



Fate of Improper Drug Disposal and its Impact on Health

Swarnali Das Paul^{1*}, Sacheen Gandhi²

1. Faculty of Pharmaceutical Science, Shri Shankaracharya Group of Institution, Shri Shankaracharya Technical Campus, Bhilai, India.

2. Founder, Social Talks (Drug Disposal Awareness Programme), New Delhi, India.

*Corresponding author's E-mail: swarnali34@gmail.com

Received: 08-06-2020; Revised: 18-08-2020; Accepted: 25-08-2020.

DOI: 10.47583/ijpsrr.2020.v64i01.034

ABSTRACT

As medicines are mostly chemical and once it expires it usually becomes a toxic agent. Therefore United States Food & Drug Administration initiated 'drug take back programme' to prevent the entry of these medication into environment. But in India drug take back programme is not well developed. People are use to dispose medicines by common methods such as burning, flushing into toilet and throwing somewhere or into waste-basket which results in serious environmental and health hazards. In this review we describe methods of drug disposal recommended by WHO, medicines which should be flushed for disposal and their toxic effects, consequences of improper drug disposal and safe guidelines for disposal. An expert opinion has also mentioned at the last for safe disposal of expired or unused medicines at home.

Keywords: Waste pharmaceutical, Environment, Expired drugs, Toxic effects, Landfill, Incineration, Cancer.

INTRODUCTION

Medicines are integral part of health care system. Each and every day millions of people are taking the medicine for numerous purposes. But after recover from the condition people no longer needed them more. Therefore, often we have gathered all those expired, unused or unwanted medicines in our home and trash it eventually. A survey was conducted by Drug disposal awareness programme (DDAP) team, Delhi on 'methods of disposing unused medicines by common people'. The answer was very simple as many of us do that is throwing them into dustbin. Have you ever think that after throwing them into dustbin what is next? From dustbin it goes to dump yard. From the yard it may be goes for burning in open air and pollute the air, some may be eroded in soil and reach to plants/ animals; some of it gets mixed with rain or water stream and reach to fishes and other water animals and humans. So by any of the mechanisms the waste of those medicines again revert back to us in a more harmful form. Several pharmaceuticals have been found in goat, cow, and human milk. The bio-accumulation of pharmaceutical products in aquatic animals, plants, and animals significantly affects the human life in turn. ¹

METHODS OF DRUG DISPOSAL

Throwing into Dustbin is the most common but improper method used by the common people. When the medications are no longer required they will just throw the medications into the dustbin or store in home itself. As the medications are made attractive for better patient compliance, there is a chance of taking these expired or unused medicines by children or pets which may lead to serious toxicity or poisoning condition. Not only this, when these medicines are disposed by means of throwing into waste basket, they will end up with reaching landfills with

other solid waste which will result in serious environmental and health hazards. Different methods of disposal recommend by WHO is discussed here ².

1. Landfill

Landfill means directly place the disposed material under soil at a specific site without prior treatment or preparation. Landfill is the oldest and the most widely practiced method of disposing of solid waste. Three types are there highly engineered sanitary landfill, engineered Landfill, open uncontrolled non –engineered dump.

2. Return to donor or manufacturer

It is not practically possible for common public to dispose the drug safely as per recommend guidelines. Therefore returning of unusable drugs to the manufacturer or authorize person is highly recommended. Drugs with high risk must be processed by this way like antineoplastics. For unwanted, unrequested donations, especially those that arrive past or unreasonably near their expiry date it may be possible to return them to the donor for disposal.

3. Cross-frontier transfer of pharmaceutical waste

There are currently no international conventions regulating transfer of pharmaceutical products across frontiers. However, expired or spoiled pharmaceuticals are considered as hazardous waste and as such, if transferred across frontiers. This involves prescribed procedures to obtain permission to cross international borders along the transit route prior to actual transport. These procedures can take several months to complete.

4. Burning

It is another improper way of disposal of medicine. Chemically, a medicine is either organic or inorganic



compound. Obviously burning of a chemical compound in the nature will result in the release of several chemical pollutants to the atmosphere. It is very dangerous to inhale the air polluted with these contents. The serious problems such as drug toxicity, drug resistance and sudden death due to poisoning condition may arise because of the burning of the medicines. Pharmaceuticals are ideally disposed of by high temperature (i.e. above 1,200°C) incineration. Such incineration facilities, equipped with adequate emission control, are mainly to be found in the industrialized world.

5. Flushing into Sink or Toilet

This method is mainly used for disposal of liquid medicines that are either unused or expired. Flushing a drug into sink or toilet will result in the contamination of water sources. However, the chances of toxicity are comparatively less than that of other two methods because of large quantity of dilution. USFDA says, it is an alternative method to dispose certain medicines (mainly centrally acting) if drug take back system is not available in your area.

