COVER STORY

Q&A

With Charlotte A. Smith, RPh, MS, HEM,
President of PharmEcology Associates, LLC

Best Practice Recommendations for Pharmaceutical Waste Management

Photos of waste containers courtesy of Stericycle

Q: What are some of the major risks that pharmaceutical waste presents to humans and the environment?

A: While we don't yet know the direct impact on humans, it has been documented that the presence of pharmaceuticals in surface and groundwater leads to significant endocrine disruption among aquatic species. We know that many of the daughters of women who were given DES (diethylstilbestrol) to prevent miscarriage developed vaginal cancer in their late teens. Male sperm counts are down by about 50% over the last 60 years, and of course, that's not only a result of drugs, but we don't know exactly how serious the risks are to the human population.

So when thinking about the impacts pharmaceutical waste can have on the human population, I urge people to keep in mind the "Precautionary Principle," developed at the 1998 Wingspread Conference in Racine, Wisconsin: "When an activity raises threats of harm to human health or the environment, precautionary measures should be taken, even if some cause-and-effect relationships are not fully established scientifically." In other words, don't wait for a rigorous scientific study to be published before you take steps to avoid a potential problem.

Q: What regulations must hospitals adhere to when managing pharmaceutical waste?

A: The primary regulation is the EPA Resource Conservation and Recovery Act, also known as RCRA; that's federal law. RCRA applies to any waste disposed of by business entities, including hospitals. Every state, with the exception of Iowa and Alaska, has its own RCRA-authorized environmental protection program, which must be at least as strict as the federal regulation. A number of states, including California, Washington, and Minnesota, have stricter regulations than RCRA. So hospitals have to adhere to state environmental regulations as well.

In addition, per the DEA, hospitals have to render controlled substances waste non-recoverable. That can get a little sticky if you're disposing of something like chloral hydrate, which is both a hazardous waste and a controlled substance. Furthermore, with controlled substances, we always have to worry about diversion. With the high cost of drugs today, many other drugs are subject to diversion. It's prudent to make sure drugs aren't just being put into a dumpster; that would not only be environmentally inappropriate, but it could also lead to diversion.

Q: What are the rules of thumb for disposing hazardous pharmaceutical waste?

A: Any pharmaceutical waste defined by RCRA as hazardous needs to go through a very rigorous storage, labeling, manifesting, and shipping sequence to a federally permitted treatment, storage, and disposal facility, or TSDF. Hazardous waste must be incinerated. Under RCRA, there are different levels of hazardous waste, the most strictly regulated of which is P-listed, or acutely hazardous, waste. P-listed drug containers remain hazardous waste even when they are "empty," with the exception of used epinephrine syringes. Sewering P-listed waste without notification and permission is a violation of RCRA. The regulations for U-listed drugs are slightly less stringent, but are still highly regulated. The hazardous drugs in the third group have one of the following characteristics: ignitability, corrosivity, toxicity, and reactivity. Those drugs need to be disposed of in the same manner as U-listed waste. That said, corrosives cannot be combined with other waste, so they have to be carefully segregated to avoid chemical reactions. Typically, there won't be a lot of corrosives in your pharmaceutical waste, with the exception of some compounding chemicals.

Once a year, a pharmacy should dispose of chemicals they aren't using and have them appropriately lab packed and shipped out. A number of national companies, such as Veolia (formerly Onyx) and Clean Harbors, can perform these services, and a number of regional brokers can provide specialized services to meet state requirements. Keep in mind that some service providers are only permitted to handle certain types of hazardous. Some states, like California and Washington, require that non-RCRA pharmaceutical waste defined as hazardous by those states be incinerated at a regulated medical waste incinerator or other approved facility. Some regulated medical or municipal incinerators can accept non-hazardous drug waste.

Q: How should non-hazardous waste be disposed of?

