bacterial meningitis. Equipment and products used during these procedures (e.g., contrast media) were excluded as probable sources of contamination. Procedural details available for seven cases determined that antiseptic skin preparations and sterile gloves had been used. However, none of the clinicians wore a face mask, giving rise to the speculation that droplet transmission of oralpharyngeal flora was the most likely explanation for these infections. Bacterial meningitis following myelogram and other spinal procedures (e.g., lumbar puncture, spinal and epidural anesthesia, intrathecal chemotherapy) has been reported previously. As a result, the question of whether face masks should be worn to prevent droplet spread of oral flora during spinal procedures (e.g., myelogram, lumbar puncture, spinal anesthesia) has been debated. Face masks are effective in limiting the dispersal of oropharyngeal droplets and are recommended for the placement of central venous catheters. In October 2005, the Healthcare Infection Control Practices Advisory Committee (HICPAC) reviewed the evidence and concluded that there is sufficient experience to warrant the additional protection of a face mask for the individual placing a catheter or injecting material into the spinal or epidural space.

Recommendations

IV.H. Safe injection practices

The following recommendations apply to the use of needles, cannulas that replace needles, and, where applicable intravenous delivery systems

IV.H.1. Use aseptic technique to avoid contamination of sterile injection equipment.
Category IA

IV.H.2. Do not administer medications from a syringe to multiple patients, even if the needle or cannula on the syringe is changed. Needles, cannulae and syringes are sterile, single-use items; they should not be reused for another patient nor to access a medication or solution that might be used for a subsequent patient.
Category IA

IV.H.3. Use fluid infusion and administration sets (i.e., intravenous bags, tubing and connectors) for one patient only and dispose appropriately after use. Consider a syringe or needle/cannula contaminated once it has been used to enter or connect to a patient's intravenous infusion bag or administration set.
Category IB

IV.H.4. Use single-dose vials for parenteral medications whenever possible.
Category IA

IV.H.5. Do not administer medications from single-dose vials or ampules to multiple patients or combine leftover contents for later use.
Category IA

IV.H.6. If multidose vials must be used, both the needle or cannula and syringe used to access the multidose vial must be sterile.
Category IA

IV.H.7. Do not keep multidose vials in the immediate patient treatment area and store in accordance with the manufacturer's recommendations; discard if sterility is compromised or questionable.
Category IA

IV.H.8. Do not use bags or bottles of intravenous solution as a common source of supply for multiple patients. *Category IB*

IV.I. Infection control practices for special lumbar puncture procedures Wear a surgical mask when placing a catheter or injecting material into the spinal canal or subdural space (i.e., during myelograms, lumbar puncture and spinal or epidural anesthesia. *Category IB*
IV.J. Worker safety Adhere to federal and state requirements for protection of healthcare personnel from exposure to bloodborne pathogens. *Category IC*

Date last modified: March 28, 2008
Content source:
Division of Healthcare Quality Promotion (DHQP)
National Center for Preparedness, Detection, and Control of Infectious Diseases

Centers for Disease Control and Prevention, 1600 Clifton Rd,
Atlanta, GA 30333, USA
800-CDC-INFO (800-232-4636) TTY: (888) 232-6348, 24 Hours/Every Day - **cdcinfo@cdc.gov** (TTY)

Safe Injection Practices Education and Awareness Campaign

The Safe Injection Practices Coalition is comprised of patient advocacy organizations, foundations, provider associations and societies and industry partners. The Coalition is in the process of developing a national pilot public health education and awareness campaign aimed at both healthcare providers and the public to advance and promote safe injection practices, especially in outpatient settings.

The Coalition was established in June 2008 to address the lack of understanding and adherence to the most basic safe injection practices in nonhospital settings. Issues of concern include the common reuse of syringes and misuse of multidose vials. Coalition partners include the following organizations:

- Accreditation Association for Ambulatory Health Care (AAAHC)
- American Association of Nurse Anesthetists (AANA)
- Ambulatory Surgery Foundation, Association for Professionals in Infection Control and Epidemiology, Inc. (APIC)
- Becton, Dickinson and Company (BD)
- Centers for Disease Control and Prevention (CDC)
- CDC Foundation
- HONOReform Foundation
- Nebraska Medical Association (NMA)
- Nevada State Medical Association (NSMA)

Unsafe injection practices by U.S. healthcare professionals have exposed more than 60,000 patients to life-threatening hepatitis B or C over the past decade, according to a groundbreaking review by the Centers for Disease Control and Prevention (CDC) published in this month's edition of the *Annals of Internal Medicine*. See press release below for further details.

Press Release
New Study Confirms Cases of Unsafe Injection Practices (PDF)

CDC Article
Nonhospital Health Care–Associated Hepatitis B and C Virus Transmission: United States, 1998-2008

One Needle, One Syringe, Only One Time

- **Book Details Nebraska Hepatitis C Outbreak Tragedy**
- **Enough Is Enough: Healthcare Leaders Unite to Launch Injection Safety Campaign**
- **Press Conference Message from AANA President Jackie Rowles**

Position Statement 2.13: Safe Practices for Needle and Syringe Use

- **Member News: Important New Position Statement on Safe Injection Practices**
- **Position Statement 2.13: Safe Practices for Needle and Syringe Use**
- **AANA Members: Master Bibliography**

Also see:

1. **Infection Control Problem: Syringe Reuse in Nevada**
2. **Coalition for Patients' Rights**

In the News

Campaign Addresses Unsafe Injection Practices
Nurse.com, March 9, 2009

For Immediate Release
February 11, 2009

Contact: Nick Manetto (202.312.7499)
nick.manetto@bakerd.com

Enough is Enough: Healthcare Leaders Unite to Launch Injection Safety Campaign

Spurred by Hepatitis Outbreaks Caused by Reused Syringes, Campaign will Educate Providers and Patients

Washington – Less than one year after health officials revealed what became the largest outbreak investigation of its kind in U.S. healthcare history, a broad-based group of national healthcare leaders has launched a campaign to prevent future tragedies.

Today, the Safe Injection Practices Coalition — comprised of patient advocacy organizations, foundations, the Centers for Disease Control and Prevention (CDC), including Dr. Richard Besser, Acting Director, Centers for Disease Control and Prevention Acting Administrator, Agency for Toxic Substance and Disease Registry, provider associations and societies and industry partners — joined Congresswoman Shelley Berkley (D-NV) and Senate Majority Leader Harry Reid (D-NV) to launch the **One & Only Campaign**, an education and awareness initiative aimed at both healthcare providers and patients.

The One & Only Campaign will attack the root cause of many recent outbreaks — the reuse of syringes — by educating healthcare providers and patients about the fundamental evidence-based injection safety practices that ensure patient safety.

The campaign's launch follows a recent article, published in the January 6, 2009 edition of the *Annals of Internal Medicine*, that revealed the occurrence of 33 outbreaks of viral hepatitis in nonhospital healthcare settings over the last decade. All of these outbreaks involved failure on the part of healthcare providers to adhere to fundamental infection control practices, most notably by reusing syringes.

"Sadly, the continued occurrence of life-threatening outbreaks of infectious diseases caused by healthcare providers' misuse of needles, syringes and medication vials shows no signs of abating. Even after last year's horrific tragedy in Las Vegas made national headlines, similar incidents continue to occur," said Evelyn V. McKnight, President/Co-founder of HONOReform and campaign co-chairman who was a victim of a similar tragedy involving an outpatient cancer center in Nebraska.

In February 2008, state and federal health officials announced that 40,000 patients – a number that has climbed to more than 50,000 – were possibly exposed to deadly bloodborne diseases at an endoscopy center in Las Vegas because healthcare providers reused syringes.

