



A Dose of His Own Medicine

SAFETY IN THE HOSPITAL PHARMACY

By Ron Stoker

We are all excited when we watch a movie or read a book in which the villain ends up getting his just rewards. We often refer to this as he is getting "a dose of his own medicine." It is important, however, that those who are providing our pharmaceutical needs in hospitals are not exposed to the drugs that they dispense for our benefit. Hospital pharmacies have traditionally been "safe harbors" against contaminated needles because relatively few patients are actually treated in the pharmacy. Pharmacists are subjected, however, to a variety of occupational injuries and exposures. Many of the procedures that pharmacies are

involved in can potentially result in personal and environmental contamination. Some of these injuries include accidental needlesticks, broken glass from ampoules, and the exposure to a wide variety of toxic drugs including monoclonal antibodies, immunosuppressive drugs, antibiotics, antivirals, and antineoplastic therapies (cancer chemotherapeutics).

The proper use of safety products can protect hospital employees and others from these potential injuries. This article will discuss some of the safety products that can be used in hospital pharmacies to reduce the risk of accidental sharps injuries and the unnecessary exposure to blood and toxic medications.

Glass Ampoule Openers

Many medications come prepared in glass ampoules. Ampoules are small glass vessels in which liquids for injections are hermetically sealed. A typical pharmaceutical ampoule has a narrow neck between a cylindrical body and a conical tip. Ampoules are opened by snapping off the glass top at the neck. The scoring at the neck does not always break where it is intended. This is due to the glass re-melting to some degree at the score line.

When the cap is snapped off, glass chips can fly off and a jagged or sharp edge can cut the hands of the healthcare worker. Some of the medication has to be discarded because of glass shards. In the past, healthcare workers would try to work around this problem by wrapping the glass with a towel or gauze, holding the vial upright and snapping it open at the score line. This procedure was not always successful. Safer products exist that remove the risk of broken glass cuts when breaking off the top of the glass ampoule. Examples of these products include the following:

- ▶ SafeBreak™ from MediDose Inc. - EPS Inc. The SafeBreak™ is a disposal plastic fracture and safety collar. No glass filing of the ampoule is required. The use of gauze pads to protect hands becomes unnecessary as the ampoule is contained during the time of opening. The clinician simply swabs the ampoule head and fits the Safebreak™ snugly over the ampoule. The Safebreak™ Safety Collar is used to snap the "head" off of the glass ampoule. The ampoule and the Safebreak™ Safety Collar are disposed to prevent contamination. For more information, visit <http://www.medidose.com/catalog/ivpharm/index.html>
- ▶ Disposable Ampoule Breaker from Androus; <http://www.androusa.com/>
- ▶ Ampoule Breaker from Daniels; <http://www.daniels.co.uk/pages/productsearch/ampoule/mainframeampoule.htm>
- ▶ Med Star 2000 Ampoule Opener; <http://www.medstar2000.ws/index.htm>
- ▶ Ampoule Neck Breaker from SPI Laboratories; <http://www.2spi.com/catalog/tools/smtol21.shtml>
- ▶ CLIC-OPEN Ampoule Opener from Sepha; <http://www.sepha.com/cl.htm>

Reconstitution Devices

Many medications have been lyophilized and require reconstitution. In addition, a number of medicants must be diluted into additional fluids. This has been done in the past by the use of a needle and a syringe. Newer methods are available that can remove that additional needle.

Dispensing-Spike II Reconstitution Device From MediDose Inc.—EPS Inc

The Dispensing-Spike II Reconstitution Device is designed for medication from multiple-dose IV vials, while providing

sterile air filtration. It features a large, 0.2-micron hydrophobic air filter to trap aerosoled meds and minimize blowback. The streamlined construction creates short venting and fluid pathways, and the sharp, thin, piercing spike minimizes coring and permits easy penetration of rubber stoppered vials. The luer lock port design maintains a secure closure between the device and the syringe, while the hinged cap and easy-gripping.

Additional reconstitution products include:

- ▶ Bioset Infusion and Bioset Injection Sets from Baxter; <http://www.bio-set.com/htm/Choice.htm>
- ▶ BD Monovial™ Luer AXs Dry Drug Reconstitution System; <http://www.bd.com/pharmaceuticals/>

Pre-Filled Syringes

The use of prefilled syringes has been growing at a rate of about 20% a year for at least five years. This is expected to continue for the foreseeable future. There is a great benefit to using prefilled syringes instead of the traditional method of aspirating medication from a vial and then injecting it. Several steps are required to reconstitute a drug if it is lyophilized, which also requires the use of a sharp needle. Prefilled syringes are available right off of the shelf and contain the exact deliverable dose. A number of companies have prefilled syringes.

Some examples include the following:

- ▶ Pre-filled Saline Flush Syringes from B. Braun Medical Inc.; <http://www.bbraunusa.com/>
- ▶ Prefill Flush Syringe from Tyco Kendall Healthcare; <http://www.kendallhq.com/>
- ▶ Carpuject Therapeutic Medications Prefilled Syringes with Luer Tip from Abbott Laboratories; <http://abbott.com/>
- ▶ Abbott Ansyr® Emergency Syringe System from Abbott Laboratories; <http://abbott.com/>
- ▶ LifeShield® Abboject® Syringes Features and Benefits from Abbott Laboratories; <http://abbott.com/>
- ▶ LuproLok™ Safety Pre-filled Syringe from TAP Pharmaceutical; <http://www.tap.com/>
- ▶ Safety Tip-Lok (prefilled Tip-Lok® syringes packed with BD SafetyGlide™ Needles for pediatric doses of Havrix® (Hepatitis A Vaccine, Inactivated) and Engerix-B® [Hepatitis B Vaccine (Recombinant)]) from GlaxoSmithKline; <http://www.gsk.com/>
- ▶ BD Hypak™ Glass Pre-filled Syringe compatible with BD SafetyGlide™ Needle from Becton Dickinson; <http://www.bd.com/>
- ▶ BD Monovial™ Luer AXs Dry Drug Reconstitution System
- ▶ BD Sterifill™ Plastic Pre-Fillable Syringe System (Compatible with BD SafetyGlide™ Needles)
- ▶ BD PosiFlush™ Pre-filled syringes

