

Is Your Infusion Clinic One of the Good Guys?

By Dan Bennett

It sounds like a plot for a bad science-fiction movie.

A healthcare provider infuses a patient with the wrong medical product. And even if that product is only saline solution, when the patient desperately requires immune globulin (IG) or some other vital drug, it's a bad scene indeed.

Denise Hasenstab is an Orange County, Calif., patient who recently sued an infusion clinic for altering or replacing her IG injections with saline solution—for seven years.

Expert testimony from outside medical experts indicated that Hasenstab's claims were accurate, that she indeed was not infused with the product she needed, and that her health suffered. The clinic denied medical negligence, but admitted faulty record keeping, and settled the case for \$300,000.

"Dealing with the emotional aspects of this experience is beyond words," Hasenstab said. "It is an absolutely devastating thing to find out that doctors you trusted, doctors who took an oath to help you, lied to you purposely. It's one thing when it's an innocent mistake, quite another when it is calculated."

Though Hasenstab settled the case, the state medical board in California continues to investigate the clinic. Meanwhile, Hasenstab now receives her infusions at the University of California Irvine Medical Center, and after six months of treatment, at last has begun feeling better.

"There is no dollar amount I ever could have received that could even come close to making up those lost years of my life," she said. "Money



can't bring back that time with my children. Those years are gone."

Now, Hasenstab says she will become an advocate for better monitoring of infusions and victims' rights, and she offers advice for patients just starting their infusions. Though Hasenstab says she recommends teaching-hospital settings such as the one she visits now, patients who visit infusion clinics can help protect themselves.

"To start with, research the doctor's credentials," she recommends. "Check to see if the doctor is board certified. If the doctor does not have hospital privileges, that's a red flag. Get as much information as possible about the drug product they expect to give you. You may feel run-down when you first start, so find an advocate such as a family member or friend who can ask questions on your behalf. Call the manufacturer yourself and

ask questions about the product. And make sure the product is clearly labeled. If not, there is a problem."

In other reported cases during the last several years, law enforcement authorities have investigated and sometimes prosecuted healthcare providers who are often motivated by the potential financial rewards of insurance fraud and other illegal activities.

Such things happen, if rarely, so what can be done? How can a patient in need of regular IG infusions trust that the proper product is used? What are the questions a patient can ask when visiting a clinic for the first time, and how can the patient monitor his or her own ongoing care?

Healthcare providers at infusion clinics echoed Hasenstab's advice for infusion patients.

"A patient should always know what brand they are using for their infusions," said Kristin Epland, a nurse practitioner at Midwest Immunology Clinic in Plymouth, Minn. "One of the first ways a patient can discern what infusion centers are giving is understanding what they are supposed to be giving. My opinion is that patients should not switch back and forth between products, because of supply issues and adverse reactions. An important step for patients is taking control of their own infusion needs."

At Midwest Immunology Clinic, patients are provided with diaries to keep track of their infusions. "Among other things, these diaries act as safety checks," Epland said. "So, if there's a product recall, even if the infusion nurse makes a mistake, the patient will have a record of what

product they have taken. Every time a patient is getting an infusion, they should ask an infusion nurse what the product is. It's crucial that patients maintain control of their therapy."

Epland says first-time visitors should ask the clinic personnel how many IG infusions they do in a week.

"If the answer is only one, then maybe they don't have as firm a standard policy on infusion procedure as a clinic that does 100 infusions a week," she said.

Epland often coordinates follow-up infusion treatments at other locations for patients who live a long distance from her clinic. She monitors the treatments performed on her patients at the other infusion clinics.

"Even smaller locations are now able to do complicated infusions, so again it's important for the patient to stay on top of the treatments, especially if the clinic is not experienced with a particular infusion," she said.

Communication with primary physicians is essential, infusion clinic specialists say. If the immunoglobulin levels are not correct following three months of treatments, start asking questions.

"People can lie to you, though my experience in this field is that the overwhelming majority of providers are honest, dedicated professionals," Epland said. "The stopgap is the patient. Never be afraid to ask questions."

Though the illegal substitution of medicines can fall under federal law statutes in some cases, infusion clinics are for the most part regulated by each state's department of health services, which approves licensing and investigates complaints.

The physicians at infusion clinics, meanwhile, are monitored by state medical boards, which maintain the power to suspend or revoke licenses to practice medicine. Departments

of health and state medical boards often work in tandem to investigate complaints. In some cases, clinics are shut down by state health services when law enforcement authorities begin making inquiries, at least temporarily, until the issue is resolved.

Most state medical boards and health services departments have websites where the public can research whether a physician or infusion clinic has come under previous investigation. These agencies also have dedicated phone numbers to handle patient complaints.

Because stand-alone infusion clinics can often serve as "one-stop shops" for a variety of medical services, monitoring these clinics can be a challenge. And the challenge starts at the source.

Ray Wilson, chief of the drug and consumer products division for the California Department of Health Services, says his department monitors for fraud starting with release of the drug from the manufacturer.

"What happens at an infusion clinic is one thing, but consumers should know that drugs are monitored from the time they leave the manufacturer," Wilson said. "If a drug is misrepresented by its label or in some other way, our department has the responsibility of taking action."

Some such instances can be accidental, some on purpose, but Wilson says the majority of manufacturers take careful steps for accuracy.

"As the costs of healthcare products continue to rise, counterfeiting and things like that could become even more of a problem," Wilson said. "But manufacturers know it's in their best interest to be careful and stay on track, for many different reasons, including their own liability."

For the patient, it all starts with questions and record keeping.

"One of the things patients can do is keep their own infusion logs," said

Kimberly Duff, a clinical nurse for IG provider NuFACTOR. "When we do an infusion, we peel the sticker off the bottle and place the sticker on the infusion sheet. The patient can then take the bottle and use it to record the infusion on a log they keep privately. This way, they know what the product they received was supposed to be, and when they received it. It's a good way of tracking."

Duff also encourages patients to become familiar with their own testing and lab work.

"The patient should monitor their levels," Duff said. "Know what your numbers are and what they mean. If you suspect those numbers are not what they should be, always check with your physician."

Trust becomes a big element.

"Identify one of the providers you have a comfort level with, and develop a relationship with somebody you trust at the clinic," Duff said. "With trust, you can help alleviate the fear of asking questions." ■

Editor's note: It is important to note there may be valid medical reasons why levels and labs don't predictably respond to proper doses. While it is important for patients to ask questions about their treatment, unusual levels are not necessarily an indicator that deception is taking place.

For More Site of Care Information

The American Academy of Allergy, Asthma & Immunology website, www.aaaai.org, has downloadable site-of-care guidelines, http://www.aaaai.org/members/resources/initiatives/ivig_toolkit/ivig_site_of_care.pdf.