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Look back in anger: HCV outbreak may bring IC changes to ambulatory care

What happens in Vegas . . . can happen anywhere

IN THIS ISSUE

- **Anesthesia wake-up call:**
Will Vegas case finally be the wake-up call to sweeping changes? cover
- **Q & A on largest look-back:**
Answers to common questions on the Las Vegas outbreak . . 40
- **Call for national action:**
After the latest outbreak in ambulatory care, a call for dialogue between all medical groups 42
- **Stressing safe practices:**
AANA addresses safe needle practices to its 37,000 members 44
- **DNA tells the tale:** HCV investigation hinges on a sequence of representative letters gleaned from a rapidly mutating virus 46
- **Inserted in this issue:**
— 2008 Reader Survey

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The largest patient “look-back” notification in medical history — involving some 40,000 patients potentially exposed to hepatitis C, HBV, and HIV in a Las Vegas endoscopy clinic — allegedly was driven by policies designed to save money and carried out by medical staff who should have known they were putting patients at risk, *Hospital Infection Control* has learned.

Unsafe needle practices and the reuse of single-dose vials have resulted thus far in six cases of HCV — including five patients treated on the same day: Sept. 21, 2007. “Every time an incident like this occurs, it shocks and disappoints us,” says **Joseph Perz, PhD**, acting team leader for prevention in the Centers for Disease Control and Prevention’s division of healthcare quality promotion. “We feel strongly that we need to communicate with all providers and all settings across the country. This kind of injection safety is the most basic type of infection control during patient care. It has to be met as a very basic expectation.”

Special Report: Las Vegas HCV outbreak

An outbreak of hepatitis C virus (HCV) that recently sparked a massive testing effort affecting 40,000 patients in Las Vegas comes as the largest, latest “look-back” in a series of ambulatory care exposures that shows no signs of stopping. Unsafe needle safety practices, particularly during administration of anesthesia, are a common theme of the outbreaks. Indeed, the latest outbreak in ambulatory care related to unsafe needle practices invoked a stunning familiarity, as a series of similar incidents involving blatant violations in basic infection prevention have occurred in grim succession in recent years. Calls for national action to improve infection prevention in ambulatory care are mounting.

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Physicians' offices and clinics should look closely at their practices, he adds. "They should review infection control practices of all staff under their supervision with an eye toward injection safety," Perz says. "Syringe reuse is not something that can be tolerated in terms of patient risk."

The latest outbreak in ambulatory care related to unsafe needle practices invoked a stunning familiarity, as a series of similar incidents involving blatant violations in basic infection prevention have occurred in grim succession in recent years. "We should be reminding each one of these ambulatory units right now if this can happen in Las Vegas, it

can happen in North Carolina," says **William Schaffner**, MD, chairman of the department of preventive medicine at Vanderbilt University Medical Center in Nashville, TN. "This is the biggest [look-back effort] ever. It's hepatitis C, but of course lurking in the background is hep B, HIV, maybe even syphilis. Bloodborne infections of all kinds are potentially involved here."

If there is any solace to be taken from the most recent outbreak, it is that it may finally be the wake-up call that leads to sweeping changes and increased oversight in ambulatory care, physician offices and clinics. Still, that same alarm has been muted to "snooze" time and again after egregious violations have been documented, clinics shuttered and lives ruined. In the most recent incident, there are the aforementioned six cases of HCV, which could lead to chronic infection, cirrhosis, and in 1% to 5% of cases, death. It is the No. 1 indication for liver transplant. Of course, as noted, all patients are being advised to be tested for HBV and HIV as well in a look-back effort that will extend testing at least into this summer to account for the window period for all patients seen between March 2004 and Jan. 11, 2008, at the Endoscopy Center of Southern Nevada. The clinic's principal owner, Dipak Desai, MD, denied any wrongdoing and the clinic issued a statement. Due to the investigation, the clinic reportedly eliminated the unsafe needles practices as of Jan. 12, 2008. Regardless, city officials shut it down on Feb. 29 shortly after the massive look-back effort was announced. (See related stories, pp. 45-46.)

Single-use vials likely contaminated

The practices described at the clinic involved using a syringe to administer anesthetic to an endoscopy patient, then changing the needle — but not the syringe — before drawing up additional medication to be used on the same patient. The process of redrawing medication using the same syringe could have contaminated the medication vial. The same vial of anesthetic then was used for a second patient with a clean needle and syringe. "They used the same syringe, but a new needle, and went back to the [same] vial," Perz says. "That practice can result in the introduction of blood into the vial. Then downstream patients, who are not sharing the needle or syringe, are at risk."

