



THE HEALTH CARE IMPROVEMENT FOUNDATION
Building Partnerships For Better Health Care

THOMAS JEFFERSON UNIVERSITY HOSPITAL

Pharmaceutical Waste Management

Pharmaceutical waste management is an ever-changing and challenging task that must be mastered. The damage to the environment, the potential harm to ourselves, and the growing liability associated with pharmaceutical waste disposal is on everyone's radar. The EPA has stepped up enforcement of the RCRA act of 1976 as well as other environmental regulations. The Department of Transportation has also increased its regulation of the transportation of pharmaceutical waste. There are substantial fines associated with many of these violations. In addition, the Joint Commission has recently included four standards that could affect hospital accreditation.

The following are questions to consider for proper handling of pharmaceutical waste. Are expired or discarded oral medications thrown into the regular trash? Do the expired IV medications go down the sink? If the answer is "yes" to either of these questions, drinking water is being polluted, and ground water is being contaminated indefinitely. More and more studies show the impact of years of dumping pharmaceuticals into the environment and the significant damaging effects it has had on the animal population. New studies are being conducted yearly on the harmful effects of pharmaceutical waste on the human population.

Recently, the EPA has stepped up enforcement of the Resource Conservation and Recovery Act of 1976 (RCRA). This legislation was always thought to apply to industry and the big pharmaceutical companies, but, as many hospitals have found out in the way of fines, it also applies to the healthcare industry. Below is a list of the common EPA or DOT violations for which hospitals have been cited:

Common EPA Inspection Violations

- Improper disposal of chemotherapy agents
- Improper management of expired medication
- Pouring hazardous waste down the drain
- Incorrect labeling or no labeling of hazardous waste
- Hazardous waste determinations done incorrectly or not at all
- Inadequate training for employees in hazardous waste management
- No or inadequate hazardous waste manifests
- Not conducting weekly inspections of hazardous waste storage
- Lack of an emergency contingency plan

Source: "Identification and Management of Regulated Hazardous Waste," John Gorman, Chief of Compliance Assistance, EPA Region 2; "EPA Enforcement & Compliance History Online (ECHO)", http://www.epa-echo.gov/echo/compliance_report_rcra.html.

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Thomas Jefferson University Hospital (TJUH) undertook a pilot to evaluate and implement an effective pharmaceutical waste management program and summarizes the key steps of its journey as follows:

Getting Started

It is critical to solicit a group of leaders in the organization who have a passion for protecting the environment. This group will be the liaison to upper management, whose support is imperative. It will also be the liaison to the whole organization to convey the environmental impact and potential liability of improperly disposed pharmaceuticals. The following departments at Jefferson had champions who participated in the group and advocated responsible pharmaceutical waste collection:

- Pharmacy
- Nursing
- Nursing Education
- Infection Control
- Information Systems
- Environmental Safety and Health
- Environmental Services
- Risk Management
- Facilities Management

Members from these departments played a significant role in obtaining “buy-in” from the staff as well as continued reinforcement of the program once it was up and running. All members made a commitment from the start to protect the environment, themselves, and future generations from a polluted earth.

Selection and Assessment

The pharmaceutical work group’s first task was to determine which pharmaceuticals were hazardous and if disposal could be managed in-house. In addition, they researched vendors that had programs in place and invited several to make presentations to the group. The group considered many established medical waste companies as well as more specialized companies that offered alternative methods for collection, such as a machine similar to a Pyxis™ or Omnicell™ that uses bar code technology to assist in waste identification.

It was determined that the potential cost and risk of one or several existing employees performing the job was equal to or greater than outsourcing. The work group also concluded that the smaller companies did not have the appropriate infrastructure to support TJUH’s needs. In addition, the machine type technology was limited to certain computer systems as well as being cost-prohibitive, except perhaps for offsite areas. After many presentations, the group decided to contract with a large medical waste company.

The pharmaceutical work group also looked at the cost of a waste characterization. A waste characterization segregates formulary by EPA and DOT waste streams. It also identifies the compatibility of hazardous and non-hazardous pharmaceuticals based on chemical content. The interviewed companies providing this service tended to be similar in upfront costs, but the smaller companies had higher monthly service fees. It was decided to utilize the same company that was contracted for collection and disposal of TJUH pharmaceutical waste since it had the lowest monthly service fees. These fees include continual updates to the waste characterization, initial training for employees, and new employee training.