Table 1: Different disposal method and their applications as recommend by WHO

S.No.	Disposal Method	Description	Application for Pharmaceutical	Remarks
1.	Return to donor or manufacture	Transfrontier transfer for disposal	All bulk waste pharmaceuticals Particularly antineoplastic	Not practical, time consuming
2.	Incineration	High temperature incineration with temperature greatly in excess of 1200°C	Solids, semisolid powders, antineoplastic, controlled substance	Expensive
		Medium temperature incineration with two – chamber incinerator	solids, semisolids, powders, controlled substance, antineoplastic	Minimum temperature of 850°C
	Immobilization	Water encapsulation	Solid, Semi-solid, powders, liquids, antineoplastic, controlled substance	Can be used by individual person at home or colony or municipality
		Inertization	Solid, Semi-solid, powders, liquids, antineoplastic, controlled substance	
3.	Landfill	Highly engineered sanitary landfill	Limited quantities of untreated solids, semisolid and powder, disposal of water pharmaceuticals after immobilization preferable PVC Plastic	Should be outside to township or highly populated area
		Engineered Landfill		
		Open uncontrolled non –engineered dump	At last report untreated solid, semisolid, powder, must be covered immediately with municipal waste . immobilization of solids, semisolids powders is preferable	Not for untreated controlled substance
4.	Flushing	Sewer	Diluted liquids, syrups, intravenous fluids, small quantities of diluted disinfectants (supervised)	Antineoplastic, and undiluted disinfectants and antiseptics not recommended
		Fast –flowing watercourse	Diluted liquids, syrup, intravenous fluid, small quantities of diluted disinfectant (supervised)	Antineoplastic, and undiluted disinfectants and antiseptics not recommended
5.	Burning at low temperature	Burning in open containers	At last resort, packaging paper, cardboard	Not acceptable for PVC plastic or pharmaceuticals
6.	Chemical treatment	Chemical decomposition	Not recommended unless special	Not practical for quantities

Medicines on this flush list may be especially harmful and, in some cases, fatal with just one dose if they are used by someone other than the person for whom they were prescribed. List of medicines recommended for disposal by flushing are discussed in table 2.

Table 2: List of medicines disposed by flushing as recommended by WHO

Drug Name	Use	Toxic Effect
Benzhydrocodon	Short-term management of acute pain requiring opioid therapy.	Respiratory depression, skeletal muscle flaccidity, cold and clammy skin, constricted pupils, pulmonary edema, bradycardia, hypotension
Acetaminophen	Analgesic, antipyretic	renal tubular necrosis, hypoglycemic coma, and thrombocytopenia
Fentanyl	maintenance, and recovery from general or regional anesthesia, These injections are also used with a neuroleptic for premedication	Respiratory depression, drowsiness, confusion. Drug addiction is another problem.
Diazepam	Anxiety in conditions dominated by tension, acute alcoholic withdrawal	Ataxia, drowsiness, dysarthria, sedation, muscle weakness, profound sleep, hypotension, bradycardia,
Hydromorphone	Moderate to severe pain	respiratory depression, drug dependence, adrenal insufficiency, coma, raised intracranial pressure, seizure, suicidal thoughts,
Meperidine	Moderate to severe pain (postoperative, labor)	Patients can have shallow or no breathing, signs of cyanosis like blue lips or fingernails, fatigue, convulsion, low blood pressure
Methadone	Management of pain, detoxification treatment of opioid addiction	similar effects and risks of other opioids such as morphine, hydromorphone, oxycodone, and fentanyl.
Methylphenidate	treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients more than 6 years of age, narcolepsy	Vomiting, agitation, tremors, hyperreflexia, muscle twitching, convulsions, euphoria, confusion, hallucinations, delirium
Morphine	Management of chronic, moderate to severe pain	Respiratory depression, somnolence, skeletal muscle flaccidity, cold and clammy skin, miosis, and mydriasis
Oxycodone	Treatment of moderate to severe pain	
Oxymorphone	Cough suppressant, moderate to severe pain, including pain in obstetrics.	
Tapentadol	Relief of moderate to severe acute pain, neuropathic pain associated with diabetic peripheral neuropathy	Dizziness, nausea, vomiting, somnolence, and headache.
Sodium Oxybate	Treatment of cataplexy and extreme daytime sleepiness (EDS) associated with narcolepsy	Depressed consciousness, ataxia, coma, emesis, diaphoresis, headache and impaired psychomotor skills

6. Waste immobilization: encapsulation

Encapsulation involves immobilizing the pharmaceuticals in a solid block within a plastic or steel drum. Drums should be cleaned prior to use and should not have contained explosive or hazardous materials previously. They are filled to 75% capacity with solid and semi-solid pharmaceuticals, and the remaining space is filled by pouring in a medium such as cement or cement/lime mixture, plastic foam or bituminous sand. Once the drums are filled to 75% capacity, the mixture of lime, cement and water in the proportions 15:15:5 (by weight) is added and the drum filled to capacity. A larger quantity of water may be required sometimes to attain a satisfactory liquid consistency. Steel drum lids should then be bent back and sealed, ideally by seam or spot welding. The sealed drums should be placed at the base of a landfill and covered with fresh municipal solid waste. However encapsulation of antineoplastic drugs requires a slightly different technique.