"Almost a year ago, thousands of Nevadans were exposed to Hepatitis C and HIV as a result of unsafe practices by clinics that were reusing single-use vials and syringes. It should be common sense that these materials be used only once but unfortunately that doesn't always happen, especially in nonhospital settings," said Nevada Senator Harry Reid. "I appreciate the Centers for Disease Control and Prevention and the Safe Injection Practices Coalition for launching the 'One & Only' campaign to educate everyone involved on this issue. The simple act of raising awareness about safe injection practices will help to protect Nevadans against preventable exposures to deadly diseases."

"Americans trust their doctors and other healthcare providers to keep them safe when they receive medical services like cancer screenings. But as we learned from tragic events in southern Nevada last year, patients must be taught how to ensure they are protected," said Congresswoman Berkley. "Exposure incidents like the one in Las Vegas happened as result of inexcusable lapses in basic patient safety and because of unsafe cost-cutting efforts. A foolproof system involving both patients and providers is needed to prevent these types of exposures from being repeated. The "One & Only" campaign will help to empower patients to ask the right questions of their doctors. And it teaches healthcare providers to remember the importance to patient safety of 'one needle, one syringe, and only

one time for every single injection'. I commend the leadership of those taking part in this new campaign and those who have developed this important response to dangerous medical practices uncovered in Las Vegas and other communities nationwide."

"The public deserves to be reassured they will be safe when seeking healthcare whether in a hospital, outpatient clinic or private physician's office. This campaign is much needed, especially in my home state of Nevada, and will help restore the public trust in our healthcare system," said Dr. Lawrence Sands, chief health officer of the Southern Nevada Health District (SNHD), a member of the campaign.

Recognizing the magnitude of the tragedy in Las Vegas, the One & Only Campaign will be piloted in Nevada. The campaign includes a set of training materials designed to remind doctors, nurses and other healthcare providers that syringes must be used one time only. It will also produce a set of patient-focused materials designed to empower patients, helping erect another layer of protection.

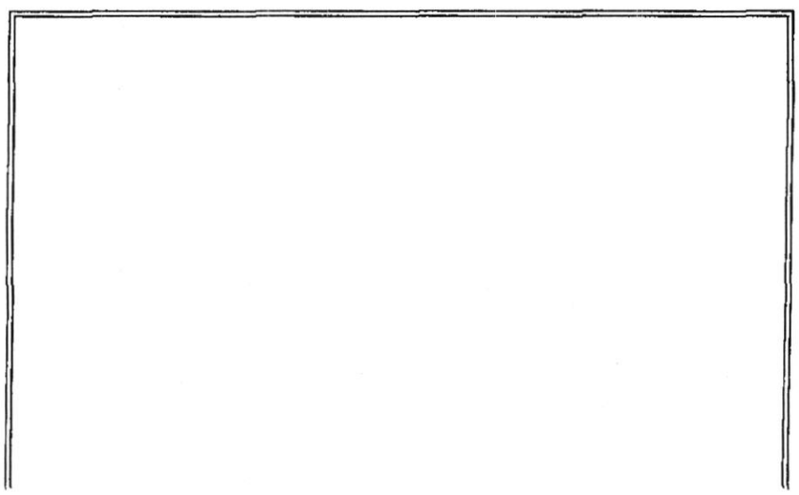
"This One & Only Campaign has been designed by providers and patients to have a lasting impact. While providers ultimately must be held responsible for following all safety standards, we want patients to feel empowered and able to speak up if they have a concern," said Charlie Stokes, CEO/President of the CDC Foundation and campaign co-chairman.

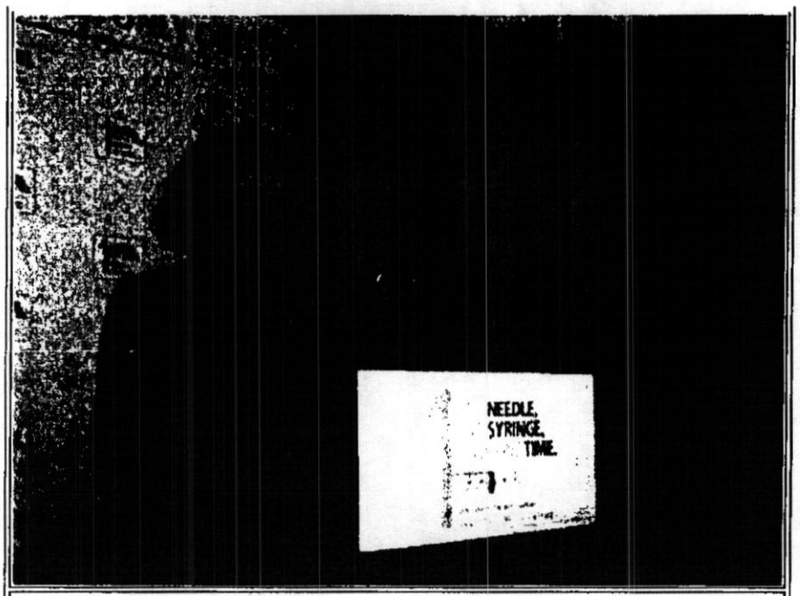
In addition to the CDC Foundation, HONOReform and SNHD, the campaign is funded by multiple partners including the Accreditation Association for Ambulatory Health Care (AAAHC), American Association of Nurse Anesthetists (AANA), Ambulatory Surgery Foundation, Association for Professionals in Infection Control and Epidemiology, Inc (APIC), BD (Becton, Dickinson and Company), Nebraska Medical Association (NMA) and Nevada State Medical Association (NSMA).

Once launched in Nevada, the Safe Injection Practices Coalition will conduct an evaluation to measure its effectiveness and make necessary adjustments prior to introducing it in other states – likely those impacted by similar recent outbreaks – and ultimately nationwide.

"Our healthcare system must institute a zero tolerance policy when it comes to unsafe injection practices so such outbreaks are seen as 'never events'. These tragedies are 100 percent preventable, and I am hopeful this campaign will save lives by ensuring all healthcare providers follow fundamental safe injection practices," McKnight said.

About the One & Only Campaign
The goal of the One & Only Campaign is to promote safe injection practices across healthcare settings to protect all patients. For more information, please visit: *www.oneandonlycampaign.org.*

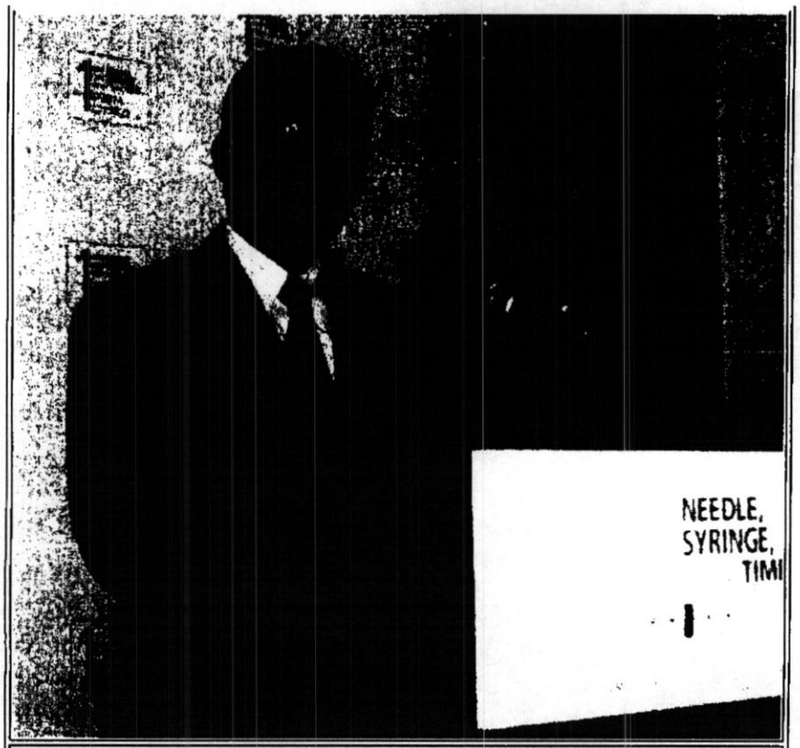




The Patient Perspective
Evelyn McKnight, AuD, president and founder, HONOReform Foundation, speaks at the One Needle, One Syringe, Only One Time press conference in Washington, D.C. February 11, 2009.