Reverse Distributers

Reverse distributers give partial credit for expired pharmaceuticals returned in the manufacturers' original packaging. This effectively offsets a small portion of the cost of expired pharmaceutical disposal. TJUH was issued credits totaling \$10,000 for the first six months of the pilot program. This practice also saves on disposal fees, as less weight has to be processed by the pharmaceutical waste vendor. TJUH uses a reverse distributor not associated with its medical waste contractor.

Identification and Information Systems

Once the waste characterization was complete, it was necessary to evaluate the hospital's formulary for the volume of waste generated from hazardous medications. This shows the true cost of a disposal system, since the disposal cost of hazardous pharmaceuticals is much greater per volume than non-hazardous pharmaceuticals. Various sorting procedures were evaluated, since more sorting increases labor cost. The following is a summary of TJUH's formulary characterization:

1.	Compatible Non-Hazardous	96 % of formulary
2.	Compatible Hazardous	2% of formulary
3.	Non-Compatible Hazardous	Oxidizers 0.7 % of formulary
		Corrosives 0.8 % of formulary
4.	Dual Waste (Hazardous and Infectious)	0.5% of formulary

Based on the formulary characterization, TJUH chose to collect pharmaceuticals in five containers. Two of the containers were placed on the floors at every nursing station and one at a designated soiled utility room on each floor. The other two are used for Non-Compatibles and were placed in the hospital storeroom due to low accumulation.

Once the bin collection system was determined, it was necessary to identify a symbol or a code easily recognized and not confusing to ensure disposal in the proper bin. As this relates to the level of compliance of the staff, it was one of the most important decisions for the program at TJUH. An information systems pharmacist worked with the hospital's Information Systems Department to create an area on the medication labels that would stand out and would not interfere with existing information. Following is a summary of the color-coded bin system established, with examples from the corresponding color-coded labeling system:

Blue Bin (nursing units on floor)	=	Compatible Non-Hazardous
Black Bin (nursing units on floor)	=	Compatible Hazardous
Purple Bin (on floor limited areas)	=	Hazardous and Infectious
Black Bin (remote area/OR)	=	Oxidizers
Black Bin (remote area/OR)	=	Corrosives

Example #1 shows the label design.

The box in the lower right corner shows the designation **B**, which indicates "**Black Bin Disposal**," which is for **Compatible Hazardous Waste**.

Example #1 Label

TJUH DEPARTMENT OF PHARMACY	01/01/09	2:34 p
DOE, John		RMBD: 3200P
DOB: 01/01/09		ACCT#: 123456789
MR#: 12345678		ORD#: 011
WARFARIN 1 MG TABLET		
Equivalent to : COUMADIN		
1	MGS	/
ROUTE : PO		
TODAY : 01/01/09 2:34 p		
EXPIRES:		

TJUH DEPARTMENT OF PHARMACY	01/01/09	2:34 p
DOE, John		RMBD: 3200P
DOB: 01/01/09		ACCT#: 123456789
MR#: 12345678		ORD#: 011
WARFARIN 1 MG TABLET		
Equivalent to : COUMADIN		
1	MGS	/
ROUTE : PO		
TODAY : 01/01/09 2:34 p		
EXPIRES:		

Example #2 below shows a “Blank Box”, which indicates “Blue **Bin Disposal**,” which is for **Compatible Non-Hazardous Waste**.

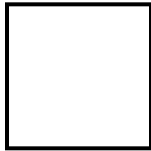
Examples #1 and #2 represent approximately 98% of TJUH’s formulary. The waste exemplified in **Examples #3 and #4**, below, was already collected through existing procedures, so the lettering system was used for reinforcement of that policy.

Example # 3 shows the letter **R**, which indicates “**Red Bag Disposal**” for blood products, including wasted Albumin, Hemophilic factors, IVIG, etc. At TJUH’s facility, red bags are in every room.