Infection control professionals are all too familiar with contamination of multidose vials, but the anesthetic vials being used in the clinics were

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Editorial Questions

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packaged as single use. “We are not even talking about a multidose vial here,” Perz emphasizes to *HIC*. “We are talking about a vial that is only intended for single use. Just because the catalogue may have the larger size [single-use] vial, which is appropriate for some procedures — doesn’t mean that it is appropriate to order that vial and use it for multiple patients. It wasn’t designed that way and, that in itself is a violation.”

The vials typically were used up over the course of a day, suggesting that cases may have been more likely to occur in clusters through cross-transmission between patients than intermittently over time as contaminated vials remained on the shelves. “I don’t think they reused vials day to day,” says **Devin Barrett**, BS, disease investigation and intervention specialist with the Southern Nevada Health District. “They had a lot of patients going through there, so the vials were pretty much used up at the end of the day.”

Given the well-established risk of such practices — which are in clear violation of recommended precautions — the first question among infection control professionals and epidemiologists was whether the case was caused by greed or ignorance. Maybe it was a bit of both, as some staff members told investigators they were instructed to deliver the pain medications in such a manner. “Going by what they said in employee interviews, it was a practice that the managers had impressed upon them to do,” Barrett tells *HIC*. “That’s what they said. I have no idea what the actual cost savings were by doing that, but that is what we were told.”

Perz adds, “It seems like this was a suggested practice which some people did go along with, which should have been against their better judgment. Why some practice that way we can only speculate, but it does appear that this was something that was suggested to them by their managers.”

Some staff members reportedly refused to comply with the practice, but a cloud has settled over the case as a class-action lawsuit and a criminal investigation are under way. At least four members of the staff who worked during 2007 were certified registered nurse anesthetists (CRNAs), Perz says. The American Association of Nurse Anesthetists (AANA) — which provides such certification — harshly reminded that guidelines for safe needle practices should be well known and have been reiterated in recent years due to other incidents. “It is astounding that in this day and age, there are nurse anesthetists, anesthesiologists, and other health care

professionals who still risk using needles and syringes on more than one patient, or know of such activities and don’t report them,” **Wanda Wilson**, CRNA, PhD, president of the 37,000-member AANA, said in a statement. “Published standards and guidelines dictate that single-use and disposal of these products is the best way to ensure patient safety. Patient safety is our primary focus — not cost savings, time savings, or any other factor.” (See related story, p. 44.)

Asked about the cost-savings aspect of the case, Perz says the practice would not result in any great financial benefit. “We have seen with some of the expensive drugs — such as in dialysis — there is perhaps an incentive to scavenge,” he says. “In this case, syringes are cheap; this is not an expensive [anesthetic].”

Seeking 120 patients treated on two days

In terms of the actual outbreak, one case occurred on July 25, 2007, and the cluster of five patients was seen Sept. 21. DNA sequencing of the HCV virus then was used at the CDC to link the cases. “The attempt here is to look very carefully at the subset of the 40,000 patients who were treated on days where we believe transmission occurred,” Perz says. “The health department is going out of its way to try to contact those patients, arrange testing, and look very carefully at those results. They will be sending serum to the CDC from people who do have evidence of hepatitis for further molecular testing.”

The clinic saw approximately 60 patients a day, so there are some 120 patients who were seen on the days transmission was known to occur. “We already have acute hepatitis [cases] on those days and particularly the one day with five cases — that is certainly beyond coincidence,” Perz says. “That is not to say that in the last four years there weren’t other days where transmission occurred and it just simply was not evident because infections lacked symptoms or for whatever reason were not reported. Some of that is going to get sorted out as time goes on.”

Going beyond the notification letter sent to all patients, the health department is calling the patients who were treated at the clinic on the two days in question. “We want them tested here at the health district so that if we do find any positives we will send it to the CDC for genetic testing,” Barrett says. “I would say we have reached at least 75% of them.”

The health department uncovered the outbreak

because health care exposure is listed as a risk factor on newly reported cases of HCV. The first two cases were detected last December. "As part of our regular hepatitis C and hepatitis B interviews, we always ask — first about general surgical procedures — and then specifically about endoscopic or colonoscopy procedures," Barrett says. "The first case we asked that and we got a 'yes.' The second case we asked that again and we got a 'yes.' Both of them had procedures at the endoscopy center. That's when we started looking closer and we got a third case a week later. That sealed it, we called in the CDC and we went to the clinic."

