



Pharmaceutical Waste Management in the Pharmaceutical Industries of Kathmandu, Nepal

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Degree Thesis
Materials Processing Technology
2021

DEGREE THESIS	
Arcada	
Degree Programme:	Materials Processing Technology
Identification number:	22674
Author:	Roshan Chaudhary
Title:	Pharmaceutical Waste Management in the Pharmaceutical Industries of Kathmandu, Nepal
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Commissioned by:	
Abstract:	
<p>With the advancement of science and technology, the pharmaceutical industries have flourished drastically in recent years. However, the domain of pharmaceutical waste management is not in check and hence the improper disposal of pharmaceutical waste like dumping, burning, flushing, landfilling has led to harmful impact in the environment like air and water pollution, change in aquatic ecosystem, destruction of flora and fauna, genetic changes, antimicrobial resistance, etc. The objective of this thesis is to assess the current status of pharmaceutical waste management in Kathmandu, Nepal. A descriptive cross-sectional study was conducted using quota sampling. 5 officials working in different pharmacies and pharmaceutical companies were recruited for the study. Structured questionnaire was developed and used. Descriptive statistics was used. The knowledge and practices of pharmaceutical waste management was overall found acceptable. However, the current practice of pharmaceutical waste management should be regulated to minimize the adverse effects in environment.</p>	
Keywords:	Drugs, Management, Pharmaceutical, Waste
Number of pages:	54
Language:	English
Date of acceptance:	

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Abbreviations

ETP	Effluent Treatment Plant
HCW	Healthcare waste
NGO	Non-Government Organization
R & D	Research and Development
WHO	World Health Organization
WWTPs	Wastewater treatment plants

1 INTRODUCTION

The pharmaceutical industry is an important component of health care systems throughout the world; it is comprised of many public and private organizations that discover, develop, manufacture and market medicines for human and animal health. The pharmaceutical industry is based primarily upon the scientific research and development (R&D) of medicines that prevent or treat diseases and disorders. Drug substances exhibit a wide range of pharmacological activity and toxicological properties.

The aim of this thesis is to assess the current status of pharmaceutical waste management in Kathmandu, Nepal. The objectives of this study are:

- To assess the knowledge regarding pharmaceutical waste management.
- To find out the practices regarding pharmaceutical waste management.
- To find out the level of understanding of the impact of improper pharmaceutical waste management in the environment.
- To explore the factors influencing improper pharmaceutical waste management.

The structure of this thesis includes introduction to the study, literature, research methodology, results, discussion, conclusion and recommendations respectively. Introduction consists of brief background of the thesis and its aim and objectives. Literature consists of concepts in pharmaceutical waste, importance of pharmaceutical waste management and recent studies in pharmaceutical waste management. The succeeding section deals with the research methodology. A descriptive cross-sectional study is used as the research method. After the research methodology, findings have been presented and their discussion has been done along with the conclusion part. Suitable recommendations have been made at the end of the study.

2 CONCEPTS IN PHARMACEUTICAL WASTE

2.1 History of development of pharmaceutical industry

Scientific breakthroughs and legislative initiatives have initiated emergence of large, modern pharmaceutical companies. The milestones in the field of medicine were with mind-blowing discoveries such as insulin and penicillin in the 1920s and 1930s, as it created development of a unique economic sector in the world. The large pharmaceutical companies have mainly originated from Switzerland, Germany, Italy, the United Kingdom, and the United States. Legislative improvements that facilitate the growth of the industry include quality and safety control, appropriate labeling, and separation of prescription from nonprescription drugs. The advancement in pharmaceutical-related sciences, such as in molecular biology, led to fruitful results in the 1950s and 1960s, which were considered the beginning of the golden age in drug discovery. A large number of effective pharmaceuticals were invented and produced in this period including the first oral contraceptives; blood-pressure drugs and heart medications; and psychiatric medications (MAO Inhibitors), chlorpromazine (Thorazine), Haldol (Haloperidol), the tranquilizers, and Valium (diazepam). In the 1970s, cancer treatment became a major focus of drug development.

The need for regulations over pharmaceutical safety was strongly perceived in the 1960s because of the occurrence of certain life-threatening incidents. Among them, the most serious was the use of Thalidomide, which was causing birth defects among many infants. In the 1970s, the industry began to expand and was on its way to becoming a mega-industry. In the mid-1980s, horizontal and vertical integration led to the emergence of large multinational pharmaceutical companies. Strategic partnerships were formed between large pharmaceutical companies and small biotechnology firms. The high-growth scenario experienced a change in the 1980s. Increasingly, the industry was facing barriers in innovation, regulatory pressure, and the need to address global health challenges. There was an urgent need to create effective drugs for HIV/AIDS that could be accessed by a large number of the resource poor populations in developing countries.

