The Desert Shadow clinic was closed when the acute case was reported, the health district could not observe clinic practices, and the source of disease transmission cannot be determined.
- If additional information becomes available, the health district will continue its investigation and revise recommendations to patients as appropriate.

I did not get my notification letter and I know I was a patient

- The health district will be sending a letter to patients of the Desert Shadow clinic to advise them about the findings of the investigation as well as information about the Hepatitis C Exposure Registry.
- There is no way verifying that the patient list from the Desert Shadow clinic is complete. If you were a patient at the clinic and did not receive a letter or have a question about the registry, visit the health district website, www.SouthernNevadaHealthDistrict.org.

Do I need a letter to get tested?

- As with any lab testing, you will need an order from your physician that you must bring to the lab. The health district does not provide lab orders for testing. You should contact your physician about testing.

I was a patient at the Burnham Ave. clinic and I want to get tested, but I don't have a primary care doctor or insurance. What should I do?

- The Southern Nevada Health District website has a list of resources available www.SouthernNevadaHealthDistrict.org.

What if I was a patient at one of the other clinics? Do I need to get tested?

- The health district recommends that patients who are concerned about their health, have questions about hepatitis C or are worried about potential exposure should speak with their physician or health care provider.
- The health district has not received any reports of illness at other affiliated clinics or ambulatory surgical centers. If you have questions or are concerned about a possible exposure to hepatitis C, you should contact your physician or health care provider.

Will the health district notify me if my tests are positive?

- You will receive your test results from the physician or healthcare provider who ordered your lab tests. The health district will not contact you to provide test results.

Blood Donation

I donated blood recently - don't they test my blood for hepatitis C?

- Donated blood and plasma are screened for HIV, Hepatitis B, Hepatitis C, and a number of other viruses.

How good is the blood test used by blood donation centers?

- The hepatitis C test used by blood donation centers is only a screening test to eliminate hepatitis C virus from the nation's blood and plasma supply.
- A positive finding for hepatitis C should be followed up with additional testing to confirm the screening test results.

If I already have one of the diseases, do I need to be tested again?

- It is recommended that persons be tested for Hepatitis B, Hepatitis C, and HIV. Although you do not need to be tested for the virus with which you are infected, it is recommended that you are tested for infection by the other two.

Healthcare Provider Information

As a medical professional, how do I report a case of disease?

- Contact the Southern Nevada Health District.
- Report acute hepatitis B or C cases to the Office of Epidemiology by phone at xxx-xxxx.
- Report chronic hepatitis B or C cases to the Office of Epidemiology by fax at xxx-xxxx.
- Report HIV or AIDS cases to the Office of HIV/AIDS by phone at xxx-xxxx, or by fax at xxx-xxxx.

I am a physician. Can you help me interpret the test results for a patient?

- Information on the testing process, including the recommended tests to order and their interpretation is available in a technical bulletin distributed by the health district entitled "Hepatitis C Exposure at a Medical Clinic".

I am a doctor and have a patient in my office with your letter. Which tests should I order?

- Information on the testing process, including the recommended tests to order and their interpretation is available in a technical bulletin distributed by the health district entitled “Hepatitis C Exposure at a Medical Clinic”.
- If you have not received this bulletin, is available on the health district website (www.southernnevadahealthdistrict.org) on the “Hepatitis C Investigation” section,

Legal Concerns

Should I sue?

- We cannot provide you with legal advice

Do I have a legal claim if I'm infected?

- We cannot provide you with legal advice

Can you recommend a lawyer?

- We cannot endorse or recommend the services of any lawyer or law firm

I am a lawyer and would like to represent victims in a lawsuit. Will you pass my contact information along?

- No. We cannot endorse or recommend the services of any lawyer.

I am a lawyer and would like specific information on the investigation. How do I obtain it?

- The final report of the investigation will be available approximately three months after the investigation is completed. You may request it at that time.

I saw on the news that a lawsuit was filed. How do I become part of that suit?

- The health district is not involved in any pending litigation and cannot provide information on any ongoing lawsuits.

Isn't this against the law? Has there been any type of crime committed here?

- Questions about the criminal culpability of the facility or any individual are beyond the scope of this investigation, which focused on the public health aspects of disease transmission. When the investigation is completed, our findings will be made available to the appropriate authorities so that they can make that determination.

Is this physician negligence or malpractice?

- Questions about the civil liability of the facility or any individual are beyond the scope of this investigation, which focused on the public health aspects of disease transmission.

Is there a victim compensation fund?

- No, not at this time.

I have been instructed to contact the SNHD to become part of an action/lawsuit against the Endoscopy Center of Southern Nevada.

- The Southern Nevada Health District cannot sue to collect damages on behalf of individual patients. It is recommended that you consult with an attorney if you have any questions about making a claim against the Endoscopy Center of Southern Nevada or its physicians.

Media Information

I am a reporter and would like to interview someone about this. How do I get in touch with someone to interview?

- For questions about the investigation, hepatitis C, lab testing, or the notification of patients, contact the Southern Nevada Health District Public Information Office at xxx-xxxx
- For questions about facility inspections and oversight, contact the Nevada State Health Division PIO at xxx-xxxx.

Appendix H

News Releases



MEDIA ADVISORY
February 27, 2008

Southern Nevada Health District to issue patient notifications

- WHO** The Southern Nevada Health District and the Nevada State Health Division/Bureau of Licensure and Certification.
- WHAT** The Southern Nevada Health District and its partners will hold a news conference to discuss a large-scale patient notification in relation to an investigation.
- WHEN** 1 p.m., Wednesday, February 27, 2008
- WHERE** Southern Nevada Health District
Auditorium
625 Shadow Lane
Las Vegas, NV 89106



FOR IMMEDIATE RELEASE
February 27, 2008

Health District notifies patients of potential exposure to hepatitis C
urges testing for approximately 40,000 patients

LAS VEGAS – The Southern Nevada Health District announced it is notifying approximately 40,000 patients of a local medical clinic about potential exposure to hepatitis C following an investigation of several acute cases of the illness. Patients who had procedures requiring injected anesthesia at the Endoscopy Center of Southern Nevada, located at 700 Shadow Lane, Las Vegas will begin to receive letters this week. The health district's notification includes patients who had procedures at the clinic between March 2004 and January 11, 2008, and recommends they contact their primary care physicians or health care providers to get tested for hepatitis C as well as hepatitis B and HIV.

The health district identified a cluster of three acute cases of hepatitis C in January 2008 and has identified a total of six cases to date. Hepatitis C infections must be reported by medical providers and laboratories in Nevada and the health district typically receives reports of approximately two cases of acute hepatitis C annually. Five of the cases had procedures requiring injected anesthesia on the same day. Following a joint investigation with the Nevada State Bureau of Licensure and Certification (BLC) and with consultation from the Centers for Disease Control and Prevention, the health district determined that unsafe injection practices related to the administration of anesthesia medication might have exposed patients to the blood of other patients. The exposures did not result from the medical procedures performed.

The joint investigation identified the re-use of syringes (not needles) and the use of single dose vials of anesthesia medication on multiple patients as the potential sources of contamination. The clinic took corrective action when notified by staff conducting the investigation.

When cases were identified the health district notified the Nevada State Health Division, Bureau of Licensure and Certification. The endoscopy center holds an ambulatory surgical center license with the state and licensing regulations require a surgical center to maintain systems for quality assurance and for the governing body to oversee the effectiveness of those systems. The licensing inspection focused on rapid identification of deficient regulatory practices that were brought to the immediate attention of the center for correction. The surgical center has been issued a formal Statement of Deficiencies relating to both state licensing requirements and federal regulations for Medicare certification. The center has responded with a written Plan of Correction. The bureau will conduct additional on-site inspections to determine that the center continues to implement and maintain its corrective action plan.

(more)

Health District/Hepatitis C Notification – add one

“Based on the information we discovered during our investigation it appears the injection practices that can lead to the transmission of hepatitis C and other bloodborne infections have been occurring at this clinic for several years. We are recommending all patients during this timeframe to get tested because we cannot determine which patients may have been exposed,” said Dr. Lawrence Sands, chief health officer. “Hepatitis C is a serious medical condition and infected patients may not have outward symptoms of the disease for many years. As a precaution, and in order to take appropriate steps to protect their health, it is important for these patients to get tested and for anyone with the illness to seek medical treatment,” Sands said.

The health district is also recommending patients get tested for hepatitis B and HIV, as both of these diseases can be transmitted through the same unsafe injection practices identified as the likely source of transmission. However, the risk of transmission of hepatitis B and HIV is lower, and no associated cases of hepatitis B or HIV have yet been identified. The prompt identification of these infections is important, as there are treatment and/or medical management options available.

Eighty percent of people infected with hepatitis C will have no signs or symptoms. In acute cases, there is a clearly defined onset of symptoms, that may include loss of appetite, stomach pain, nausea, vomiting and sometimes jaundice (a yellowing of the skin or the whites of the eyes). Individuals with chronic hepatitis C virus and HIV infections typically are asymptomatic for many years and are often not aware they are infected. Persons with chronic hepatitis C infection may have the disease for many years without symptoms before more severe liver disease develops.

Approximately 2 percent of the general population will test positive for hepatitis C and based on the average age of the patients at the clinic, it is expected that approximately 4 percent will test positive as many people have contracted the virus through other sources. Hepatitis C is more common among people who received blood transfusions or organ transplants prior to 1992 and intravenous drug users, therefore, it will not be possible to determine if patients who test positive were infected at the clinic.

The risk to the general population is very low as hepatitis C is not spread by casual contact or in typical school, work or food service settings. It is not spread by coughing or sneezing or by drinking from the same glass used by someone who is infected. The role of person-to-person contact or sexual activity is not well understood at this time.

The Southern Nevada Health District has posted additional information on its website at www.SouthernNevadaHealthDistrict.org. In addition, the health district has set up a hotline at (702) 759-4636 (INFO) for people with questions about this notification or hepatitis C.



FOR IMMEDIATE RELEASE
February 29, 2008

Health District reiterates exposure information

LAS VEGAS – The Southern Nevada Health District is reiterating the unsafe injection procedures identified as the likely source of the potential exposure of more than 39,000 patients of the Endoscopy Center of Southern Nevada to hepatitis C involved the reuse of syringes on one patient combined with the use of single dose vials of anesthesia medication on multiple patients.

The Southern Nevada Health District is responsible for receiving reports of illness and related investigations. The Nevada State Health Division, Bureau of Licensure and Certification is the agency responsible for licensing medical facilities in Nevada.

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FOR IMMEDIATE RELEASE
March 10, 2008

Health District website updated regarding hepatitis C investigation

LAS VEGAS – The Southern Nevada Health District has updated its website with current information for patients regarding the hepatitis C investigation. The information can be found on the home page of the health district's website: www.SouthernNevadaHealthDistrict.org. The hotline is (702) 759 4636 or 759-INFO.

The health district continues to update its frequently asked questions as well as information from our community partners under Resources and Announcements from Community Partners, including lab information and links. A health care providers page has been updated with technical information for requesting lab work for patients.

The health district continues to update its website as information becomes available.

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FOR IMMEDIATE RELEASE
March 18, 2008

Health District advises of a seventh acute hepatitis C case

LAS VEGAS – The Southern Nevada Health District has preliminary information regarding an acute case of hepatitis C in a patient who received a procedure at the Desert Shadow Endoscopy Center at 4275 Burnham Avenue in Las Vegas. The health district is continuing its investigation of the potential case and will determine its next steps based on that investigation.

The seventh identified case was diagnosed in 2006, but never reported to the health district. Based on the preliminary investigation the patient had been tested for hepatitis C, as part of a routine health screening, just prior to undergoing the procedure at the endoscopy center and the test was negative. The patient was diagnosed with acute hepatitis C several weeks after the procedure and within the incubation period for developing the illness. The health district advised the Clark County Commission of the potential case as the commission considered extending the limitations on the clinic's business license.

"Our investigation is continuing regarding this potential case and we currently do not have enough information to determine what type of notification is required," said Dr. Lawrence Sands, chief health officer. "We advised the Commission because we believe it is important information and should be taken into consideration as the clinic's business license is debated." The patient received a procedure at the location in June 2006.

The health district is stressing this is an ongoing investigation and further information is needed in order to determine the extent of the patient notification. Patients who are concerned about procedures at other clinics should discuss their need for testing with their personal physician.

"Our goal is to notify patients that may have been exposed to bloodborne illnesses in a timely manner. However, we need to review clinic records in order to determine how many patients may have been exposed due to unsafe injection practices. We will continue to make informed recommendations to the public based on identified risk, verified by the findings of our epidemiologic investigations," said Dr. Sands.

The Southern Nevada Health District continues to update information on its website, including patient and physician information at www.SouthernNevadaHealthDistrict.org. In addition, the health district has set up a hotline at (702) 759-4636 (INFO).



FOR IMMEDIATE RELEASE
March 27, 2008

Health District reports increase in positive lab results of hepatitis C

LAS VEGAS – The Southern Nevada Health District is reporting an increase in positive laboratory reports of hepatitis C. Typically the health district receives 20 to 40 positive reports daily. Recently the daily report totals have exceeded 150. These higher numbers were expected based on increased rates of testing and the background rate for the disease.

The health district has finalized a survey tool for interviewing patients and will begin contacting patients this week. Patients who had procedures requiring injected anesthesia at the center in January will have to wait six months from their procedure date to be tested and therefore the interview process will take several months to complete.

Considerations of the investigation include:

- The patient list received by the health district was incomplete and part of the interview process will include identifying patients who had procedures at the endoscopy center.
- Approximately 4 percent of the clinic population would have been previously infected with hepatitis C and laboratory testing cannot distinguish between recent and older infections.
- Because many of the newly reported infections may have been acquired years previously it may not be possible to determine the source of the infection.
- The evaluation of acute hepatitis C infections involves examining a patient's risk for six months prior to the onset of symptoms. The evaluation of chronic hepatitis C infections involves examining a patient's risk over the course of their lives.
- The health district routinely investigate acute hepatitis B and HIV cases, however, the risk of acquiring either of these two infections is thought to be much lower for persons possibly exposed at the clinic.
- A set of criteria is being developed for evaluation of risk factors in order to classify cases based on their likelihood of exposure at the clinic.

As the health district begins to compile results from the interview process reports will be available and posted to the website at www.SouthernNevadaHealthDistrict.org.



Media Advisory
April 11, 2008

Southern Nevada Health District to host special hepatitis C community event, Saturday, April 19

WHO The Southern Nevada Health District is hosting a community forum about hepatitis C.

WHAT The event includes two panel discussions (9 a.m. – 10:45 a.m. and another 1 p.m. – 2:45 p.m.); each panel will cover the same topics. Information booths will be available throughout the day.

Topics for the panel discussion include an overview and update on the outbreak investigation, an overview of hepatitis C, emotional support information, life with hepatitis C, legal aspects and a general discussion with questions and answers.

Scheduled speakers include:

Dr. Lawrence Sands, Southern Nevada Health District chief health officer
Brian Labus, Southern Nevada Health District senior epidemiologist
Dr. Robert Gish, Physician Foundation at California Pacific Medical Center liver transplant program
Dr. Tom McKnight, HONORreform (Hepatitis Outbreak National Organization for Reform) founder and private practice physician
Dr. Evelyn McKnight, HONORreform, founder
Kathleen Risdon, Bridge Counseling social worker
Robert Corrales, UNLV Boyd School of Law

WHEN 8:30 a.m. – 3 p.m., Saturday, April 19, 2008

WHERE Southern Nevada Health District
Auditorium
625 Shadow Lane
Las Vegas, NV 89106

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FOR IMMEDIATE RELEASE
April 21, 2008

Health District advises of an eighth acute hepatitis C case
Seventh tied to Endoscopy Center of Southern Nevada

LAS VEGAS – The Southern Nevada Health District has identified an additional case of acute hepatitis C in a patient who underwent a procedure at the Endoscopy Center of Southern Nevada, 700 Shadow Lane. This additional case brings the total number of acute hepatitis C cases associated with this outbreak to eight and it is the seventh linked directly to the clinic.

The eighth case underwent a procedure at the clinic in June 2005 and developed symptoms of acute hepatitis C nine weeks after the procedure. The patient had no other reported risk factors for the illness and has since recovered.

“Our investigation into this case will continue and we will continue to work to identify additional dates when disease transmission occurred. We believe that since this patient underwent a procedure in 2005, our investigation and notification of patients who visited the clinic as early as March 2004 appears well founded,” said Dr. Lawrence Sands, chief health officer.

The health district’s investigation is ongoing and it continues to receive more than 150 reports of positive hepatitis C cases daily. Typically, the health district receives 20 to 40 positive reports daily. The higher numbers are expected based on increased rates of testing and the background rate of the disease.

Interviews of patients of the Endoscopy Center of Southern Nevada who have tested positive for hepatitis C have begun. Patients who had procedures requiring injected anesthesia at the center in January will have to wait six months from their procedure date to be tested and therefore the interview process will take several months to complete.

-more-

Health District advised of eighth acute case – add one

Considerations of the investigation include:

- The patient list received by the health district was incomplete and part of the interview process will include identifying patients who had procedures at the endoscopy center.
- Approximately 4 percent of the clinic population would have been previously infected with hepatitis C and laboratory testing cannot distinguish between recent and older infections.
- Because many of the newly reported infections may have been acquired years previously it may not be possible to determine the source of the infection.
- The evaluation of acute hepatitis C infections involves examining a patient's risk for six months prior to the onset of symptoms. The evaluation of chronic hepatitis C infections involves examining a patient's risk over the course of their lives.
- The health district routinely investigates acute hepatitis B and HIV cases, however, the risk of acquiring either of these two infections is thought to be much lower for persons possibly exposed at the clinic.
- A set of criteria has been developed for evaluation of significant risk factors in order to classify cases based on their likelihood of exposure at the clinic.

"It is important to note that this is an ongoing investigation that will take some time to complete," said Sands. "I am encouraged that people are getting tested and patients who are concerned about procedures at other clinics should discuss their need for testing with their personal physician."

In March, the Southern Nevada Health District reported that it identified an acute case of hepatitis C in a patient who received a procedure at the Desert Shadow Endoscopy Center at 4275 Burnham Avenue in Las Vegas. The health district is continuing its investigation of this case and will determine its next steps based on that investigation. This seventh identified case was diagnosed in 2006, but never reported to the health district.

The Southern Nevada Health District continues to update information on its website, including patient and physician information at www.SouthernNevadaHealthDistrict.org. In addition, the health district has set up a hotline at (702) 759-4636 (INFO).



FOR IMMEDIATE RELEASE
May 8, 2008

Health District identifies 77 potential clinic-associated infections

LAS VEGAS – The Southern Nevada Health District has identified 77 potential clinic-associated hepatitis C infections during its continuing investigation into the outbreak associated with the Endoscopy Center of Southern Nevada, 700 Shadow Lane. There have been a total of eight acute hepatitis C cases associated with the outbreak, seven of which can be linked directly to the Shadow Lane clinic. To date, the health district has interviewed approximately 400 people who received positive test results and were patients at the clinic between March 2004 and January 11, 2008.

Since the initial patient notification February 27, approximately 50,000 test panels have been ordered through local labs; however, this number represents the number of tests ordered and not the number of patients who have been tested. The health district cannot say for certain that the number of test panels represents everyone who received a notification.

“Because the patient list we received was not complete, we cannot say for certain if all of the affected patients have been tested,” said Dr. Lawrence Sands, chief health officer. “The health district continues to receive a higher number of positive test results than we did before the notification in February, which means people are getting tested and that is a positive outcome.” In the coming months, patients who underwent procedures at the end of 2007 or early 2008 will need to be tested at a later date because it can take as long as six months for a positive test result to occur. Negative test results are not reported to the Southern Nevada Health District.

Health district investigators continue to sort through positive test results to determine which patients received procedures at the clinic, what prior risk factors they have to determine potential exposure, and which results are duplicates or retests. It is possible that some patients are tested regularly as part of ongoing management of their chronic medical conditions. The evaluation of chronic hepatitis C infections involves examining a patient’s risk over the course of their lives. The evaluation of acute hepatitis C infections involves examining a patient’s risk for six months prior to the onset of symptoms.

To evaluate patients’ risk factors and to determine if their infection is related to the clinic, a set of criteria has been developed to classify cases based on whether they are chronic or acute cases. In addition, classifications about the likelihood that the patient was exposed at the clinic have also been developed to help investigators better understand patient risk factors prior to having a procedure at the clinic.

-more-

Health District identifies 77 potential infections – add one

“We anticipate that this investigation is going to take many months to complete and we will likely see additional positive test results that could be associated with the clinic,” said Sands.

Approximately 4 percent of the clinic population would have been previously infected with hepatitis C and laboratory testing cannot distinguish between recent and older infections. Because many of the newly reported infections may have been acquired years previously it may not be possible to determine the source of the infection.

In addition to the recommendation to get tested for hepatitis C, the health district advised patients to get tested for hepatitis B and HIV. To date, there have been no acute hepatitis B cases or an increase in HIV infection rates associated with the clinic or the outbreak. The health district routinely investigates acute hepatitis B and HIV cases, however, the risk of acquiring either of these two infections is thought to be much lower for persons possibly exposed at the clinic.

The health district continues to update its website as resources and information become available, www.SouthernNevadaHealthDistrict.org. For additional information, patients can contact the helpline, (702) 759-4636 (INFO).



FOR IMMEDIATE RELEASE
June 5, 2008

Health District concludes Desert Shadow Endoscopy Center investigation,
announces implementation of a Hepatitis C Exposure Registry

LAS VEGAS - The Southern Nevada Health District has concluded its investigation into the acute case of hepatitis C associated with the Desert Shadow Endoscopy Center, formerly located at 4275 Burnham Avenue, Suite 101, based on the information and records that are currently available. While it has been determined this acute case is linked to the center there is not sufficient information at this time to determine the likely source of disease transmission.