The surveillance for surgical- or endoscopy-related outbreaks was added due to other reported hepatitis outbreaks in recent years, she adds. "It is hard to pick up sometimes because new hepatitis C infections are often asymptomatic," Perz says. "Not every health department necessarily would have made the connection. The index of suspicion in the U.S. is still generally low, even though we have tried to build awareness through our reports of these outbreak investigations. The average clinician and many public health professionals don't associate health care in the U.S. as a risk for HCV of HBV transmission."

Labs inundated, probe may expand

Local labs in the Las Vegas area are inundated with patients seeking testing and, as this issue went to press, there were ongoing efforts to set up some kind of free testing or compensation system. "Clinics have called and said they are overwhelmed with patients calling and trying to get in, but I do not know how many have been tested up to this point," Barrett says, adding that about 1,500 of the 40,000 letters mailed have been returned because the patient no longer is at that address. Another major difficulty will be determining if a patient's bloodborne infection is the result of clinic exposure or another risk factor. For example, the generally elderly patient population could expect to have a higher incidence of hepatitis infections and liver problems than average. According to estimates distributed by the health department to local clinicians, the pre-existing background rate of infection for the clinic patient population should be about 4% for HCV and 0.5% for HIV. Regarding HBV, about 0.5% will show evidence of current infection and another 5% will show past HBV infection. Looking at the universe of 40,000 patients, those percentages mean there are some 4,000 clinic patients who

acquired their bloodborne infection elsewhere. Ruling out that they didn't acquire it in the clinic is the the unenviable epidemiological challenge. "We're going to have to do the best we can with in-depth interviews, [gathering information] on past exposures or risk factors," Barrett says. "Good old-fashioned detective work, basically."

That will prove all the more difficult because the clinic's records are incomplete, and it is not easy to determine patient admission order and other factors that could epidemiologically suggest cross transmission, she adds. Making the case via molecular epidemiology also will be challenging, particularly for HCV, Perz adds. "This virus is hard to analyze in a molecular way," he says. "There are [viral] regions where the PCR tests and the sequencing can proceed fairly quickly. But it is sometimes necessary to apply quasi-species analysis, which is a whole other story and very labor-intensive."

In response to the hepatitis C outbreak, Nevada health inspectors are investigating all of the state's ambulatory surgery centers, where several violations of standard practice already have been found, according to the Associated Press. Since 1999, the CDC has reported 14 hepatitis outbreaks in the United States linked to improper injection practices. "I don't know how it is in other states and other counties, but I know here in Nevada there is just not a lot of oversight for ambulatory care centers," Barrett says. "This is what can happen if there isn't a governing body to make sure that people are doing what they are supposed to do. A lot of people are pushing for change now because of this situation, which is a good thing." ■

Q & A on largest patient look-back effort in history

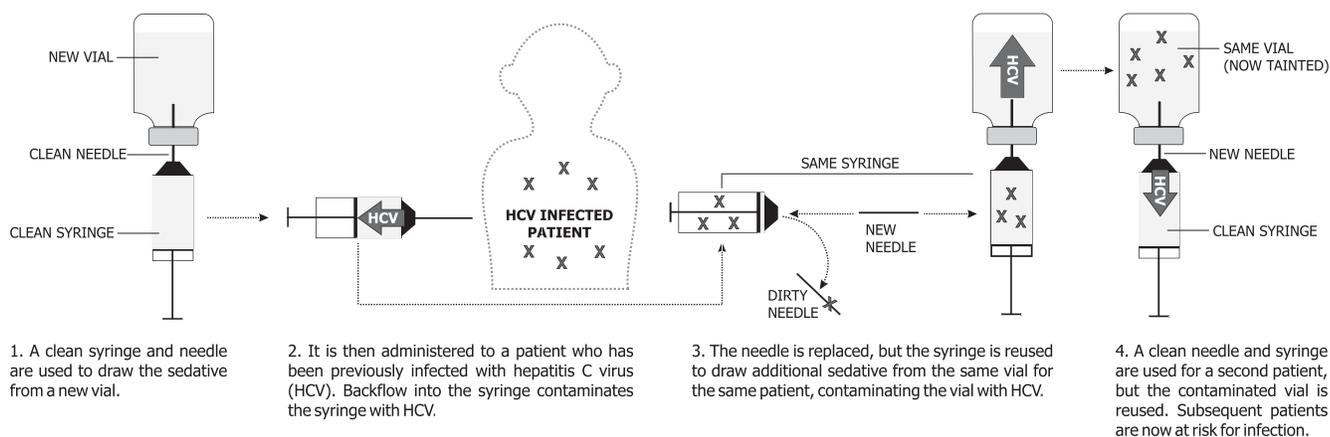
Forty thousand patients have plenty of questions