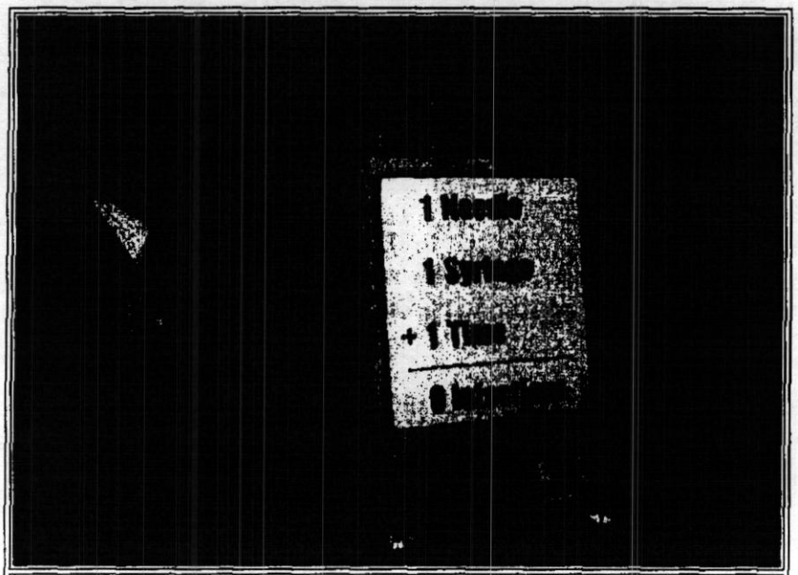
Campaign Announcement
Charlie Stokes, president and CEO, CDC Foundation, officially launches the campaign.

A National Challenge - Assuring Safe Injections
Richard E. Besser, MD, acting director, Centers for Disease Control and Prevention (CDC), acting administrator, Agency for Toxic Substance and Disease Registry, challenges healthcare providers around the country to assume responsibility for administering safe injections.



A National Challenge - Assuring Safe Injections
Joseph Perz, DrPH, MA, epidemiologist, Division of Healthcare Quality and Promotion, CDC, speaks at the One Needle, One Syringe, Only One Time press conference.

T. Brian Callister, MD, National Medical Director, LifeCare; Representative **Shelley Berkley** (D-NV), U.S. House of Representatives; AANA President **Jackie Rowles**, CRNA, MBA, MA, FAAPM; and **Lawrence Sands**, DO, MPH, chief health officer, Southern Nevada Health District; support the campaign.



Tom McKnight, MD; **Evelyn McKnight**, AuD; and **Jackie Rowles**, CRNA, MBA, MA, FAAPM, in support of the One & Only Campaign.

Safe Injection Practices Education and Awareness Campaign

Coalition for Patients Rights Homepage

February 11, 2009

Text from Jackie Rowles' Address at One & Only Press Conference

Good afternoon.

I'm Jackie Rowles, a Certified Registered Nurse Anesthetist from Indianapolis and president of the American Association of Nurse Anesthetists. I am here representing the nation's 40,000 nurse anesthetists who provide more than 30 million safe anesthetics to patients each year in the United States. As anesthesia specialists, the use of needles, syringes, medication vials, and IV tubing is part of our daily routine as we prepare our patients to undergo surgery, deliver a baby, or receive trauma stabilization care in the emergency room. During these procedures we commonly administer anesthetic drugs and other medications using accepted injection techniques. In my own practice, which is a somewhat unique specialty within nurse anesthesia, I administer multiple types of injections for the diagnosis and treatment of acute and chronic pain.

For the vast majority of nurse anesthetists across the country—***indeed***, for the vast majority of ***all*** healthcare providers who administer injections—quality assurance and patient safety is our mantra. There ***simply is no room for, excuse for, or reason for*** putting a patient at risk of infectious disease by reusing a needle or syringe. Not ***ever***. Managing case load isn't a good reason. Saving money on supplies isn't a good reason. Lack of knowledge of the accepted standards of practice isn't a good reason. Being told by a superior you must practice in an unacceptable manner isn't a good reason. Simply put, ***there is no good reason*** for these "Never Events" to happen.

The message of the Coalition and the One & Only Campaign reflects the CDC guidelines and the infection control standards of practice for nurse anesthetists and other healthcare specialists: ***One*** needle, ***one*** syringe, ***one*** use on ***one*** patient, and then safely dispose of the needle and syringe in an appropriate container.

The message is as simple, powerful, and unyielding as the number "1" itself.

Thank you.

Safe Injection Practices Education and Awareness Campaign

Coalition for Patients Rights

SCHEDULING STATUS: S 5

PROPRIETARY NAME (and dosage form):

Diprivan® 2% 50 ml (Infusion [Parenteral])

COMPOSITION:

50 ml vials containing 20 mg propofol/ml. The vehicle contains soya-bean oil, purified egg phosphatide and disodium edetate 0,005% w/v (microbial growth inhibitor).

PHARMACOLOGICAL CLASSIFICATION:

A 2.1 Anaesthetics

PHARMACOLOGICAL ACTION:

Pharmacodynamic properties:

DIPRIVAN 2% (2,6-diisopropylphenol) is a short-acting intravenous anaesthetic agent with a rapid onset of action of approximately 30 seconds. The mechanism of action is poorly understood.

Falls in mean arterial blood pressure and changes in heart rate are observed when DIPRIVAN 2% is administered.

Ventilatory depression can occur following administration of DIPRIVAN 2%.

DIPRIVAN 2% reduces cerebral blood flow, intracranial pressure and cerebral metabolism.

Recovery from anaesthesia is usually rapid and clear-headed.

DIPRIVAN 2% has an anti-emetic effect.

Studies have shown that DIPRIVAN 2%, at the concentrations likely to occur clinically, does not inhibit the synthesis of adrenocortical hormones.

31-05-2006
36/2.1/0084

Pharmacokinetic properties:

The decline in propofol concentrations following a bolus dose or following the termination of an infusion can be described by a 3 compartment open model. The first phase is characterised by a rapid distribution (half-life: 2-4 minutes) followed by rapid elimination (half-life: 30-60 minutes) and a slower final phase, representative of redistribution of propofol from poorly perfused tissue.

Propofol is extensively distributed and rapidly cleared from the body (total body clearance: 1,5-2 litres/minute). Clearance occurs by metabolic processes, mainly in the liver, to form inactive conjugates of propofol and its corresponding quinol, which are excreted in the urine.

The pharmacokinetics are linear over the recommended range of infusion rates of DIPRIVAN 2%.

Under the usual maintenance regimens, significant accumulation of propofol does not occur.

INDICATIONS:

a) Induction and maintenance of general anaesthesia as part of a balanced anaesthetic technique.
b) Sedation of ventilated adult patients receiving intensive care, for a period of up to 72 hours.

