

Review Article

## PHARMACEUTICAL WASTE MANAGEMENT- A REVIEW

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**ABSTRACT**

Since there has been high demand for production of pharmaceuticals with the increase in the population, the utilization as well as the disposal of the pharmaceutical has been linearly increasing. Hence the pharmaceutical disposal is an alarming issue today. Pharmacist has the potential to be on forefront and should educate patients about safe drug disposal. Proper patient counseling on safe medication disposal can make as significant different to public health and environment. The knowledge of method of disposal of unused medicines is equally important as that of consumption medicines.

**Objective:** The articles aims to provides a background, the importance and significance of proper medication disposal, correct method of dispose of unwanted and expired medication.

**Methods:** The enlightenment about methods of proper disposal, precautions to be taken at the time of disposal as well as role of pharmacist in waste disposal.

**Conclusion:** Careful and proper disposal of medication can help to decrease environmental load of drugs.

**KEYWORDS:** Pharmaceutical Waste management, Medication Disposal, Disposal Precautions, Patient education.

**INTRODUCTION**

Waste includes any substance which is discarded after primary use or worthless or of no use. Waste such as sewage sludge, household garbage, packaging items, electronic waste, medical waste, industrial chemicals, garden waste etc, arises from a huge variety of sources. Pharmaceutical wastes do not comprise a single waste stream. These include expired product, dispensed drugs that are unwanted or discontinued and contaminated medications. The waste is discarded into receiving streams, which may pollute lakes, or even intakes of drinking Water Treatment Plants.

During the last 20 years, the active pharmaceutical ingredients (API) and healthcare products have been increased detection in aquatic environment. These compounds enter the environment through various routes. Many APIs being obstinate; these cannot be removed effectively with the help of Waste Water Treatment Plant (WWTP) [1].

Drugs like Atenolol and Carbamazepine are not fully

biodegraded during the treatment processes and thus have an elimination rates below 10% [2, 3]. Powerful antibiotics like Ciprofloxacin have been discharged 45 kgs per day and also like Lomifloxacin, Olfloxacin, Norfloxacin, etc were detected at levels which are toxic even to plants and algae.

In India according to the Central Pollution Control Board, Registered Health Care Facilities generate 4057 tons of waste per day. Pharmaceutical waste is thrown into sink or toilet which is led into sewer waste stream. Most sewage and waste treatment facilities do not take pharmaceutical contaminants into considerations and hence these waste are not biodegraded and eliminated during the treatment.

Pharmaceutical packaging wastes are majorly composed of plastics and metals which are difficult to recycle. Pollution of the environment is also contributed by presence of Polyvinyl chloride (PVC) wastes. These wastes threaten the life of incinerators in which they are treated by generating the dioxin, HCL gas etc [4].

In order to minimize the improper management of waste, proper handling, treatment, disposal and segregation of waste is important and even the quantity of waste generated is equally important. A lesser amount of waste means a lesser burden on waste disposal. Hence, healthcare providers should always try to reduce the waste generation in day-to-day work in the clinics or at the hospitals [5].

To protect environment and community health, the minister of environment and forest has notified (biomedical

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waste management and handling) rules 1998/2000 under

environment protection act 1986.



Fig. 1: Pharmaceutical waste disposal



Fig. 2: Pharmaceutical hazardous waste

### Types of Health Care Wastes:

**1. Communal waste:** Also known as "General health care wastes". It is defined as solid wastes that are not infectious, chemical or radioactive [6,7]. E.g.: cardboard boxes, paper, food waste, glass bottles and plastic.

**2. Biomedical waste:** also known as "Hazardous health care waste" or "Health carerisk waste". It is defined as any solid or liquid waste generated in the diagnosis, treatment of immunization of human beings or animals in research, production or testing of biological material [2,5].



Fig. 3: Waste classification

**3. Infectious waste:** [8] Pathogens such as bacteria, viruses, parasites or fungi are suspected to be present in infectious wastes that cause diseases in hosts when present in ample concentrations. They are further include Microbial cultures, stocks of infectious agents and wastes produced during the procedures carried on infected patients (disposable towels, gowns, aprons, gloves, etc.)

Tissues and instruments that have been used during surgeries and autopsies on patients suffering from infectious diseases.

**4. Pathological waste:** Pathological waste is defined as any recognizable human or animal body part like organs, body parts, human fetus, blood, tissues and body fluids etc.

**5. Sharps:** Wastes which have the capability to injure by piercing and cutting the skin come under this category. For e.g. needles, scalpels, blades, broken glass, endodontic files, reamers etc.