The Southern Nevada Health District issued the following questions and answers after launching the largest patient look-back effort in history by contacting 40,000 patients potentially exposed to bloodborne pathogens in a Las Vegas endoscopy clinic:

• **Why is the health district making these recommendations?** The health district received notification of three acute cases of hepatitis C in January 2008 and has identified a total of six cases to date.

Unsafe Injection Practices and Disease Transmission

Reuse of syringes combined with the use of single-dose vials for multiple patients undergoing anesthesia can transmit infectious diseases. The syringe does not have to be used on multiple patients for this to occur.



Source: Southern Nevada Health District, Las Vegas.

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.

- **How were the cases discovered?** The cluster of illnesses came to the attention of the health district in January 2008. These cases were reported to the health district by area physicians. 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.

- **Why did it take several months for this to come to the attention of the health district?** 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 that results in the patient developing symptoms (acute disease) is rare so it is 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.

- **How were patients exposed?** 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 was contaminated with the blood of the first patient, any subsequent patients given medication from that vial could have been exposed to bloodborne pathogens. (See graphic, above.)

- **How did you determine the link between these cases?** Of the six known cases, five had procedures on the same day. Genetic testing on four of the cases from that day has identified they likely came from a common source. The patient who had a procedure on a different day does not share a common source as the other four. This indicates 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 that manner.

- **What actions have been taken to correct the unsafe injection control practices?** The unsafe injection practices associated with these cases were identified during the investigation conducted in mid-January. The injection practices that lead to the exposure 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 might be identified despite no ongoing transmission of disease.

- **Why is the health district also recommending testing for hepatitis B and HIV?** The investigation revealed practices that 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.

- **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. Hepatitis C, B, and HIV are routinely found in the population. A significant number of people might have been infected prior to their procedure. Although testing can determine if a person is infected, it cannot determine the source of the infection.

- **How serious are these illnesses?** Hepatitis C, B, or HIV can result in a range of disease severity, and can eventually result in death. It is important that patients speak with a physician or health care provider if you have one of these diseases. A physician will be able to address specific risks for serious illness and develop a plan to monitor your health.

- **How many cases of hepatitis C are reported to the health district each year?** On average, two cases of acute hepatitis C are identified each year in Clark County. 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.

- **As a patient, how can I protect myself when getting these types of medical procedures?** It is important to remember the transmission of the disease in these cases was not related to the medical procedures, but rather to the anesthesia administered to the patient. When proper injection practices are followed, medical procedures, including colonoscopies or similar procedures, generally are safe. All health care professionals and medical facilities should follow safe injection practices and infection control procedures. Patients can and should ask their medical providers about the practices used in their facility.

- **What are the recommendations for people who test positive for hepatitis C, B, or HIV?** 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. ■

Call for national action after Vegas look-back

Senate majority leader acting as 'clearinghouse'

An outbreak of hepatitis C virus (HCV) that recently sparked a massive testing effort affecting 40,000 patients in Las Vegas comes as the largest, latest "look-back" in a series of ambulatory care exposures that shows no signs of stopping. Unsafe needle safety practices, particularly during administration of anesthesia, are the common theme of the outbreaks.

"Highly specialized medical units — surgicenters, radiology units, endoscopy units — that are separate from hospitals and no longer under the umbrella of infection control — often don't have real knowledge about contemporary infection control practices," says **William Schaffner**, MD, chairman of the department of preventive medicine at Vanderbilt University Medical Center in Nashville, TN. The series of outbreaks raises a compelling question that goes beyond guidelines and expressions of shock and outrage: "What is the responsibility of public health, organized medicine, and health care in supervising and educating these units?" he says. "This has gone beyond [the state level]. This is a problem."