Waste immobilization by inertization

Inertization is a variant of encapsulation and involves removing the packaging materials, paper, cardboard and plastic, from the pharmaceuticals. Pills need to be removed from their blister packs. The pharmaceuticals are then ground and a mix of water, cement and lime added to form a homogenous paste. Worker protection in the form of protective clothing and masks is required as there may be a dust hazard. The paste is then transported in the liquid state by concrete mixer truck to a landfill and decanted into the normal urban waste. The paste then sets as a solid mass dispersed within the municipal solid waste. The process is relatively inexpensive and can be carried out with unsophisticated equipment. The main requirements are a grinder or road roller to crush the pharmaceuticals, a concrete mixer, and supplies of cement, lime and water.

7. Chemical decomposition

If an appropriate incinerator is not available, the option of chemical decomposition can be used in accordance with the manufacturer's recommendations, followed by landfill. This method is not recommended unless chemical expertise is readily available. Chemical inactivation is tedious and time consuming, and stocks of the chemicals used in treatment must be made available at all times. For disposal of a small quantity of antineoplastic drugs this method may be practical. However for large quantities, for example, more than 50 kg of antineoplastics, chemical decomposition is not practical, as even small consignments need to be treated through repeated application of this method.

CONSEQUENCES OF IMPROPER DISPOSAL OR NON-DISPOSAL

Most pharmaceuticals past their expiry date become less efficacious and a few may develop a different adverse drug reaction profile. There are some categories of expired drugs or defective disposal practices that carry a public health risk. Improper disposal may be hazardous if it leads to contamination of water supplies or local sources used by nearby communities or wildlife. Flushing down any substance including drugs results in them entering the water supply. Treating water before putting it back into the Public water supply does remove foreign substances, however, they do not process water to remove drugs. The substances become a part of both water and soil, thereby having a negative impact on the environment. Our drinking and household water are part of this very environment³.

1. Drug abuse and poisoning

Expired drugs may come into the hands of scavengers and children if a landfill is insecure or stocking in home and result into accidental poisoning. Each year, more than 60,000 kids ages 5 and under unintentionally take a medicine or overdose on it. Even more alarmingly, studies have found that 95 percent of unintentional medication overdose visits to emergency rooms are caused by a young child who got into medicine while a parent or caregiver wasn't looking⁴. Pilfering from a stockpile of waste drugs or during sorting may result in expired drugs being diverted to the market for resale and misuse. 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.

2. Antimicrobial resistance

Millions of metric tons of antibiotic compounds have been released into the biosphere over the last half-century. Antimicrobial resistance occurs when a microorganism evolves to resist the effects of an antimicrobial agent. Globally about 700,000 people die of resistant infections every year because available antimicrobial drugs have become less effective at killing the resistant pathogens.⁵

Clear evidence shows that antimicrobial compounds from households, hospitals, pharmaceutical facilities and agricultural run-off released into the environment, combined with direct contact between natural bacterial communities and discharged resistant bacteria, is driving bacterial evolution and the emergence of more resistant strains. A major study finds 'excessively high' levels of drug residues in water bodies of Hyderabad allowing microbes to build resistance to medicines^{6,7}. Not only this, a new study by researchers at the Indian Institute of Technology, Delhi found high levels of β -lactam resistant bacteria and genes, particularly carbapenem and extended spectrum β -lactam (ESBL)-resistant bacteria and genes from STPs in Delhi⁸. These two cases indicate that the reason for treatment failure may be improper drug disposal also.

3. Contaminated food

In India, the bacteria resistant to ciprofloxacin have been found downstream of a pharmaceutical factory, genes for antimicrobial multiresistance have been found in drinking water, and multiresistant Salmonella have been identified in water sprayed on vegetables. The epidemic with multiresistant enterohemorrhagic *E. coli* at Europe originated from water-sprayed vegetables.

Additionally, harmful chemicals entered into the food chain through drinking water. About 80% fruits and vegetables in Pakistan are irrigated using waste water and in another study multi-resistant Salmonella was found in the water used on vegetables in India.⁹

4. Cytotoxicity

Medicines for cancer are cytotoxic that means kills the healthy cells along with cancerous cells. Due to improper disposal these drugs may get into our water or food directly or indirectly through plant and other animal resources and can cause cancer, infertility, mental retardation or other severe health issues. Therefore improper disposal is one of the major causes of cancer.