Patients of this clinic are encouraged to discuss their risk for disease transmission 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.

"It is unfortunate we are not able at this time to conclusively determine the route of disease transmission that lead to this patient's infection," said Dr. Lawrence Sands, chief health officer for the health district.

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

A clinic staff person was observed reusing single use vials of propofol at this facility during an inspection by the State Health Division Bureau of Licensure and Certification in January 2008, and propofol logs provided further documentation the bottles of anesthesia were reused on multiple patients. However, staff has not been able to document 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 document 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. Seven additional cases are

(more)

Burnham clinic recommendation/registry – add one

associated with the Endoscopy Center of Southern Nevada. This clinic was the subject of the initial investigation and the identification of unsafe injection practices lead to the notification of more than 40,000 patients of their potential exposure to bloodborne illnesses.

Hepatitis C Exposure Registry

The health district is announcing the implementation of a Hepatitis C Exposure Registry in order to gather additional information related to patients of both the Endoscopy Center of Southern Nevada and the Desert Shadow Endoscopy Center. The registry was developed to assist in the identification of patients who had procedures at the clinics, including those who are infected with the hepatitis C virus, and will allow those patients who have tested positive 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.

The health district 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, www.SouthernNevadaHealthDistrict.org. In addition, enrollment forms will be available at the health district's public health centers or patients can contact the hepatitis C helpline at (702) 759-4636 to request a form.

"There are many patients we have not been able to locate during this outbreak because clinic records were not complete," said Sands. "We are encouraging patients to enroll in the registry so we can continue to identify people who were exposed at the clinics. This information will aid in our continuing investigation and may allow us to make additional recommendations to patients of the clinics."

Since the initial notification 77 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.

The health district continues to update its website as resources and information become available. For additional information, patients can contact the helpline, (702) 759-4636 (INFO).

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FOR IMMEDIATE RELEASE

July 24, 2008

**Health District identifies source cases for hepatitis C outbreak
Exposure Registry includes 6,000 enrollees**

LAS VEGAS – The Southern Nevada Health District has identified two source cases related to the hepatitis C outbreak at the Endoscopy Center of Southern Nevada, 700 Shadow Lane. One patient had a procedure on July 25, 2007, and the other on September 21, 2007. These are the dates that disease transmission was known to occur. An additional chronic (non-acute) case of hepatitis C infection has also been linked to the September 21 source case. The health district can now link a total of eight hepatitis C cases directly to the Endoscopy Center on Shadow Lane and one acute case to the Desert Shadow Endoscopy Center, 4275 Burnham Avenue.

As part of the investigation, genetic testing was performed to determine if the hepatitis C cases on these two days are linked. The testing and results of the epidemiologic investigation allowed the health district's epidemiology team to positively identify two individuals as the source cases among clusters of patients who underwent procedures on the same dates. Samples were tested by the Centers for Disease Control and Prevention (CDC).

"These results will help us to better understand how the disease was transmitted on those days and supports the initial findings of our investigation," said Dr. Lawrence Sands, chief health officer. "It is important for us to remember that this outbreak is not the result of any actions on the part of the patients, but it is the result of unsafe practices by the staff of these clinics."

The health district previously reported the identification of 77 cases of hepatitis C infections that are considered potentially associated with the Shadow Lane clinic. These patients had different procedure dates, and the health district will not be able to perform genetic testing for these cases because there is no identified source for comparison. No additional cases have been identified in the investigation of the acute case related to the Burnham Avenue clinic, and a source case cannot be identified. This patient was diagnosed in 2006 and the case was not reported to the health district until March of this year.

In June, the health district announced the development of the Hepatitis C Exposure Registry. The registry was developed to assist in the identification of patients who had procedures at both clinics, including those who are infected with the hepatitis C virus, and allows patients who have tested positive to learn their case classification. To date, the health district has received 6,000 completed enrollment forms for the Hepatitis C Exposure Registry.

"We are very encouraged by participation in the registry," said Sands. "Patients are providing us with important information about their procedures, their test results, and health status. The registry will allow us to identify additional cases or exposures at either clinic."

- more -

Health District IDs source cases – add one

In early June, former patients of the Endoscopy Center of Southern Nevada and the Desert Shadow Endoscopy Center were notified by mail about the development of the Hepatitis C Exposure Registry. Patients who wish to enroll in the registry can obtain forms at any public health center location or download from the health district website.

For additional information, visit www.SouthernNevadaHealthDistrict.org or call the hotline, (702) 759-4626.

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FOR IMMEDIATE RELEASE
October 23, 2008

Health District identifies 105 potential clinic-associated hepatitis C infections

LAS VEGAS – The Southern Nevada Health District has classified 101 cases of chronic hepatitis C infection as possibly associated with the Endoscopy Center of Southern Nevada, 700 Shadow Lane, and four cases possibly associated with the Desert Shadow Endoscopy Center, 4275 Burnham Avenue. The number of hepatitis C cases directly linked to the clinics remains at nine.

To date, the health district has received 7,331 Hepatitis C Exposure Registry enrollment forms since its implementation in June. Information received by contacting patients with positive laboratory reports and patients who were part of the case investigations were also entered into the registry database.

Laboratory confirmed patients with verified procedure dates, no identified risk factors and no history of positive laboratory reports were classified as “possibly associated.” The health district classified 35 laboratory confirmed cases as “indeterminate” if the patient reported having one or more of the risk factors associated with hepatitis C infections. This classification does not rule out possible infection at the clinic. However, the health district cannot make any further determination because of the presence of other likely sources of infection.

The evaluation of chronic hepatitis C infections involves examining a patient’s risk over a lifetime. The evaluation of acute hepatitis C infections involves examining a patient’s risk for six months prior to the onset of symptoms. To evaluate patients’ risk factors and to determine if their infection was related to the clinic, the health district developed a set of criteria to classify cases based on whether they were chronic or acute. In addition, classifications about the likelihood that the patient was exposed at the clinic were developed to help investigators better understand patient risk factors prior to having a procedure at the clinic.

“The registry, the interviews, and the criteria developed to identify and classify cases provided the investigators with important information to help us better understand the scope of this outbreak. This is the largest disease investigation that our health district has undertaken and we recognize the importance of sharing these results with the community,” said Dr. Lawrence Sands, chief health officer. “The identification of these additional cases as well as the identification of the source cases from July and September reinforces our longstanding recommendation for patients of the clinic to get tested for possible infections.”

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Health District Identifies 105 Cases - add one

In July, the health district reported that it identified two source cases related to the Endoscopy Center of Southern Nevada outbreak. One patient had a procedure on July 25, 2007, and the other on September 21, 2007. These are the dates that disease transmission was known to occur.

Results of genetic testing allowed the health district's epidemiology team to positively identify the two individuals as the source cases among clusters of patients who underwent procedures on the same dates. Samples were tested by the Centers for Disease Control and Prevention (CDC).

Information about the hepatitis C outbreak, including the health district's Interim Report on the outbreak, is available on the website, www.SouthernNevadaHealthDistrict.org.

Appendix I

Technical Bulletins

Hepatitis C Exposure at a Medical Clinic

Current Situation

Earlier today, the Southern Nevada Health District began contacting close to 40,000 Southern Nevada residents to recommend that they visit their primary care provider to be tested for hepatitis C, hepatitis B, and HIV due to exposures resulting from unsafe injection practices. In an attempt to reach patients for whom current addresses were not available, the health district held a press conference in conjunction with the Nevada State Health Division and its Bureau of Licensure and Certification. Please be advised that you may be contacted by your patients after they receive a notification letter or learn about the exposure through their media.

In early January, the health district began investigating a cluster of hepatitis C cases who had reported undergoing procedures at the Endoscopy Center of Southern Nevada, located at 700 Shadow Lane, Las Vegas. The investigation identified the use of unsafe injection practices related to the administration of intravenous anesthetic that could result in the transmission of bloodborne pathogens among the clinic's patients. Although these practices have since been corrected, these were the prevailing practices of the clinic for an extended period of time. With consultation from the Centers for Disease Control and Prevention (CDC), the health district determined that patients seen at the clinic between March of 2004 and January 11, 2008, and had procedures performed which required administration of intravenous anesthetic, should be notified of the exposure risk and the recommended for hepatitis C, hepatitis B, and HIV testing.

The number of people who were infected as a result of clinic practices cannot be determined. The recommendation for testing is based on the identification of an increased risk for exposure to bloodborne pathogens. Even in acute cases, it is not possible to determine the source of infection for an individual patient from the results of available laboratory testing.

It is expected that a significant number of patients were infected prior to undergoing procedures at the clinic. Based on national statistical data for popula-

tion prevalence of disease it is estimated that:

- About 4% of patients may be previously infected with hepatitis C
- Less than 0.5% of patients may be previously infected with HIV
- About 0.5% will show evidence of current infection with hepatitis B and about 5% will show past hepatitis B infection.

HIV or hepatitis seroconversion may take up to 6 months. The date of the patient's most recent procedure performed at the center should be used to identify the best timing for testing. Initial negative tests performed prior to the 6 month seroconversion window may have to be repeated.

Patient Communication

Although the cases under investigation have been linked to only one particular clinic, it is not unreasonable to expect patients who had undergone procedures at different clinics to request testing. The health district is not recommending the routine testing of any other group of patients. However, testing should be ordered if indicated because of illness or based on your risk assessment of an individual patient.

The Southern Nevada Health District has established a hotline for patients at (702) 759-INFO. Patients can also obtain information from the health district website at <http://www.southernnevadahealthdistrict.org>. The health district has identified resources for patients without insurance or access to a physician, and information on this topic can be obtained on the website.

Disease Reporting

Per Nevada Administrative Code 441A, all known or suspected cases of hepatitis C, hepatitis B, and HIV must be reported to the Southern Nevada Health District. As it is important to the ongoing investigation, please report acute hepatitis cases by phone at (702) 759-1300, option #2. This number is available 24-hours, seven days a week. Due to the expected high volume of calls, please report all non-acute (chronic) hepatitis cases by fax at (702) 759-1414.

Please report all HIV cases to the office of HIV/AIDS at (702) 759-0702.

Laboratory Testing Recommendations

Because screening for blood borne pathogens in an asymptomatic population may result in false positive test results, the CDC and the health district are recommending the initial and reflex laboratory testing listed in Table 1 for persons who were administered intravenous anesthetic during procedures performed at Endoscopy Center of Southern Nevada located at 700 Shadow Lane in Las Vegas between March 2004 and January 11, 2008.

To assist with the testing follow up and to ensure appropriate reflex testing occurs, Labcorp and Quest laboratories will provide custom panels and tests for clients located in Nevada (see Tables 2 and 3).

Additional information regarding supplemental testing for Hepatitis C Antibody (HCV Ab)

The "Guidelines for Laboratory Testing and Result Reporting of Antibody to Hepatitis C Virus" published by CDC in MMWR, February 7, 2003, 52 (RR03):1-16 provides recommendations for use of the signal-to-cutoff ratio (s/co) of positive HCV screening test results to identify samples which would require additional supplemental testing. The recommended s/co ratio will vary depending on the testing equipment used. Contact the reference laboratory for details regarding the supplemental testing performed at their facility.

Based on the MMWR recommendations:

- HCV Ab positive screening test results with high s/co ratios can be considered anti-HCV positive without supplemental testing.
- HCV Ab positive screening test results with low s/co ratios should have supplemental testing performed, preferably by Recombinant Immunoblot Assay (RIBA) for anti-HCV.
- If Nucleic Acid Test (NAT) for HCV RNA is performed, CDC recommends RIBA follow up for a negative NAT.

Medicare patients

Medicare carriers have implemented policies that ensure the medical necessity of certain services rendered to Medicare beneficiaries. These policies are called Local Medical Review Policies (LMRPs). HIV and

hepatitis testing may be subject to LMRPs. Contact your reference laboratory representative for more information regarding medical necessity guidelines.

References

Guidelines for Laboratory Testing and Result Reporting of Antibody to Hepatitis C Virus, MMWR, February 7, 2003:<http://www.cdc.gov/mmwr/PDF/rr/rr5203.pdf>

Alter MJ. Healthcare should not be a vehicle for transmission of hepatitis C virus. J Hepatology 48 (2008); 2-4.

Transmission of Hepatitis B and C Viruses in Outpatient Settings—New York, Oklahoma, and Nebraska, 2000-2002. MMWR 52(38); 901-906.

Additional Resources

CDC website: Hepatitis:

<http://www.cdc.gov/ncidod/diseases/hepatitis/>

American Liver Foundation:

<http://www.liverfoundation.org/>

Hepatitis C physicians booklet:

http://www.cdc.gov/ncidod/diseases/hepatitis/c/hcv_physician_booklet.pdf

Safe injection practices poster:

<http://www.cdc.gov/ncidod/diseases/hepatitis/spotlights/ambulatory.pdf>

Table 1 Initial and reflex laboratory testing

| Test Name | Description | Synonyms | Reflex testing for positives |
|------------------|---|---|--|
| HBcAb, 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. | Hepatitis B Core Antibody, Total; Anti-HBc (total); HBV Core Total Antibody | Positives reflex to Hepatitis B core antibody, IgM and Hepatitis B surface antigen |
| 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

| 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 automatically 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 based on the tests listed in Table 1, only if custom test codes are ordered |
| 1590E | Hepatitis C Antibody (HCV) | |
| 3200 | HIV1/2 EIA Antibody Screen with reflexes | |

Hepatitis C Investigation Update #1

Current situation

The Southern Nevada Health District (SNHD) is still recommending testing for hepatitis C, hepatitis B, and HIV for patients who received injected anesthesia medication at the Endoscopy Center of Southern Nevada (700 Shadow Lane, Suite 165B) between March of 2004 and January 11, 2008. At this time, the health district is not recommending testing of patients who have had procedures at other clinics. As of April 18, 2008, SNHD has not been able to access records from other clinics to determine if further notifications are warranted.

Since February 27, 2008, over 20,000 samples have been analyzed for Southern Nevada residents who may have been exposed to hepatitis C virus (HCV), hepatitis B virus (HBV) or HIV due to unsafe injection practices at the Endoscopy Center of Southern Nevada. Testing of large numbers of asymptomatic persons may result in false positive test results. The initial testing algorithm outlined in the technical bulletin distributed on February 27th

(<http://www.southernnevadahealthdistrict.org/physician/download/tb-hepc-022708.pdf>), 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 their primary care provider for any additional diagnostic testing needed

The current HBV serologic testing algorithm was developed to meet the urgent and fast-breaking needs of the southern Nevada outbreak investigation. This algorithm will identify individuals with current acute and chronic infections. It also will identify individuals infected in the past, but with resolved infections of no clinical significance. However, it will not yield information about the timing or source of infection for individuals previously infected, but with resolved infections.

NOTE: this testing algorithm differs from current CDC

guidelines, which is to first test with HBsAg, with follow-up testing as indicated. [See *"A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP) Part II: Immunization of Adults"* at

http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5516a1.htm?s_cid=rr5516a1_e

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 are receiving 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.
2. 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.

To assist with testing follow-up, and to ensure appropriate reflex testing occurs, LabCorp (Table 2), Quest (Table 3) and Clinical Pathology Laboratories (Table 4) will provide custom panels and tests for clients located in Nevada.

Hepatitis C Serology Interpretations

The "Guidelines for Laboratory Testing and Result Reporting of Antibody to Hepatitis C Virus" published by CDC in MMWR, February 7, 2003, 52 (RR03):1-16 provides recommendations for use of the signal-to-cutoff ratio (s/co) of positive HCV screening test results to identify samples which would require additional supplemental testing. The recommended s/co

Table 1 Initial and reflex laboratory testing

| Test Name | Description | Synonyms | Reflex testing for positives |
|------------------|---|---|--|
| HBcAb, 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. | Hepatitis B Core Antibody, Total; Anti-HBc (total); HBV Core Total Antibody | Positives reflex to Hepatitis B core antibody, IgM and Hepatitis B surface antigen |
| 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 automatically 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 based on the tests listed in Table 1, only if custom test codes are ordered |
| 1590E | Hepatitis C Antibody (HCV) | |
| 3200 | HIV1/2 EIA Antibody Screen with reflexes | |

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 automatically occur based on the tests listed in Table 1 |

ratio will vary depending on the testing equipment used. Contact the reference laboratory for details regarding the supplemental testing performed at their facility. If the custom panels and tests are ordered, the reflex testing for HCV will occur as recommended by CDC in the MMWR cited above. These recommendations include:

- HCV antibody positive screening test results with high s/co ratios can be considered anti-HCV positive without supplemental testing.
- HCV antibody positive screening test results with low s/co ratios should have supplemental testing performed, preferably by Recombinant Immunoblot Assay (RIBA) for HCV antibody.
- If Nucleic Acid Test (NAT) for HCV RNA is performed, CDC recommends RIBA follow up for a negative NAT.

Hepatitis B Serology Interpretations

The initial recommended test for HBV, total hepatitis B core antibody, is a non-specific marker of acute, chronic or resolved hepatitis B. If the custom panel or test codes are ordered, a positive test will reflex to hepatitis B core antibody IgM and hepatitis B surface antigen. These tests will assist the physician in distinguishing current from past infection and acute from chronic infection. Some physicians are ordering an additional test, Hepatitis B surface antibody (anti-HBs). This test is typically used to evaluate Hepatitis B immunity and may not provide useful information for this investigation.

Table 5, which provides guidance for interpretation of Hepatitis B panels is adapted from a CDC table. Reference: <http://www.cdc.gov/ncidod/diseases/hepatitis/>

Table 5. Interpretation of the Hepatitis B Panel

| Tests | Results | Interpretation | Action |
|---|----------------------------------|--------------------------------------|--|
| HBsAg anti-HBc | negative negative | Not infected | No action |
| HBsAg anti-HBc IgM anti-HBc | negative positive negative | Previous infection at undefined time | No action |
| HBsAg anti-HBc IgM anti-HBc | positive positive positive | Acutely Infected | Report to SNHD Evaluation and follow up |
| HBsAg anti-HBc IgM anti-HBc | positive positive negative | Chronically infected | Report to SNHD Evaluation and follow up |
| Pathology consultation from the reference laboratory is available to assist with interpretation or follow-up testing. | | | |

b/Bserology.htm

Definitions:

Hepatitis B Surface Antigen (HBsAg): A serologic marker on the surface of HBV. It can be detected in high levels in serum during acute or chronic hepatitis. 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 HBV 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 (HBV) in an undefined time frame.

IgM Antibody to Hepatitis B Core Antigen (IgM anti-HBc): This antibody appears during acute or recent HBV infection and is present for about 6 months.

Patient Resources

Individuals who have potentially been exposed as a result of the unsafe injection practices at the Endoscopy Center of Southern Nevada 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 <http://www.southernnevadahealthdistrict.org/outbreaks/hepc-patients.htm>. Among the informational items included here 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.

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, www.SouthernNevadaHealthDistrict.org. 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/physician/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

their primary care provider for any additional diagnostic testing needed.

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:

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2. 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 www.SouthernNevadaHealthDistrict.org.

Hepatitis B & C Result Interpretations

Additional information regarding interpretation of hepatitis B and C test results can be found on the SNHD website at: http://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 <http://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 |
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| 9327 | Hepatitis B Core Antibody, total (2730) Hepatitis C Antibody (4647) HIV1 & 2 EIA Antibody Screen (3540) | Reflex testing for positives will automatically occur based on the tests listed in Table 1 |

Appendix J

CDC Epi-Aid Trip Report

Date: May 15, 2008

From: Gayle Fischer, MD, MPH, EIS Officer, Division of Viral Hepatitis (DVH), National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).
Melissa Schaefer, MD, EIS Officer, Division of Healthcare Quality Promotion (DHQP), National Center for Preparedness, Detection, and Control of Infectious Diseases (NCPDCID)

Subject: Epi-Aid Trip Report (2008-019): Investigation of acute hepatitis C among patients who underwent procedures at Clinic A: Nevada 2007

To: Ihsan Azzam, MD, State Epidemiologist, Nevada State Health Division
Lawrence Sands, DO, Chief Health Officer, Southern Nevada Health District
Douglas Hamilton MD, PhD, Director, Epidemic Intelligence Service, Career Development Division, OWCD

Through: Scott Holmberg, Branch Chief, Epidemiology and Surveillance Branch, DVH, NCHHSTP
Joseph Perz, DrPH, Acting Prevention Team Leader, Prevention and Response Branch, Division of Healthcare Quality Promotion (DHQP), National Center for Preparedness, Detection and Control of Infectious Diseases (NCPDCID)

Background

On January 2, 2008, the Nevada State Health Division (NSHD) contacted CDC regarding surveillance reports received by Southern Nevada Health District's (SNHD) regarding two persons recently diagnosed with acute hepatitis C. A third person with acute hepatitis C was reported the following day. SNHD typically confirms 0-4 cases of acute hepatitis C per year. The three case-persons had a common link—all had received procedures at the same endoscopy clinic (Clinic A) within 35-90 days of illness onset. A description of these three cases follows:

- *Case 1.* A person presented on October 24, 2007 with weight loss, dark urine and scleral icterus. The patient had an elevated alanine aminotransferase (ALT) of 552 units/L and was negative for IgM antibodies to hepatitis A virus (anti-HAV) and IgM antibodies to hepatitis B core antigen (anti-HBc). Antibodies to hepatitis C virus

(anti-HCV) were positive and HCV RNA level was 5.5 million IU/ml via polymerase chain reaction (PCR). The patient denied common risk factors for hepatitis C within the previous 6 months, such as injection drug use (IDU), and sexual or other contact with a hepatitis C virus-infected person, but did report having had a colonoscopy at Clinic A on July 25, 2007.