**6. Genotoxic waste:** Genotoxic wastes include items that can induce carcinogenicity, teratogenicity or mutagenicity and usually create severe problems. Such wastes should be disposed

off with ultimate attention and caution. Cytotoxic drugs form a major part of this category (drugs used in the chemotherapy of cancer). Oncology and radiotherapy units are the departments where these drugs are used and their utilization has been increasing day by day.

**7. Chemical waste:** Chemical waste is a waste that is made from harmful chemicals mostly produced by discarded chemicals from diagnosis and experimental work, cleaning, housekeeping and disinfecting procedures.

E.g. Lab reagents, film developers, disinfectants.

**8. Wastes with high content of heavy metals:** The main sources of heavy metals are constituted of garden pesticides, pharmaceuticals, personal healthcare products, mercury wastes from broken clinical equipments, etc. Wastes with heavy metal content are usually highly toxic and leach into soil which contaminates the soil with heavy metals like lead, copper, zinc, etc [9].

**9. Radioactive waste:** The biomedical wastes containing radioactive substances include unwanted solutions of radio nuclides intended for diagnostic or therapeutic use, waste from

spills and decomposition of radioactive spills. This waste is very dangerous and remains this way for not just a few years but for thousands of years.

**10. Pharmaceutical waste:** [9, 21] Pharmaceutical waste is potentially generated through a wide variety of activities of health care facility and not limited to intravenous (IV) preparation, general Pharmaceutical waste may include:

- Expired drugs;
- Patients' discarded personal medications;
- Waste materials containing excess drugs (syringes, IV bags, tubing vials, etc.);
- Waste materials containing chemotherapy drug residues;
- Open containers of drugs that cannot be used;
- Containers that held acute hazardous waste (p-listed) drugs;
- Drugs that are discarded;
- Contaminated garments, absorbents and spill cleanup material.

Pharmaceutical waste is further classified in 3 categories:-

1. Hazardous waste,
2. Non-hazardous waste,
3. Chemo waste.

### 1. Hazardous Wastes:

Wastes that are dangerous or potentially harmful to human health or environment are called as hazardous waste. These can be liquids, solids, gases, or sludge's.

Hazardous wastes are divided into two categories:

- (1) Listed wastes, and
- (2) Characteristic wastes.

Pharmaceutical wastes come under listed wastes since they contain commercial chemical products.

Wastes that are not listed and do not exhibit a characteristic are considered solid waste. Solid wastes should

be discarded according to state and/or local regulations, including regulated medical waste requirement.

The EPA defines four characteristics of hazardous waste:

- Ignitability (D001)
- Corrosivity (D002)
- Reactivity (D003)
- Toxicity (D number specific to the chemical)

**i. Ignitability (D001):** The objective of the ignitability is to identify wastes that either present a fire hazard under routine storage, disposal, and transportation or are capable of exacerbating a fire once it has started. Many of the wastes that pharmacies handle are hazardous because they are ignitable.

**ii. Corrosivity (D002):** Corrosive wastes damage metals or other materials or burn the skin. These liquids have a pH of 2 or lower (or) 12.5 or higher.

Generations of corrosive pharmaceutical wastes are generally limited to compounding chemicals in the pharmacy.

**iii. Reactivity (D003):** Reactive wastes are unstable under "normal" conditions. They can cause explosions, toxic fumes, gases, or vapors when heated, compressed, or mixed with water.

E.g. Clinatext (test tablet to determine sugar in urine).

**iv. Toxicity (Multiple D Codes):** Wastes are toxic if they contain toxic organic chemicals or certain heavy metals such as chromium, lead, mercury, cadmium. Approximately 40 chemicals meet specific leaching 12 concentrations which classify them as toxic. Forty chemicals have been included in "Resource conservation and recovery act (RCRA)" as a concern in a solid waste landfill environment above certain concentrations. Wastes that exceed these concentrations must be managed as hazardous waste [10, 11].



Fig. 4: Pathway of hazardous waste

### 2. Non-Hazardous waste:

Materials in this category are considered to present no significant hazardous properties. It is worth noting, however, that this is not an indication that there are no hazardous components present, only that any such components are below the threshold for causing harm to human health.

Certain medicinal products have no pharmaceutical properties but are still controlled and administered by medical staff (examples include sodium chloride or dextrose solutions). These products may become contaminated, or mixed with other compounds and therefore require assessment for hazardous properties prior to disposal.

### 3. Chemo waste:

Chemo waste is most hazardous waste in the medical field. They are highly toxic and corrosive. They cause damage to natural resources.

