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New Nevada regulations driving Botox costs out of patient reach

Jul 15, 2008

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CST WEB EXCLUSIVE

All bottled up
New Nevada regulations driving Botox costs out of patient reach

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LAS VEGAS — A hepatitis C outbreak in southern Nevada has prompted the state’s governor to enact new regulations barring practitioners from administering medications from single-dose vials to multiple patients. Although investigators didn’t specifically target Botox (botulinum toxin A; Allergan, Irvine, Calif.), local cosmetic surgeons say that the rule has driven Botox costs out of reach for many patients while spotlighting long-standing confusion over Botox’s labeling.

SYRINGE AND MEDICATION REUSE

At the center of the controversy sits the now-closed Endoscopy Center of Southern Nevada, reports Ihsan Azzam, M.D., M.P.H., Nevada State Health Division (NSHD) epidemiologist. In December 2007, the Southern Nevada Health District (SNHD) contacted him to report two cases of acute viral hepatitis C in patients who had outpatient procedures at this center within one to three months of disease onset. Shortly after these reports, an investigation conducted jointly by the SNHD, the Centers for Disease Control and Prevention (CDC) and the NSHD’s Bureau of Licensure and Certification found that clinic staff had been reusing syringes and single-use medication vials on multiple patients.

At press time, the investigation had uncovered a total of eight acute hepatitis C cases, seven of which were linked to the endoscopy clinic, Dr. Azzam reports. “On February 27,” he adds, “SNHD mailed a mass notification to patients who had undergone procedures at the facility from March 1, 2004, through January 11, 2008.” Subsequently, health officials tested approximately 50,000 at-risk individuals for blood borne pathogens including hepatitis C and B and HIV, and identified 77 additional chronic (asymptomatic) hepatitis C cases whose only risk factor is the clinic, says Dr. Azzam. All told, he adds, 500 patients tested positive for hepatitis C.

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In response to these findings, Nevada Governor Jim Gibbons issued emergency regulations for ambulatory surgery centers, emphasizing the importance of following accepted infection control standards. On June 20, Nevada's Board of Health adopted the regulations as permanent. Next, they will go before the Nevada Legislature's Legislative Committee, although no date has been set, says Lorne Malkiewich, chief of Nevada's Legislative Counsel Bureau. Barring unforeseen circumstances, he says, the legislature likely will approve the regulations without objection.

Additionally, the NSHD issued a bulletin saying all health care providers must not administer medications from single-dose vials to multiple patients. When it comes to injection safety, says Dr. Azzam, "I don't know why additional regulation would be needed. If a vial is labeled single-dose, it must be used as a single dose, regardless of its contents."

RISK ASSESSMENT

"Most doctors know there is a risk from drawing up any injectable medication from multi-use vials," says Joseph Niamtu, III, D.M.D., a Richmond, Virginia-based cosmetic facial surgeon who serves on the Cosmetic Surgery Foundation's board of directors. Even with sterile syringes, he says, "Mistakes happen, and someone inadvertently picks up a contaminated syringe and inoculates the entire vial."



Dr. Niamtu

To avoid this possibility, Dr. Niamtu says that in his practice, "We dilute the vial with 2.5 cc of preserved sterile saline, then use a bottle opener to pop off the top of the vial and draw up four 0.5-cc syringes."

However, Lane F. Smith, M.D., a Las Vegas-based plastic surgeon and president-elect of the Rocky Mountain Plastic Surgery Society, says that withdrawing multiple sterile syringes from the same Botox bottle is "perfectly safe. The state of Nevada is probably overreacting."

Moreover, Dr. Smith says the fact that Allergan's label specifies single-patient use is "a surprise to us. Nevada is the only state being held to that. Everybody else in the country expects a standard Allergan bottle to be used for two or three patients, sometimes more," he says.

IMPROPER INSTRUCTION?