CONTRA-INDICATIONS:

Known hypersensitivity to DIPRIVAN 2%.

DIPRIVAN 2% is not recommended in children under the age of 3 years.

Sedation of children of all ages with croup or epiglottitis receiving intensive care (see "Warnings").

Appropriate care should be applied in patients with disorders of fat metabolism, patients predisposed to fat embolism and in other conditions where lipid emulsions must be used cautiously.

31-05-2006
36/2.1/0084

Propofol Vials:

Introduction:

Propofol was the anesthetic used in the majority of the procedures performed at both clinics. The vials of propofol are marked by the manufacturer as "Single Use Only" (Exhibit 4). Vendors were subpoenaed for sales to GCN, ECSN and DSEC and provided records pursuant to the subpoenas. Records were received from McKesson, Baxter, and Green Valley Drugs and scheduled on a spreadsheet (Exhibit 18).

Witnesses stated that supplies were shared between the two clinics. In order to show the relationship between patients and propofol, the number of patients who had procedures performed and the number of propofol vials delivered to each clinic were totaled by year and then compared for a ratio.

Prices for propofol ranged from $2.28 for a 20mL vial to $13.25 for a 50mL vial in 2006 and 2007.

Analysis:

Safe injection practices required that one syringe, one needle and one vial of propofol were used for one patient. Based on these requirements, I calculated a ratio using the number of patients who had procedures to the number of vials of propofol ordered by the clinics.

According to clinic and vendor records, orders were placed for 20mL and 50mL vials of propofol. The clinics started ordering 50mL vials in 2005 for the Shadow location and in 2006 for the Burnham location. In 2008, after the clinics were notified of the infection transmission, they stopped ordering the 50mL vials (Exhibit 21) and returned the remaining vials (Exhibit 18).

I conducted an analysis to either support or refute the allegations of propofol vial re-use. The allegation of re-use is supported if there were more patients than vials of propofol ordered; the allegation is refuted if there were more vials of propofol ordered than patients.

The number of patients were counted instead of procedures because some patients had more than one procedure at the same time and thus, may only have required one vial.

In 2006, there were 22374 patients seen at both clinics. There were 6600 vials of propofol ordered. The ratio of patients to vials is 3.39:1[7], thus there was no existing inventory available for use in 2007.

In 2007, there were 23576 patients seen at both clinics. There were 11844 vials of propofol ordered. The ratio of patients to vials is 1.99:1[8], thus the allegation of propofol vial re-use is supported.

---

[7] 22374/6600 = 3.39, 6600/6600 = 1

[8] 23576/11844 = 1.99, 11844/11844 = 1

A chart which graphically represents the ratio is at Exhibit 20.

The clinics also changed their orders for propofol for the first five weeks compared to the entire year for 2007. From January 14 - February 28, 2008 (5 weeks), the clinics ordered 3125 vials of propofol compared to 11844 for the entire year in 2007. To break it down by week: in 2007, the clinics ordered 228 vials per week[9]; in 2008, the clinics ordered 625 vials per week[10]. The orders placed after January 9, 2008 when the clinics were informed of the Hepatitis C outbreak show that an inadequate number of propofol vials had been purchased for previous years.

---

[9] 11844/52 = 227.76

[10] 3125/5 = 625

Syringes:

Introduction:

Witnesses stated that medical supplies were transferred between clinics. CRNA Vincent Sagendorf stated that he used a needleless system to inject propofol into the heplocks, but he used syringes. Since not every syringe required a needle, needle orders were not considered for this analysis. Witnesses and syringe orders show that #10 cc syringes were the ones used for procedures.

Patient procedure files contained an Anesthesia Record on which the CRNA documented the propofol injections for each patient, broken down by the amount of propofol and the number of injections. In order to show if syringes were re-used, an average number of injections for each patient was determined from the Anesthesia Records for the two specific dates of the infections, July 25 (CRNAs Keith Mathahs and Ronald Lakeman) and September 21 (CRNAs Linda Hubbard and Ronald Lakeman) (Exhibits 12 and 13).

The price of 10cc syringes from McKesson ranged from $7.30 to $7.98 in 2006-2007.

Analysis:

On July 25, 2007, the Register and procedure files show there were 65 patients who underwent 67 procedures. One patient file was missing, so that information could not be included. Thus, 64 patients received propofol injections which were documented in the procedure files.

I counted the number of injections for July 25 and there were 123 injections given as documented on the Anesthesia Record by the CRNA who administered the propofol. I utilized division to determine the average number of injections[11], thus, on the average, each patient received 1.9 injections for that day.

On September 21, 2007, the Register and procedure files show there were 63 patients who received 64 procedures. I counted the number of injections for September 21 and there were 185 injections given as documented on the Anesthesia Record by the CRNA who administered the propofol. I utilized division to determine the average number of injections for that day[12], thus, on the average, each patient received 2.93 injections.

I averaged the two numbers[13] to determine how many injections each patient received during their procedure. I utilized the safe injection practice standard to show that the CRNAs should have used 2.4 syringes for each patient at the Shadow and Burnham clinics. In order to support or refute the allegation of syringe re-use, I multiplied each patient by 2.4 to determine how many syringes should have been ordered in 2006 and 2007 to adhere to safe injection practices.

In 2006, there were 22,374 patients at both clinics. They ordered 31,100 syringes (Exhibit 21). To adhere to the ratio I developed, they should have ordered 53,698

---

[11] 123/64 = 1.92

[12] 185/63 = 2.93

[13] 1.92 + 2.93 = 4.85/2 = 2.425

syringes[14]. Thus the allegation of syringe re-use in 2006 is supported and there was no existing inventory for 2007.

In 2007, there were 23,576 patients at both clinics. They ordered 36,000 syringes (Exhibit 22). To adhere to the ratio I developed, they should have ordered 56,582 syringes[15]. The allegation of syringe re-use is supported.

The orders placed after January 9, 2008 when the clinics were informed of the Hepatitis C outbreak show that an inadequate number of syringes had been purchased for previous years. The number of syringes ordered per week in 2007 was approximately 692. The number of syringes ordered for 5 weeks in 2008 was approximately 1040.

A chart showing the comparison of patients to syringes for both locations is at Exhibit 24 and the supporting schedule is at Exhibit 23.

Developed Ratio for Syringes Applied to Both Clinics (Shadow and Burnham):

Records reviewed for two days in 2007 showed that the ratio of patient to injections was 1:2.4. The ratio was applied to the number of patients for the year and showed that there were not enough syringes ordered to support the ratio, thus confirming the allegation of syringe re-use.