- *Case 2.* A person with no significant past medical history presented on November 9, 2007 with a one-week history of jaundice, anorexia, dark urine and right upper quadrant pain. On November 12, 2007 the patient had an ALT of 560 units/L and was negative for IgM anti-HAV and IgM anti-HBc. At that time, the patient tested positive for anti-HCV and had an HCV RNA PCR level of 7.5 million IU/ml. The patient denied having any common risk factors for HCV infection, but did report a dental cleaning done within 6 months of the diagnosis. The patient reported having had a colonoscopy on September 20, 2007 and upper endoscopy on September 21, 2007 at Clinic A.

- *Case 3.* A person presented on November 29, 2007 with dark urine and abdominal pain and had an ALT of 1070 units/L. On December 20, 2007, the patient tested negative for IgM anti-HAV and IgM anti-HBc, but positive for anti-HCV. The patient had an HCV RNA PCR level of 5.9 million IU/ml. The patient denied having any risk factors for acute HCV infection, but had a colonoscopy done at Clinic A on September 21, 2007.

As a result of the increase in reported cases and the potential for a common exposure, SNHD requested CDC's assistance with the investigation. EIS officers from the Division of Viral Hepatitis (DVH) and the Division of Healthcare Quality Promotion (DHQP) departed for Clark County, Nevada on January 9, 2008.

The subsequent investigation also revealed three more cases (Cases 4-6), as described below.

Objectives

- 1) To interview and collect specimens from identified hepatitis C patients for phylogenetic analysis at CDC
- 2) To investigate infection control procedures at Clinic A, especially use of multi-dose vials, reuse of single-use vials and reprocessing of endoscopes
- 3) To advise and assist the local and state health departments in appropriate medical chart abstraction, related data collection, and notification and testing procedures for other patients who were potentially exposed at the clinic in question.

Methods

Case Definitions

Acute hepatitis: Acute illness with discrete onset of symptoms (nausea, anorexia, fever, malaise or abdominal pain) and jaundice or elevated serum aminotransferase levels.

Acute hepatitis C: Acute hepatitis and alanine aminotransferase (ALT) more than seven times upper limit of normal ($>7\times\text{ULN}$), and IgM anti-HAV negative and anti-HCV-positive by EIA and RIBA or with an appropriate signal-to cutoff ratio for a given assay or HCV RNA-positive.

Clinic-associated acute hepatitis C case: Person who had a procedure at Clinic A in July 2007 through December 2007 who was diagnosed with acute hepatitis C within 6

months of the procedure date and does not have other significant risk factors for HCV infection.

Review of Incident Cases

The diagnosis of clinic-associated acute hepatitis C was confirmed in the three known incident cases by laboratory test results and interviews with the three case patients. Descriptions of the procedures, including timing, instrumentation, staff involvement, medications and complications were obtained from procedure records at Clinic A. Additionally, past medical history, surgical history, laboratory data and risk factors for hepatitis were obtained from the case-patients' medical charts. Blood specimens were sent to CDC for HCV molecular testing by PCR. Genotyping was determined by the NS5B region by PCR and analysis of the hypervariable region 1 (HVR1) was used to determine genetic relatedness among case patients, the methodologies for which have been previously described [1].

Review of Infection Control Practices

The personnel roster, layout of the clinic and the patient flow during procedures were reviewed with the nurse manager. An entire endoscopic procedure was observed, starting from intravenous (IV) catheter placement to endoscopic reprocessing. Additionally, each anesthetist and nurse involved in the care of incident cases, were observed and/or interviewed regarding their infection control practices.

Case Finding

We sought to identify potential source patients and additional clinic-associated cases of acute hepatitis C or HCV infection. The procedure records of persons who preceded known clinic-associated case-patients on the days they had procedures were reviewed for evidence of past HCV infection. Additionally, names of patients who had a procedure on the same days that clinic-associated case-patients had procedures were compiled and cross-matched against (a) SNHD's database containing HCV commercial laboratory results and (b) SNHD's hepatitis C public health surveillance records. After receiving verbal informed consent, we also obtained health histories on all staff that have contact with patients and sent blood specimens to CDC for bloodborne infection screening.

Results

Description of Clinic A Practices, Staff and Procedures

According to interviews with clinic staff, Clinic A was a freestanding, private endoscopy clinic that primarily performs upper endoscopies and colonoscopies, and occasionally places gastrostomy tubes and esophageal pH probes. Clinic A has performed procedures for ~18 years and moved to its current site within the past 4 years. Although considered a separate facility, they shared staff with an affiliated gastroenterology clinic. There were 9 physicians, 4 certified registered nurse anesthetists (CRNA), 10 registered nurses (RNs), 9 technicians and 2 licensed practical nurses (LPNs) who engaged in patient care. The clinic performed ~50-60 procedures a day, 5 days a week.

The layout of the clinic consisted of a small waiting area, 4 patient bays separated by curtains where pre- and post-procedure assessments took place, a preparation room where IV catheters were placed and 2 procedure rooms (Figure 1). In between the

procedure rooms, there was a room where reprocessing of the endoscopes took place. A room off of the reprocessing room is where clean endoscopes were kept. A utility room was present behind a closed door next to the IV preparation room.

From observations of clinic staff, each morning, an RN opened a combination lock in order to access keys to open the medication cabinet. One cabinet contained propofol, lidocaine and saline. This cabinet remained open throughout the day. CRNAs were given vials of propofol and a bottle of lidocaine each morning. Fentanyl, meperidine or midazolam, which are kept in a separate lockbox, were used for sedation if the patient could not tolerate propofol and were distributed just before sedation occurs. The contents of the lockbox were checked each morning.

From observations at the facilities, at the start of each procedure, patients changed into gowns and were escorted to a bay area. They were then called back into the preparation room. In the room, IVs were usually placed by RNs or CRNAs. The patients then moved to the procedure room where CRNAs and technicians interviewed and positioned the patient in the procedure room. An RN recorded patient vital signs and findings while in the procedure room. Technicians then brought an endoscope from the clean room into the procedure room. After gowning and gloving, a clinician entered the room and performed endoscopy after an anesthetic (usually propofol) had taken effect on the patient. After the procedure, the patient was brought back to the patient bay for post-procedure assessment and recovery. IV fluids were available, but, according to staff interviews and chart reviews, rarely needed to be administered after the procedure. Clinic A did not have authorization to conduct any blood testing, including fingerstick glucose monitoring.

Review of Infection Control Practices

Observations of Work Environment

Clinic A generally appeared clean and well organized. There was a separation between clean and contaminated equipment areas. Puncture-resistant sharps containers were conveniently located where IVs were inserted or parenteral medications delivered. Sharps containers were never overflowing during the observation period; at the end of the day, these were disposed of in the utility area.

Sinks and hand sanitizers were located throughout the Clinic. However, on multiple occasions, staff were observed not performing proper or adequate hand hygiene between patients. Additionally, anesthesiologists did not always wear gloves when they administered IV medications. Such improper infection control practices were pointed out to staff and administrators soon after breaches were noted.

Injection Practices

Before placing IVs, RNs or CRNAs generally wore gloves, but one CRNA was observed not to do so. They cleansed the patient's skin with alcohol. They did not have safety-locking needles, but most disposed of needles into proper receptacles. However, one CRNA was observed moving about the room with an uncapped needle. RNs flushed the IVs with 1-2 ccs of saline obtained from 20cc vials after placement of the IVs. They usually did not wipe the stopper with alcohol. CRNAs generally did not report using saline flushes after IV insertions since they immediately administered sedation.

We observed and inquired about preparation and administration of sedation over several days. At the start of the day, each CRNA was given one 30cc multi-dose vial of lidocaine and several vials of 200mg/20cc or 500mg/50cc single-use propofol. Using a

new syringe and needle each time, a CRNA would prefill multiple 10cc syringes with 1cc of lidocaine, recap the needles, and store them in a drawer. The syringes were neither labelled with their contents nor dated. If syringes with lidocaine drawn from previous days were still in the drawer, they would be used. At the start of a case, a CRNA would draw 9ccs of propofol using a syringe containing lidocaine and administer this to the patient.

Thereafter, the techniques of the CRNAs varied, particularly in regard to the manner in which propofol was administered to patients who required additional sedation during an endoscopy procedure. CRNA 1 was observed placing a new needle on the same syringe that had been used to administer initial sedation to a patient. This syringe then was used to withdraw additional propofol from an open propofol vial for the same patient. When questioned, the CRNA indicated that reuse of syringes in this manner for an individual patient was his routine practice and reflected what clinic staff had instructed him to do. According to an interview with the CRNA, if the patient did not require more sedation, the CRNA disposed of the needle and syringe, but kept the remainder of the propofol vial in order to use it for the next patient. CRNA 2 was observed using several new syringes to withdraw propofol in addition to the syringe that contained the lidocaine and propofol. These additional syringes filled with propofol were then available if the patient required additional sedation. CRNA 2 disposed of partially used syringes, but kept the unused ones for subsequent patients. CRNA 2 also reported having been instructed to reuse syringes to administer multiple doses of propofol to an individual patient, but did not do so. CRNA 3 was observed drawing additional doses of propofol for an individual patient with a new needle and syringe as needed. CRNA 3 reused propofol single use vials between patients after wiping the stopper with alcohol and used a new needle and syringe each time. CRNA 4 no longer worked at the Clinic and had moved out of state. By phone conversation, CRNA 4 reported a practice similar to CRNA 1. CRNA 4 would reuse a syringe to access propofol if a patient required additional sedation. The CRNA would discard the syringe at the end of the case, but would use the remainder of the propofol vial on subsequent patients.

CRNAs tended to remain in the same procedure room, except during lunch time (usually ~11:30am) when they changed rooms to cover for another CRNA. The medications were supposed to stay in the original room, and that was observed. No formal sign-out as to what was contained in used syringes and vials occurred between CRNAs. At the end of the day, partially used propofol vials were discarded and unused ones placed back into the cabinet. Unused prefilled syringes of lidocaine that were not marked with their contents or date remained in the medication drawers.

Endoscope reprocessing

Staff reported that the clinic owned 18 endoscopes; 6 used for upper endoscopies and 12 used for colonoscopies. The individual endoscope number used during a particular procedure was recorded on the nursing chart. Upon completion of endoscopy, the endoscope was passed to the medical technician, who was gowned, gloved and masked. The distal portion of the endoscope was immediately placed in a container of cleaning detergent, which was kept at the bedside and changed between patients. The detergent solution was sucked through the tubing to flush the endoscope and clear the channel. The biopsy equipment was disposable and thrown out at the end of the procedure.

The endoscope was then taken into the adjacent Reprocessing Room (Figure 1). First, a leak check was performed using a handheld manometer. If the endoscope passed

the leak test, the technician then performed manual cleaning of the endoscope. All caps were removed from the endoscope and placed in a detergent solution. Then, the endoscope was submerged in a mixture of water and enzymatic cleaning solution. The air and biopsy ports were brushed clean using disposable brushes, which were thrown out after each use; also, a disposable brush was used to wipe the external surface of the endoscope. A pump was then attached, which has a set timer that pumped the enzymatic solution through the endoscope channels for one minute. When this process was completed, the endoscope and caps were then transferred to a water bath, where the endoscope was again submerged and the pump pushed water through the channels for one minute. The water and enzymatic cleaning baths were changed after every two endoscopes; however, the directions for use on the detergent bottle state that fresh detergent should be used for each endoscope or set of instruments and that the dilute detergent solution was to be discarded after each use.

After these manual cleaning steps were completed, the endoscope and caps were transferred to an automated reprocessor, which used a glutaraldehyde solution, to perform high-level disinfection. The clinic owned two reproprocessors and each machine was capable of holding and reprocessing two endoscopes in the same basin, simultaneously. There was no record of which endoscopes were disinfected by which machine and in which order. Automated reprocessing was a timed process that pumped the glutaraldehyde solution over and through the ports of the endoscope. When the high-level disinfection was completed, the machine alarmed to notify the technician to inject a syringe containing 70% isopropyl alcohol and another syringe containing air for the final drying cycle. The disinfecting and drying cycles took approximately 17 minutes from start to finish, not including the manual cleaning steps. The technician then removed the endoscope from the machine, used compressed air to further dry the open ports, and then took it into the adjoining Equipment Supply Room (Figure 1) where it was hung in a cabinet to complete the drying process and await its next use. Colonoscopes were hung on one side of the closet and endoscopes on the other side. The endoscopes were not tagged and the reprocessing was not logged, but the staff claimed to be able to recognize that only endoscopes that have undergone complete reprocessing are to be hung in the clean supply room.

According to staff interviews, each morning, a maintenance test was performed on the automated reprocessor to make sure that the machine and the glutaraldehyde solution still met the necessary standards for high-level disinfection. A strip tested the chemical concentration of the glutaraldehyde reservoir in the machine. The solution was replaced when the test strip indicated the solution did not meet the necessary standards. Clinic staff stated that normally the glutaraldehyde solution lasted for 14 days, but because they do so many procedures, they would change the fluid more frequently. The daily review also involved checking the water flow, air flow, level of disinfectant, and temperature of the disinfectant. Review of the daily logs for September 2007, indicated there were no problems with either automated reprocessor machine in the two days before and after the case patients received their procedures. According to records, the glutaraldehyde solution was changed on September 10, 17 and 25 in both machines. In July 2007, the clinic had only one of the newer reproprocessors and was also using an older model machine for reprocessing. Logs from the older machine were not available, but review of logs for the newer reprocessor that was used for the month of July demonstrated no problems in the two days immediately before and after one of the case

patients received their procedure (July 25). The glutaraldehyde solution had been changed on July 2 and 30.

The glutaraldehyde solution instructions state that the solution should be maintained with a pH between 6.0 to 7.0 and a minimum recommended concentration (MRC) of 1.5% glutaraldehyde. The expiration date was 28 days after the solution was first put into use or when the MRC drops below 1.5%, whichever came first. The clinic logs indicated that the recommended daily tests were performed.

There was no distinction or difference between reprocessing of the endoscopes and colonoscopes. Biopsy equipment for both endoscopes was disposable and both types of endoscopes were compatible with the same reprocessing equipment. There were diagrams of the reprocessing steps hung on the wall in the reprocessing room and, according to interviews with administrator, technicians were trained by an assigned mentor, until it was felt that they understood and completed the steps correctly and independently.

Clinic-Associated HCV Cases and Potential Sources Patients

Three additional cases of clinic-associated acute hepatitis C were identified.

- *Case 4* was identified as a patient who noticed light stools on October 29, 2007, which was followed by dark urine, jaundice, abdominal pain, nausea, vomiting and anorexia. The person was hospitalized on November 6, 2007. Initial blood results at that time were negative for anti-HAV, IgM anti-HBc and anti-HCV. However, the patient was positive for enzyme immunoassays (EIA) anti-HCV on testing 9 days later, with a high signal-to-cut-off ratio (4.3). The patient denied any significant risk factors for HCV within the past 6 months. The patient reported undergoing procedures at Clinic A on September 19, 2007 and September 21, 2007, dates which were confirmed in the procedure records.

- *Case 5* was a patient who became symptomatic with nausea, vomiting, anorexia and jaundice on October 22, 2007 and was hospitalized on November 6, 2007. The patient's ALT was 1165 units/L, and was positive for anti-HCV and anti-HAV, negative for anti-HBc. On subsequent testing, the patient was IgM anti-HAV- negative and HCV RNA was >50 million IU/ml. Hospital records indicated having had a colonoscopy and an upper endoscopy at Clinic A; Clinic records verify that these tests were done on September 21, 2007 and September 28, 2007, respectively.

- *Case 6* was identified by physician report. The patient was a individual who was diagnosed with laboratory-confirmed acute hepatitis C on October 18, 2007. The patient had a colonoscopy on September 21, 2007. Details regarding the timing of symptoms and clinical course are pending.

The six confirmed clinic-associated case-patients ranged in age from 37 to 72 years and had onset of symptoms between October 24, 2007 and November 29, 2007 (Figure 2). Five case-patients – cases 2, 3, 4, 5 and 6 – all had procedures done on September 21, 2007, with details as follows. Intravenous lines for these five case-patients were inserted by three different RNs. Anesthesia was provided by either CRNA 1 (cases 2 and 3) or CRNA 4 (cases 4, 5, and 6) (Table 1). All case-patients from September 21st received multiple doses of propofol during their procedures. We could not determine if the CRNAs changed rooms or used previously drawn medications since the procedure room numbers were not recorded in the chart. Four case-patients had colonoscopies and one had an upper endoscopy; records indicated that the same

endoscope was used on two of the patients. Two of the five case-patients had a biopsy as part of their procedure. Case-patients 2, 4 and 5 also had procedures done on September 20, 2007, September 19, 2007 and September 28, 2007, respectively. Thus far, there have been no other acute hepatitis C cases identified on those days.

Two potential source patients with chronic HCV infection were identified from medical chart reviews of patients who preceded the incident cases on July 25, 2007 and September 21, 2007 (Table 2). Both of these potential source patients with chronic HCV infection had HCV genotype 1, as did the case-patients. A blood sample from the person who had their procedure on September 21, 2007 has not yet been analyzed and a blood sample from the person who had their procedure on July 25, 2007 has not yet been obtained. None of the staff members tested positive for HCV (or current HBV) infection.

Molecular Laboratory Results

Samples from five of six clinic-associated case-patients were available for molecular testing by PCR. All were genotype 1a as determined by analysis of the NS5b region (Figure 3). Four of four persons who had procedures on September 21, 2007 had HVR1 regions that were identical or nearly identical (Figure 4). The sequence from the case-patient who had their procedure on July 25, 2007 differed from the September 21, 2007 cluster of patients.

Testing for Other Bloodborne Pathogens

Specimens from five of six patients with incident HCV infection were sent to CDC for HBV and HIV testing. Four of five showed no evidence of HBV infection by antibodies to hepatitis B core antigen (anti-HBc) testing, and one showed evidence of previous infection (total anti-HBc-positive, IgM anti-HBc-negative) but was not chronically infected (hepatitis B surface antigen negative). None were infected with HIV based on anti-HIV testing.

Discussion

Our investigation identified six cases of acute hepatitis C in persons who underwent procedures at Clinic A between 35-90 days before the onset of their illness. None of the case-patients had significant risk factors for HCV infection within the typical incubation period (15-160 days prior to the onset of symptoms) and five of the cases had procedures on the same day (September 21, 2007). The genetic relatedness of the viruses from case patients who had procedures on September 21, 2007 supports the epidemiologic findings and points to a common source of infection. The lack of genetic relatedness to the patient seen in July 2007 suggests a separate transmission incident. Observation of anesthesia administration practices indicated that some staff routinely reused syringes during individual procedures to withdraw anesthesia from single-use propofol vials that were inappropriately used to provide medication for multiple patients. Similar practices have previously been implicated in the transmission of bloodborne pathogens [2-7].

HCV is primarily transmitted through percutaneous or mucosal contact with an infected person's blood. Most (60-70%) persons acutely infected are not symptomatic or have non-specific symptoms. The remainder may have classic signs of hepatitis, such as

jaundice (20-30%), or non-specific symptoms, such as anorexia, fatigue and abdominal pain (10-20%) Regardless of whether or not they have symptoms in the acute period, approximately 70% of those infected will remain chronically infected. Among those chronically infected, 10-20% will develop cirrhosis over a 20-30 year period [8].

In the United States, transmission of HCV in healthcare settings is thought to be uncommon and is primarily recognized in the context of outbreaks [6]. During the last decade, most healthcare-associated outbreaks of HCV have involved patient-to-patient transmission and were attributed to unsafe injection practices. There have been numerous reports implicating the reuse of syringes and needles and/or the mishandling of medication vials [2-7]. In some instances, syringes and/or needles used on HCV-infected patients have been directly reused on other patients [3]. Alternatively, indirect contamination of a shared medication vial or container of flush solution has been described; this can occur when a syringe that was used on HCV-infected patients is re-used for that patient [2, 6, 9]. Backflow that occurs while injecting the patient or from removal of the needle can contaminate the syringe. If the contaminated syringe is used to withdraw medication from a vial or container that will be used for subsequent patients, these patients are placed at risk of infection. The practice of reusing syringes during a procedure to access shared propofol was observed, and interviews suggested it was a common practice at Clinic A. This was considered the most likely mode of transmission in clinic A.

Occasionally, patient-to-patient HCV transmission has been attributed to inadequate cleaning or disinfection of patient equipment [10, 11], but we consider this mechanism less likely in the context of our investigation. In clinic A, endoscope reprocessing procedures were generally followed, except that enzymatic cleaning solution was used on more than one endoscope. Manual cleaning with brushes to remove biofilms and high-level disinfection, which are considered most important for reducing potential bloodborne pathogen transmission, were judged adequate. However, because record-keeping was lacking in some respects, we could not determine whether endoscopes had been processed at the same time or by the same machine (this was not recorded in the charts). We also noted that on September 21, 2007, patient records indicated that two of the case-patients had procedures performed with one particular endoscope, although clinic staff attributed this to a clerical error. In addition, in one report, endoscopic biopsies were found to be an independent risk factor for HCV infection [11], (though deficiencies in the handling of parenteral medications were also noted). In our investigation, only three of six clinic-associated case-patients had a biopsy done, and the needle used was reported to be a single-use disposable item.

Transmission of HCV from infected staff has occasionally been reported and typically involved diversion of narcotics such as fentanyl [6]. This route of transmission appears unlikely in the clinic A setting given that no staff members have tested positive for HCV infection and propofol is not a commonly abused medication.

Actions and Recommendations

Given the findings of this ongoing investigation, we took the following actions and made the following recommendations.

Clinic A: Infection Control Practices

As we observed and interviewed individual staff members, we pointed out best practices in infection control.