The American Association of Nurse Anesthetists (AANA) called for some type of medical summit on the issue while reiterating its guidelines. (See **related story, p. 44.**) "These types of incidents are completely unacceptable," says **Wanda Wilson**, CRNA, PhD, president of the 37,000-member AANA. "We invite other national health care organizations, as well as governmental entities and drug manufacturers, to work with us to restore public trust and achieve this goal of ensuring and enhancing patient safety when it comes to the use of needles, syringes, and single-use medication vials."

Schaffner agrees, noting that "we need to get the dialogue going." The conversation needs to involve the major infection control groups along with the professional associations representing the various disciplines that practice in ambulatory care and freestanding clinics, he says. "A combination of ignorance, negligence, and cost savings has conspired to having people cut corners when it comes

to infection control," he says. Indeed, knowing all too well the history of prior incidents and the current nature of infection control in ambulatory care, CDC director Julie Gerberding, MD, MPH, warned in press reports that the Las Vegas outbreak could be the tip of the proverbial iceberg.

While previous outbreaks in ambulatory care failed to capture the public imagination — and engender sufficient outrage to spark change — the sheer scale of the Las Vegas look-back has jaws dropping and phones ringing. A hotline on the issue has received more than 25,000 calls, with some demanding state and national action to prevent future occurrences. Nevada lawmakers say the state will take a leadership role on ambulatory care infection control both locally and nationwide, according to published reports. Senate Majority Leader Harry Reid, (D-NV) said he will act as a "clearinghouse" on the issues, but it was too early to discuss specific national legislation.

Anesthesia practiced according to professional guidelines is safe, but the incidents must be used to address the problem once and for all, Wilson emphasizes. "What is clearly not the answer to the problem is for any group of providers — physician or other — to insist that 'it couldn't happen to us,' because that's certainly not in our patients' best interests," she says. Speaking of the patient, the Consumers Union, publishers of *Consumer Reports* — which has hounded hospitals to improve infection control in recent years — also is aware that health care is shifting to ambulatory care settings and taking patient infections with it. "We have focused on hospitals because we felt that is where the major problem was and where the most patients are infected," says **Lisa McGiffert**, director of the Stop Hospital Infections project at the Consumers Union. "But we agree that it has to go beyond that. Many of the states are including ambulatory surgical centers and outpatient clinics in their [infection control] legislation. We definitely will be looking at this in the future."

The number of incidents is occurring with striking regularity. Last year, a physician anesthesiologist in Long Island was investigated by the New York State Department of Health for allegedly reusing syringes to draw up medicine from multi-dose vials. The department contacted approximately 8,500 patients who had been treated by the physician prior to Jan. 15, 2005, urging them to be tested for hepatitis and HIV. However, in the latest HCV outbreak in Las Vegas, the providers administering the anesthetic were not physicians, the American Society of Anesthesiologists (ASA)

emphasized. "The training and education anesthesiologists receive is what sets them apart from other medical "providers" who deliver anesthesia care," the ASA stated. "Typically, an anesthesiologist has completed four years of college, four years of medical school, and has completed a minimum of four additional years of training accredited by the Accreditation Council for Graduate Medical Education in the medical specialty of anesthesiology. Anesthesiologists are responsible for the safe delivery of over 90% of all anesthesia care provided in the U.S. They can and do, in some settings, supervise and direct nonphysicians such as nurse anesthetists and anesthesiology assistants."

The ASA encouraged patients to ask the following questions before undergoing any procedures requiring anesthesia:

- Who will administer my anesthesia medication? Do I have an option to request an anesthesiologist?
- What type of anesthesia care will I be given?
- Do you throw out needles, syringes, and vials after every patient use?

A painful past

In recent years, four large outbreaks of HBV and HCV infections have occurred in the United States among patients in ambulatory care facilities that include a private medical practice, a pain clinic, an endoscopy clinic, and a hematology/oncology clinic. The 2002 pain clinic outbreak in Oklahoma resulted in 31 clinic-associated HBV infections and 71 HCV infections. In that outbreak, a nurse anesthetist reportedly drew medication into a single large syringe and injected it into the IV lines of numerous patients. In a previously reported endoscopy clinic outbreak, it appears that reinserting needles into contaminated multiple-dose anesthetic vials resulted in HCV infection to 19 patients. In the hematology/oncology clinic outbreak, syringe reuse apparently led to the contamination of saline bags used to flush out implanted catheters, resulting in 99 identified HCV infections. All four outbreaks could have been prevented by adherence to basic principles of aseptic technique for needle use and the preparation and administration of parenteral medications, CDC investigators stressed.^{1,2}