Witnesses stated that supplies were shared between clinics, so the developed ratio was applied to each clinic (see chart below) to determine if one of the clinics was closer to the ratio than the other clinic. The Burnham clinic did not order an appropriate number of syringes, and were approximately 1,700 syringes short[16], while the Shadow clinic ordered significantly fewer syringes. The Shadow clinic may have taken some syringes from Burnham, however, they would have had to take 18,797 syringes, which was almost the entire Burnham inventory, in order to have 2.4 syringes on hand for each patient.[17]

Developed Ratio	Burnham	Actual Ratio	Shadow	Actual Ratio
	Patients / Syringes		Patients / Syringes	
1:2.4	8619 / 18900	1:2.19	14957 / 17100	1:1.14

[14] 22,374 x 2.4 = 53,697.6

[15] 23,576 x 2.4 = 56,582.4

[16] 8,619 x 2.4 = 20,686 / 20,686 - 18,900 = 1,786

[17] 14,957 x 2.4 = 35,897 / 35,897 - 17,100 = 18,797

Exhibits:

1. Robison, Jennifer, "Five of six centers now closed by local entities," *Las Vegas Review Journal*, March 5, 2008.
2. Copies of medical supplies' packaging which were taken from 700 Shadow Lane.
3. Safe Injection Practice information research.
4. Propofol (Diprivan) Internet research. Package insert from Astrazeneca, dated May 31, 2006; date of publication February 2007 (p.11); dosage instructions (p.5).
5. Schedule of vendors prepared from vendor files, bank records, bookkeeping records, and records subpoenaed from Charles Kelly.
6. Schedules of procedures from Endoscopy Register Books for 2006.
7. Schedules of procedures from Endoscopy Register Books for 2007.
8. Schedules of Patients for 2006.
9. Schedules of Patients for 2007.
10. Schedules of Bite Blocks ordered by year and vendor.
11. Chart showing Upper Endoscopies Performed Compared to Bite Blocks Ordered at Both Clinic Locations for 2007.
12. Patient schedule for July 25, 2007, based on Endoscopy Register Book and patient procedure files.
13. Patient schedule for September 21, 2007, based on Endoscopy Register Book and patient procedure files.
14. Copy of Propofol Daily Sign Out Log for July 25, 2007.
15. Copy of Propofol Daily Sign Out Log for September 21, 2007.
16. Chart showing Comparison of Patients to Propofol Vials checked out for July 25 and September 21, 2007.
17. Copy of Propofol Daily Sign Out Log for February 21, 2008.
18. Schedule of Propofol vials ordered, broken down by year.
19. Schedule of Propofol vials ordered, broken down by year and location.
20. Chart comparing patients to propofol vials at each location for 2007.
21. Copy of Propofol Daily Sign Out Log for January 14, 2008.
22. Schedule of Syringes ordered, broken down by year.
23. Schedule of Syringes ordered, broken down by year for 2006 and 2007 and by location.
24. Chart comparing patients for syringes for both locations for 2007.

Mar. 05, 2008

Five of six centers now closed by local entities

By JENNIFER ROBISON
REVIEW-JOURNAL

The Endoscopy Center of Southern Nevada on Shadow Lane is just one branch of the Gastroenterology Center of Nevada, a 14-doctor practice with six locations, three physicians' assistants and about 60 employees valleywide. Some of the company's locations have clinics for endoscopies and colonoscopies, while others house only doctors' offices:

Endoscopy Center of Southern Nevada

700 Shadow Lane

Las Vegas

Practice includes: Doctors' offices for consultations with patients, plus a two-bed clinic for endoscopies and colonoscopies

City of Las Vegas officials suspended the center's business license Friday.

Desert Shadow Endoscopy Center

4275 Burnham Ave.

Las Vegas

Practice includes: Doctors' offices for consultations with patients, as well as a clinic for endoscopies and colonoscopies

Clark County officials suspended the center's business license Monday.

Spanish Hills Surgical Center

5915 S. Rainbow Blvd.

Las Vegas

Practice incudes: Doctors' offices, endoscopic clinic

Clark County officials suspended the center's business license Monday.

Gastroenterology Center of Nevada

2610 W. Horizon Ridge Parkway

Henderson

Practice includes: Doctors' offices

City of Henderson officials attempted to visit the business Tuesday to determine whether the location houses an endoscopy clinic, but they were denied entrance.

City of Henderson officials suspended the center's business license Tuesday.

Gastroenterology Center of Nevada

1815 E. Lake Mead Blvd.

North Las Vegas

Practice includes: Doctors' offices.

City of North Las Vegas officials were trying to determine late Tuesday whether doctors at the location perform endoscopies and colonoscopies.

City of North Las Vegas issued a cease-and-desist order late Tuesday, calling the center a "public nuisance" and telling the owners their practices violated municipal codes.

Gastroenterology Center of Nevada

3150 Tenaya Way

Las Vegas

Practice includes: Doctors' offices

Location was still open as of late afternoon Tuesday.

Contact reporter Jennifer Robison at jrobison@reviewjournal.com or (702) 380-4512.

Find this article at:
http://www.lvrj.com/news/16249961.html

Check the box to include the list of links referenced in the article.

DA - ENDOSCOPY 005220

RA000433

DA - ENDOSCOPY 005221

RA000434

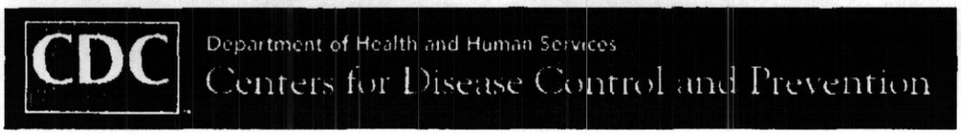
MINI-TR
STERILE
vice package has been
opened or damaged.

LMA
The Laryngeal Mask Company Limited
Single Use
Syringe/Lubricant
LOT FF507091
04/2008
Distributed by:
DA - ENDOSCOPY 005228

COPY 005224

RA000437

10ml Syringe
BD 10 ml Syringe
Luer-Lok™ Tip
Latex Free. Not for Oral Use
Do not Reshield Used Needles
Sterile. Do not Reuse
REF 309604
BD, Franklin Lakes
NJ 07417
Made in Mexico
Reg. 480CSI SSA
www.bd.com
DA-M12335 327258
BD, BD Logo and
Luer-Lok are
trademarks
of Becton Dickinson
and Company
© 2004 BD
(01)00382903096046
LOT 7289580
R 2011-05
EXP 616726
6 mL
medex



Injection Safety

Safe Injection Practices to Prevent Transmission of Infections to Patients

Excerpted from **Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007**.

III.A.1.b. Safe Injection Practices

The investigation of four large outbreaks of HBV and HCV among patients in ambulatory care facilities in the United States identified a need to define and reinforce safe injection practices. The four outbreaks occurred in a private medical practice, a pain clinic, an endoscopy clinic, and a hematology/oncology clinic. The primary breaches in infection control practice that contributed to these outbreaks were 1) reinsertion of used needles into a multiple-dose vial or solution container (e.g., saline bag) and 2) use of a single needle/syringe to administer intravenous medication to multiple patients. In one of these outbreaks, preparation of medications in the same workspace where used needle/syringes were dismantled also may have been a contributing factor. These and other outbreaks of viral hepatitis could have been prevented by adherence to basic principles of aseptic technique for the preparation and administration of parenteral medications. These include the use of a sterile, single-use, disposable needle and syringe for each injection given and prevention of contamination of injection equipment and medication.

Whenever possible, use of single-dose vials is preferred over multiple-dose vials, especially when medications will be administered to multiple patients. Outbreaks related to unsafe injection practices indicate that some healthcare personnel are unaware of, do not understand, or do not adhere to basic principles of infection control and aseptic technique. A survey of US healthcare workers who provide medication through injection found that 1% to 3% reused the same needle and/or syringe on multiple patients. Among the deficiencies identified in recent outbreaks were a lack of oversight of personnel and failure to follow-up on reported breaches in infection control practices in ambulatory settings. Therefore, to ensure that all healthcare workers understand and adhere to recommended practices, principles of infection control and aseptic technique need to be reinforced in training programs and incorporated into institutional polices that are monitored for adherence.