1. **Injection safety:** We reviewed with the Clinic A staff the following: never reuse needles or syringes when drawing medications; never pool medications from individual vials; never use single-use vials for multiple patients; never recap needles; and immediately dispose of sharps in appropriate containers. Improper practices were promptly brought to the attention of staff (e.g., syringe reuse by CRNA 1 was immediately corrected after it was recognized).
2. **Hand hygiene:** We informed staff of the need to wash their hands or use hand sanitizer before providing injections, after blood contamination, and between patients; and to wear gloves for procedures that might involve contact with blood and to change gloves between patients.
3. **Patient-care equipment:** We instructed staff that the use of a batch of reprocessing detergent solution must be restricted to only one endoscope.

SNHD

1. **Case finding and epidemiologic studies:**
 - a. Clinic A staff's routine mishandling of injection equipment and single-use medication vials represented practices that have been previously implicated in bloodborne pathogen transmission. Such practices warrant patient notification advising testing for HCV, HBV and HIV [12]. Since the clinic had been operating in its current structure and format for 4 years and it was not possible to determine which individual patients might have been exposed to contaminated vials or equipment, a general notification advising testing for patients who underwent procedures over the entire 4 year period was discussed and agreed upon.
 - b. Clinic records of persons who had procedures on the days that one or more acute hepatitis C cases were identified (July 25, 2007 and September 21, 2007) were reviewed by CDC and the results were entered into a database which was provided to SNHD. We discussed and recommended the use of these data in the context of analytic epidemiologic studies to further elucidate patterns of infection and identify risk factors for infection. To the extent possible, efforts should be made to insure the highest degree of overall ascertainment of HCV infection status (i.e., acute HCV infection, previous HCV infection, HCV-uninfected) for this subset of patients.
 - c. CDC recommends and offers to perform HCV genotyping and RNA sequencing on all specimens that test positive for anti-HCV for persons who had procedures on July 25, 2007 or September 21, 2007 in order to identify potential source patients and further elucidate patterns of transmission.
 - d. Where feasible, CDC is available to perform HCV genotyping and RNA sequencing on specimens that test positive for anti-HCV to assist SNHD with the investigation of additional clusters of infections that might be identified as a result of the patient notification and testing.
 - e. We recommended that reviews of infection control practices at other affiliated endoscopy clinics should be considered and patient notification decisions be made based on those findings.

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2. CDC. Transmission of hepatitis B and C viruses in outpatient settings--New York, Oklahoma, and Nebraska, 2000-2002. *Morbidity and Mortality Weekly Report* **2003**;52(38):901-6.
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4. Krause G, Trepka MJ, Whisenhunt RS, et al. Noscomial transmission of hepatitis C virus associated with the use of multidose saline vials. *Infection Control and Hospital Epidemiology* **2003**;24:122-7.
5. Tallis GS, Ryan GM, Lambert SB, et al. Evidence of patient-to-patient transmission of hepatitis C through contaminated intravenous anaesthetic ampoules. *Journal of Viral Hepatitis* **2003**;10:234-9.
6. Williams IT, Perz JF, Bell BP. Viral hepatitis transmission in ambulatory health care settings. *CID* **2004**;38:1592-8.
7. Alter MJ. Healthcare should not be a vehicle for transmission of hepatitis C virus. *J Hepatol* **2008** Jan;48(1):2-4.
8. CDC. Recommendations for prevention and control of hepatitis C virus (HCV) infection and HCV-related chronic disease. *MMWR Morb Mortal Wkly Rep* **1998**;47(RR-19):1-39.
9. Macedo de Oliveira A, White KL, Leschinsky DP, et al. An outbreak of hepatitis C virus infections among outpatients at a hematology/oncology clinic. *Ann Intern Med* **2005** Jun 7;142(11):898-902.
10. Desenclos JC, Bourdiol-Razès M, Rolin B et al. Hepatitis C in a ward for cystic fibrosis and diabetic patients: possible transmission by spring-loaded finger-stick devices for self-monitoring of capillary blood glucose. *Infect Control Hosp Epidemiol*. 2001 (11):701-7
11. Bronowicki JP, Venard V, Botte C, et al. Patient-to-patient transmission of hepatitis C virus during colonoscopy. *The New England Journal of Medicine* **1997**;337(4):237-40.
12. CDC. http://www.cdc.gov/ncidod/dhqp/bp_steps_for_eval_IC_breach1.html.

Figure 1: Layout of Clinic A

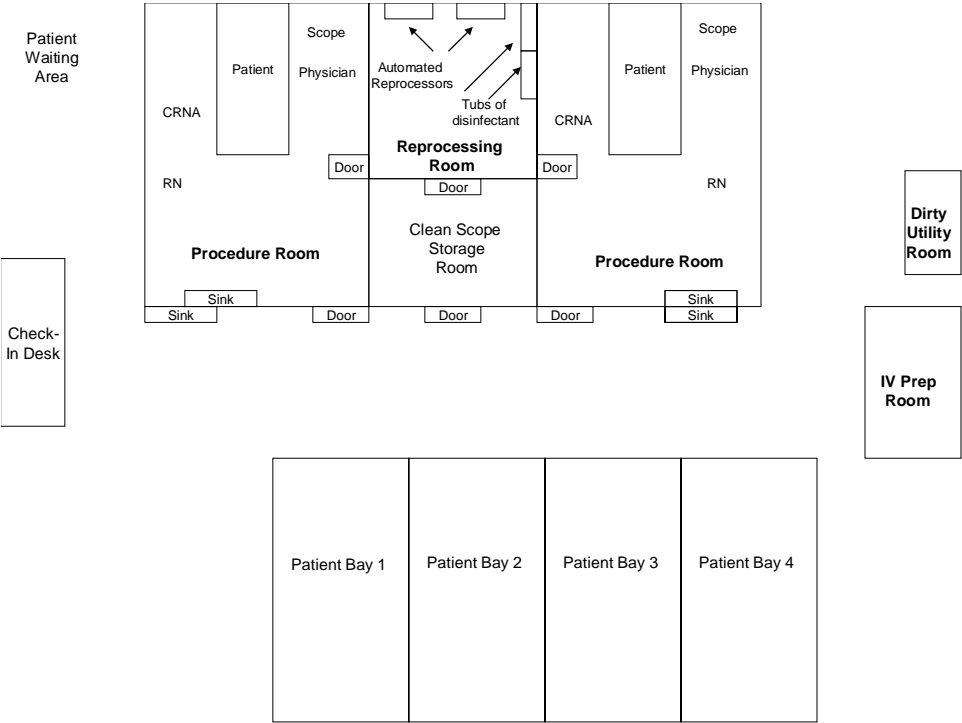


Figure 2. Acute hepatitis C in persons who underwent endoscopies at Clinic A, by date of procedure and onset of symptoms: Nevada 2007

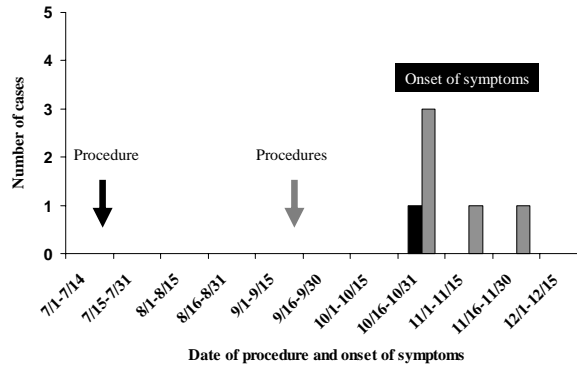


Table 1. Characteristics of procedures, staff involvement and anesthesia administered for incident case of acute hepatitis C:
Clinic A, Nevada 2007

| Incident Case | Date of Procedure | Start Time | Type of Procedure | Endoscope # | Biopsy? | IV start | Anesthetist | Multiple doses of propofol administered? |
|---------------|-------------------|------------|-------------------|-------------|---------|----------|-------------|--|
| Case 1 | 7/25/07 | 8:17am | Colonoscopy | 155 | Yes | CRNA 4 | CRNA 4 | No |
| Case 4 | 9/19/07 | 12:35pm | Upper endoscopy | 136 | Yes | RN 3 | CRNA 4 | Yes |
| Case 2 | 9/20/07 | 12:20pm | Colonoscopy | 170 | Yes | RN 5 | CRNA 1 | Yes |
| Case 5 | 9/21/07 | 9:55am | Colonoscopy | 57 | No | RN 2 | CRNA 4 | Yes |
| Case 3 | 9/21/07 | 10:24am | Colonoscopy | 41 | No | RN 1 | CRNA 1 | Yes |
| Case 6 | 9/21/07 | 10:30am | Colonoscopy | 57 | Yes | RN 3 | CRNA 4 | Yes |
| Case 4 | 9/21/07 | 12:25am | Colonoscopy | 155 | No | RN 1 | CRNA 4 | Yes |
| Case 2 | 9/21/07 | 1:12pm | Upper endoscopy | 70 | Yes | RN 1 | CRNA 1 | Yes |
| Case 5 | 9/28/07 | 9:25am | Upper endoscopy | 170 | Yes | CRNA 1 | CRNA 2 | Yes |

Table 2. Characteristics of procedures, staff involvement and anesthesia administered for potential source patients (known to be chronically infected before the procedure and preceded known clinic associated case-patient): Clinic A, Nevada 2007

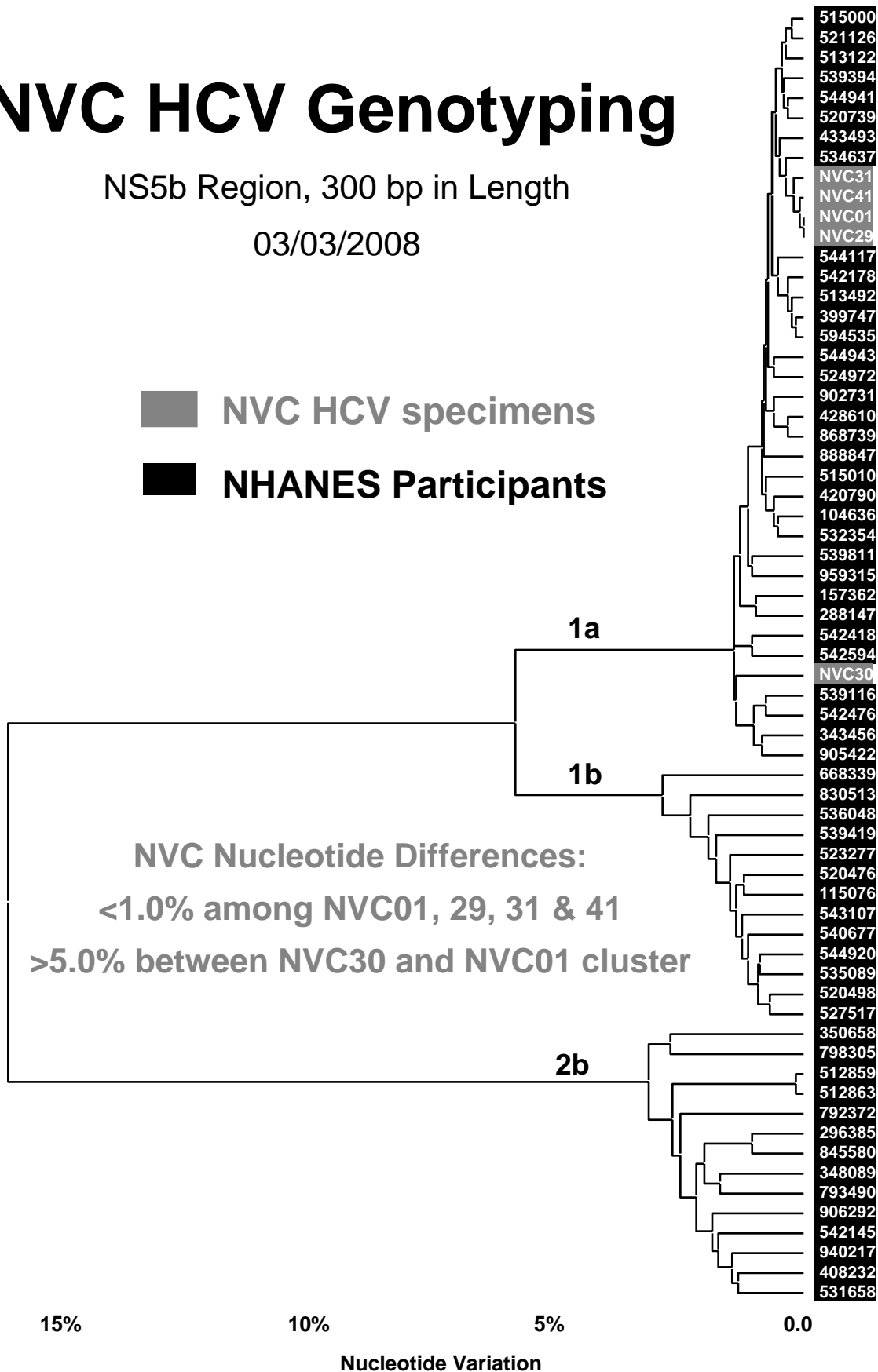
| Incident Case | Date of Procedure | Start Time | Type of Procedure | Endoscope # | Biopsy? | IV start | Anesthetist | Multiple doses of propofol administered? |
|--------------------|-------------------|------------|-------------------|-------------|---------|----------|-------------|--|
| Potential source 1 | 7/25/07 | 7:05am | Upper endoscopy | 301 | Y | CRNA 4 | CRNA 4 | Yes |
| Potential source 2 | 9/21/07 | 9:49am | Colonoscopy | 170 | Y | RN 3 | CRNA 1 | Yes |

NVC HCV Genotyping

NS5b Region, 300 bp in Length

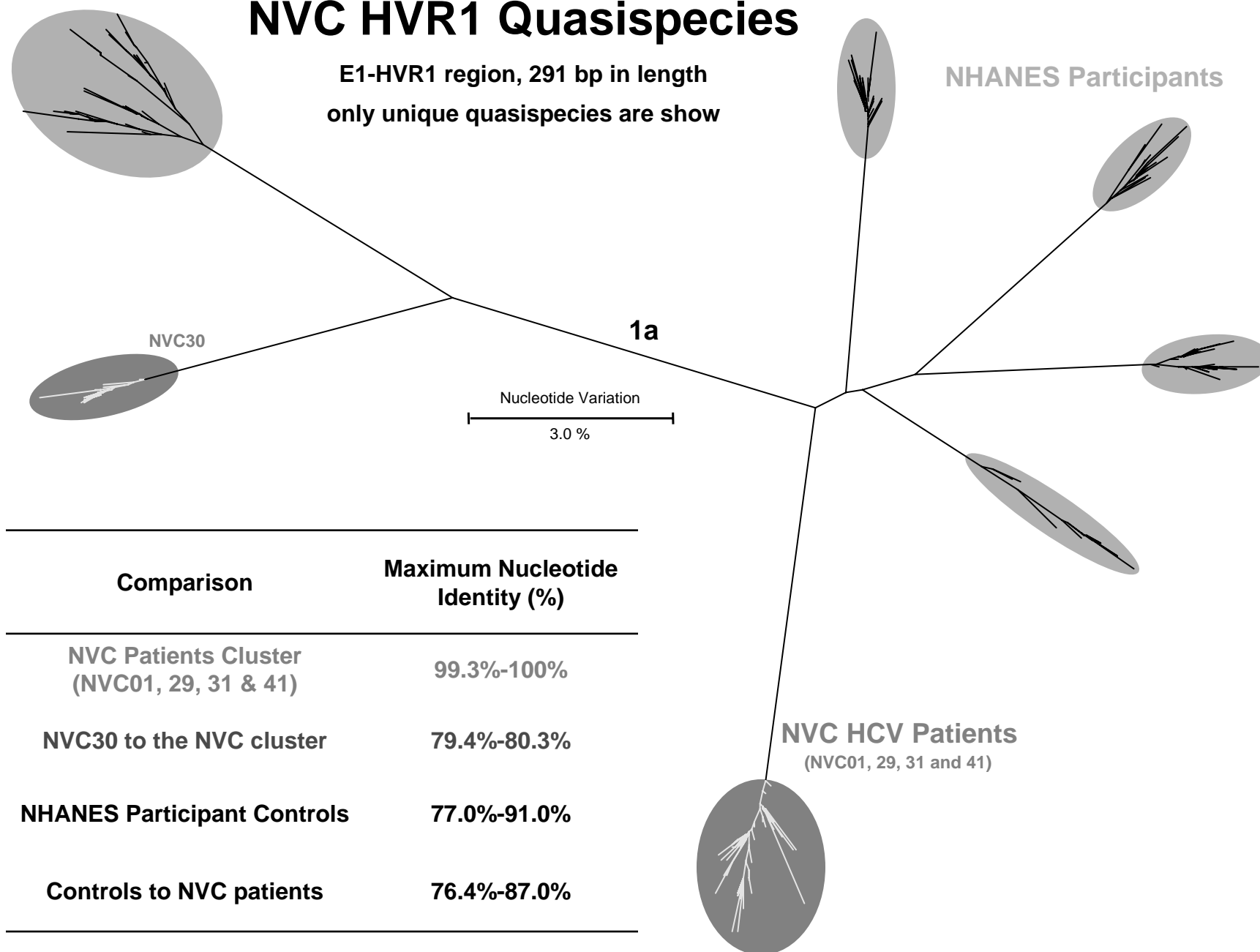
03/03/2008

■ NVC HCV specimens
■ NHANES Participants



NVC HVR1 Quasispecies

E1-HVR1 region, 291 bp in length
only unique quasispecies are show



Appendix K

BLC Report: Endoscopy Center of Southern Nevada

JIM GIBBONS
Governor

MICHAEL J. WILLDEN
Director



RICHARD WHITLEY, M.S.
Administrator

State Health Officer

STATE OF NEVADA
DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH DIVISION
BUREAU OF LICENSURE AND CERTIFICATION

☐ Health Facilities/Lab Services
1550 College Parkway
Suite 158
Carson City, Nevada 89706
(775) 687-4475
Fax: (775) 687-6588

☒ Health Facilities/Lab Services
4220 S. Maryland Parkway
Suite 810, Building D
Las Vegas, Nevada 89119
(702) 486-6515
Fax: (702) 486-6520

☐ Emergency Medical Services
4150 Technology Way
Suite 200
Carson City, Nevada 89706
(775) 687-7590
Fax: (775) 687-7595

☐ Emergency Medical Services
1020 Ruby Vista Drive
Suite 103
Elko, Nevada 89801
(775) 753-1154
Fax: (775) 753-4112

☐ Emergency Medical Services
P.O. Box 1227
Tonopah, Nevada 89049
(775) 482-3722
Fax: (775) 482-6975

February 4, 2008

Dipak Desai, MD, Administrator
Endoscopy Center of Southern Nevada
700 Shadow Lane, Suite 165B
Las Vegas, NV 89106

IMPORTANT NOTICE – PLEASE READ CAREFULLY

Dear Dr. Desai:

Enclosed is a Statement of Deficiencies and Plan of Correction that was generated as a result of the State Licensure complaint investigation survey conducted at your facility on January 17, 2008.

Plan of Correction

Please indicate in the right hand column opposite each deficiency how the corrective action will be accomplished for those found to have been affected by the deficient practice; how the facility will identify others having the potential to be affected by the deficient practice; what measures will be put into place or systematic changes made to ensure that the deficient practice will not recur; how the facility will monitor its corrective actions; the responsible party for accomplishing and/or monitoring compliance with the corrective action; and the anticipated date of correction. Please sign and date where indicated, retain a copy for your files and return the original to the Bureau of Licensure and Certification. Your Plan of Correction (POC) must be received by the Bureau no later than 10 days after receipt of this letter. Failure to submit an acceptable POC in a timely manner may result in sanctions.

Informal Dispute Resolution

In accordance with NAC 439.345.1(d) the Bureau provides these instructions for the informal dispute resolution process. The facility has one opportunity to question cited deficiencies through an informal dispute resolution process. In order for the facility to be given such an opportunity, the facility must send a written request for informal dispute resolution including the following information: 1) specific deficiencies identified either by TAG number or regulation/section number being disputed, 2) relevant information (evidence) as to why the facility is disputing each deficiency.

A statement of disagreement in the POC does not constitute an implied request for informal dispute resolution. An explicit request for informal dispute resolution must be submitted as a separate document and sent during the same ten days you have for submitting a POC. An incomplete informal dispute resolution process will not delay the effective date of the implementation of any sanctions being imposed.

The facility may not dispute the following: 1) the process used by the survey team to investigate the deficiency, 2) inconsistency in the citation of deficiencies between facilities, 3) inconsistency in the citation of deficiencies from survey to survey and 4) deficiencies that have a severity score of one or two except for those deficiencies with a severity score of two and a scope score of three.

Public Health: Working for a Safer and Healthier Nevada

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FEB 15 2008
BUREAU OF LICENSURE AND CERTIFICATION
STATE OF NEVADA
(702) 883 197

Dr. Desai, Endoscopy Center of Southern Nevada
02/04/08
Page 2

The outcome of the informal dispute resolution cannot be appealed. However, the licensee continues to have all appeal rights afforded by NRS 449.170 if sanctions are imposed.

Application of Sanctions


Nevada Administrative Code (NAC) 449.99851 indicates sanctions must be imposed for deficiencies that have either a combined Severity and Scope score of six or more or that have a severity level of four. The health division will send a separate notice when it intends to impose sanctions for these deficiencies. In accordance with NAC 449.99863, the sanctions available for all facilities include:

1. The imposition of a plan of correction as directed by the bureau;
2. The issuance of a provisional license as provided by NRS 449.091;
3. The imposition of a limitation on the occupancy of a residential facility;
4. The imposition of a ban on admissions;
5. Monitoring of the facility by the bureau;
6. The assessment of monetary penalties;
7. The requirement that the facility be managed temporarily by a person appointed by the bureau; and
8. The denial, suspension or revocation of the license of the facility.