Experimental studies have shown that many antineoplastic drugs are carcinogenic and mutagenic and secondary neoplasia is well documented in literature.^{10,11} A study from Finland observed increased incidence of spontaneous abortions during pregnancy and malformations in children of females with a history of working with anticancer agents.¹²

5. Genotoxicity

It describes the property of chemical agents that damages the gene within a cell and cause mutations, which may lead to cancer or other hazards and can be carried it next generations. Any discharge of genotoxic waste into the environment has disastrous ecological consequences in the form of persistent land, air, and water pollution. According to the documents of the World Health Organization (WHO), about 80% of hospital waste categorized as non-risk waste, while 20% of them is considered as hazardous waste. Genotoxic wastes are a subset of hazardous waste that may have mutagenic, teratogenic or carcinogenic properties.



This kind of wastes include residues of certain cytostatic drugs or vomit, urine and feces from patients treated with cytostatic drugs, chemicals and radioactive material¹³.

6. Impact on animals

The direct impact of medicine to the wild life is responsible for the decline of vulture population in South Asia by diclofenac through cattle.¹⁴ Pharmaceutical products used for humans, animals, and birds have been detected in water bodies. The feminization and demasculisation of male fish are attributed estrogens which are formed as by-products in industries.¹⁵

The tetracyclines and quinolones are not metabolized in the human body and can be toxic to other animals, microorganisms, and fish. In India, several broad-spectrum antibiotics were found in concentrations toxic to microbes, animals, and plants, with enterococci resistant to all known antibiotics. Several pharmaceuticals have been found in goat, cow, and human milk.¹⁵ The bio-accumulation of pharmaceutical products in aquatic animals, plants, and animals significantly affects the human life in turn.

Guideline for safe disposal

- Contamination of drinking water must be avoided. Landfills must be sited and constructed in a way that minimizes the possibility of leachate entering an aquifer, surface water or drinking water system.
- Non-biodegradable antibiotics, antineoplastics and disinfectants should not be disposed of into the sewage system as they may kill bacteria necessary for the treatment of sewage. Antineoplastics 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 sewerage system or watercourse but can be introduced if well diluted.
- Burning pharmaceuticals at low temperatures or in open containers results in release of toxic pollutants into the air. Ideally this should be avoided.
- 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.
- Some liquid pharmaceuticals, e.g. syrups and intravenous (IV) fluids, can be diluted with water and flushed into the 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 hydrogeologist or sanitary engineer may

be required in situations where sewers are in disrepair or have been war damaged.

- Cytotoxic and genotoxic drugs should return to the original supplier or take-back program, incineration at high temperatures, and chemical degradation in accordance with manufacturer's instructions. Full destruction of all cytotoxic substances requires incineration temperatures up to 1200°C and a minimum gas residence time of 2 s in the secondary chamber with gas-cleaning equipment.

EXPERT OPINION FOR SAFE DISPOSAL AT HOME

World Health Organization has mentioned several guidelines for safety disposal like proper land filling, flushing into sink or toilet, high temperature incineration and others. But all these practices are generally feasible for industries or municipalities and not possible for common public to do. Therefore author suggest an easy and effective solution that can be used by common public in their home. This method is originates from WHO recommended immobilization process. The idea is to incorporate those discarded medicines either in its original pack or by unpacking it with cement or ceramic and convert those into solid brick or other structures like flower pot for gardening. After solidifying the medicines with cement it become very hard and non breakable therefore chances to mix in water or air is negligible. With this simple trick people can safely dump the medicines easily in home instead of throwing them into dustbin.

CONCLUSION

Inspite of the safe methods suggested to dispose date expired and unused medicines by WHO fate of these medicines are not proper till date. Moreover these methods are not much effective and not followed by people sincerely. Studies have shown that these methods sometime poses a risk not only to human beings by increasing chances of taking wrong medications, accidental poisoning, adverse drug reactions, drug-drug interactions that increases health burden but also to the environment. In India, the knowledge regarding disposal of date expired and unused medicines is lacking among common people. Awareness programme should be conducted to create awareness among the general population regarding harmful effects of improper drug disposal system. There is a need to educate the people that, a simple and silly mistake (disposing drug improperly) can cause a huge loss (death of lives) and hazardous effects to nature as well as public.

Acknowledgement: Authors are grateful to the whole team of Drug Disposal Awareness Programme, New Delhi, India for their sincere efforts towards public awareness regarding improper drug disposal.

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Source of Support: None declared.

Conflict of Interest: None declared.

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