III.A.1.c. Infection Control Practices for Special Lumbar Puncture Procedures

In 2004, CDC investigated eight cases of post-myelography meningitis that either were reported to CDC or identified through a survey of the Emerging Infections Network of the Infectious Disease Society of America. Blood and/or cerebrospinal fluid of all eight cases yielded streptococcal species consistent with oropharyngeal flora and there were changes in the CSF indices and clinical status indicative of

IN THE SUPREME COURT OF THE STATE OF NEVADA

DIPAK KANTILAL DESAI

Petitioner,

vs

THE EIGHTH JUDICIAL DISTRICT COURT OF THE STATE OF NEVADA, COUNTY OF CLARK, THE HONORABLE KATHLEEN DELANEY, DISTRICT JUDGE,

Respondent,

and

THE STATE OF NEVADA,
Real Party in Interest.

Case No. 60038

District Court Case Number:
10C265107

RESPONDENT'S APPENDIX
Volume III

RICHARD A. WRIGHT, ESQ.
Wright Stanish & Winckler
Nevada Bar #000886
300 S. Fourth Street, Suite 701
Las Vegas, Nevada 89101
(702) 382-4004

Counsel for Petitioner

MARY-ANNE MILLER
Interim Clark County District Attorney
Nevada Bar #001419
Regional Justice Center
200 Lewis Avenue
Post Office Box 552212
Las Vegas, Nevada 89155-2212
(702) 671-2500

CATHERINE CORTEZ MASTO
Nevada Attorney General
Nevada Bar #003926
100 North Carson Street
Carson City, Nevada 89701-4717
(775) 684-1265

Counsel for Respondent

INDEX

CERTIFICATE OF SERVICE

I hereby certify and affirm that this document was filed electronically with the Nevada Supreme Court on January 23, 2012. Electronic Service of the foregoing document shall be made in accordance with the Master Service List as follows:

CATHERINE CORTEZ MASTO
Nevada Attorney General

RICHARD A. WRIGHT, ESQ.
Counsel for Appellant

MICHAEL V. STAUDAHER
Chief Deputy District Attorney

BY */s/ jennifer garcia*
Employee, District Attorney's Office

MEDICAL SUPPLIES ANALYSIS

BITE BLOCKS
PROPOFOL VIALS USED ON SPECIFIC DAYS
PROPOFOL ORDERS
AND SYRINGES

2006-2008

Prepared by Nancy P. Sampson #4627
Analyst
Las Vegas Metropolitan Police Department

September 2, 2009

DA - ENDOSCOPY 005202

L V M P D
interoffice
MEMORANDUM

To : Robert Whiteley #4996, Detective
From : Nancy P. Sampson #4627, Financial Analyst
Subject : Medical Supply Analysis
Date : September 2, 2009

Executive Summary:
Witnesses in the Hepatitis C infection investigation alleged that medical supplies were re-used at the Burnham and Shadow clinics. Specifically, those supplies were bite blocks, propofol and syringes. I analyzed records from this investigation,and determined the following (ratios were rounded up from .5 or above and rounded down from .4 or below):

- Records from 2006 were reviewed to determine if there was an existing inventory that could have been used in 2007. Based on the ratios developed, there was no existing inventory of bite blocks, propofol or syringes.

- Records from 2007 were reviewed to determine if supplies were re-used. Ratios for the following items are as follows:
  - Bite Blocks
    In 2007, there were 7521 EGD procedures conducted and 3250 bite blocks ordered. The ratio of procedures to bite blocks was 2:1, thus the allegation of bite block re-use is supported.

  - Propofol Logs
    The ratio of patients to vials for July 25, 2007 was 3:1 and the ratio of patients to vials for September 21, 2007 was 3:1. The ratios prove that there were not enough propofol vials checked out to have one vial per patient, so the allegation of re-use is supported.

  - Propofol Vials
    In 2007, there were 23576 patients seen at both clinics. There were 11844 vials of propofol ordered. The ratio of patients to vials is 2:1, thus the allegation of propofol vial re-use is supported.

  - Syringes
    On two days in 2007 when the infection was spread, the ratio of patient to injections was 1:2.4. This average was applied to all patients and syringes ordered. In 2007 the clinics should have ordered 56,582 syringes to provide a new syringe for each patient's 2.4 injections. They ordered 36,000 syringes, thus the allegation of syringe re-use is supported.

- Records from January 9 - February 29, 2008 (after the SNHD informed the clinics of the Hepatitis C outbreak) were reviewed to compare numbers to the previous year. Orders were placed over 5, 6, or 7 weeks. The information developed from these records is as follows:
  - Bite Blocks
    In 2008, 1400 bite blocks were purchased for the period reviewed (6 weeks) and in 2007, 3250 bite blocks were purchased for the entire year.

    The orders placed after January 9, 2008 when the clinics were informed of the Hepatitis C outbreak show that an inadequate number of bite blocks had been purchased in previous years. Almost half as many bite blocks were ordered for six weeks as were ordered in the entire previous year.

  - Propofol Logs
    The Log and Register for February 21, 2008 show that 38 vials were checked out for 34 patients. The ratio of patients to propofol vials was 1:1.1.

    The 2008 ratio proves that the clinic started using at least one vial of propofol for each patient after they were informed of the infection. The change in the propofol check out process shows that the clinics stopped re-using vials of propofol.

  - Propofol Vials
    For the period reviewed in 2008, the clinics ordered 3125 vials of propofol. They ordered 11844 propofol vials for the entire year in 2007.

    The orders placed after January 9, 2008 when the clinics were informed of the Hepatitis C outbreak show that an inadequate number of propofol vials had been purchased for previous years. The number of vials ordered per week in 2007 was approximately 228. The number of vials ordered for 6 weeks in 2008 was approximately 521 per week.

  - Syringes
    For the period reviewed in 2008, the clinics ordered 5,200 10cc syringes. They ordered 36,000 for the entire year in 2007.

    The orders placed after January 9, 2008 when the clinics were informed of the Hepatitis C outbreak show that an inadequate number of syringes had been purchased for previous years. The number of syringes ordered per week in 2007 was approximately 692. The number of syringes ordered per week for 5 weeks in 2008 was approximately 1040.

Introduction:
As part of the ongoing investigation of the Hepatitis C Outbreak case, I conducted an analysis of the medical supplies ordered by the Gastroenterology Center of Nevada (GCN), Desert Shadow Endoscopy Center (DSEC) and the Endoscopy Center of Southern Nevada (ECSN) in order to support or refute the allegations that medical supplies marked "Single Use Only" had been re-used on multiple patients.

On January 2, 2008, the Southern Nevada Health District (SNHD) became aware of a Hepatitis C outbreak in the Clark County area. Their investigation showed that the patients had all undergone procedures at the same clinic so the investigators informed the Gastroenterology Center of Nevada (GCN) about the outbreak on January 9, 2008.

Search warrants were served on the clinics and doctors offices at six locations in the Las Vegas metropolitan area. The clinics were located at 700 Shadow Lane, 4275 Burnham and 5915 S. Rainbow #8, all in Las Vegas NV. Records were taken in the search warrants which included Endoscopy Registers (Registers), Propofol Daily Sign Out Logs (Logs), vendor files, bookkeeping records, bank statements, and patient files.

In addition to the documents recovered from the businesses, grand jury subpoenas were served on the vendors and Mr. Charles Kelly, attorney representing the GCN. The records were reviewed and analyzed to prepare the ratios which would either support the allegations of re-use or refute them.

Witnesses stated that medical supplies were transferred between the clinic locations as needed. Records taken in the search warrants were used to determine how many procedures were conducted at the Shadow Lane and Burnham clinics, how many propofol vials were signed out each day for use in the procedures, how many patients underwent procedures, and how many propofol vials were ordered for the clinics. In addition to the procedures, patients and propofol vials, bite block records as well as syringe orders were analyzed.