Sanctions, if imposed, will be applied according to NRS 449.163 through 449.170 and NAC 449.9982 through 449.99939. The imposition of sanctions is based on the severity and the scope of the deficiency as defined by NAC 449.99861 and NAC 449.9986.

If you have questions concerning the instructions contained in this letter, please contact me at (702) 486-6515, ext. 246.

Sincerely,


Denise L. Hoyes, RN, BSN
Health Facility Surveyor III

For Lisa M. Jones, REHS, MPA
Chief

LMJ/DLHJ

Enclosures: 14 Page(s) Statement of Deficiencies and Plan of Correction
4 Pages Plan of Correction Memo

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FEB 15 2008

Division of Health Care Regulation
Las Vegas, Nevada

| | | | | |
|--|--|--|--|---|
| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: NVS472ASC | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | (X3) DATE SURVEY COMPLETED C 01/17/2008 |
| NAME OF PROVIDER OR SUPPLIER ENDOSCOPY CENTER OF SO NV LLC | | STREET ADDRESS, CITY, STATE, ZIP CODE 700 SHADOW LANE STE 165B LAS VEGAS, NV 89106 | | |
| (X4) ID PREFIX TAG | SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) | ID PREFIX TAG | PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) | (X5) COMPLETE DATE |
| A 00 | <p>INITIAL COMMENTS</p> <p>This Statement of Deficiencies was generated as a result of a complaint investigation conducted in your facility from 1/9/08 - 1/17/08.</p> <p>The survey was conducted using Nevada Administrative Code (NAC) 449, Surgical Centers for Ambulatory Patients, adopted by the Nevada State Board of Health on September 27, 1999.</p> <p>The findings and conclusions of any investigation by the Health Division shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.</p> <p>Forty - four (44) clinical records were reviewed.</p> <p>The following complaints were investigated.</p> <p>Complaint #NV17058- unsubstantiated Complaint #NV17004- substantiated (See Tag A010, A052, A213)</p> <p>The following regulatory deficiencies were identified.</p> | A 00 | <p><u>Tag A 00</u></p> <p><u>Epidemiology Review and Development of Remediation Plan:</u></p> <p>Because the facility believes it is essential to fully understand the facts and given the facility's sincere desire to constructively participate in remediation in the best interest of patients and the public health, the facility has engaged in a national search and retained preeminently qualified epidemiologists.</p> <p>To assist and expedite the process, the facility request that the Department provide it with the epidemiologic information that has been developed.</p> <p>The facility intends to fully cooperate in an appropriate remediation program.</p> <p>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 and should be preferred rather than general public media notification.</p> <p>Dr. Clifford Carrol, Senior Medical Staff Member has been designated to work with the facility's epidemiology consultants and to assist in developing the remediation plan.</p> | |
| A 10 | <p>NAC 449.980 Administration</p> <p>The governing body shall ensure that:</p> <p>7. The center adopts, enforces and annually reviews written policies and procedures required by NAC 449.971 to 449.996, inclusive, including an organization chart. These policies and procedures must:</p> <p>(a) Be approved annually by the governing body.</p> <p>This Regulation is not met as evidenced by:</p> | A 10 | | |

If deficiencies are cited, an approved plan of correction must be returned within 10 days after receipt of this statement of deficiencies.

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

STATE FORM

6899

CGV011

TITLE

ADMINISTRATOR

(X6) DATE

2-15-08

If continuation sheet 1 of 14

FEB 15 2008

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LAS VEGAS, NEVADA

| | | | | | |
|---|---|---|--|--------------------|---|
| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: NVS472ASC | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | | (X3) DATE SURVEY COMPLETED C 01/17/2008 |
| NAME OF PROVIDER OR SUPPLIER ENDOSCOPY CENTER OF SO NV LLC | | | STREET ADDRESS, CITY, STATE, ZIP CODE 700 SHADOW LANE STE 165B LAS VEGAS, NV 89106 | | |
| (X4) ID PREFIX TAG | SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) | ID PREFIX TAG | PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) | (X5) COMPLETE DATE | |
| A 10 | <p>Continued From page 1</p> <p>Based on observation, interview, and document review, the facility failed to ensure the center adopted and reviewed written policies and procedures for the 1. use of single dose of Propofol vials, 2. the first step of the cleaning process for the upper G.I. (gastrointestinal) endoscopy and colonoscopy scopes, and 3. the use of disposable biopsy instruments.</p> <p>Findings include:</p> <p>1. Propofol use</p> <p>Document Review</p> <p>Retrieved from the website: www.astrazeneca-us.com/pi/diprivan</p> <p>The Propofol (Diprivan) medication information documented " ...Diprivan injectable emulsion is a single-use parenteral product which contains 0.005% Disodium Edetate to retard the rate of growth of microorganisms in the event of accidental extrinsic contamination. However, Diprivan injectable emulsion can still support the growth of microorganisms as it is not an antimicrobially preserved product under USP standards." The center lacked policies and procedures for Propofol administration.</p> <p>Spotlights: Ambulatory Health Care / CDC Viral Hepatitis printed from the Internet</p> <p>"Injection safety</p> <p>* Use a sterile, single-use, disposable needle and syringe for each injection and discard intact in an appropriate sharps container after use.</p> <p>*Use single- dose medication vials, prefilled syringes, and ampules when possible. Do not administer medications from single-dose vials to</p> | A 10 | <p>Tag A10</p> <p>1. Propofol Use</p> <p>a) The facility has implemented a policy, approved by the Governing Body, outlining the strict adherence to the administration of Propofol. The policy states that all Propofol vials are to be utilized as single dose only. One vial per patient. The policy also states that needles and syringes are to be utilized as single use only and are to be discarded intact in an appropriate sharps container immediately after use. The nurse anesthetists and staff nurses have been informed and re-educated regarding the newly implemented policy and proper protocols for single dose vial medications and needle and syringe utilization. The facility no longer uses any multi-dose medication vials. The 50ml 2% Lidocaine and 0.9% Normal Saline vials have been discontinued and removed from the facility. The 0.9% Normal Saline now comes in a pre-filled, single use, 3cc labeled syringe. 2% Lidocaine injectable for use with Propofol has been stopped until further notice. If the 2% Lidocaine is re-implemented for use with Propofol at a later date, 5ml single dose vials will be utilized.</p> <p>b) All newly hired nurse anesthetists and staff nurses will be oriented to the Policy & Procedure Manual and expected to adhere to all policies and procedures of the facility. This will include the policy regarding Propofol administration and proper use of needles and syringes. CRNA's, MD's and RN's will be attending a Universal Precautions & Blood Borne Pathogen Compliance Class on 2/19/2008</p> | 02/07/2008 | 2/19/2008 |

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| A 10 | <p>Continued From page 2</p> <p>multiple patients or combine leftover contents for later use.</p> <p>*If multiple- dose vials are used, restrict them to a centralized medication area or for single patient use. Never re-enter a vial with a needle or syringe used on one patient if that vial will be used to withdraw medication for another patient. Store vials in accordance with manufacturer's recommendations and discard if sterility is compromised.</p> <p>*Do not use bags or bottles of intravenous solution as a common source of supply for multiple patients.</p> <p>*Use aseptic technique to avoid contamination of sterile injection equipment and medications."</p> <p>Interview</p> <p>On 1/9/08 in the afternoon, the Charge Nurse indicated the Propofol was utilized as a multidose vial to induce sedation during the endoscopic procedure. The Propofol would be discarded at the end of the day.</p> <p>On 1/10/08 at 3:55PM, the Certified Nurse Anesthetist (CRNA) indicated any Propofol left in the bottle after the procedure would be used for the next patient. The CRNA would obtain a new syringe to withdraw the medication.</p> <p>On 1/16/08 in the afternoon, one CRNA indicated that in the past the Propofol was not used as a single use vial. The Propofol may be used for two patients. The CRNA stated a clean syringe and needle would be used for each patient.</p> <p>The center failed to ensure manufacturer's recommendations for single dose use for Propofol were followed.</p> | A 10 | <p>Tag A10 (Continuation of Propofol)</p> <p>c) All 50ml Propofol vials have been removed from the facility to prevent excess Propofol remaining in the vial following a patient's procedure. The nurse anesthetists have been re-educated that all 20ml Propofol vials are single patient use only and any Propofol remaining in the vial or syringe following the patient's procedure is to be disposed of immediately. They have also been re-educated regarding needles and syringes being single use only. The nurse anesthetists have signed a written notice acknowledging they have been informed of the revised practices expected of them. The entire nursing staff has been informed that all multi-dose medication vials have been removed from the facility.</p> <p>d) Quarterly chart audits will include anesthesia records that will reflect the CRNA's compliance with facility policy and procedures.</p> <p>e) Dipak Desai, M.D., Medical Director, Clifford Carrol, M.D., Senior Medical Staff Member, Katie Maley, RN, Director of Nursing, Jeffrey Krueger, RN, Nurse Manager, will conduct chart audits on anesthesia records for compliance.</p> <p>f) Dipak Desai, M.D., Medical Director, Clifford Carrol, M.D., Senior Medical Staff Member, Katie Maley, RN, Director of Nursing, Jeffrey Krueger, RN, Nurse Manager will be responsible for accomplishing and monitoring compliance with the corrective action.</p> <p>g) Date of correction is 2/7/08.</p> <p>Please See Exhibit A-1, A-2</p> | | 02/07/2008 |

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| A 10 | <p>Continued From page 3</p> <p>2. EmPower-enzymatic detergent</p> <p>Document Review</p> <p>The direction for use of the EmPower- dual enzymatic detergent printed on the bottle documented "...Use fresh EmPower (enzymatic detergent) for each endoscope or set of instruments. Discard diluted EmPower solution after each use ... Manual cleaning: "Add 1 ounce (1 pump yields 1 ounce) of concentrate to one gallon of warm water (68 degrees Fahrenheit - 104 degrees Fahrenheit.) Soak instruments for a minimum of 1 minute."</p> <p>The Fujinon Scope training information documented "...D. Cleaning...2.a. Fresh detergent solution should be used for each endoscope to prevent cross-contamination..."</p> <p>Employees Orientation and Training Policies and Procedures</p> <p>"D. All new employees are trained to the specifications of their job description. Each new employee is assigned to the charge nurse, or supervising employee in their position, for a period of time of not less then one week to train and become familiar with the duties required of them."</p> <p>Observation</p> <p>On 1/10/08, step by step instruction for use of the Fujinon G-5 Endoscopes Cleaning and High-level Disinfection was displayed on the wall over the dirty sink area where the scopes were cleaned.</p> <p>The step by step instructions for the</p> | A 10 | <p>Tag A10</p> <p>2. Empower-enzymatic detergent</p> <p>a) The facility's staff, primarily the GI technicians have been re-educated and trained on the proper protocol for using the enzymatic cleaning detergent. They were instructed that the solution gets changed out following each scope's use. The policy has also been revised to reflect this change. There are now laminated forms directly above the blue basins in the processing room instructing the GI technician on the proper dilution strength of the enzymatic cleaning detergent and changing the solution after each scope is cleaned.</p> <p>b) The clinical competency checklist that each new staff member receives in orientation has been revised to include specific instructions related to proper scope cleaning practices. All new GI technicians will be oriented and initially trained according to the facility's policies and procedures, including those policies related to scope cleaning.</p> <p>c) The Governing Body has approved the revised facility policy relating to proper scope cleaning procedures. Each GI technician at the facility has signed a memo acknowledging they have read and been informed of the proper protocol for changing and replacing the enzymatic cleaning detergent. Laminated forms have been placed directly above the blue basins in the processing room to continuously remind staff members.</p> | 02/07/2008 |

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| A 10 | <p>Continued From page 4</p> <p>Gastrointestinal Technician identified the following::</p> <ol style="list-style-type: none"> 1. Precleaning 2. Leak Test 3. Manual Cleaning 4. High Level Disinfection 5. Dry All items, flush and wipe with Alcohol 6. Storage <p>On 1/10/08 at 3:35PM, after the procedure was completed, the GI (gastrointestinal) technician flushed the endoscope in the procedure room. The endoscope was then taken to the reprocessing room for thorough enzymatic detergent cleaning and disinfection. The endoscope was checked for any leaks and then placed in a tub of EmPower enzymatic detergent solution. The endoscope was cleaned by a double headed brush and then attached to a scope buddy for additional cleaning. The endoscope was then rinsed in water and placed in the automated reprocessing machine. The GI technician cleaned two endoscopes after use on other patients before discarding the enzymatic detergent solution and water rinse.</p> <p>Interview</p> <p>On 1/10/08 at 3:35PM, the GI technician indicated two endoscopes would be cleaned before the enzymatic detergent solution and water rinse was changed.</p> <p>On 1/10/08 at 3:35PM, the Charge Nurse confirmed the enzymatic detergent solution and water rinse was changed after two scopes were cleaned.</p> <p>On 1/16/08 at 8:00AM, the Director of Nursing indicated the enzymatic detergent solution was</p> | A 10 | <p>Tag A10 (Continuation of Em-Power)</p> <p>technician at the facility has signed a memo acknowledging they have read and been informed of the proper protocol for changing and replacing the enzymatic cleaning detergent. Laminated forms have been placed directly above the blue basins in the processing room to continuously remind staff members.</p> <p>d) The Jeffrey Krueger, RN, Nurse Manager or charge nurse will conduct quarterly competency testing on all staff that are responsible for the proper practice of cleaning the scopes. Katie Maley, RN, Director of Nursing and/or Jeffrey Krueger, RN, Nurse Manager will review any new products and or equipment introduced to facility prior to being utilized for any new procedural changes or implementations</p> <p>e) The Jeffrey Krueger, RN, Nurse Manager will continuously observe and monitor for compliance with the proper practice of cleaning the scopes. Tracking from accounts payable will reveal an increase in the quantity of enzymatic cleaning detergent being ordered and utilized.</p> <p>f) The Jeffrey Krueger, RN, Nurse Manager will be responsible for the compliance.</p> <p>g) Date of correction is 2/7/08.</p> <p>Please See Exhibit B-1, B-2, B-3, B-4 B-5</p> | 02/07/2008 |

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| A 10 | <p>Continued From page 5</p> <p>changed after two endoscopes were cleaned.</p> <p>On 1/16/08, the GI technician was asked to describe the measured amount of EmPower with what amount of water. The GI technician stated: "Add 2-3 pumps not sure the capacity of the basin. I do not have an answer to that."</p> <p>On 1/16/08, the Director of Nursing indicated: the staff had been instructed on the ratio of EmPower to water. The indicator line on the basin was measured for 2 1/2 to 3 gallons. The amount of EmPower was three pumps.</p> <p>There was no documented evidence to ensure all employees had knowledge the manufacturer's recommendations for the mixture of EmPower.</p> <p>3. Disposable instruments</p> <p>The policies and procedures were not updated to reflect the facility's current practice for the use of disposable equipment.</p> <p>Interview</p> <p>On 1/16/08, the administrative staff indicated the facility used disposable biopsy instruments. The policies and procedures had not been updated to reflect the current practice.</p> <p>The administrator failed to ensure the policies and procedures were evaluated and revised to reflect the current practice at the center.</p> <p>Complaint #NV17004</p> <p>Severity: 4 Scope: 3</p> | A 10 | <p>Tag A10</p> <p>3. Disposable instruments</p> <p>a) The policy has been updated to reflect the facility's practice of utilizing only single use, disposable biopsy forceps and snares.</p> <p>b) No others should be affected by this deficient practice. The policy has been revised. All new staff members have been and will continue to be properly trained that all biopsy forceps and snares are single use only.</p> <p>c) The Katie Maley, RN, Director of Nursing has reviewed the entire Policy & Procedure manual and updated and revised all necessary policies to reflect the facility's current practices. The Governing Body has approved all revisions. All policies will be periodically reviewed, not less than at least once a year for updates and revisions.</p> <p>d) The Policy & Procedure Manual will be periodically reviewed, not less than at least once yearly for updates and revisions.</p> <p>e) The Katie Maley, RN, Director of Nursing will be responsible for maintaining current policies sand procedures that reflect current practices of the facility.</p> <p>f) Date of completion is 2/7/08.</p> <p>Please See Exhibit C-1, C-2</p> | 02/07/2008 |

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| A 52 | Continued From page 6 | A 52 | Tag A52 | 02/07/2008 |
| A 52 | <p>NAC 449.981 Appointment/Responsibilities of Administrator</p> <p>5. The administrator shall: (b) Annually develop, evaluate, revise and carry out policies and procedures for the center. This Regulation is not met as evidenced by: Based on observation, interview and review of the policies and procedure, the center failed to ensure the administrator evaluated and revised the policies and procedures for the center.</p> <p>Findings include:</p> <p>1. Propofol use</p> <p>Document Review</p> <p>Retrieved from the website: www.astrazeneca-us.com/pi/diprivan</p> <p>The Propofol (Diprivan) medication information documented "...Diprivan injectable emulsion is a single-use parenteral product which contains 0.005% Disodium Edetate to retard the rate of growth of microorganisms in the event of accidental extrinsic contamination. However, Diprivan injectable emulsion can still support the growth of microorganisms as it is not an antimicrobially preserved product under USP standards." The center lacked policies and procedures for Propofol administration.</p> <p>Spotlights: Ambulatory Health Care /CDC Viral Hepatitis printed from the Internet</p> <p>"Injection safety * Use a sterile, single-use, disposable needle and syringe for each injection and discard intact in an appropriate sharps container after use.</p> | A 52 | <p>1.</p> <p>a) The facility has implemented a policy, approved by the Governing Body, outlining the strict adherence to the administration of Propofol. The policy states that all Propofol vials are to be utilized as single dose only. One vial per patient. The policy also states that needles and syringes are to be utilized as single use only and are to be discarded intact in an appropriate sharps container immediately after use. The nurse anesthetists and staff nurses have been informed and re-educated regarding the newly implemented policy and proper protocols for single dose vial medications and needle and syringe utilization. The facility no longer uses any multi-dose medication vials. The 50ml 2% Lidocaine and 0.9% Normal Saline vials have been discontinued and removed from the facility. The 0.9% Normal Saline now comes in a pre-filled, single use, 3cc labeled syringe. 2% Lidocaine injectable for use with Propofol has been stopped until further notice. If the 2% Lidocaine is re-implemented for use with Propofol at a later date, 5ml single dose vials will be utilized.</p> <p>b) All newly hired nurse anesthetists and staff nurses will be oriented to the Policy & Procedure Manual and expected to adhere to all policies and procedures of the facility. This will include the policy regarding Propofol administration and proper use of needles and syringes. CRNA's, MD's and RN's will be attending a Universal Precautions & Blood Borne Pathogen Compliancy Class on 2/19/2008</p> | |

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| A 52 | <p>Continued From page 7</p> <p>*Use single- dose medication vials, prefilled syringes, and ampules when possible. Do not administer medications from single-dose vials to multiple patients or combine leftover contents for later use.</p> <p>*If multiple- dose vials are used, restrict them to a centralized medication area or for single patient use. Never re-enter a vial with a needle or syringe used on one patient if that vial will be used to withdraw medication for another patient. Store vials in accordance with manufacturer's recommendations and discard if sterility is compromised.</p> <p>*Do not use bags or bottles of intravenous solution as a common source of supply for multiple patients.</p> <p>*Use aseptic technique to avoid contamination of sterile injection equipment and medications."</p> <p>Interview</p> <p>On 1/9/08 in the afternoon, the Charge Nurse indicated the Propofol was utilized as a multidose vial to induce sedation during the endoscopic procedure. The Propofol would be discarded at the end of the day.</p> <p>On 1/10/08 at 3:55PM, the Certified Nurse Anesthetist (CRNA) indicated any Propofol left in the bottle after the procedure would be used for the next patient. The CRNA would obtain a new syringe to withdraw the medication.</p> <p>On 1/16/08 in the afternoon, one CRNA indicated that in the past the Propofol was not used as a single use vial. The Propofol may be used for two patients. The CRNA stated a clean syringe and needle would be used for each patient.</p> <p>The center failed to ensure manufacturer's</p> | A 52 | <p>Tag A52 (Continuation of Propofol)</p> <p>c) All 50ml Propofol vials have been removed from the facility to prevent excess Propofol remaining in the vial following a patient's procedure. The nurse anesthetists have been re-educated that all 20ml Propofol vials are single patient use only and any Propofol remaining in the vial or syringe following the patient's procedure is to be disposed of immediately. They have also been re-educated regarding needles and syringes being single use only. The nurse anesthetists have signed a written notice acknowledging they have been informed of the revised practices expected of them. The entire nursing staff has been informed that all multi-dose medication vials have been removed from the facility.</p> <p>d) Quarterly chart audits will include anesthesia records that will reflect the CRNA's compliance with facility policy and procedures.</p> <p>e) Dipak Desai, M.D., Medical Director, Clifford Carrol, M.D., Senior Medical Staff Member, Katie Maley, RN, Director of Nursing, Jeffrey Krueger, RN, Nurse Manager, will conduct chart audits on anesthesia records for compliance.</p> <p>f) Dipak Desai, M.D., Medical Director, Clifford Carrol, M.D., Senior Medical Staff Member, Katie Maley, RN, Director of Nursing, Jeffrey Krueger, RN, Nurse Manager will be responsible for accomplishing and monitoring compliance with the corrective action.</p> <p>g) Date of correction is 2/7/08.</p> <p>Please See Exhibit A-1, A-2</p> | <p>02/07/2008</p> <p>02/19/08</p> | |