Since willful intent to put patients in danger seems an unlikely explanation for all the incidents, it is clear that some portion of the problem is educational. A survey of anesthesiologists conducted by

the AANA after the Oklahoma outbreak in 2002 found that 3% of anesthesiologists who responded indicated they reused needles and/or syringes on multiple patients. (See *Hospital Infection Control*, December 2002, p. 140.) CRNAs, other physicians, nurses, and oral surgeons reported reuse at 1% or less, the AANA reported. Extrapolating from the survey's findings, 3% of anesthesiologists and 1% of CRNAs equated in 2002 to approximately 1,000 anesthesia professionals who might have been exposing more than a million patients to risks of contaminated needles and syringes, the AANA concluded. According to Wilson, the AANA distributed this information widely among public and professional communities, including to the CDC. Despite these alarming results, the AANA was unable to generate interest in a summit meeting of health care organizations to address the issue, she says. "Perhaps if the issue had been given more attention at the time, we wouldn't be revisiting it again today," Wilson says.

More evidence of a safety culture problem within the anesthesiology community came in 2006, when a survey revealed that anesthesia providers (APs) in hospitals with some of the best infection control programs in the country were reusing needles and contaminated multiple dose vials on multiple patients.³ The researchers surveyed anesthesiologists working at the seven national prevention "epicenter" hospitals that collaborate with the CDC on infection control projects. Anesthesia providers reported reusing syringes, entering IV tubing and multidose vials without using aseptic techniques, using equipment from more than one patient without cleaning or disinfecting the items, they found. The web-based survey netted 339 (32%) responses from 963 APs. Thirty-one percent said they have used a "used" syringe or a needle in a multidose vial.

The problem is not just anesthesiology, however. Even as the number of medical procedures performed in physician offices, clinics, and other ambulatory care settings continues to increase, these settings still operate with little regulatory oversight, experts warn. Nor is the only issue bloodborne pathogens, which are much easier to pick up in surveillance than bacterial infections. The hepatitis outbreaks resulted in calls for action and public health discussions that included the CDC's Healthcare Infection Control Practices Advisory Committee (HICPAC). HICPAC formed a working group to look into the issue, but ultimately no guidelines or recommendations resulted. One issue cited in early discussions was

that the problem that led to the outbreaks was not so much a lack of guidance but a lack of compliance. Indeed — in terms of guidance — in 1999, a panel of infection control experts issued a consensus document calling in part for nonhospital health care settings to seek the advice and consultation of hospital-based ICPs or infection control consultants.⁴ The general perception is that cost disincentives and other factors have left that recommendation largely unfulfilled.

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Nurse anesthetists group stresses safe practices

Infection control guidelines distributed nationally

In response to a hepatitis C virus outbreak in an endoscopy center in Las Vegas, the American Association of Nurse Anesthetists (AANA) in Park Ridge, IL, is reiterating safe needle practices to all of its members. Certified Registered Nurse Anesthetists across the country were mailed a copy of AANA infection control guidelines along with a letter reinforcing the importance of strict compliance to ensure patient safety. The issues and recommendations being reiterated by the AANA include the following:

Administration of Drugs and Solutions

The potential for infection and transmission of microorganisms exists during the administration of drug therapy. Instructions for preparation, storage, and administration of all pharmaceutical agents provided by each manufacturer shall be read and followed. Drug administration by injection offers

many opportunities for contamination. These include previously used needles, syringes, drug administration sets, intravenous tubing, and fluid containers. Whenever eye ointment, nose drops, topical medications, aerosol sprays, and other non-injectable drugs or agents are used, the risk of cross-contamination also is present. Because it is not always possible to identify all patients who have a bloodborne pathogen, every patient must be treated with the same precautions. These include but are not limited to the following:

1. Strict adherence to infection control procedures and Standard Precautions is required.

2. Multiple-dose vials should be limited to a single patient use unless strict aseptic technique is used and a new sterile syringe and access device are used each time the vial is penetrated. The danger of cross-contamination from multiple dose vials used for more than one patient must be weighed against any cost savings.

3. Properly dispose of all needles and syringes after use. Do not reuse needles and syringes. Once used, all needles and syringes are contaminated. They are single-use items.

4. Do not recap needles, purposely bend or break them by any means, remove them from disposal syringes, or otherwise manipulate them. An exception to this requirement may be made in circumstances in which the employer can demonstrate no feasible alternative. Needle recapping may be accomplished by using a mechanical device or a one-handed technique.