They are further classified as trace chemotherapy and bulk chemotherapy waste.

Trace chemotherapy waste usually includes vials, syringes, IV bags, tubing's, gowns, gloves, wipes and other material used during routine cleaning and decontamination of a biological and now qualify as "Resource conservation and recovery act (RCRA)" empty.

Bulk chemotherapy waste includes items that used to contain chemotherapy agents and don't qualify as "RCRA" empty [12].

### Sources of Entry of Pharmaceuticals into Environment: [13-18]

- From low cost pharmaceutical production industries in developing countries such as India and China.
- Improper disposal of unused or expired medicines by consumers who flush them down toilets or pour them into drains.
- Disposal by pharmacist and Hospital discharges
- Leaching from defective landfills
- Sorption of acidic pharmaceuticals to sludge
- Veterinary use as medicine as well as additives to animal food; which is excreted into soil or surface waters
- Household water/sewage, solid garbage mix with drug surplus
- Release from aquaculture which has medicated feed, as well as excretion from the aquaculture
- Disposal of medicated animal carcasses

### Impact of Improper Disposal: [18, 19]

Expired drugs do not pose a serious threat to environment or other living beings but their improper disposal may be hazardous if it leads to contamination of water supplies or local sources used by nearby communities or wildlife. Expired drugs may come into the hands of Scavengers and children if a landfill is insecure. Pilfering from a stockpile of waste drugs or during sorting may result in expired drugs being diverted into the market for resale and misuse. Most of the expired pharmaceuticals are less efficacious and very few of them may develop a different adverse drug reaction profile [17]. Pharmaceuticals and Personal Care Products (PPCP) have been found as pollutant in water and the environment.

Here are some of the examples of the impact of drugs through environment on human beings and animal. Evidence from rodent and fish study suggest that some endocrine-disrupting compounds, including those found in prescribed synthetic hormones, may contribute to tumor formation in humans [20]. A large scale ecological disaster occurred in the Indian subcontinent was dramatic decrease in vulture population where vultures that fed on carcasses of cattle treated with Diclofenac died from renal failure because they were unable to excrete the drug [21, 22]. Abnormal thyroid function, decreased fertility, decreased hatching success and alteration of immune function in birds and demasculinization and feminization of male fish has been linked to exposure to endocrine disrupting chemicals (EDCs) by-products of industrial waste [23, 24].

### Regulatory Bodies that Oversee Pharmaceutical Waste Management:

Environmental Protection Agency (EPA)  
 Department of Transportation (DOT)  
 Drug Enforcement Administration (DEA)  
 Occupational Safety and Health Administration (OSHA)  
 State Environmental Protection Agencies,  
 State Pharmacy Boards,  
 Local Publicly Owned Treatment Works (POTW)

### Methods of Disposal of Pharmaceutical Waste: [25]

#### 1. Incineration:

Incineration is a disposal method in which solid organic wastes are subjected to high temperature, dry oxidation so as to convert them into residue and gaseous products. This process reduces the volume of solid waste to 20-30 % of the original volume. Incineration and other high temperature systems are described as "thermal treatment". It is used to dispose of solid, liquid and gaseous waste. Incineration is not suitable for healthcare wastes such as pressurized gas containers, large amounts of reactive chemical wastes, wastes treated with halogenated chemicals, halogenated plastics such as polyvinyl chloride, wastes with mercury or cadmium (such as broken thermometers, used lead or mercury batteries), or radiographic wastes [26].

#### 2. Autoclaving:

Autoclaving uses saturated steam in direct contact with the waste in a pressure vessel at time sufficient to kill the pathogens. The Biomedical Waste Rules specify the minimum temperature, pressure, and residence time for autoclaves for safe disinfection. Autoclaving is not suitable for human anatomical, animal, chemical, or pharmaceutical waste. Before autoclaving, BMWs require shredding to an acceptable size, an operation that would involve frequent breakdown. Autoclaving produces a waste that can be landfilled with municipal waste [2].

#### 3. Microwaving:

Application of an electromagnetic field over the waste provokes the liquid in the waste to oscillate and heat up, destroying the infectious components by conduction. This technology is effective if the ultraviolet radiation reaches the waste material. Before microwaving, waste requires shredding to an acceptable size and humidification. Microwaving is not suitable for human anatomical, animal, chemical, or pharmaceutical wastes, or for large metal parts. Microwaving produces a waste that can be land filled with municipal waste. This technology requires medium investment and operating costs.