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| A 52 | <p>Continued From page 8</p> <p>recommendations for single dose use for Propofol were followed.</p> <p>2. EmPower-dual enzymatic detergent</p> <p>2. Observation</p> <p>On 1/10/08, step by step instruction for use of the Fujinon G-5 Endoscopes Cleaning and High-level Disinfection was displayed on the wall over the dirty sink area where the scopes were cleaned.</p> <p>The step by step instructions for the Gastrointestinal Technician identified the following::</p> <ol style="list-style-type: none"> 1. Precleaning 2. Leak Test 3. Manual Cleaning 4. High Level Disinfection 5. Dry All items, flush and wipe with Alcohol 6. Storage <p>On 1/10/08 at 3:35PM, after the procedure was completed, the GI (gastrointestinal) technician flushed the endoscope in the procedure room. The endoscope was then taken to the reprocessing room for thorough enzymatic detergent cleaning and disinfection. The endoscope was checked for any leaks and then placed in a tub of EmPower enzymatic detergent solution. The endoscope was cleaned by a double headed brush and then attached to a scope buddy for additional cleaning. The endoscope was then rinsed in water and placed in the automated reprocessing machine. The GI technician cleaned two endoscopes before discarding the enzymatic detergent solution and water rinse.</p> | A 52 | <p>Tag A52 (2)</p> <p>2.</p> <p>a) The facility's staff, primarily the GI technicians have been re-educated and trained on the proper protocol for using the enzymatic cleaning detergent. They were instructed that the solution gets changed out following each scope's use. The policy has also been revised to reflect this change. There are now laminated forms directly above the blue basins in the processing room instructing the GI technician on the proper dilution strength of the enzymatic cleaning detergent and changing the solution after each scope is cleaned.</p> <p>b) The clinical competency checklist that each new staff member receives in orientation has been revised to include specific instructions related to proper scope cleaning practices. All new GI technicians will be oriented and initially trained according to the facility's policies and procedures, including those policies related to scope cleaning.</p> <p>c) The Governing Body has approved the revised facility policy relating to proper scope cleaning procedures. Each GI technician at the facility has signed a memo acknowledging they have read and been informed of the proper protocol for changing and replacing the enzymatic cleaning detergent. Laminated forms have been placed directly above the blue basins in the processing room to continuously remind staff members.</p> | | 02/07/2008 |

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: NVS472ASC | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | (X3) DATE SURVEY COMPLETED C 01/17/2008 |
| NAME OF PROVIDER OR SUPPLIER ENDOSCOPY CENTER OF SO NV LLC | | STREET ADDRESS, CITY, STATE, ZIP CODE 700 SHADOW LANE STE 165B LAS VEGAS, NV 89106 | | |
| (X4) ID PREFIX TAG | SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) | ID PREFIX TAG | PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) | (X5) COMPLETE DATE |
| A 52 | <p>Continued From page 9</p> <p>Interview</p> <p>On 1/10/08 at 3:35PM, the GI technician indicated two endoscopes would be cleaned before the enzymatic detergent solution and water rinse was changed.</p> <p>On 1/10/08 at 3:35PM, the Charge Nurse confirmed the enzymatic detergent solution and water rinse was changed after two scopes were cleaned.</p> <p>On 1/16/08 at 8:00AM, the Director of Nursing indicated the enzymatic detergent solution was changed after two endoscopes were cleaned.</p> <p>On 1/16/08, the GI technician was asked to describe the measured amount of EmPower with what amount of water. The GI technician stated: "Add 2-3 pumps not sure the capacity of the basin. I do not have an answer to that."</p> <p>On 1/16/08, the Director of Nursing indicated: the staff had been instructed on the ratio of EmPower to water. The indicator line on the basin was measured for 2 1/2 to 3 gallons. The amount of EmPower was three pumps.</p> <p>There was no documented evidence to ensure all employees had knowledge the manufacturer's recommendations for the mixture of EmPower.</p> <p>Document Review</p> <p>The direction for use of the EmPower- dual enzymatic detergent printed on the bottle documented " ...Use fresh EmPower (enzymatic detergent) for each endoscope or set of instruments. Discard diluted EmPower solution after each use ... Manual cleaning: "Add 1 ounce</p> | A 52 | <p>Tag A52 (2)(Continuation)</p> <p>d) The Jeffrey Krueger, RN, Nurse Manager or charge nurse will conduct quarterly competency testing on all staff that are responsible for the proper practice of cleaning the scopes. Katie Maley, RN, Director of Nursing and/or Jeffrey Krueger, RN, Nurse Manager will review any new products and or equipment introduced to facility prior to being utilized for any new procedural changes or implementations</p> <p>e) The Jeffrey Krueger, RN, Nurse Manager will continuously observe and monitor for compliance with the proper practice of cleaning the scopes. Tracking from accounts payable will reveal an increase in the quantity of enzymatic cleaning detergent being ordered and utilized.</p> <p>f) The Jeffrey Krueger, RN, Nurse Manager will be responsible for the compliance.</p> <p>g) Date of correction is 2/7/08.</p> <p>Please See Exhibit B-1, B-2, B-3, B-4 B-5</p> | 02/07/2008 |

If deficiencies are cited, an approved plan of correction must be returned within 10 days after receipt of this statement of deficiencies.

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If continuation sheet 10 of 14

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: NVS472ASC | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | | (X3) DATE SURVEY COMPLETED C 01/17/2008 |
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| A 52 | <p>Continued From page 10</p> <p>(1 pump yields 1 ounce) of concentrate to one gallon of warm water (68 degrees Fahrenheit - 104 degrees Fahrenheit.) Soak instruments for a minimum of 1 minute."</p> <p>The Fujinon Scope training information documented "...D. Cleaning...2a. Fresh detergent solution should be used for each endoscope to prevent cross-contamination..."</p> <p>Employees Orientation and Training Policies and Procedures</p> <p>"D. All new employees are trained to the specifications of their job description. Each new employee is assigned to the charge nurse, or supervising employee in their position, for a period of time of not less then one week to train and become familiar with the duties required of them."</p> <p>There was no documented evidence to ensure all employees had knowledge the manufacturer's recommendations for the mixture of EmPower.</p> <p>3. Disposable Biopsy Instruments</p> <p>The policies and procedures were not updated to reflect the facility's current practice for the use of disposable biopsy instruments.</p> <p>Interview</p> <p>On 1/16/08, the Director of Nursing indicated the facility used disposable biopsy instruments. The policies and procedures had not been updated to reflect the current practice.</p> <p>The administrator failed to ensure the policies and procedures were evaluated and revised to</p> | A 52 | <p>Tag A52 (3)</p> <p>3.</p> <p>a) The policy has been updated to reflect the facility's practice of utilizing only single use, disposable biopsy forceps and snares.</p> <p>b) No others should be affected by this deficient practice. The policy has been revised. All new staff members have been and will continue to be properly trained that all biopsy forceps and snares are single use only.</p> <p>c) The Katie Maley, RN, Director of Nursing has reviewed the entire Policy & Procedure manual and updated and revised all necessary policies to reflect the facility's current practices. The Governing Body has approved all revisions. All policies will be periodically reviewed, not less than at least once a year for updates and revisions.</p> <p>d) The Policy & Procedure Manual will be periodically reviewed, not less than at least once yearly for updates and revisions.</p> <p>e) The Katie Maley, RN, Director of Nursing will be responsible for maintaining current policies sand procedures that reflect current practices of the facility.</p> <p>f) Date of completion is 2/7/08.</p> <p>Please See Exhibit C-1, C-2</p> | 02/07/2008 | |

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: NVS472ASC | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | | (X3) DATE SURVEY COMPLETED C 01/17/2008 |
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| A 52 | Continued From page 11 reflect the current practice at the center. Complaint #NV17004 Severity: 4 Scope:3 | A 52 | | | |
| A213 | NAC 449.9945 Administration/Record of Anesthesia 1. Anesthetics must be administered in the operating room of an ambulatory surgical center by an anesthesiologist, a qualified physician, a dentist or, under the direction of the operating physician and in accordance with the provisions of chapter 632 of NRS and the regulations adopted pursuant thereto, a certified registered nurse anesthetist. This Regulation is not met as evidenced by: Based on interview and document review, the center failed to ensure anesthetics were administered by CRNA (certified registered nurse anesthetist) in accordance with the provision of Chapter 632 of NRS and the regulations adopted pursuant thereto certified registered nurse anesthetist. Findings include: Nevada State Board of Nursing- Nevada Practice Act- Revised May 2004 NAC 632.510 Performance of duties in accordance with guidelines of facility A certified registered nurse anesthetist practicing in a facility shall practice in accordance with written guidelines and conform to NAC 632.500 to 632.550, inclusive. A review of the guidelines may be conducted by the board to determine if they conform to NAC 632.500 to 632.550, inclusive. | A213 | | | |

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: NVS472ASC | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | | (X3) DATE SURVEY COMPLETED C 01/17/2008 |
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| A213 | <p>Continued From page 12</p> <p>1. Propofol use</p> <p>Document Review</p> <p>Retrieved from the website: www.astrazeneca-us.com/pi/diprivan</p> <p>The Propofol (Diprivan) medication information documented " ...Diprivan injectable emulsion is a single-use parenteral product which contains 0.005% Disodium Edetate to retard the rate of growth of microorganisms in the event of accidental extrinsic contamination. However, Diprivan injectable emulsion can still support the growth of microorganisms as it is not an antimicrobially preserved product under USP standards." The center lacked policies and procedures for Propofol administration.</p> <p>Spotlights: Ambulatory Health Care/ CDC Viral Hepatitis printed from the Internet</p> <p>"Injection safety</p> <p>* Use a sterile, single-use, disposable needle and syringe for each injection and discard intact in an appropriate sharps container after use.</p> <p>*Use single- dose medication vials, prefilled syringes, and ampules when possible. Do not administer medications from single-dose vials to multiple patients or combine leftover contents for later use.</p> <p>*If multiple- dose vials are used, restrict them to a centralized medication area or for single patient use. Never re-enter a vial with a needle or syringe used on one patient if that vial will be used to withdraw medication for another patient. Store vials in accordance with manufacturer's recommendations and discard if sterility is compromised.</p> | A213 | <p>Tag A213</p> <p>1.</p> <p>a) The facility has implemented a policy, approved by the Governing Body, outlining the strict adherence to the administration of Propofol. The policy states that all Propofol vials are to be utilized as single dose only. One vial per patient. The policy also states that needles and syringes are to be utilized as single use only and are to be discarded intact in an appropriate sharps container immediately after use. The nurse anesthetists and staff nurses have been informed and re-educated regarding the newly implemented policy and proper protocols for single dose vial medications and needle and syringe utilization. The facility no longer uses any multi-dose medication vials. The 50ml 2% Lidocaine and 0.9% Normal Saline vials have been discontinued and removed from the facility. The 0.9% Normal Saline now comes in a pre-filled, single use, 3cc labeled syringe. 2% Lidocaine injectable for use with Propofol has been stopped until further notice. If the 2% Lidocaine is re-implemented for use with Propofol at a later date, 5ml single dose vials will be utilized.</p> <p>b) All newly hired nurse anesthetists and staff nurses will be oriented to the Policy & Procedure Manual and expected to adhere to all policies and procedures of the facility. This will include the policy regarding Propofol administration and proper use of needles and syringes. CRNA's, MD's and RN's will be attending a Universal Precautions & Blood Borne Pathogen Compliance Class on 2/19/2008</p> | 02/07/2008 | 2/19/2008 |

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: NVS472ASC | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | (X3) DATE SURVEY COMPLETED C 01/17/2008 |
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| A213 | <p>Continued From page 13</p> <p>*Do not use bags or bottles of intravenous solution as a common source of supply for multiple patients. *Use aseptic technique to avoid contamination of sterile injection equipment and medications."</p> <p>Interview</p> <p>On 1/9/08 in the afternoon, the Charge Nurse indicated the Propofol was utilized as a multidose vial to induce sedation during the endoscopic procedure. The Propofol would be discarded at the end of the day.</p> <p>On 1/10/08 at 3:55PM, the Certified Nurse Anesthetist (CRNA) indicated any Propofol left in the bottle after the procedure would be used for the next patient. The CRNA would obtain a new syringe to withdraw the medication.</p> <p>On 1/16/08 in the afternoon, one CRNA indicated that in the past the Propofol was not used as a single use vial. The Propofol may be used for two patients. The CRNA stated a clean syringe and needle would be used for each patient.</p> <p>The center failed to ensure manufacturer's recommendations for single dose use for Propofol were followed.</p> <p>Complaint #NV17004</p> <p>Severity: 4 Scope:3</p> | A213 | <p>Tag A213 (Continuation of Propofol</p> <p>c) All 50ml Propofol vials have been removed from the facility to prevent excess Propofol remaining in the vial following a patient's procedure. The nurse anesthetists have been re-educated that all 20ml Propofol vials are single patient use only and any Propofol remaining in the vial or syringe following the patient's procedure is to be disposed of immediately. They have also been re-educated regarding needles and syringes being single use only. The nurse anesthetists have signed a written notice acknowledging they have been informed of the revised practices expected of them. The entire nursing staff has been informed that all multi-dose medication vials have been removed from the facility.</p> <p>d) Quarterly chart audits will include anesthesia records that will reflect the CRNA's compliance with facility policy and procedures.</p> <p>e) Dipak Desai, M.D., Medical Director, Clifford Carrol, M.D., Senior Medical Staff Member, Katie Maley, RN, Director of Nursing, Jeffrey Krueger, RN, Nurse Manager, will conduct chart audits on anesthesia records for compliance.</p> <p>f) Dipak Desai, M.D., Medical Director, Clifford Carrol, M.D., Senior Medical Staff Member, Katie Maley, RN, Director of Nursing, Jeffrey Krueger, RN, Nurse Manager will be responsible for accomplishing and monitoring compliance with the corrective action.</p> <p>g) Date of correction is 2/7/08.</p> <p>Please See Exhibit A-1, A-2</p> | 02/07/2008 |

If deficiencies are cited, an approved plan of correction must be returned within 10 days after receipt of this statement of deficiencies.

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Endoscopy Center of Southern Nevada, LLC

700 Shadow Lane, Ste. 185B
Las Vegas, Nevada 89106

Propofol Administration Policy

This policy is to ensure the proper administration of the sedative agent used at the Endoscopy Center of Southern Nevada, LLC.

Each patient undergoing an Endoscopic procedure is sedated with Propofol administered by a Certified Registered Nurse Anesthetist. Alternative sedation medications, such as Versed and Demerol, may be used when deemed appropriate by the CRNA.

Propofol is to be utilized as a single use vial. An appropriate first dose, as determined by the CRNA, is drawn from an unopened, new 200mg single use Propofol bottle. When a syringe of Propofol has been utilized, the syringe and attached needle is immediately discarded into an appropriate sharps container. The needle is not recapped prior to its disposal. If more Propofol is required to sedate the patient, the second dose is drawn from the same bottle using a new syringe and needle. Prior to entering the Propofol bottle, alcohol will be utilized to appropriately clean the rubber cap. If any Propofol remains after the procedure is completed, it is immediately discarded. If more than 200mg of Propofol is required, a new, unopened 200mg vial is opened and entered with a new syringe and needle. Any unused Propofol in this second vial will be immediately discarded once the procedure is completed.

To ensure strict adherence to this policy, the CRNA will chart on the anesthesia record the following information:

- Uncapped needle discarded
- New Propofol vial utilized
- Unused Propofol discarded
- Rubber cap cleaned with alcohol if reentered

PROPOFOL ADMINISTRATION POLICY

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FEB 15 2008

Endoscopy Center of Southern Nevada, LLC
Las Vegas, Nevada

GASTROENTEROLOGY CENTER OF NEVADA

MEMO

Date: 01/31/2008

To: All CRNA Staff

From: Dipak Desai, M.D. Clifford Carrol, M.D. Tonya Rushing, C.O.O.

CC: File

IMPORTANCE: HIGH

This memo is to re-iterate the established policy and regarding the administering of Propofol, 2% Lidocaine and the use of syringes and needles.

The Propofol vials are clearly labeled, single dose only and it is required that the medication is utilized as single use. All remaining Propofol left in the vial at the end of each procedure, it is to be immediately and properly disposed of.

2% Lidocaine is not to be used any longer in our facilities until further notice. Our organization is currently conducting an internal quality management study to determine the effects of Propofol use without Lidocaine. This study will be conducted throughout the month of February and the results will determine the outcome of future use of 2% Lidocaine.

Please sign and date below where indicated to confirm receipt of this memo. A copy will be placed in your employee file. Thank you for your full co-operation.

If you have any questions, please contact Dr. Carrol at the Shadow Lane office or Tonya Rushing at 382-8101 ext. 1105.

PRINT NAME

SIGNATURE

DATE

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JAN 31 2008

CLIFFORD CARROL, M.D.
Tanya Rushing, C.O.O.

Endoscopy Center of Southern Nevada, LLC

700 Shadow Lane, Ste. 165B
Las Vegas, Nevada 89106

CLEANING AND DISINFECTION OF FIBEROPTIC SCOPES POLICY

This policy is to assure proper cleaning and disinfecting of fiberoptic scopes and accessory equipment by appropriately trained personnel, in order to protect patients against cross contamination, prevent damage to scopes, and keep equipment in good working order.

- A. The process in cleaning and disinfecting the scopes includes the following:
1. Immediately after the endoscopy procedure is finished, leave the scope attached to the light source, water bottle and suction.
 2. Depress water/air button and flush the water/air channel, then block water inlet opening and clear all water from internal channel.
 3. Turn on the suction, insert distal tip of the scope into a container of water and flush out the suction channel while all secretions are still in liquid form.
 4. Wipe down barrel of the scope with moist 4x4. Scope is now transported into the decontamination cleaning room into an awaiting tub of enzymatic cleaning solution with a dilution of one (1) ounce enzymatic cleaning solution to (1) gallon of water to achieve a total of two (2) gallons of cleaning solution within the basin.
 5. The outside of the scope is thoroughly washed in the enzymatic cleaning solution with a sponge.
 6. The scope channels are flushed with the enzymatic cleaning solution and the proper brush is used to clean the suction channels.
 7. The suction channel is flushed again to remove any particles loosened by the brush.
 8. The scope and channels are washed and flushed again in water.
 9. Once the manual cleaning of each scope is completed, the enzymatic cleaning solution is disposed of and a basin of newly prepared enzymatic cleaning solution awaits the next scope.

Cleaning and Disinfection of Video Scopes 1

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CLINICAL DEPARTMENT
LAS VEGAS, NEVADA

10. The scope is now put into the heated, disinfectant cleaning machine for a period of 28 minutes to achieve high level disinfecting.
 11. The aldehyde based high level disinfectant solution is tested daily for solution effectiveness and quality control. As soon as the solution fails the testing, the machine is temporarily taken out of service so the the aldehyde based disinfectant solution can be dumped and replaced with fresh solution. The fresh solution is tested prior to the machine being put back into service. A log of the daily testing and solution changing for each machine is kept in the processing room.
 12. After soaking the scope, it is rinsed in clear water inside and out. Alcohol is then flushed through the channel so that all moisture will evaporate after the scope is hung up to air dry.
 13. All removable parts and accessories should be cleaned and processed the same as the scopes.
- B. Random cultures will be taken of diagnostic and procedural equipment on a quarterly basis to ensure proper disinfecting techniques and document that portion of the infection control policy.

ENDOSCOPY CENTER OF SOUTHERN NEVADA I, LLC

INTER-OFFICE MEMORANDUM

DATE: JANUARY 16, 2008

TO: ALL ENDO STAFF

FROM: ENDO ADMINISTRATION

RE: ENZYMATIC DETERGENT

CC: FILE

Effective immediately the enzymatic cleaning solution is to be changed out after each individual scope cleaning. If you have any questions or concerns or need further clarification, please contact either Katie or Jeff.

Thank you.

Information will be explained in detail
at Saturday's staff meeting.

All staff mbrs please sign to acknowledge
this memo. Thank you

San Belaw

A series of handwritten signatures, including one that appears to be "Phil" and another that looks like "P. Craig".

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FEB 16 2008

ENDOSCOPY CENTER OF SOUTHERN NEVADA I, LLC
217

Enzymatic Cleaning Solution Instructions

One (1) Pump = One (1) Ounce

Dilution Strength:

One (1) Ounce Enzymatic Solution to One (1)
Gallon Water.

1:1 Ratio

- 1) With a cleaned, rinsed out blue basin, put two (2) full pumps of enzymatic cleaning solution into basin.
- 2) Fill blue basin with water to the black marker fill line. This will equal 2 gallons.
- 3) Clean scope per policy and protocol.
- 4) Once scope has been cleaned and placed in high level disinfectant machine, dispose of enzymatic solution in the blue basin and rinse basin.
- 5) Repeat steps 1, 2, 3, and 4 for each scope utilized.