5. Place contaminated needles and syringes in a readily available puncture-resistant container that is leakproof. It shall be color-coded to demonstrate that a biohazard is present.

6. Contaminated needles and syringes should be contained in an appropriate receptacle at all times. The receptacle should be stored upright and disposed of in accordance with the facility's hazardous waste program.

7. Alternatives to the needlestick test are available to determine the level of a regional anesthetic and include: a peripheral nerve stimulator, a tactile stimulation device, or a special temperature sensor. If needles are used, they must be considered contaminated and disposed of in the appropriate manner.

8. The use of sterile, disposable equipment for performing regional anesthesia is recommended. There is limited economic incentive for processing reusable regional anesthesia trays.

9. Ampules should be appropriately cleaned prior to opening. Their contents should be aspirated

with a filter needle, which is removed prior to administration.

10. Cleanse rubber stoppers of vials prior to each use. Only sterile access systems should be used for each penetration of the stopper.

11. Do not reprocess for multiple use any intravenous fluids, tubing, or other intravascular infusions or connectors that are single-use disposable items. This includes transducers, tubing, and other items that make contact with the vascular system or other body compartments. Stopcocks and injection ports are major sites of contamination. When administering medications intravenously, all access portals must be maintained with sterile technique. ■

Owner issues statement on 'unfounded allegations'

Separate statement by clinic issued earlier

In light of an outbreak of hepatitis C virus that resulted in public health officials advising 40,000 patients to be tested, **Dipak Desai**, MD, majority owner of the Endoscopy Center of Southern Nevada at 700 Shadow Lane, issued the following statement on March 10, 2008:

"As a longtime resident of Southern Nevada, I share our community's sorrow and concern for those who have been affected by this situation. I understand that many have questions about the allegations which have been levied against me and the Endoscopy Center of Southern Nevada. While I wish I were allowed to answer those questions, I am unfortunately unable to do so at this time on the advice of legal counsel. These unfounded allegations will be addressed in a court of law, when facts have been presented and substantiated. I look forward to that day, when I will be afforded the right to due process to which we are all entitled as Americans."

The statement said Desai will not issue any more statements until after legal proceedings have concluded.¹ Earlier, the Endoscopy Center of Southern Nevada issued the following statement, which was posted on the web site of a law firm pursuing a class-action case in the outbreak:

"On behalf of the Endoscopy Center of Southern Nevada, we want to express our deep concern about this incident to the many patients who have put their trust in us over the years. As

always, our patients remain our primary responsibility and we have already corrected the situation. The recent events related to the Southern Nevada Health District study mark the first time anything like this has ever happened at our facility. We have already taken steps to ensure that it will never happen again. The health district began its investigation in January, and we have been fully cooperating with them. We were officially notified by the health district on Feb. 6, 2008, and submitted our detailed Plan of Correction on Feb. 15, 2008. All concerns noted by the health department were addressed immediately. We continue to work closely with the Southern Nevada Health District and other health agencies during this ongoing review. We want to be sure that every patient who may have been exposed is informed and tested. . . . In addition to our corrective actions, we are on a mission to maintain the trust our patients have had in us during our years of service to southern Nevada. We wish to emphasize that the actual risk of anyone being affected by this is extremely low, but as a precaution, anyone who has undergone procedures at the Endoscopy Center who required anesthesia should be tested. As I'm sure you understand this situation brings with it a number of complex elements including patient privacy and regulatory guidelines. At this time, our counsel has asked that we limit our comments to this statement, and we are unable to take questions."

Reference

1. Manning M. "Desai: Can't comment on 'unfounded allegations,'" *Las Vegas Sun*. March 10, 2008, at <http://www.lasvegassun.com>. ■

Outbreak investigation hinges on DNA matches

Pattern of letters will make the match

Appropriately enough in Las Vegas, the largest patient look-back investigation in history will come down to something akin to a high-stakes bingo game.