Witnesses stated that needles were not re-used, however, some of the CRNAs utilized a needle-less system to inject propofol into the hep-locks (Interview with Vincent Sagendorf, 7/10/08, p. 8). Not every syringe utilized a needle but 10cc syringes were used in each procedure to administer propofol. I determined a ratio of patients to propofol injections from the two specific dates in 2007 when the infections occurred. This ratio is discussed in the specific "Syringe" section, below. The ratio was applied to syringe orders to determine if syringes had been re-used.

Records for 2006 were analyzed to determine if an existing inventory of medical supplies was available for use at the clinics in 2007.

In order to refute the re-use allegations, the 2007 records were analyzed to determine:

1. If there were more bite blocks ordered than upper endoscopy (EGD) procedures, the allegation of bite block re-use was not true.
2. If the number of propofol vials checked out for the two days the infection was transmitted was at least the same number as patients for the days, the allegation of propofol vial re-use was not true.
3. If the number of propofol vials ordered for all three clinics was more than the number of patients undergoing procedures, then the allegation of overall propofol

vial re-use was not true.

4. If the number of syringes ordered was the same or greater than the average number of propofol injections per patient (averaged for the two specific days in 2007 when the infections occurred), then the allegation of syringe re-use was not true.

The 2008 records were analyzed to compare the orders for 2007 to the orders placed from January 9 through February 28, 2008 to determine if the business practice changed after the GCN was informed of the infection. The clinics operated for seven weeks in 2008, after they were informed of the transmission. The Southern Nevada Health District informed GCN on January 9, 2008 of the Hepatitis C infections transmitted from their facility. On February 29, 2008, the City of Las Vegas suspended the business license at the Shadow location and on March 3, 2008, Clark County suspended the business licenses for the Burnham and Rainbow clinics. The doctor's offices were also closed down the same week (Exhibit 1).

The bite blocks, vials of propofol, syringes and needles are all "Single Use Only" items and are clearly marked on the packaging. Samples of the items used at the clinic were taken in the search warrants and all are marked "Single Use Only." Copies of the packaging of some of the items are included with this report (Exhibit 2).

In addition, safe injection practices which are a standard in the medical field, call for a single syringe, a single needle, and a single vial of medicine to be used for a single patient (Exhibit 3). This medical standard was used in the analysis of each medical supply item.

Propofol, the anesthetic used in the procedures at the clinics is noted in the literature provided on the Internet in 2007 by Astra Zeneca (the manufacturer) as a single use in a single patient only (Exhibit 4, p.5).

Supporting spreadsheets and charts are attached to this report and noted as Exhibits.

Records Used:
I utilized the following records in the analysis of each section:

1. Endoscopy Registers (Registers)
   The Registers are large blue and maroon books which were used in the clinics to record the patients and their procedures for each day. Registers were taken from the Shadow Lane clinic location in the search warrant. Some Registers were taken from the Burnham clinic in the search warrant and the remaining Registers were subpoenaed from Mr. Charles Kelly. Kelly supplied the original Registers to Detective Robert Whiteley pursuant to the subpoena. Separate Registers were kept for the VA patients. In 2006, VA patient information was kept for the dates 11/13/06-12/29/06.

   Copies of the Registers are <u>not</u> attached as Exhibits because they are too large to reproduce on the copier.

   I performed several tests to determine if the Registers were accurate.
   1. In an interview with Lisa Falzone, a nurse at the clinic, she stated

that Dr. Desai would refer to the Registers each day and check the number of patients listed, an indication that the Registers accurately reflected the clinics' daily schedule. (Interview with Lisa Falzone, 9/4/08, p.23)

2. The GCN gave the Registers to the Southern Nevada Health Division (SNHD) investigators to help them determine how the Hepatitis C infection was transmitted. (Interview with Brian Labus, 5/19/08, p.48)
3. There were two days in 2007 (July 25 and September 21) where patients were infected with Hepatitis C. A comparison of the procedure files to the Registers show the Registers accurately reflected the information in the patient and procedure files located for those days.
4. In addition to the names and procedure file numbers, other information was handwritten on the same line as the patient name, including the diagnosis, follow up appointments and referring doctors. The additional information was corroborated by reviewing some of the patient files from September 21.
5. Notes included in the Registers indicated when patients were transported to the Emergency Room, further indication that the Registers were correct (Book 1/27/05-5/5/06, Burnham - 2/9/06).

2. Propofol Daily Sign Out Logs (Logs)

The Logs were typed forms maintained at the clinics to record the propofol vials checked out each day, including the date and time, personnel signing out medication, personnel accepting medication, vials given and accepted, vials returned and total vials remaining. The pertinent information is handwritten in each box and signed off. The propofol was ordered in 50mL vials and 20mL vials. Each vial had 10mg per mL, thus the 50mL vial had 500mg and the 20mL vial had 200mg. The vial amounts are noted at the top of the Logs.

The Logs analyzed for this report show how many vials of propofol were signed out for each day of the infections (July 25, 2007 and September 21, 2007). In addition to the 2007 records, I reviewed the Logs for 2008 to compare the vial sign outs to 2007. The Logs were reviewed for the dates after the clinics were informed of the infection to determine if the number of vials signed out changed.

The Logs were given to the SNHD investigators while they were reviewing the clinic's records to determine how the Hepatitis C outbreak occurred.

3. Vendor Files

Vendor files were taken in the search warrants. The files were maintained by year. The vendor files include items ordered, amounts due, shipping information, and vendor contact information.

The vendor files were utilized to identify the vendors who sold the bite blocks, propofol, and syringes. Grand jury subpoenas were served on the vendors who responded with the items ordered by the clinics, including dates, amounts and prices.

In addition to the files taken in the search warrants, a grand jury subpoena was served on Mr. Charles Kelly for vendor information. He provided computer printouts of vendors from the computer servers. This printout was compared to the list developed from the search warrant evidence to determine if there were any vendors not included in the vendor files and bookkeeping records. The records from the search warrant were determined to be more accurate than the records received from Mr. Kelly (Exhibit 5).

4. Bookkeeping records and Bank Statements
Bank statements and bookkeeping records were kept with the vendor files and maintained by year at the Shadow location. The bank and bookkeeping records were used to corroborate the vendor files utilized by the GCN and clinics.

5. Patient Files
Patient and procedure files were taken in the search warrant. They were used to determine the times patients were seen for July 25 and September 21, 2007. They were also used to corroborate the Registers.

The green-colored procedure files contained information entered by clinic personnel while the procedures were ongoing. In addition to the data on the various forms, a report was generated from the computer and monitors used in the procedure. The information from the computer report was utilized to re-construct the two specific days for patient procedure times. This information for each day was entered into an Excel spreadsheet which I set up for sorting purposes. The patients were assigned a number on the spreadsheet which shows how many procedures were done each day. Copies of the schedules are attached at Exhibits 12 and 13.

Methodology:
Because witnesses stated that supplies were transferred between the Shadow and Burnham clinics, information from both clinics was included in the analysis. In addition, vendor records show that bite blocks were delivered to the Rainbow clinic, so those numbers for bite blocks were included in the analysis because they would have been available to all the clinics. The Rainbow clinic was opened in late 2007 or early 2008 and any procedures conducted there were not counted in the total.

To determine ratios, I reviewed the Registers and entered the number of procedures in an Excel spreadsheet I prepared for this analysis (Exhibits 6 and 7). In addition, I counted the number of patients and entered those numbers on other spreadsheets for 2006 and 2007 (Exhibits 8 and 9). Some patients had several procedures at the same time, so I determined that one vial or more of propofol should have been used for one patient, not for each procedure conducted. Colonoscopies and upper endoscopies (EGD) were the most common procedures, however, there were a few "other" procedures. Because some of the "other" procedures were conducted at the same time, none of the "other" procedures were included in the counts.