ORIGINAL

FILED

U.S. District Court, Northern District of California
San Francisco, California 94102

**Enzymatic Cleaning
Solution Is To Be
Changed After Each
Scope Is Cleaned**

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MAY 15 2003

Division of Environmental Control
Los Angeles, California

Endoscopy Center of Southern Nevada, LLC

EMPLOYEE ORIENTATION CLINICAL CHECKLIST

| Orientation | Date Reviewed | Date Acknowledged | Employee initials | Supervisor initials |
|-------------------------------------|---------------|-------------------|-------------------|---------------------|
| Policy Review: | | | | |
| Description Job | | | | |
| Location of P&P Manual | | | | |
| Organization's Mission and Values | | | | |
| Quality Improvement Program | | | | |
| Infection Control | | | | |
| Safety | | | | |
| Fire Safety Procedures | | | | |
| Attire | | | | |
| Aseptic Technique | | | | |
| Code Blue Procedure | | | | |
| Drug Administration / Counts | | | | |
| Care of Specimens | | | | |
| Patient Rights and Responsibilities | | | | |
| Patient Confidentiality | | | | |
| Reporting of Patient Concerns | | | | |
| Reporting of Patient Grievances | | | | |
| Reporting of Adverse Incidents | | | | |
| Patient and Family Education | | | | |
| Patient Care: | | | | |
| Documentation | | | | |
| Positioning | | | | |
| IV Therapy | | | | |
| Cardiac Arrest | | | | |
| Identification | | | | |
| Privacy | | | | |
| Vital Signs: | | | | |
| *Heart Rate | | | | |
| *Blood Pressure | | | | |
| *Oxygen Saturation | | | | |
| Oxygen Therapy | | | | |
| Aldrete Score Interpretation | | | | |
| Acute Pain Management | | | | |

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ENDOSCOPY CENTER OF SOUTHERN NEVADA, LLC
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EMPLOYEE ORIENTATION CLINICAL CHECKLIST
(Cont'd)

| Orientation | Date Reviewed | Date Acknowledged | Employee initials | Supervisor initials |
|--|---------------|-------------------|-------------------|---------------------|
| Record Review: (RNs, LPNs) | | | | |
| Chart Requirements: | | | | |
| *Pre-Op Record | | | | |
| *Intra-Operative Record | | | | |
| *Post-Op Record | | | | |
| *EKG/VS Charting | | | | |
| *MD Operative Report | | | | |
| *DC Instructions | | | | |
| *Disclaimers/Consents | | | | |
| *Administrative Forms | | | | |
| Procedural Processing/Facility: | | | | |
| <u>Cleaning/Disinfecting GI Scopes:</u> | | | | |
| Scope Handling/Pre-cleaning | | | | |
| Leak Testing | | | | |
| Manual Cleaning | | | | |
| Enzymatic Cleaning Protocol | | | | |
| HLD Machine Operations | | | | |
| HLD Maintenance Protocol | | | | |
| Drying/Storage of Scopes | | | | |
| <u>Cleaning/Disinfecting Sterile</u> | | | | |
| <u>Instruments:</u> | | | | |
| Pre-Cleaning | | | | |
| Manually Cleaning | | | | |
| Enzymatic Cleaning Protocol | | | | |
| Sterilizer Operations | | | | |
| Sterilizer Maintenance Protocol | | | | |
| <u>Miscellaneous:</u> | | | | |
| Biohazard Waste | | | | |
| Linen Service | | | | |
| Emergency Power | | | | |
| Emergency Equipment: | | | | |
| *Fire Extinguishers | | | | |
| *Pull Stations | | | | |
| *Emergency Exits | | | | |
| *Code Blue | | | | |

EMPLOYEE ORIENTATION CLINICAL CHECKLIST
(Cont'd)

| Orientation | Date Reviewed | Date Acknowledged | Employee initials | Supervisor initials |
|--|----------------------|--------------------------|--------------------------|----------------------------|
| <u>Endoscopy Procedures:</u> | | | | |
| Assisting Physician | | | | |
| Biopsy Removal | | | | |
| Biopsy Retrieval | | | | |
| Polyp Removal: | | | | |
| *Bovie Operation | | | | |
| *Grounding Pads | | | | |
| Polyp Retrieval | | | | |
| Suctioning Patient | | | | |
| Dilatation | | | | |
| Provation System | | | | |
| <u>Specialty Procedural Procedures:</u> | | | | |
| Pain Management Procedures & Set-up | | | | |
| <u>Radiation Safety:</u> | | | | |
| Completed CA Radiation Safety Training | | | | |
| Policy review for Radiation Safety | | | | |
| Protective Attire Location | | | | |
| Proper Use Protective Attire | | | | |

Employee Signature: _____ Date: _____

Supervisor Signature: _____ Date: _____

Endoscopy Center of Southern Nevada, LLC

700 Shadow Lane, Ste. 165B
Las Vegas, NV 89106

New Product / Equipment Policy

This policy is to ensure proper handling and utilization of any new products and/or equipment being introduced to the facility. Patient and staff personnel safety is the goal when implementing any new products and/or equipment into the facility.

- A. Upon receiving any new products and/or equipment to the facility, the Director of Nursing or the Nurse Manager will review the manufacturer's recommendations for use and/or the operator's manual for proper procedural practice.
- B. In-services on the proper usage of new product/equipment will be provided by a professional representative, when available. Otherwise, the Director of Nursing and/or the Nurse Manager will review all material on the new product and /or equipment and provide training and competency for the personnel staff.
- C. In the event new protocol or procedures need to be practiced, a new policy and procedure will be implemented for the facility. Staff personnel will be notified of the new practice and expected to follow it.

NEW PRODUCT / EQUIPMENT POLICY

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SEP 16 2008

Endoscopy Center of Southern Nevada, LLC
Las Vegas, Nevada

Endoscopy Center of Southern Nevada, LLC

700 Shadow Lane, Ste. 165B
Las Vegas, Nevada 89106

INFECTION CONTROL POLICY AND PROCEDURE

This policy is to establish a program to identify and prevent the transmission of the diseases, maintain a sanitary environment for patients and staff. Report results to the appropriate committee for recommended actions.

A. Personnel practices:

1. All employees will wear scrubs, which are to be clean and maintained to an appropriate manner.
2. Moisture resistant gowns or aprons must be worn when danger of soiling from blood or body fluids are present.
3. Mask and eye protection must be worn when danger of splashing from blood, body fluids or disinfectant is present.
4. Gloves must be worn for procedures, touching blood, body fluids, mucous membranes of the patient. Gloves must also be worn for handling items or surfaces soiled with blood or body fluids, and for all clean up procedures.
5. Needles and all sharps must be discarded in designated disposal containers. Used needles must not be recapped by hand.
6. Personnel with open skin lesions should not perform or assist with any endoscopy procedures or handle equipment used for procedures.
7. Thorough hand washing with soap and water is essential when entering and leaving the endoscopy area, after glove removal, between each procedure, patient contact and after performing and personal hygiene.
 - a. Hand washing techniques. All personnel will be required to scrub all surfaces of hands for 10-15 seconds with soap to mechanically remove dirt and microorganisms.
 - b. Rinse hands underwater.
 - c. Dry hands with paper towel.

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8. General orientation of personnel to the Facility's Infection Control Program will be conducted at the beginning of employment and re-orientation on an annual basis.

B. Patient care practices:

1. Universal precautions will be followed for all patients at all times. This includes gloves being worn when handling soiled items. All surfaces are to be cleaned with Cavicide disinfectant, or similar disinfectant. All non-disposable items will be thoroughly cleaned with Cavicide disinfectant, or similar disinfectant solution.

C. Endoscopic scopes and equipment:

1. Cleaning of Video Scopes:

- a. When the procedure is terminated, the video scope will have clear water suctioned through all channels and the air/water channels is cleared. The barrel will be wiped down and the scope is transferred to the soiled utility room.
- b. In the soiled utility room, the whole scope will be immersed in an enzymatic detergent and the external surfaces cleaned with cleaning sponge. The scope channels will be cleaned with a cleaning brush and flushed out with an automatic channel flushing system.
- c. The scope is then immersed in clean, clear water and the scope channels are flushed again with water utilizing the automatic channel flushing system.
- d. The scope is then placed in the scope disinfectant cleaning machine, which sends it through a 28-minute wash, disinfects, and rinse cycle.
- e. The scope is then removed from the disinfectant machine and dried externally, then hung up in a clean, dry storage area until next use.

2. Cleaning snares and biopsy forceps:

- a. All biopsy forceps and snares are single use only and disposed of following single patient's use.

3. Procedure gurneys:

Paper drapes, and protective pads are changed with the linen after each patient. The gurney is wiped down with Cavicide disinfectant or Sani-Cloths disinfectant wipes after each patient's use.

D. Cleaning procedure room.

1. Nursing personnel will wipe down all items including sinks, counter tops, and carts as needed and at the end of the day. Cavicide disinfectant or Sani-Cloths disinfectant wipes will be used.
2. Cleaning and disinfectant areas should be separate from patient care areas. This area should have spaces for "clean and dirty", and separate storage area.
3. An outside, contracted cleaning company will provide cleaning and disinfecting of the floors, carpet, bathrooms and non-patient care areas five days a week.

E. Storage of supplies.

1. Outer shipping cartons are considered contaminated and will be discarded before supplies are stored in clean supply area.
2. Outer cartons may be used as dispensing bins if they are used on the bottom shelf or if they are placed on the top shelf with a plastic sheet beneath them. Paper cartons and corrugated boxes give off chaff, which may permit organisms on the surface of the box to land on the supplies below.
3. Inner paper cartons may be used as dispensing bins, but must be discarded when empty, and not reused since they may not be cleaned.
4. The stock in the storage area will be checked routinely for expiration dates.
5. The storage area must be kept clean, dry and free of insects.

F. Environment:

1. Halls and corridors will remain free of any obstacles and potential hazards.
2. Temperature in the center will be maintained at a comfortable setting.
3. Refrigerators.
 - a. Refrigerators used primarily for food will be cleaned by staff. All refrigerators will be defrosted and thoroughly cleaned as needed by facility staff. A 10% solution of bleach should be used to disinfect the interior surface.

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Las Vegas, Nevada

- b. Refrigerators used for medications will be cleaned by nursing personnel. The temperature chart is initiated if the temperature is within range of (55-450 P). If the temperature is out of range, a supervisor or designated person will be notified.

G. Linen:

- 1. Clean linen should be stored in designated area until used.
- 2. Dirty linen will be removed with as little agitation as possible.
- 3. Dirty linen will be removed from the procedure areas and is stored in a lined linen hamper with a lid. This hamper is kept in a soiled lined area within the utility room and will be picked up and emptied on a bi-weekly basis.

H. Waste disposal

1. Solid waste

- a. Solid waste will be placed in plastic lined waste containers. The plastic liner and trash are removed daily by the contracted service.
- b. Any waste materials that are contaminated with blood or body fluids will be disposed of in a plastic lined bio-hazardous waste container. Republic Services, Inc. disposes of the biohazard waste on a bi-weekly basis.
- c. Anything sharp will be discarded in puncture resistant containers.

2. Liquid waste

- a. Liquid waste is emptied and flushed down the hopper in the dirty utility room. Caution is taken to avoid splashing.
- b. Liquid chemical waste is disposed of down the hopper in the dirty utility room. The chemicals used in the disinfectant machine is disposed of via the piping and plumbing connected to the machine.

3. Needles and Sharps.

- a. Needles and sharps will be placed in a puncture resistant container as close as practical to the place of use.
- b. To be disposed of by Republic Services, Inc. a contracted waste disposal company.

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2. Liquid waste.
 - a. Liquid waste is emptied and flushed down the hopper in the dirty utility room. Caution is taken to avoid splashing.
 - b. Liquid chemical waste is disposed of down the hopper in the dirty utility room. The chemicals used in the disinfectant machine is disposed of via the piping and plumbing connected to the machine.
 3. Needles and Sharps.
 - a. Needles and sharps will be placed in a puncture resistant container as close as practical to the place of use.
 - b. To be disposed of by Republic Services, Inc. a contracted waste disposal company.
- I. Cultures:
1. Cultures of diagnostic equipment, procedural equipment and random areas of the facility will be taken quarterly.
 2. Results will be documented and presented to the appropriate committee.
- J. Infection Control Monitoring:
1. Random cultures will be taken on endoscopes, gurneys, pre-op chairs, and eye wash stations quarterly to validate the effectiveness of disinfecting techniques. This will be done by swabbing the item or area with a Culturette. If any results are positive, that piece of equipment will be taken out of service, recleaned and disinfected and re-cultured. The piece of equipment will not be allowed back into service until negative culture results are revealed.
 2. The results will be reported to the Quality Improvement Committee and the Governing Body. If any results are positive, a follow up is indicated. This follow up will include thorough cleaning of the item and re-culturing. A further search will include any adverse effect on patient care; i.e., infection and a plan to prevent any further incidents like changing the cleaning and disinfecting procedures.
 3. Post procedure complication and infection monitoring will be instituted. This will be performed by the R.N. conducting follow up calls to post procedure patients. Questions pertaining to temperature, pain or bleeding will be addressed. If the patient cannot be reached by phone, a letter will be sent out asking them to call if they have any problems. In addition a letter will be sent monthly to the physicians with a current patient list, inquiring about any post procedure infections or complications reported to them by their patients.

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Office of the Mayor
Las Vegas, Nevada

Endoscopy Center of Southern Nevada, LLC

700 Shadow Lane, Ste 165B
Las Vegas, Nevada 89106

CONTINUITY OF POLICIES: RIGHT TO CHANGE OR DISCONTINUE ANY WRITTEN POLICY

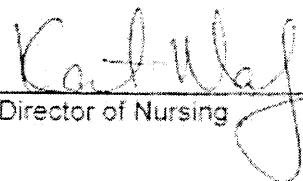
The policies and procedures in this manual are not intended to be contractual commitments by the Endoscopy Center of Southern Nevada, LLC. They are intended to be guidelines to management and merely descriptive to suggest procedures to be followed. The Governing Body of the Endoscopy Center of Southern Nevada, LLC reserves the right to revoke, change, or supplement guidelines at any time without notice. No policy is intended as a guarantee of continuity of benefits or rights. No permanent employment or employment for any term is intended or can be implied by statements in this manual.

With the above stated, the Governing Body hereby accepts and implements the policies and procedures within this manual for 2008. Any such amendments to the manual shall require the approval of the Governing Body with dates and initials of each amendment.


Operations Manager


Non-Operations Manager


Chief Operations Officer


Director of Nursing


Member

Right to Change or Discontinue
Any Written Policy

Updated 5/12/06
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Las Vegas, Nevada 229

Appendix L

BLC Report: Desert Shadow Endoscopy Center

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4-18-08
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PRINTED: 03/05/2008
FORM APPROVED

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|--|---|--|---|---|
| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: NVS4493ASC | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | (X3) DATE SURVEY COMPLETED 01/30/2008 |
| NAME OF PROVIDER OR SUPPLIER DESERT SHADOW ENDOSCOPY CENTER, LLC | | STREET ADDRESS, CITY, STATE, ZIP CODE 4275 S BURNHAM AVE SUITE 101 LAS VEGAS, NV 89119 | | |
| (X4) ID PREFIX TAG | SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) | ID PREFIX TAG | PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) | (X5) COMPLETE DATE |
| A 00 | <p>INITIAL COMMENTS</p> <p>This Statement of Deficiencies was generated as a result of a state licensure survey in conjunction with a Medicare recertification survey conducted at your facility from 1/29/08 through 1/30/08.</p> <p>The findings and conclusions of any investigation by the Health Division shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state or local laws.</p> <p>The state licensure survey was conducted in accordance with Chapter 449, Surgical Centers for Ambulatory Patients, adopted by the State Board of Health effective 9/27/99.</p> <p>The following deficiencies were identified.</p> | A 00 | | |
| A 10 | <p>NAC 449.980 Administration</p> <p>The governing body shall ensure that: 7. The center adopts, enforces and annually reviews written policies and procedures required by NAC 449.971 to 449.996, inclusive, including an organization chart. These policies and procedures must: (a) Be approved annually by the governing body.</p> <p>This Regulation is not met as evidenced by: Based on observation and interview, the center failed to ensure the policy to use single use Propofol vials and to discontinue the use of Lidocaine was enforced.</p> <p>Findings include: Observation</p> | A 10 | <p><u>Tag A 10</u></p> <p>a) The facility has implemented a policy, approved by the Governing Body, outlining the strict adherence to the administration of Propofol. The policy states that all Propofol vials are to be utilized as single dose only. One vial per patient. The policy also states that needles and syringes are to be utilized as single use only and are to be discarded intact in an appropriate sharps container immediately after use. The nurse anesthetists and staff nurses have been informed and re-educated regarding the newly implemented policy and proper protocols for single dose vial medications and needle and syringe utilization.</p> <p>The facility no longer uses any multi-dose medication vials. The 50ml 2% Lidocaine and 0.9% Normal Saline vials have been discontinued and removed from the facility. The 0.9% Normal Saline now comes in a pre-filled, single use, 3cc labeled syringe. 2% Lidocaine injectable for use with Propofol has been stopped until further notice. If the 2% Lidocaine is re-implemented for use with Propofol at a later date, 5ml single dose vials will be utilized.</p> | |

If deficiencies are cited, an approved plan of correction must be returned within 10 days after receipt of this statement of deficiencies.

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE _____ TITLE _____ (X6) DATE _____

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| A 10 | Continued From page 1 On 1/30/08 in the morning, CRNA #1 was present in Procedure Room #1 during an upper gastroenterology endoscopy. There were two vials of Propofol which contained approximately 1cc (cubic centimeters) of medication and an opened vial of Lidocaine located on the CRNA work station. Interview On 1/29/08 in the morning, the Nurse Manager indicated the CRNAs had been instructed to use single use Propofol vials and to discontinue the use of Lidocaine. The Nurse Manager indicated the CRNAs were supervised by the physicians and the physician director had a meeting (no date provided) with the CRNAs to inform them of the new policy. On 1/30/08 in the morning, CRNA #1 revealed the patient did not receive Lidocaine. CRNA #1 indicated Lidocaine was administered to the patients with small veins to decrease the burning sensation from the Propofol. The CRNA indicated the unused portion of the Propofol vials were administered to the next patient with a new syringe. There was no documented evidence to verify that the new policy had been initiated by the CRNAs for single use Propofol vials and that Lidocaine had been discontinued. On 1/30/08, during the exit conference, the physician indicated the CRNA had been informed of the new policy. Severity: 4 Scope: 3 | A 10 | <u>Tag A 10</u> b) All newly hired nurse anesthetists and staff nurses will be oriented to the Policy & Procedure Manual and expected to adhere to all policies and procedures of the facility. This will include the policy regarding Propofol administration and proper use of needles and syringes. c) All 50ml Propofol vials have been removed from the facility to prevent excess Propofol remaining in the vial following a patient's procedure. The nurse anesthetists have been re-educated that all 20ml Propofol vials are single patient use only and any Propofol remaining in the vial or syringe following the patient's procedure is to be disposed of immediately. They have also been re-educated regarding needles and syringes being single use only. The nurse anesthetists have signed a written notice acknowledging they have been informed of the revised practices expected of them. The entire nursing staff has been informed that all multi-dose medication vials have been removed from the facility. d) Senior Medical Staff, Albert Mason, MD, and/or Carmelo Herrero, MD, are on site everyday for procedures and will observe the CRNAs activities. Director of Nursing, Katie Maley has ensured the newly implemented policies have been placed in the manual for staff's review. Quarterly clinical competencies will be conducted on all CRNAs by a member of the Senior Medical Staff. e) Senior Medical Staff, Albert Mason, MD, Carmelo Herrero, MD, Director of Nursing, Katie Maley, RN will be responsible for accomplishing and monitoring compliance with the corrective action. f) Date of correction is 2/18/08. Please See Exhibit A-1, 1 | |
| A 60 | NAC 449.9812 Program for Quality Assurance | A 60 | | |

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| A 60 | <p>Continued From page 2</p> <p>2. The program for quality assurance must include, without limitation: (c) Procedures for the supervision of the professional and technical activities of the members of the staff. This Regulation is not met as evidenced by: Based on observation, interview, and document review, the center failed to ensure there were policies and procedures in place for the supervision and evaluation of the clinical activities of the certified registered nurse anesthetist (CRNA).</p> <p>Findings include:</p> <p>Observation</p> <p>On 1/30/08 in the morning, CRNA #1 was present in Procedure Room #1 during an upper gastroenterology endoscopy. There were two vials of Propofol which contained approximately 1cc (cubic centimeters) of medication and an opened vial of Lidocaine located on the CRNA work station.</p> <p>Interview</p> <p>On 1/29/08 in the morning, the Nurse Manager indicated the CRNAs had been instructed to use single use Propofol vials and to discontinue the use of Lidocaine. The Nurse Manager indicated the CRNAs were supervised by the physicians and the physician director had a meeting (no date provided) with the CRNAs to inform them of the new policy.</p> <p>On 1/30/08 in the morning, CRNA #1 revealed the patient did not receive Lidocaine. CRNA #1 indicated Lidocaine was administered to the patients with small veins to decrease the burning</p> | A 60 | <p><u>Tag A 60</u></p> <p>a) The facility has revised its policy regarding peer review of medical necessity to include the certified registered nurse anesthetists. Anesthesia records are already included in the chart reviews conducted for physicians and the CRNAs have a separate peer review form as well signed off by an attending physician. The policy now reflects the current practice. The anesthesia record and chart review forms have also been revised to include addressing universal precautions and single patient use Propofol. The facility has implemented a policy, approved by the Governing Body, outlining the strict adherence to the administration of Propofol. The policy states that all Propofol vials are to be utilized as single dose only. One vial per patient. The policy also states that needles and syringes are to be utilized as single use only and are to be discarded intact in an appropriate sharps container immediately after use. The nurse anesthetists and staff nurses have been informed and re-educated regarding the newly implemented policy and proper protocols for single dose vial medications and needle and syringe utilization. The facility has implemented a new policy that stipulates that there will no longer be any multi-dose medication vials utilized. All medication vials at the facility are single dose only. The 50ml 2% Lidocaine and 0.9% Normal Saline vials have been discontinued and removed from the facility. The 0.9% Normal Saline now comes in a pre-filled, single use, 3cc labeled syringe. 2% Lidocaine injectable for use with Propofol has been stopped until further notice. If the 2% Lidocaine is re-implemented for use with Propofol at a later date, 5ml single dose vials will be utilized.</p> <p>b) All newly hired nurse anesthetists and staff nurses will be oriented to the Policy & Procedure Manual and expected to adhere to all policies and procedures of the facility. This will include the policy regarding Propofol administration and proper use of needles and syringes.</p> <p>c) All 50ml Propofol vials have been removed from the facility to prevent excess Propofol remaining in the vial following a patient's procedure. The nurse anesthetists have been re-educated that all 20ml Propofol vials are single patient use only and any Propofol remaining in the vial or syringe following the patient's procedure is to be disposed of immediately. They have also been re-educated regarding needles and syringes being single use only. The nurse anesthetists have signed a written notice acknowledging they have been informed of the revised practices expected of them. The entire nursing staff has been informed that all multi-dose medication vials have been removed from the facility. The Governing Body will review chart and peer reviews on the CRNAs. Their reviews will be reflected in the meeting minutes.</p> | |