The fate of clinicians who may be criminally charged and civilly sued — and certainly the fate of patients who are matched together as outbreak cases — will be in large part determined by a series of representative letters gleaned from the

CNE/CME questions

13. Unsafe needle practices described at a Las Vegas endoscopy clinic include the reuse of what on more than one patient?
 - A. Needles
 - B. Single-dose vials
 - C. Multidose vials
 - D. All of the above
14. The American Society of Anesthesiologists encouraged patients to ask which question(s) when undergoing any procedures requiring anesthesia:
 - A. Who will administer my anesthesia medication?
 - B. Do I have an option to request an anesthesiologist?
 - C. Do you throw out needles, syringes and vials after every patient use?
 - D. All of the above
15. The AANA said multiple-dose vials should be limited to a single patient use unless strict aseptic technique is used and a new sterile syringe and access device are used each time the vial is penetrated.
 - A. True
 - B. False
16. In DNA sequencing tests in an outbreak investigation, which virus is more likely to create a "perfect" match?
 - A. Non-A, non-B hepatitis
 - B. HCV
 - C. HIV
 - D. HBV

CNE/CME instructions

Physicians and nurses participate in this CE/CME program by reading the issue, using the provided references for further research, and studying the questions. Participants should select what they believe to be the correct answers, then refer to answer key to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material. After completing the semester's activity, you must complete the evaluation form that will be provided and return it in the reply envelope to receive a credit letter. ■

rapidly mutating hepatitis C virus (HCV). The process is called DNA (deoxyribonucleic acid) sequencing. Combined with shoe-leather epidemiology, the high-tech process already has shown that six HCV infected patients — particularly five treated on the same day — are so closely linked that transmission must have occurred between them or from a common source. They are officially a cluster, identified by epidemiology detectives and “fingerprinted” by lab researchers at the Centers for Disease Control and Prevention. As the 40,000 patients treated at the endoscopy clinic are tested, positive results reported to state officials will be forwarded to the CDC for genetic analysis and sequencing.

“We subject the specimen to an extraction process to take out the RNA and the DNA, which are collectively called nucleic acids,” explains **Chong-Gee Teo**, MD, PhD, chief of the viral hepatitis lab at the CDC. “Usually, a polymerase chain reaction [PCR] technique is used to define as much of the sequence of interest [as possible]. The identified segments of the viral genome are then processed through a sequencing machine that provides read-outs of the various nucleotides that constitute the sequence of any particular origin.”

The sequence will appear in some order of representative letters used to identify various genetic components. The order of the sequence of genetic

information that is being passed along may appear in some repetitive pattern and be given a numerical value as part of the analysis. It may closely match another sequence from another patient, suggesting transmission or common source exposure. The trained eye can find the matches, but with HCV the phrase “perfect match” is no more likely to be shouted in the lab than “Bingo.”

“For rapidly evolving viruses like hepatitis C or HIV, very seldom do we find a perfect match,” Teo tells *Hospital Infection Control*. “Because once a virus enters a host it undergoes a route of evolution that is different from host to host. We look for how closely related one sequence is with another.”

Powerful evidence

When matches are found, they stand out dramatically from background sequences representing national HCV strains. Teo declined to give a percentage estimate of “certainty” or comment on the specific patients in Las Vegas, but he made it clear that genetic findings linked with epidemiological investigation combine to form powerful evidence that transmission has occurred. “They cluster closest to each other,” he says. “To make

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CNE/CME objectives

After reading each issue of *Hospital Infection Control*, the infection control professional will be able to do the following:

- identify the particular clinical, legal, or educational issue related to epidemiology;
- describe how the issue affects nurses, hospitals, or the health care industry in general;
- cite solutions to the problems associated with those issues, based on guidelines from the federal Centers for Disease Control and Prevention or other authorities, and/or based on independent recommendations from clinicians at individual institutions. ■

CNE/CME answers

13. B; 14. D; 15. A; 16. D.

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an inference that these sequences [are a cluster] we have to have 100% concordance with the epidemiological [investigation].”

Though some have noted that the investigation may be undermined as pre-existing viral infections are found in the clinic patients, Teo says discernment should not be difficult. “It has been our experience that [cases] epidemiologically linked to each other — whether one infected the other or whether they were infected by a common source — always cluster to each other and not to non-linked sequences,” he says. “For this investigation we already have sequences from the initial cluster, so other [identified cases] will be related to the outbreak itself. The others that are not related or linked at all will fall outside the cluster.”

As clinic patients are tested for HIV, the issues in molecular epidemiology will be very similar to HCV. However, the slower-mutating HBV will be less distinctly defined from background viruses. “HCV and HIV are very ‘light’ viruses and they mutate very fast,” he says. “Hepatitis B is a slowly evolving virus and instances where specimens are collected from a single outbreak there is higher likelihood of having identical matches.”
Bingo. ■

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