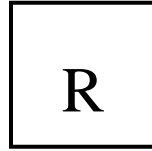
Example # 4 shows the letter **Y**, which indicates “**Chemotherapy**,” which is a reminder for Nursing to follow existing chemotherapy policies for trace and bulk chemo. (Bulk Chemo is > 3% weight to volume). At TJUH, chemotherapy is centralized for administration in a few specific areas.

Example # 5 shows the letter **S**, which indicates “**Send Back to Pharmacy.**” Once at the Pharmacy, it indicates “**Send to the Store Room,**” where it is deposited in the **Oxidizers and Corrosives** collection bins.

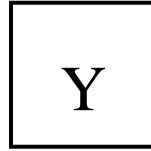
Example #2



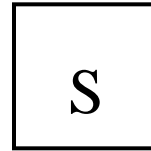
Example #3



Example #4



Example # 5



Electronic Dispensing Cabinets

It is important to flag certain items dispensed from an electronic dispensing cabinet (e.g., Pyxis™, Omnicell™, Accudose™, etc.) that might not have labels. Adding reminders is vital, and TJUH has two. The first is a formulary category added to its Pyxis™ machines that indicates when a medication has special disposal requirements when selected for removal. The second indicator is a “significance column” on the electronic medication administration record (MAR). This alerts staff when recording an administered medication that there will be special disposal requirements for waste. Both of these visual prompts help to increase compliance and are highlighted during staff education.

Education and Strategy

Prior to implementation of TJUH’s program, pertinent clinical staff was surveyed to gauge the level of knowledge and the degree of program acceptance. Through this questioning, they determined the best area of the hospital to start the program. It was important for the pilot areas to be successful, and therefore, two particular areas were chosen. An ICU unit was chosen because of the large quantity of drugs and the types of intravenous drips routinely administered. A second area, a non-acute unit, was chosen because it was challenged for space. Both of these units also offered significant program support from staff. A successful program in these conditions would enable a smoother transition on the remaining patient floors.

The unit-specific training for the staff was provided by the vendor. The managers for each discipline and key people identified by nursing education were the first to receive training so that education could be tailored to their areas of need. The training covered all shifts with multiple sessions. An important objective was to put reliable support in place to handle everyday questions before the vendor’s trainers left and before the general staff was trained. A follow-up survey was also developed to quantify the training and to refocus on any deficiencies identified. To assist staff in the learning process, color-keyed information sheets and a binder of all RCRA hazardous waste on the formulary were posted in highly visible areas next to the collection bins on all units. Quick reference color key legends for the bins were also posted in the same area.

The training consisted of:

- Review of current laws and regulations
- Outline of the process
- Review of training materials
- Individual responsibilities and the hospital's expectations
- Contact info for key people and services

It is mandatory that anyone who will potentially handle hazardous waste receives training. TJUH plans to incorporate pharmaceutical waste management training into new employee orientation and all respective employees' yearly competencies.

The Collection Process

The type and color of collection containers will depend on the health system's configuration. On TJUH's nursing units, there are eight-gallon reusable blue Compatible Non-Hazardous containers with foot pedals. In the pharmacies, which are big waste generators, they use 17-gallon reusable blue Compatible Non-Hazardous containers on wheels because of the weight, which can be upwards of 70 lbs. Throughout the institution, TJUH uses a two-gallon reusable black wall-mounted container for Compatible Hazardous pharmaceuticals. The purple Hazardous Infectious bins are in various soiled utility rooms throughout the patient floors and are not reusable. They are most frequently used in OR settings. The black bins for Oxidizers and Corrosives are located in a central accumulation area for the patient floors. These are not used with any frequency on the patient floors and are not reusable. The main use for these containers is OR settings, depending on the formulary.