A: Non-hazardous waste includes antibiotics and antidepressants. There is some concern that improperly disposed of antibiotics can lead to microbial resistance, and traces of antidepressants in ground and surface water have been shown to cause endocrine disruptions in amphibians. So they aren't "non-hazardous," per se. They just aren't regulated. So the best management practice is to consider incinerating non-hazardous drugs at a regulated medical waste or a non-hazardous waste incinerator, rather than sewering them or sending them to a landfill. Some people are uncomfortable with incineration, but it's still better than landfills or drain disposal. Drain disposal can have

Photo courtesy of Hospitec, Inc.

immediate effects on the ecosystem, and landfilling can have postponed, yet significant, effects, once the waste leaches into the groundwater. So until another technology is available for breaking up pharmaceutical compounds, incineration is the best way to render them relatively harmless.

I recommend purchasing containers specifically designed for hazardous waste. There are both blue and black containers on the market. I do not recommend re-labeling existing yellow containers, because sorting P- and U-listed drugs is confusing enough.

Q: Exactly how empty does an "empty" U-listed drug container need to be before it can be disposed of as hazardous waste?

A: Empty means that all contents that can be removed through normal means have been removed, and that no more than 3% by weight of the original contents remain in the container. If you can remove more than that 3% by normal means, you must do so.

Q: Is RCRA's list of chemotherapy drugs complete?

A: RCRA only lists nine chemotherapy drugs, and there are now over 100.

Photo courtesy of Vestara

Photo courtesy of Kendall

Q: How would you advise hospitals to treat chemotherapy drugs not listed by RCRA?

A: I highly recommend that hospitals manage any residual or non-empty chemotherapy as toxic hazardous waste, unless it happens to be ignitable, in which case it is ignitable hazardous waste. At times, toxic and ignitable waste can be combined in the same waste stream, but hospitals need to check with their hazardous waste vendor and have a waste profile done to see if that is possible. Ignitable and toxic chemotherapy containers that are not empty should not be placed in yellow chemotherapy waste containers, which is very confusing to people. Likewise, overtly contaminated chemotherapy paraphernalia, such as used spill kits, should be managed as hazardous waste. Trace contaminated items are appropriate for yellow chemotherapy containers, which are treated as regulated medical waste, not as hazardous waste. They are incinerated at a regulated medical waste facility, not an EPA permitted hazardous waste facility. So that has been a significant misunderstanding throughout the entire industry.

Q: How do you recommend hospitals handle their controlled substance waste?

A: Because of the DEA, the least expensive way to render it non-recoverable is by pouring it down the drain. So, if you must pour them down the drain, at least inform your wastewater treatment plant of what and how much you are going to dispose. Per the DEA, you need to keep records of that disposal and have it double witnessed. A more environmentally responsible way to handle larger volumes of controlled substance waste is to contract with a DEA-registered waste management broker, such as Strong Environmental, Veolia, or Clean Harbors, or you can send it to a reverse distributor that is DEA-registered and can accept solid waste. Those options are more expensive, but they are more environmentally sound because the waste is eventually incinerated.

Q: What criteria can health systems use to evaluate waste management service providers?

A: It's important to ask them for references and an audit of their permits and violations for the last three years. Make sure they have the RCRA permits to handle the kind of waste you are generating. At www.epa.gov/echo, you can see how many violations a particular vendor has. It's not unusual for a large company to have some violations, but you should make sure the number is not off the charts.

Q: What models can hospitals follow in developing their waste management programs?

A: The first – and most ideal – model is segregation at the point of waste generation; the moment a drug becomes waste, it's put into the appropriate container. There are three sub-models under this. The most elegant is the EcoRex automated waste disposal system from Vestara, which is due to become commercially available in 2007. It's a bit like a reverse Pyxis machine: You scan the bar code on your drug container, and the appropriate waste container lid pops open. If your pharmacy bar codes medications and you can make the capital investment, this is the simplest option to manage over time. The second option is for pharmacy to incorporate waste messages into their dispensing software, so that the drug labels include instructions for waste disposal, such as "black bin" or "blue bin." Third, pharmacy can manually sticker each medication to alert nursing to special disposal needs. This method can be employed relatively easily by any hospital.