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| A 60 | <p>Continued From page 3</p> <p>sensation from the Propofol. The CRNA indicated the unused portion of the Propofol vials were administered to the next patient with a new syringe.</p> <p>There was no documented evidence to verify that the new policy had been initiated by the CRNAs for single use Propofol vials and that Lidocaine had been discontinued. On 1/30/08, during the exit conference, the physician indicated the CRNA had been informed of the new policy.</p> <p>Document Review</p> <p>The center's "Supervising Physician Agreement" stated:</p> <p>"This agreement, dated 8/12/07, by and between Clinic A, a Nevada Joint Venture, or its successor or assigns and Physician #1 of Clinic B.</p> <p>Physician #1, in conjunction with Physician #2 and Physician #3 of Clinic A agrees to co-supervise and consult with CRNA's employed at Clinic A. Supervision and consultation services will be provided regarding the anesthesiology services provided by said Clinic A employees. It agrees that Physician #1 will be available for phone consultations in addition to on-call premise consultations as necessary."</p> <p>Retrieved from the website: www.astrazeneca-us.com/pi/diprivan</p> <p>The Propofol (Diprivan) medication information documented "...Diprivan injectable emulsion is a single-use parenteral product which contains 0.005% Disodium Edetate to retard the rate of growth of microorganisms in the event of accidental extrinsic contamination. However,</p> | A 60 | <p><u>Tag A 60</u></p> <p>d) Quarterly clinical competencies will be conducted on each CRNA by a member of the Senior Medical Staff, Albert Mason, MD and/or Dr. Carmelo Herrero, MD. The clinical competencies will include interviews, as well as observation of the CRNA in practice.</p> <p>e) Senior Medical Staff, Albert Mason, MD, and Carmelo Herrero, MD, will be monitoring and overseeing the CRNA's clinical activities. There is at least one of these two physicians at the facility every weekday performing procedures. The Director of Nursing, Katie Maley, Nurse Manager, Jeffrey Krueger, the facility's attending physicians, and the Governing Body will evaluate the CRNAs reviews reflecting their clinical activities from their anesthesia records.</p> <p>f) Date of correction: 2/18/08</p> <p>Please See Exhibit B-1, B-2, B-3, B-4</p> | | |

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| A 60 | Continued From page 4 Diprivan injectable emulsion can still support the growth of microorganisms as it is not an antimicrobially preserved product under USP standards." Retrieved from the Internet :Spotlights: Ambulatory Health Care/ CDC Viral Hepatitis "Injection safety * Use a sterile, single-use, disposable needle and syringe for each injection and discard intact in an appropriate sharps container after use. *Use single-dose medication vials, prefilled syringes, and ampules when possible. Do not administer medications from single-dose vials to multiple patients or combine leftover contents for later use. *If multiple-dose vials are used, restrict them to a centralized medication area or for single patient use. Never re-enter a vial with a needle or syringe used on one patient if that vial will be used to withdraw medication for another patient. Store vials in accordance with manufacturer's recommendations and discard if sterility is compromised. *Do not use bags or bottles of intravenous solution as a common source of supply for multiple patients. *Use aseptic technique to avoid contamination of sterile injection equipment and medications." Severity: 4 Scope: 3 | A 60 | | | |
| A213 | NAC 449.9945 Administration/Record of Anesthesia 1. Anesthetics must be administered in the operating room of an ambulatory surgical center by an anesthesiologist, a qualified physician, a dentist or, under the direction of the operating | A213 | | | |

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| NAME OF PROVIDER OR SUPPLIER DESERT SHADOW ENDOSCOPY CENTER, LLC | | | STREET ADDRESS, CITY, STATE, ZIP CODE 4275 S BURNHAM AVE SUITE 101 LAS VEGAS, NV 89119 | | |
| (X4) ID PREFIX TAG | SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) | ID PREFIX TAG | PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) | | (X5) COMPLETE DATE |
| A213 | <p>Continued From page 5</p> <p>physician and in accordance with the provisions of chapter 632 of NRS and the regulations adopted pursuant thereto, a certified registered nurse anesthetist.</p> <p>This Regulation is not met as evidenced by: Based on interview and document review, the center failed to ensure anesthetics were administered by a certified registered nurse anesthetist (CRNA) in accordance with the provision of Chapter 632 of NRS (Nevada Revised Statutes) and the regulations adopted pursuant thereto certified registered nurse anesthetist.</p> <p>Findings include:</p> <p>Document Review</p> <p>Nevada State Board of Nursing - Nevada Practice Act - Revised May 2004</p> <p>NAC 632.510 Performance of duties in accordance with guidelines of facility. A certified registered nurse anesthetist practicing in a facility shall practice in accordance with written guidelines and conform to NAC 632.500 to 632.550, inclusive. A review of the guidelines may be conducted by the board to determine if they conform to NAC 632.500 to 632.550, inclusive.</p> <p>Retrieved from the website: www.astrazeneca-us.com/pi/diprivan</p> <p>The Propofol (Diprivan) medication information documented "...Diprivan injectable emulsion is a single-use parenteral product which contains 0.005% Disodium Edetate to retard the rate of growth of microorganisms in the event of accidental extrinsic contamination. However,</p> | A213 | <p><u>Tag A 213</u></p> <p>a) The facility has implemented a policy, approved by the Governing Body, outlining the strict adherence to the administration of Propofol. The policy states that all Propofol vials are to be utilized as single dose only. One vial per patient. The policy also states that needles and syringes are to be utilized as single use only and are to be discarded intact in an appropriate sharps container immediately after use. The nurse anesthetists and staff nurses have been informed and re-educated regarding the newly implemented policy and proper protocols for single dose vial medications and needle and syringe utilization.</p> <p>The facility no longer uses any multi-dose medication vials. The 50ml 2% Lidocaine and 0.9% Normal Saline vials have been discontinued and removed from the facility. The 0.9% Normal Saline now comes in a pre-filled, single use, 3cc labeled syringe. 2% Lidocaine injectable for use with Propofol has been stopped until further notice. If the 2% Lidocaine is re-implemented for use with Propofol at a later date, 5ml single dose vials will be utilized.</p> <p>b) All newly hired nurse anesthetists and staff nurses will be oriented to the Policy & Procedure Manual and expected to adhere to all policies and procedures of the facility. This will include the policy regarding Propofol administration and proper use of needles and syringes.</p> <p>c) All 50ml Propofol vials have been removed from the facility to prevent excess Propofol remaining in the vial following a patient's procedure. The nurse anesthetists have been re-educated that all 20ml Propofol vials are single patient use only and any Propofol remaining in the vial or syringe following the patient's procedure is to be disposed of immediately. They have also been re-educated regarding needles and syringes being single use only. The nurse anesthetists have signed a written notice acknowledging they have been informed of the revised practices expected of them. The entire nursing staff has been informed that all multi-dose medication vials have been removed from the facility.</p> <p>d) Senior Medical Staff, Albert Mason, MD, and/or Carmelo Herrero, MD, are on site everyday for procedures and will observe the CRNAs activities. Director of Nursing, Katie Maley has ensured the newly implemented policies have been placed in the manual for staff's review. Quarterly clinical competencies will be conducted on all CRNAs by a member of the Senior Medical Staff.</p> | | |

If deficiencies are cited, an approved plan of correction must be returned within 10 days after receipt of this statement of deficiencies.

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: NVS4493ASC | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | (X3) DATE SURVEY COMPLETED 01/30/2008 |
| NAME OF PROVIDER OR SUPPLIER DESERT SHADOW ENDOSCOPY CENTER, LLC | | STREET ADDRESS, CITY, STATE, ZIP CODE 4275 S BURNHAM AVE SUITE 101 LAS VEGAS, NV 89119 | | |
| (X4) ID PREFIX TAG | SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) | ID PREFIX TAG | PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) | (X5) COMPLETE DATE |
| A213 | <p>Continued From page 6</p> <p>Diprivan injectable emulsion can still support the growth of microorganisms as it is not an antimicrobially preserved product under USP standards."</p> <p>Retrieved from the Internet :Spotlights: Ambulatory Health Care/ CDC (Center for Disease Control) Viral Hepatitis</p> <p>"Injection safety * Use a sterile, single-use, disposable needle and syringe for each injection and discard intact in an appropriate sharps container after use. *Use single dose medication vials, prefilled syringes, and ampules when possible. Do not administer medications from single-dose vials to multiple patients or combine leftover contents for later use. *If multiple-dose vials are used, restrict them to a centralized medication area or for single patient use. Never re-enter a vial with a needle or syringe used on one patient if that vial will be used to withdraw medication for another patient. Store vials in accordance with manufacturer's recommendations and discard if sterility is compromised. *Do not use bags or bottles of intravenous solution as a common source of supply for multiple patients. *Use aseptic technique to avoid contamination of sterile injection equipment and medications."</p> <p>Interview</p> <p>On 1/29/08 in the morning, the Nurse Manager indicated that the policy for the single use of Propofol vials and discontinued use of Lidocaine had been initiated. The Nurse Manager indicated the CRNAs were supervised by the physicians and the physician director had a meeting (no date</p> | A213 | <p><u>Tag A213</u></p> <p>e) Senior Medical Staff, Albert Mason, MD, Carmelo Herrero, MD, Director of Nursing, Katie Maley, RN will be responsible for accomplishing and monitoring compliance with the corrective action. f) Date of correction is 2/18/08.</p> <p>Please See Exhibit C-1, 402</p> | |

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: NVS4493ASC | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | (X3) DATE SURVEY COMPLETED 01/30/2008 |
| NAME OF PROVIDER OR SUPPLIER DESERT SHADOW ENDOSCOPY CENTER, LLC | | STREET ADDRESS, CITY, STATE, ZIP CODE 4275 S BURNHAM AVE SUITE 101 LAS VEGAS, NV 89119 | | |
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| A213 | <p>Continued From page 7</p> <p>provided) with the CRNAs to inform the CRNAs of the new policy.</p> <p>On 1/30/08 in the morning, CRNA#1 indicated the patient did not receive Lidocaine. CRNA #1 indicated the Lidocaine was administered to the patients who had small veins to decrease the burning sensation from the Propofol.</p> <p>CRNA #1 indicated the unused portion of the Propofol vials had been administered to the next patient with a new syringe.</p> <p>On 1/30/08, during the exit conference the physician indicated the CRNAs had been informed of the new policy for the single use Propofol vials and the discontinued use of Lidocaine.</p> <p>The center lacked documented evidence to verify a written policy for the single use of Propofol vials and the discontinued use of Lidocaine had been established.</p> <p>The CRNA failed to ensure the Propofol was administered according to the manufacturer's recommendations and facility policy as reported by the nurse manager.</p> <p>Severity: 4 Scope: 3</p> | A213 | | |

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Desert Shadow Endoscopy Center, LLC
Provider #29C0001062
Exit Date: 1/30/08

The CRNA (certified registered nurse anesthetist) have been assigned the following numerical identifier.

1. Ralph McDowell

The physicians have been assigned the following numerical identifiers.

1. Satish Sharma
2. Dipak Desai
3. Vishvinder Sharma

The facilities have been assigned the following identifier.

1. Clinic A- Gastroenterology Center of Nevada
2. Clinic B – Advanced Pain Management Center

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Las Vegas, Nevada

Desert Shadow Endoscopy Center, LLC

4275 Burnham Ave., Ste. 101
Las Vegas, Nevada 89119

Propofol Administration Policy

This policy is to ensure the proper administration of the sedative agent used at Desert Shadow Endoscopy Center, LLC.

Each patient undergoing an Endoscopic procedure is sedated with Propofol administered by a Certified Registered Nurse Anesthetist. Alternative sedation medications, such as Versed and Demerol, may be used when deemed appropriate by the CRNA.

Propofol is to be utilized as a single use vial. An appropriate first dose, as determined by the CRNA, is drawn from an unopened, new 200mg single use Propofol bottle. When a syringe of Propofol has been utilized, the syringe and attached needle is immediately discarded into an appropriate sharps container. The needle is not recapped prior to its disposal. If more Propofol is required to sedate the patient, the second dose is drawn from the same bottle using a new syringe and needle. Prior to entering the Propofol bottle, alcohol will be utilized to appropriately clean the rubber cap. If any Propofol remains after the procedure is completed, it is immediately discarded. If more than 200mg of Propofol is required, a new, unopened 200mg vial is opened and entered with a new syringe and needle. Any unused Propofol in this second vial will be immediately discarded once the procedure is completed.

To ensure strict adherence to this policy, the CRNA will chart on the anesthesia record the following information:

- Uncapped needle discarded
- New Propofol vial utilized
- Unused Propofol discarded
- Rubber cap cleaned with alcohol if reentered

PROPOFOL ADMINISTRATION POLICY

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Bureau of Licensure and Certification
Las Vegas, Nevada 240

Desert Shadow Endoscopy Center, LLC

4275 Burnham Ave., Ste. 101
Las Vegas, Nevada 89119
(702) 733-1291

PEER REVIEW OF MEDICAL NECESSITY

This policy is to provide a retrospective review of the success of the facility's quality care program.

A retrospective peer review of medical necessity will be conducted each quarter. A statistically significant number of the medical charts of patient's undergoing the designated procedure will be pulled and reviewed. The attending physicians of Desert Shadow Endoscopy Center, LLC, will conduct peer reviews on one another's medical charts. This will also include review of the Certified Registered Nurse Anesthetist's anesthesia record. This review may be performed by an outside review if deemed prudent to the quality functioning of the facility.

- A. Pull a statistically significant number of the designated procedural charts for that quarter to represent varying physicians performing those procedures. Each quarter will represent different physicians to ensure all physicians are reviewed.
- B. Procure the appropriate chart review / peer review forms.
- C. Complete the review forms from data gathered in the chart according to the criteria identified on the form.
- D. Submit chart and peer review results to the Medical Director and Governing Body for review, determination of appropriateness and possible intervention.

PEER REVIEW OF MEDICAL NECESSITY

Revised 2/08km

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Las Vegas, Nevada

Exhibit B-2

M _____

F _____

AGE _____

CCS _____

o2 SAT _____

PATIENT ID _____

PRE-OP DIAGNOSIS _____

B.P. _____ HT _____ WT _____

B.P.

220

200

180

160

140

120

100

80

60

40

20

ANESTHESIA AND
MONITORING
EQUIPMENT CHECK
BEFORE INDUCTION

[]

H & P REVIEWED

[]

PATIENT IDENTIFIED

[]

PATIENT EVALUATED
IMMEDIATELY PRIOR TO
INDUCTION

[YES]

PATIENT POSITIONED
SELF (LEFT LATERAL
POSITION) PRIOR TO
PROCEDURE

CATH SIZE

22 GA.

24 GA.

IV SITE

RT A H

LT A H

IV FLUIDS

SAO2

EKG

O2 L/MIN

PROPOFOL

LIDOCAINE 10 mg/CC

TOTAL:

DEMEROL

FENTANYL

MIDAZOLAM

SYRINGES & NEEDLES DISCARDED UNCAPPED FOLLOWING SINGLE USE? YES NO

PROPOFOL VIALS USED _____

UNUSED PROPOFOL VIAL DISCARDED? YES NO

DATE: _____

OPERATION

_____ COLONOSCOPY

_____ EGD

_____ PEG

_____ BRAVO

SURGEON: _____

CRNA: _____

ANES TIME

AM AM

PM PM

ANESTHESIA RECORD

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Las Vegas, Nevada

Reviewer: _____

Date: _____

Date of
Service: _____

Instructions:

Mark each box as:

Adequate +

Inadequate -

Not Applicable NA

Write all comments on back of worksheet.

Chart Number

The content and format of record is uniform and consistent.

The record is legible to clinical personnel with or without assistance.

The history and physical are adequate based on the chief complaint and other entries in the chart.

A current list of medications and dosages is present.

The diagnoses are appropriate for the findings in the history and physical.

The diagnostic procedures are appropriate based on the diagnosis.

Treatment is consistent with the working diagnosis.

Consultation and referrals are appropriate and timely.

Consent for surgery has been obtained (if applicable).

Consent for planned anesthesia has been obtained (if applicable).

Appropriate follow-up is provided.

For complex and lengthy records, diagnostic summaries are present and used appropriately.

The presence or absence of allergies, drug sensitivities and materials are clearly and consistently recorded in a prominent and uniform location on a current basis.

Documentation of follow-up for missed and cancelled appointments is present.

Laboratory reports, radiology reports and other pertinent information are recorded adequately.

Significant medical advice given by telephone is recorded.

If applicable, operative reports are present, adequate for the procedure and appropriately authenticated.

Anesthesia records, if applicable, are present and include pre- and post-operative assessment.

Anesthesia records reflect adherence to sedation administration protocol and universal precautions.

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Las Vegas, Nevada
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Gastroenterology Center of Nevada, LLC

QUARTERLY CLINICAL COMPTENCY

CRNA Name: _____

Date: _____

Reviewing Physician: _____

Interview Review Questions:

Aseptic Technique

- | | | | |
|----|---|-----|----|
| 1) | Do you utilize each Propofol vial as single patient use? | Yes | No |
| 2) | Do you utilize any vial marked "single dose only" as single patient use? | Yes | No |
| 3) | Do you wipe the stopper of each medication vial you are going to use prior to piercing with needle? | Yes | No |
| 4) | Do you keep all syringes and needles in their original packaging prior to immediate use? | Yes | No |
| 5) | Do you use each needle and syringe once and then discard immediately following use? | Yes | No |
| 6) | Do you recap any needles? | Yes | No |
| 7) | Do you pre-fill any syringes with medications prior to use? | Yes | No |
| 8) | Do you wipe the saline-lock with alcohol prior to piercing with needle? | Yes | No |

Universal Precautions

- | | | | |
|----|--|-----|----|
| 1) | Do you wear a new clean facility-provided gown at all times? | Yes | No |
| 2) | Do you wash your hands after contact with each patient and anytime you come into contact with bodily fluids? | Yes | No |
| 3) | Do you keep any food or drink in the procedural rooms at any time? | Yes | No |
| 4) | Do you don new gloves while handling medications? | Yes | No |
| 5) | Do you don new gloves with each patient you are caring for? | Yes | No |
| 6) | Do you immediately discard the gloves following their immediate use? | Yes | No |

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 Las Vegas, Nevada

Anesthesia Record Review:

| | | | |
|----|---|-----|----|
| 1) | Past medical Hx included? | Yes | No |
| 2) | Complete list of medications, including dosages? | Yes | No |
| 3) | Allergies listed? | Yes | No |
| 4) | Initial set of vital signs present? | Yes | No |
| 5) | Pre-op Dx present? | Yes | No |
| 5) | Vital signs documented throughout procedure? | Yes | No |
| 6) | All medications administered documented with dosages? | Yes | No |
| 7) | Post-op Dx present? | Yes | No |
| 8) | Post-op assessment completed? | Yes | No |
| 9) | Beginning and ending patient caret time documented? | Yes | No |

CRNA Observation by Physician:

| | | | |
|-----|---|-----|----|
| 1) | Did CRNA utilize each Propofol vial as single patient use? | Yes | No |
| 2) | Did CRNA utilize any vial marked "single dose only" as single patient use? | Yes | No |
| 3) | Did CRNA wipe the stopper of each medication vial prior to piercing with needle? | Yes | No |
| 4) | Did CRNA keep all syringes and needles in their original packaging prior to immediate use? | Yes | No |
| 5) | Did CRNA use each needle and syringe once and then discard immediately following use? | Yes | No |
| 6) | Did CRNA recap any needles? | Yes | No |
| 7) | Did CRNA pre-fill any syringes with medications prior to use? | Yes | No |
| 8) | Did CRNA wipe the saline-lock with alcohol prior to piercing with needle? | Yes | No |
| 9) | Did CRNA wear a new clean facility-provided gown at all times? | Yes | No |
| 10) | Did CRNA wash hands after contact with each patient and anytime coming into contact with bodily fluids? | Yes | No |
| 11) | Did CRNA keep any food or drink in the procedural rooms at any time? | Yes | No |
| 12) | Did CRNA don new gloves while handling medications? | Yes | No |
| 13) | Did CRNA don new gloves with each patient they cared for? | Yes | No |
| 14) | Did CRNA immediately discard the gloves following their use? | Yes | No |

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Las Vegas, Nevada

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Deficiencies Noted: _____

Comments: _____

Reported to Governing Body: _____
Date

Physician Signature: _____

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Las Vegas, Nevada

Desert Shadow Endoscopy Center, LLC

4275 Burnham Ave., Ste. 101
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To ensure strict adherence to this policy, the CRNA will chart on the anesthesia record the following information:

- Uncapped needle discarded
- New Propofol vial utilized
- Unused Propofol discarded
- Rubber cap cleaned with alcohol if reentered

PROPOFOL ADMINISTRATION POLICY

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Bureau of Licensure and Certification
Las Vegas, Nevada

References

Note: All hyperlinks were valid as of December 15, 2009.

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- 15 Duty of persons to cooperate with health authority during investigations and carrying out of measures for prevention, suppression and control of communicable diseases. NAC 441A.280. Available at: <http://www.leg.state.nv.us/NAC/NAC-441A.html#NAC441ASec280>
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- 17 Consent for uses or disclosures to carry out treatment, payment, or health care operations. 45 CFR 164.506. Available at: http://edocket.access.gpo.gov/cfr_2002/octqtr/45cfr164.506.htm
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