A few specific processes warrant notation:

1. **All Salts, Sugars and Electrolytes CAN go down the drain.** Examples are D5W, D51/2NSS, D51/2NSS w 20mEq K, NSS, etc.
2. **What to do with primed IV lines:** The implementation process requires plastic zip lock bags at collection sites of removal of IV bags with primed lines still attached. Staff needs to place the IV, including the primed line, in the zip-lock bag and seal the bag before disposal. (A foot pedal helps.) This is extremely important, as any free-flowing liquid in the collection bins is unidentifiable and must be considered the highest level of hazard.
3. **What to do with the P-Listed medication:** P-Listed medications are always hazardous no matter how they are altered. For example, they cannot be diluted enough to become Non-Hazardous. **These medications require that the wrappers, vials, and anything that is in contact with the medication be handled as Hazardous waste.** Warfarin and Nicotine are two medications that present a challenge for collection of the wrappers. TJUH dispenses these two medications in single bags so the wrappers go in the plastic bag prior to disposal. If these medications are in an electronic dispensing cabinet, they can be labeled with a black sticker as a reminder. Also, the screen upon removal from the cabinet should alert the staff member. (Note: this regulation was intended for industry, and there is pending legislation to repeal for the clinical setting).

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For effective collection of full bins, it is important to set regular collections for workable defined periods based on the fill rate, which could be once a week or once a day. There also needs to be a system in place for collection of bins that fill up off-hours or in excessive volumes.

Environmental Services generally takes care of this issue when the vendor is not on-site and is designated in the initial training as a back-up to the regularly scheduled vendor pickups.

Normally, the bins are collected and replaced by the medical waste vendor and taken to a sorting room or designated area. There are special requirements for this area, according to volume collected and occupational safety requirements. At TJUH, a minimum area of approximately 300 sq.ft. for 800 patient beds is needed. Finding space can be the rate-limiting step at any system.

Table #1 represents the volume of pharmaceutical waste collected the first six months in TJUH's pilot area, which covered 150 patient beds and all the inpatient pharmacies. The inpatient pharmacies generate as large a volume of pharmaceutical waste as the operating rooms. **Based on pilot data, it is expected that Thomas Jefferson University Hospital will collect approximately 70,000 pounds (35 tons) of pharmaceutical waste in the first year.** The EPA's recommendation is to incinerate all pharmaceutical waste.

Table # 1

Thomas Jefferson University Hospital-Pharmaceutical Waste Program Pilot Area -150 Patients Plus Pharmacy			
TOTALS	Total Rx	Non-RCRA Hazardous Rx	RCRA Hazardous Rx
Month/Year	Waste Weight (lbs.)	Waste Weight (lbs.)	Waste Weight (lbs.)
January-09	1,805	1,750	55
February-09	2,050	1,968	82
March-09	2,870	2,741	129
April-09	2,695	2,593	102
May-09	1,935	1,874	61
June-09	<u>2,180</u>	<u>2,110</u>	<u>70</u>
TOTALS	13,535	13,036	499

Summary

The Pharmaceutical Work Group at Thomas Jefferson University Hospital has summarized its best practices of pharmaceutical waste management in the ten most important components listed below:

The TJUH Pharmaceutical Work Group's Top Ten List:

1. **GOAL:** Help keep the environment clean.
2. **Team Building:** Solicit Champions from specific disciplines.
3. **Understanding the Laws and Regulations:** As applicable to pharmaceutical waste
4. **Assessment of the Facility:** Liability, Hazardous Collection Area, Space Constraints
5. **Waste Characterization:** Formulary, Waste Codes & Bin Colors
6. **Reverse Distributers:** Expired Medications, Credits, Repackaged Medication
7. **Information Systems:** Labels, Reminders, Electronic Dispensing Cabinets
8. **Education:** Training, Surveys, Follow-up, Yearly Competencies
9. **Collection Process:** Timely, Back-up Plan, Sort Data, Re-tooling
10. **Continuous Follow-up:** Yearly Program Evaluations, Continuous Improvements

It is Thomas Jefferson University Hospital's aspiration not only to meet the legal requirements of proper collection and disposal of pharmaceutical waste, but to make a positive impact and mitigate damage to the environment. It wishes to express appreciation to a great group of people who made the transition to proper pharmaceutical waste management a fairly smooth one. This document was composed by a dedicated champion at TJUH who spent relentless hours to ensure the institution's success of proper pharmaceutical waste management. The purpose of sharing these best practices is to educate and assist those who assume the challenge of instituting pharmaceutical collection programs at their respective institutions. Thomas Jefferson University Hospital will continue to take a leadership role in pursuing environmentally friendly policies and practices.