Exposure to Toxic Medications

An important part of treatment for cancer patients is the use of antineoplastic agents. Unfortunately, these agents have been associated with potential adverse health effects for the individuals who prepare, administer, and dispose of these medications. This is a major concern because there are more cancer patients than in the past, greater combinations of chemotherapeutic drugs are being used, more potent drugs are being used, and new procedures and settings have now been implemented. Oftentimes the drugs used for chemotherapy have a similar structure or activity known to hazardous drugs. Many of these drugs are carcinogenic, teratogenic, and can create reproductive and organ toxicity.

Healthcare workers exposed most frequently to these antineoplastic drugs are primarily pharmacists, pharmacy technicians, oncology nurses, physicians, operating room personnel, and housekeeping and laundry personnel. This group typically prepares drugs, administers them to patients and takes care of waste handling.

Most antineoplastic drugs are delivered to the pharmacy either as a powder or in solution. The powder is dissolved in a vial and loaded into syringes or infusion bags, ready to be administered to the patient. Oncology nurses will administer the drug to the patient and discard the waste products appropriately. The problem with this scenario is that cytotoxic drugs leak from these types of devices during the preparation, administration and waste handling of these drugs.

Pharmacy staff is used to preparing these materials while working in safety cabinets. They wear gloves and gowns. However, the evidence from a variety of studies have shown that cytotoxic drugs vaporize at room temperature; therefore, safety cabinets cannot protect the personnel from the dangerous vapor that is emitted. The drugs have also been found under gloves and gowns. Contamination of many of these products on the outside of the glove can penetrate through the latex and vinyl.

Several studies have shown contamination by these cytotoxic drugs on working trays, on floors, on vials and on the outside surfaces of safety cabinets. Contamination has even been found on floors outside of the preparation room. Of course, the most disturbing discovery is that cytotoxic drugs are frequently found in the urine of personnel who prepare and administer them—and even among personnel who are not even in contact with the vials. This is a major problem because healthcare workers can be exposed to several drugs during the course of the workday. The long-term cumulative effect of the exposure to several chemotherapeutic drugs over long periods of time has not yet been quantified. We should, however, eliminate or reduce the exposure to hazardous drugs whenever it is possible.

One method to reduce this long-term exposure is the use of a new product. PhaSeal[®], manufactured by Carma Pharma and distributed by Baxa Corporation, provides a solution to this contamination issue. PhaSeal[®] (See Figure 4) is a sealed and needleless system that is used for the preparation, administration and waste handling of antineoplastics and other toxic drugs.



Figure 4

The PhaSeal[®] is a double-membraned system that creates leak-free transfer of high-potency drugs. It seals off each element of the system through the use of membrane covers. The transfer of the medication is made through a specially cut injection cannula. The membranes act as tight seals preventing leakage of any material. (See Figure 5) The cytotoxic drugs have no contact with the atmosphere and all connections are kept dry. There is *no* exposure to the cytotoxic materials that pass through the PhaSeal[®].



Figure 5

Testing of the PhaSeal Product

The PhaSeal product was tested in a head-to-head test with current methods of mixing and preparing these types of products. The tests were conducted using a fluorescein powder. (Fluorescein emits a bright green light when exposed to UV lighting.) The fluorescein powder was treated as the cytotoxic drug and was tested in both current products and with the PhaSeal product. The fluorescein was reconstituted, removed from the vial, transferred to an IV bag, and then a drug administration and an IV push were simulated with the fluorescein fluid. Each activity was repeated up to 20 times. The results of the tests were very interesting.

Each of the procedures that used a standard needle and syringe resulted in some level of environmental contamination (See Figure 6). The leaks came from each of the various steps of the simulated procedure. Some of the largest leaks resulted from the withdrawal of the needle from an over pressurized vial. Even the removal of a needle from the IV bag resulted in the formation of a drop of fluorescein solution on the port and drops that fell onto the drape.



The PhaSeal system was put through similar paces and then was repeated many times with up to 75 manipulations of the product. Even with this abuse of the product, the PhaSeal system did not create even a single fluorescein drop on equipment, gloves, or drapes during or following the procedure (See Figure 7).



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The use of the standard needle/syringe technique for the preparation of antineoplastic and other hazardous drugs has the potential to release drug solutions into the work environment. All phases of drug preparation and the administration using standard equipment resulted in the leakage of the fluorescein solution and contamination of equipment and work surfaces.

The experiments showed that the PhaSeal[®] successfully contained toxic drugs and reduced the level of environmental contamination. The PhaSeal should be implemented as a standard technique for the preparation of all toxic drugs.

Conclusion

Over the last few years serious shortages of nurses, pharmacists and physicians have started to pose a threat to patient safety. There has been a mass exodus of these professionals just at the time when the baby boomer generation is aging and requiring more from the healthcare system. The needs are outstripping the care and services that our health practitioners can safely supply.

Dramatic shortages of pharmacists have left vacancies in community pharmacies, public and private hospitals and federal facilities. It is important, therefore, to protect and give our pharmacists support in the prevention of injuries and exposure to toxic materials. They should not have to receive "a taste of their own medicine." +

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