#### 4. Chemical disinfection:

Chemical disinfection is most suitable for treating liquid wastes such as blood, urine, stools, or health care facility sewage. Addition of strong oxidants like chlorine compounds, ammonium salts or phenol compounds kills or inactivates pathogens in the waste. Microbiological cultures, sharps, or shredded solids can also be treated by chemical disinfection. Disinfection efficiency depends on such factors as the type and amount of chemical used, and the extent and duration of contact between the disinfectant and waste. As chemical disinfectants have hazardous (toxic) properties, users should wear protective clothes. Chemical disinfectants should not be discharged to surface waters, and no large quantities should be allowed into sewers.

### 5. Deep burial:

The Biomedical Waste Rules require that human anatomical and animal wastes in cities with population less than 500,000 and in rural areas is disposed of by deep burial. Accordingly, the deep burial site should be prepared by digging a pit of about 2 meters deep in an area that is not prone to flooding or erosion, and the risk to surface water contamination is remote. The pit should be half-filled with the waste, and then covered with lime within 50 cm of the surface, before filling the rest of the pit with soil.

### 6. Secure land filling:

Secure land filling involves disposal of solid wastes at a landfill designed and operated to receive hazardous wastes. The Biomedical Waste Rules require disposal of discarded medicines, solid chemical wastes, and incineration ash in secured landfills.

Disposing of waste in a landfill involves covering the waste, and this remains a common practice in most countries. Landfills were often established in unused quarries, mining voids or borrow pits. A properly designed and well-managed landfill can be a hygienic and relatively inexpensive method of disposing of waste materials.

Another common byproduct of landfills is gas (mostly composed of methane and carbon dioxide), which is produced as organic waste breaks down anaerobically. This gas can create odor problems, kill surface vegetation, and is a greenhouse gas. Design characteristics of a modern landfill include methods to contain leachate such as clay or plastic lining material.

### 7. Waste immobilization: Encapsulation:

The method of encapsulation involves immobilizing the pharmaceutical products in a solid block within a plastic or steel drum which should be cleaned prior to use and should not have contained explosive or hazardous materials previously. These drums are filled up to one-third of their capacity with the waste and the remaining space is filled up with cement or cement lime mixture or bituminous sand. This mixture requires a large quantity of water so that a paste of appropriate liquid consistency should be attained. The drums are then sealed and placed at the base of a landfill and covered with municipal wastes.

### 8. Waste immobilization (Inertization):

This method is a type of encapsulation. This method involves the separation of pharmaceutical products from their packaging materials and then the pharmaceutical products are ground and mixed with cement, lime and water to form a homogenous paste. The paste is then dispersed in an urban waste collection. The paste then solidifies within the municipal solid waste. The process is comparatively inexpensive and do not require any sophisticated instruments or equipments.

### 9. Sewer:

Some liquid pharmaceuticals, e.g. syrups and intravenous (IV) fluids, can be diluted with water and flushed into these sewers in small quantities over a period of time without serious public health or environmental affect. Fast flowing watercourses may likewise be used to flush small quantities of well-diluted liquid pharmaceuticals or antiseptics. The assistance of a hydro geologist or sanitary engineer may be required in situations where sewers are in disrepair or have been war damaged<sup>[27]</sup>.

### Precautions to be taken at the Time of Disposal:<sup>[28, 29]</sup>

- Non-biodegradable antibiotics, anti-neoplastics and disinfectants should not be disposed into the sewage system as they may kill bacteria necessary for the treatment of sewage. Anti-neoplastics should not be flushed into watercourses as they may damage aquatic life or contaminate drinking water. Similarly, large quantities of disinfectants should not be discharged into a sewage system or watercourse. They can be introduced if well diluted.
- Contamination of drinking water must be avoided. Landfills must be sited and constructed in a way that minimizes the possibility of leaching entering a ground water, surface water or drinking water system.
- Burning pharmaceuticals at low temperatures or in open containers results in release of toxic pollutants into the air. Ideally this should be avoided.
- Inefficient and insecure sorting and disposal may allow drugs beyond their expiry date to be diverted for resale to the general public. In some countries scavenging in unprotected insecure landfills is a hazard.
- In the absence of suitable disposal sites and qualified personnel to supervise disposal, unwanted pharmaceuticals present no risk, provided they are securely stored in dry conditions. If stored in their original packing there is a risk of diversion and to avoid this they are best stored in drums with the pharmaceuticals immobilized.

### Reduction of Environmental Pollution by Minimizing the Pharmaceutical Waste:<sup>[13, 25]</sup>

Waste minimization motivates us to reduce the quantity of the generated waste. We cannot completely terminate the waste but we can decrease the toxicity being generated and then we can discard the waste material.