The second model is centralized segregation, by which a facility puts all of its drug waste into hazardous waste containers around the facility. The contents of those waste containers are then sorted in a central storage area. It's messier than the first model, but it is easier to implement; you don't have to train personnel on handling each type of hazardous waste. However, the cost of paying a hazardous waste broker to segregate your waste can be high. Many hospitals under intense pressure to comply with regulations are using the centralized model as an interim step, while they work towards segregating their waste at the point of generation.

The last method is the easiest but the most expensive: managing all drug waste as hazardous waste. This model only makes sense in a small hospital that does not generate a great deal of waste anyway.

Q: What specific waste management duties are pharmacists responsible for?

A: That is not a trivial question, because waste management is a multi-disciplinary duty. Pharmacy probably will bear the brunt of identifying the drugs that qualify as hazardous waste and of segregating the items that become hazardous waste in the pharmacy, but nursing, environmental services, and safety also play a very important role. Pharmacy will also be involved in labeling hazardous drugs in a manner that will help the nursing staff identify them.

Q: Should one person from the pharmacy department spearhead the waste management program?

A: I think one person each from pharmacy, nursing, environmental services, and safety should be appointed to a task force for waste management. There should be a pharmacy champion for the program, and that person should read "Managing Pharmaceutical Waste: A 10-Step Blueprint for Healthcare Facilities in the United States," which is available for download at www.h2e-online.org.

Q: How can hospitals ensure that employees are adhering to its waste management guidelines?

A: It's extremely important to get nursing involved immediately, because nurses spend a lot of time and effort dealing with pharmaceutical waste. Pilot the program in a number of units in which the nurses are interested in the program, and work out the bugs there. Develop a well-defined rollout schedule and a just-in-time training program, for all three shifts, so everyone knows what to do. Waste management procedures should also be part of new employee training. Once the system is in place, perform random spot checks and waste-stream audits just to see how people are doing, and of course, consistently reinforce the importance of adherence.

Q: How can pharmacists stay up to date with the regulations?

WHERE TO FIND PRODUCTS AND SERVICES:

Vendor	Reader Service#
Attentus Medical Sales, Inc.	36
Clean Harbors Environmental Services	44
Hospitec, Inc.	55
Kendall Co.	48
Stericycle Inc.	30
Strong Pharmaceutical Services	49
Veolia Environment (formerly Onyx)	43
Vestara	45

WEB RESOURCES:

EPA Enforcement & Compliance History Online: www.epa.gov/echo

Hospitals for a Healthy Environment: www.h2e-online.com

Our Stolen Future: www.ourstolenfuture.org

PharmEcology Associates, LLC: www.pharmecology.com

Pharmwaste Listserv: http://lists.dep.state.fl.us/cgi-bin/mailman/listinfo/pharmwaste

RCRA Online: www.epa.gov/rcraonline

A: Appoint a staff member to connect with your state regulatory group to find out if they offer a technical assistance program. In some states, technical assistance is offered by the investigating authority, but in a non- threatening, non-reporting manner. They inspect your facility, and provide instruction for improving your waste management program. In six months, they will probably come back to inspect your progress again, at which time they will most likely be in more of an enforcement mode. So that is one way to keep abreast of state regulations, which are changing rapidly.

Q: Are health systems sufficiently aware of their waste management responsibilities?

A: This is still a pioneer effort in most facilities. The RCRA regulation was passed in 1976; it's not new. However, the EPA has recently begun focusing more attention on hospitals as generators of hazardous waste. So now we have to step up to the plate. On the other hand, the language in RCRA is often not logical in its application to final pharmaceutical dosage forms. So the EPA needs to hear from constituencies such as the AHA and the ASHP about the discrepancies in the regulation. There are definitely areas in which the regulation could be more rational and more specific to waste pharmaceuticals – not just chemical compounds – but more people have to speak up and raise their concerns to the EPA on the national level. ■

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