

Little cause for worry with storage of Botox beyond set time

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If you're keeping an open, reconstituted vial of botulinum A exotoxin (Botox, manufactured by Allergan Pharmaceuticals in Irvine, CA) for more than four hours before drawing another dose to inject, you're going counter to the manufacturer's instructions approved by the U.S. Food and Drug Administration (FDA). Although some plastic surgeons abide by this cautious approach, most say keeping open vials longer than the directions state is standard practice.

So what are the risks? Is safety or efficacy compromised in surgeons' efforts to avoid wasting opened vials?

Not likely, say experienced surgeons and the latest research. It appears that you would have to keep an opened vial in the refrigerator for an inordinately long time, such as two months, or fail to take basic safety precautions in order to pose any real risk to patients.

Allergan's instructions for using Botox state that you should reconstitute the vacuum-dried medication with sterile normal saline without a preservative. The only recommended diluent is 0.9% sodium chloride. The instructions further say that you should record the date and time of reconstitution on the vial's label and then the Botox should be administered within four hours after reconstitution.

Rely on research

But that's not what really happens in most physician practices—and that's okay, says **Hema A. Sundaram, MD**, a dermatologist in Rockville, MD, who administers Botox injections and has researched related safety issues.

It is appropriate to be cautious with any multiuse medication vial, and plastic surgery practices should be strict about following proper infection-control procedures, Sundaram says. However, the most recent research indicates that the way most physicians use Botox is quite safe and that the FDA-approved Botox insert does not represent the best practice. The insert instructs surgeons to reconstitute the product only with a preservative-free saline solution, even though studies have shown that a preservative enhances patient safety by expanding the window for safe storage, Sundaram notes.

With a preservative, the research suggests, a Botox vial remains safe and effective for as long as seven weeks. Most physicians use saline with preservative, she says.

“In my two offices, it is unusual for a vial of Botox to last more than a week. Very frequently I’ll finish the vial off in one day,” she says. “That seems to be the common practice, and that means that what physicians are doing with Botox is well within the safety parameters even though it is off-label use according to the FDA-approved insert.”

Exercise caution with any vials

According to Sundaram, using saline with preservative is important to ensure that the Botox vial remains safe and effective beyond the four-hour limit specified by the manufacturer. The preservative does not diminish the efficacy of the product and actually has been shown to reduce pain at the injection site, she says.

In addition, always pay close attention to sterility, whether you’re using the vial once or multiple times. This is an infection-control issue just as with any other multiuse vial of medication, Sundaram says.

“I’ve heard these horror stories of people storing Botox in the same refrigerator where the staff keep their lunches, and that is totally unacceptable. I also advise

a locked refrigerator because this is a toxic substance and you don't want anyone to gain access to it," she says. "It would be terrible if someone accessed the vial and harmed themselves with it or contaminated it before you used it on another patient."

Follow sterile protocol

Henri P. Gaboriau, MD, director of the Sammamish (WA) Center for Facial Plastic & Reconstructive Surgery, agrees that plastic surgeons have little to worry about with storage of Botox vials if they don't push the envelope too much.

"It is clear that if the solution is refrigerated, it will retain its full potency for at least a week," he says. "I rarely have a bottle that remains overnight, and I suspect most plastic surgeons would not have one in storage for more than a day or so."

Gaboriau says he is not aware of any reports of infection from spoiled vials of Botox, but emphasizes that sterile techniques must always be followed.

"We always clean with alcohol and use a new, fresh needle, and a fresh syringe, to draw from the vial," he says. "In terms of infection risk, it should be no different from other multiple use vials as long as you follow sterile protocol."

Consider creative scheduling

Despite the relatively low storage risks, a cavalier attitude is not acceptable, says **Elan Singer, MD**, a plastic surgeon in New York City. After all, your patients are healthy and a life-threatening infection from a cosmetic procedure would be especially tragic, says Singer, who tends to adhere closely to the manufacturer's recommendations for using the solution within four hours.

To make sure that doesn't result in a lot of wasted Botox and money down the drain, his practice schedules Botox injections in blocks.

With multiple patients booked back to back, Singer can ensure that he finishes a vial quickly, usually with little left to store.

“Sometimes if we end up with some left over, we’ll store it for up to 24 hours and see if we use it the next day on someone,” he says. “But after 24 hours, we’re done with it. It goes in the trash.”

Although Singer says he has never seen an infection from Botox, he feels more comfortable taking a conservative approach.

“I’m sure the risk is very low, but it makes sense that for every day that vial sits around, the infection risk has to go up some,” he says. “It’s a matter of whether you want to subject patients to even a small risk to avoid discarding some Botox—and I just sleep better at night when I play it very safe.”

Don’t push the envelope

So if—through some quirk of scheduling—you end up with a vial of Botox that has been in the refrigerator for longer than day or so, how do you know when it’s time to toss it out?

The research suggests seven weeks would be safe. But would a cautious plastic surgeon ever use it after that much time?

Gaboriau would not, and neither would Sundaram. Although they have confidence that Botox can be stored safely, they both say you should be conservative if there is ever any doubt.

Gaboriau says that, in his experience, the Botox results do not last as long when the product has been stored for more than a few days, even though its still safe for much longer than that.

“The longest I have stored a vial of Botox is four days, and that was over a long holiday weekend,” Gaboriau says.

“After that I think it still is safe and effective, but I think effectiveness can start to drop off after seven days. So after a few days I’m getting into a grey zone where I’d rather not use it on my patients. I will still use it on myself or my staff at that point.”