Although Botox Cosmetic hasn't been implicated in any

infections, the hepatitis investigation has highlighted the fact that "the way physicians were taught by Allergan to use the product is incorrect," says Julio Garcia, M.D., a Las Vegas-based plastic surgeon in private practice. Since Botox Cosmetic debuted in 2002 (carrying a single use, single-patient label), he says, "When we were taught by Allergan's representatives and clinical instructors, they all demonstrated treating multiple patients out of one vial."

"Dr. Garcia is likely not referencing direct Allergan promotional material, but rather statements and views of third-party physicians and physician speakers," responds Caroline Van Hove, Allergan's vice president, corporate communications.



Dr. Garcia

Whatever the source of the instruction, the new regulations have proven costly for cosmetic surgeons.

"A Botox bottle costs around \$560," says Dr. Smith. "One patient doesn't need a whole bottle." But initially he had to charge patients at least \$550 no matter how small the treatment area. "We were charging them what it cost us to buy the vial so that we didn't anger any patients. That's what most of us were doing," he explains.

Responding to physicians' requests, in May Allergan debuted a single use/single patient, 50-unit Botox Cosmetic vial costing about \$289, says Ms. Van Hove.

Nevertheless, 50 units is still 2.5 times the approved dose, says Dr. Garcia, who estimates he's lost 20 to 25 percent of his Botox business to injectors who ignore the new rules.

"It may be more costly to follow the manufacturer's directions," counters Dr. Azzam, "but not as costly as the negative health outcomes for the patient and provider if we don't follow these recommendations."

LEGAL CONSEQUENCES

Regarding legal consequences, Dr. Garcia says that as the state Board of Medical Examiners pursues a malpractice investigation, Las Vegas attorneys representing some 3,000 patients are filing a class-action lawsuit against owners of the offending endoscopy clinics.

Nationally, adds Dr. Azzam, "There have been at least three

outbreaks of hepatitis C related to unsafe injection practices." As a result of a hepatitis outbreak in New York, Dr. Garcia reports, Senator Hillary Clinton has urged the FDA to support production and use of "cost-effective alternatives to multi-dose vials."

Meanwhile, in Las Vegas, Dr. Garcia says reuse of single-use vials continues despite the fact he has sent letters to the American Society for Aesthetic Plastic Surgery (ASAPS), American Society of Plastic Surgeons (ASPS) and Nevada's Board of medical examiners alerting them about the practice.

Although plastic surgeons are closely monitored, adds Dr. Smith, "We worry more about the nurses and nonphysician injectors, some of whom continue to advertise prices that suggest they're still splitting Botox vials among multiple patients."

However, Lynn Beggs, legal counsel for the Nevada State Board of Medical Examiners, tells *Cosmetic Surgery Times* that the Board considered the issue of injection safety at its quarterly meeting in mid-July and recommends to its licensees that they follow injection safety information updated by the CDC in March 2008. ASAPS and ASPS officials did not respond to requests for comments.

Meanwhile, to help infected patients and identify others at risk that the investigation may have missed, the SNHD has implemented a Hepatitis C Exposure Registry to gather additional information related to patients of the Endoscopy Center of Southern Nevada and of a second endoscopy clinic linked with the eighth acute infection. Nevada health officials also plan to test patients who underwent procedures at these clinics in late 2007 and early 2008 because patients can carry hepatitis C for up to six months before testing positive.

DELIVERY SYSTEM OF THE FUTURE

Regarding the Botox issue, Dr. Niamtu says, "Having a multi-dose vial that requires reconstitution is a huge drawback. Someday we will laugh that we had to go through all these steps just to get a few simple injections." Physicians hope Allergan and/or its competitors ultimately will devise a way to provide botulinum toxin A in a ready-to-inject delivery system, he says. "Until then," he adds, "it's imperative that all providers are cognizant of the ability to inadvertently infect other patients by using a multi-dose system with Botox or any other injectable medication." **CST**

Disclosures

Drs. Garcia and Smith report no relevant financial interests. Dr. Niamtu is a consultant for Allergan and has received lecture honoraria from the company.

For more information

www.southernnevadahealthdistrict.org

www.cdc.gov

www.leg.state.nv.us/Register/2008Register/R096-08I.pdf (proposed regulations)

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