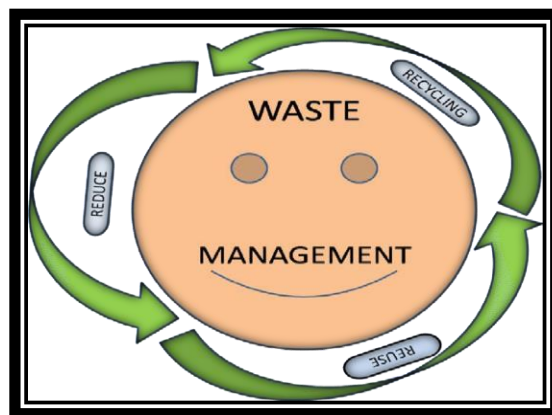


Fig. 5: Cycle showing Reduction of pharmaceutical waste

- **Reduce:** Reduction of the waste which is being generated is an important method of waste management and is known as waste reduction. Methods of prevention include using products again and again if they are reusable, fixing the damaged items instead of buying new, constructing products that can be reusable (such as cotton instead of plastic shopping bags), motivating consumers to avoid using disposable products, removing any food/liquid remains from cans, packaging.
- **Reuse:** Re-use means that the product can be used multiple times, either for the same reason or for a different reason,

without the need for reprocessing. Re-use avoids discarding a material to a waste stream when its initial use has concluded. There are some products which are left as it is so it is our duty not to discard it directly and these products should be sent to

the preferable place for reusing it. Some e.g., returnable plastic pallets, using an empty glass jar for storing items and using second hand clothes. Reuse precedes recycling as it reduces energy and material of earth.



Fig. 6: Recycling waste material

- **Recycling:** Recycling is a process which involves the treatment of substance that can be recycled to its original form or to its intermediate form. It includes recycling of organic wastes but excludes energy recovery. Recycling benefits the environment by reducing the use of raw materials and can be saved for sustainable development. It is said that Recycle today, for better tomorrow.

#### Role of Pharmacist:

Pharmacist is the best person that knows the worthlessness of most medicines. Pharmacist should accept the degree of responsibility for changing the entire medication use process, finding the cure and minimizing the toxic effects of pharmaceuticals on environment. Pharmacist is involved with the entire process of prescribing, advising, dispensing, pharmaceutical care, disposal of expired medicines and ultimately reduction in metabolic waste discharge into the environment. The pharmacist practitioner has the opportunity to influence more rational prescribing that would reduce the amount of leftover medicines. This would decrease potential risks to the environment as well [18, 30].

Being respected, trusted and most accessible drug information resources, pharmacists are in the forefront of tackling issues of prudent drug disposal methods to end users of drugs. All pharmacists should familiarize themselves with their region's drug disposal activities and be able to recommend them to their patients. Continuing education and training at every level is desirable to generate awareness of hazards associated with indiscriminate disposal of unused/expired pharmaceutical products an emerging environmental issue [31].

Pharmacists are the medication experts and the most knowledgeable health care professionals, which can provide valuable education to people on how to dispose the unwanted waste in an effective manner. Drug disposal programs and pharmaceutical collection events serve not only as resources to the community for safely disposing of unused or unwanted medications, but also as platforms for examining the causes of medication waste. Unused or unwanted drugs, accidental overdose, or prescription drug abuse cause a great threat to our society and have the potential to destroy our environment. Pharmacists provide information regarding proper disposal of medicines, drug abuse and several drug-managing programs and can be the part of several NGOs for environment protection. [32-34].

#### CONCLUSION

In today's scenario with the growing life style, the need of pharmaceutical compounds is also increasing and they are with environment in extremely large quantity and the system present is not able to control the untreated or partially pharmaceutical waste. Pharmaceutical waste management continues to be new frontier for health care facilities.

New waste classification is observed which is increasing the complexity of management of waste, so the new techniques of disposal are developing regularly to make surrounding eco-friendly. But one thing we should keep in mind that technique also should be cost-effective with better treatment facilities.

Entering of drugs or any pharmaceutical waste into ecosystem, biotic, abiotic factors and humans causing severe side-effects, so we should sincerely investigate to control them. All the stake holders, government, NGO'S, physician, pharmacists, patient and public should work hand in hand to make more and more awareness to professionals and well as consumers to reduce burden of unused and expired medicine on ecosystem.

As we take care of our mother, environment is also our second mother we should be equally concerned about it as it is the only source of life i.e. power, oxygen, and water. So, "COSUME LESS" "EMIT LESS" "CONSERVES MORE" and protect our environment.

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