Vendor records were subpoenaed and the information was entered onto Excel spreadsheets I prepared for the data. The supply records were combined for the three clinics, sorted by year and then added to determine how many items were ordered for each year (Exhibits 10, 18 and 21).

Addition was used to determine how many patients had procedures, how many procedures were conducted, and how many medical supplies were ordered.

I determined ratios[1] from the information on the spreadsheets and utilized division to calculate the ratios.

I used addition and division to determine an average number of injections per patient, and multiplication to determine how many syringes should have been ordered.

I used multiplication and subtraction in the application of the developed ratio to the syringes ordered for each clinic to determine if the clinics ordered enough syringes to have the developed ratio of patients:syringes.

The "safe injection practice" of one syringe, one needle and one vial of medicine per patient was applied to this analysis.

		2006		2007	
Location	Exhibit #	Patients	EGD Procedures	Patients	EGD Procedures
Shadow	6-9	15095	5092	14957	5040
Burnham	6-9	7279	2025	8619	2481
TOTALS		22374	7117	23576	7521

Single Use Item	Exhibit #	2006	2007	2008 (after 1/9/08)
Bite Blocks	10-11	201	3250	1400
Propofol Vials	12-19	6600	11844	3125
Syringes, 10cc	20-22	31100	36000	5200

The analytical techniques for the Propofol Logs ratio used on July 25 and September 21, 2007 are discussed in that specific section (see below). I utilized addition, subtraction and division to perform the analysis.

The ratio for the average number of injections was determined by analyzing the information from July 25 and September 21. I utilized addition, multiplication and division to perform the analysis.

---

[1]Http://www.aaastudy.com/rat62bx2.htm "How to Determine a Ratio. Ratios represent how one quantity is related to another quantity. A ratio may be written as A:B or A/B or by the phrase "A to B." A ratio of 1:5 says that the second quantity is five times as large as the first. The following steps will allow a ratio to be determination if two numbers are known. Example: Determine the ratio of 24 to 40. Divide both terms of the ratio by the greatest common factor (24/8 = 3, 40/8 = 5). State the ratio (The ratio of 24 to 40 is 3:5)"

Bite Blocks:

Introduction:

Allegations in this case were that various "Single Use Only" items used in procedures were re-used on patients, including bite blocks. Bite blocks are plastic items that are inserted in the patients' mouths when they are having an upper endoscopic (EGD) procedure. After the bite block is in place, the gastroenterologist inserts a scope in the patient's mouth and then the scope goes down the throat. The bite block is used in the patient's mouth so the patient would not inadvertently bite down on the scope and damage it while under anesthesia.

Records for bite blocks were received from McKesson and US Endoscopy which show the number of items ordered, where they were shipped to and the cost per item. Bite blocks ranged in price from $1.45 to $5.00 each.

Analysis:

I conducted this analysis to either support or refute the allegations of bite block re-use. The analysis supports the allegation by showing there were more EGD procedures than bite blocks ordered or refutes it by showing there were at least as many or more bite blocks ordered than EGDs performed.

I utilized the Registers and vendor records to count how many procedures were conducted and how many bite blocks were ordered in 2006 and 2007. For 2008, I counted how many bite blocks were ordered and compared those figures to the number for 2007 (See Methodology, above).

In 2006, there were 7117 EGD procedures conducted and 201 bite blocks ordered. The ratio of procedures to bite blocks was 35.4:1[2], thus there was no existing inventory available for use in 2007.

In 2007, there were 7521 EGD procedures conducted and 3250 bite blocks ordered. The ratio of procedures to bite blocks was 2.3:1[3], thus the allegation of bite block re-use is supported.

In 2008, there were 1400 bite blocks purchased from January 16 - February 29 (6 weeks). In 2007, there were 3250 bite blocks purchased for the entire year. To break it down by week, in 2007, they ordered 62.5 bite blocks and had approximately 145 procedures per week at both clinics; in 2008, they ordered 234 bite blocks per week (procedures for 2008 were not counted). The orders placed after January 9, 2008 when the clinics were informed of the Hepatitis C outbreak show that an inadequate number of bite blocks had been purchased in previous years.

Schedules supporting the analysis are at Exhibit 10 and the chart depicting the re-use of bite blocks is at Exhibit 11. The formulas I used are footnoted below and are on the chart.

---

[2]7117/201 = 35.40, 201/201 = 1

[3]7521/3250 = 2.3, 3250/3250 = 1

Propofol Logs:

Introduction:

During the search warrant at the Shadow Lane location, the 2007 and 2008 Propofol Daily Sign-out Log Books (Log) were taken. Allegations in this investigation were that patients were infected with Hepatitis C by the re-use of syringes and propofol vials. In order to determine if an adequate number of propofol vials had been signed out of the medicine supply cabinet on the two days that patients were infected (July 25 and September 21, 2007), schedules based on the Registers for those two days and the corresponding patient procedure files were prepared and sorted by computer report time and room (Exhibits 12 and 13). The Logs show a running total of vials given and accepted back to the medicine supply cabinet, who signed the vials out, how many were signed out, the date the vials were signed out and how many were returned (Exhibits 14 and 15).

Analysis:

I conducted an analysis to either support or refute the allegations of propofol vial re-use for the two specific days of the infection transmission. The reason for the analysis was to either support the allegation by showing there were more patients who underwent procedures than vials checked out for the specific day or to refute the allegation by showing there were at least as many or more vials checked out than patients undergoing procedures.

The results of the analysis are as follows:

- July 25, 2007
  - On this date, there were two patients who had both procedures, so there were 65 patients (VA and non-VA patients) and 67 procedures.
  - One patient was infected on this date.
  - According to the Log (Exhibit 14), CRNA Ronald Lakeman signed out 5 vials and returned none.
  - CRNA Lakeman signed out 20 vials and returned 5.
  - The total number of vials signed out was 20.
  - The ratio of patients to vials for July 25, 2007 was 65:20 or 3.25:1.[4]

- September 21, 2007
  - On this date, there were 63 patients (VA and non-VA). One of the patients had two procedures, making 64 procedures for the day.
  - Six patients were infected on this date.
  - According to the Log (Exhibit 15), CRNA Keith Mathahs signed out 18 vials and returned none.
  - CRNA Mathahs signed out 20 vials and returned 14.
  - The total number of vials signed out was 24.
  - The ratio of patients to vials for September 21 was 63:24 or 2.62:1.[5]

The allegation of propofol vial re-use is supported by the ratios for the two dates in 2007 of the infection transmission. A chart (Exhibit 16) demonstrates graphically the

---

[4]65/20 = 3.25, 20/20 = 1

[5]63/24 = 2.62, 24/24 = 1

ratio of patients to propofol vials.

In order to determine if the pattern of propofol vial check out changed after SNHD advised the clinics of the Hepatitis C infection, I looked at the Propofol Log for a random date in 2008. I chose information from the Log from February 21 to February 26, 2008 (Exhibit 17). The Log shows that on February 21, 21 vials were checked out and none were returned, then 25 vials were checked out and 8 were returned, for a total of 38 vials of propofol used for that day. A review of the Registers (Shadow VA and Non-VA) for that date shows that there were 34 patients who underwent procedures. The ratio of patients to propofol vials was 1:1.1[6].

The 2008 ratio proves that the clinic started using at least one vial of propofol for each patient after they were informed of the infection. This comparison also shows that the clinics stopped re-using vials of propofol because of the change in their propofol check out process.

---

[6]34/34 = 1, 38/34 = 1.11