Despite the breakthrough in the invention of useful drugs for heart disease that became a major source of profit for pharmaceutical companies at the time, their criticism increased. In the 1990s, with the aid of advancements in science and technology, the industry was growing at a new level and continued the vertical and horizontal integration momentum by involving a larger number of partners in the drug development process. The outlets for pharmaceutical sale increased. The emergence of internet pharmacy during this time affected quality control quite a bit due to which large pharmaceutical industries started developing marketing strategies. The proliferation of new and intractable diseases has rendered this industry even more opportunities than before. Advancement in the sciences, especially in biotechnology and genetics, have produced major breakthroughs in the discovery and making of medicines, such as gene therapy or individualized medicine. Scrutiny and criticism of the industry, targeting such issues as manipulation of pricing, insensitivity to the needs of the developing world, inflating efficacy claims and disease mongering, and lack of innovation, has also intensified. As critics are increasing their scrutiny, linkages between the industry and regulator are exposed to the public. Nevertheless, throughout the history of pharmaceutical development, it is thought the regulatory bodies in developed markets have in general played a positive role overall. (Wang, 2009)

2.2 Pharmaceutical waste

Pharmaceutical waste refers to a variety of expired, unused, spilt and contaminated pharmaceutical products such as drugs, vaccines, and sera that cannot be used anymore and need to be disposed accordingly. Pharmaceutical waste also consists of abandoned items (such as bottles or boxes with residues, gloves, masks, connecting tubing, and drug vials) used in the operation of pharmaceuticals. Just a portion of the active ingredient of a drug is metabolized when it is prescribed prophylactically or in response to an acute or chronic illness. The non-metabolized parent compound as well as its metabolites, reach the natural aquatic environment through waste discharged into receiving streams, potentially polluting recreational lakes or even drinking water treatment intakes. (Muhammed Jaseem, 2017).

The categorization of wastes that came from bio-medical companies are illustrated in the figure below:

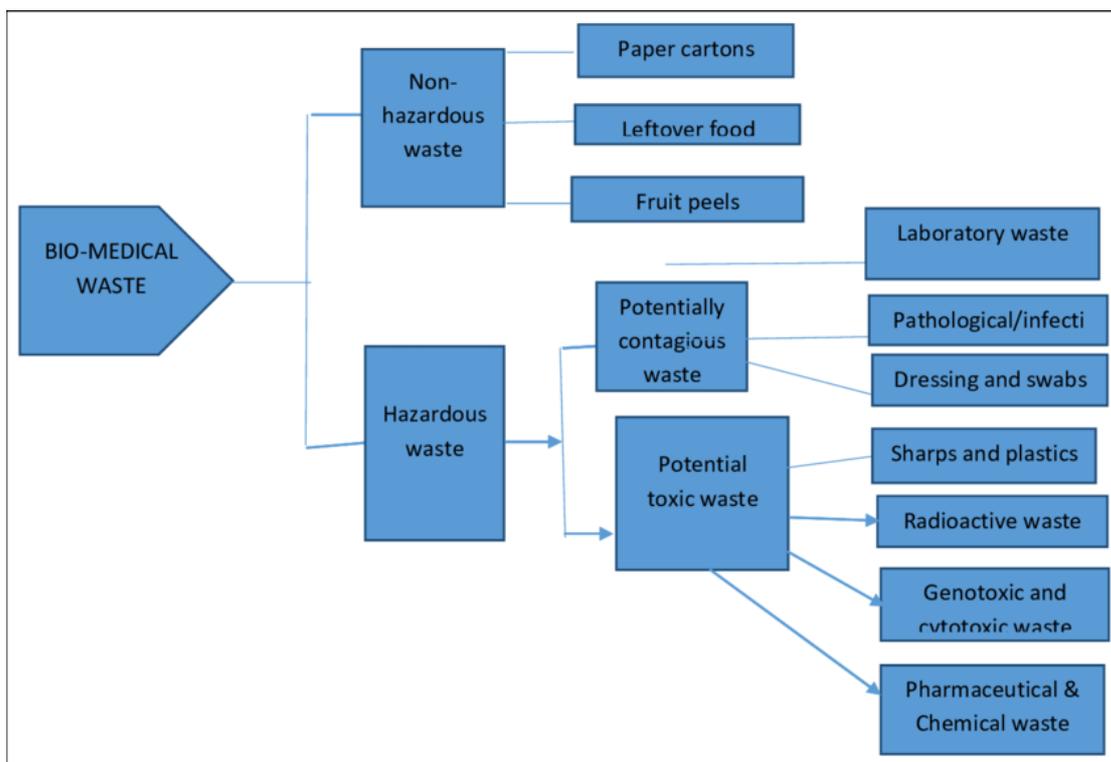


Figure 1. Categorization of wastes that came from bio-medical companies.

2.2.1 Types of pharmaceutical waste

A. Over-the-counter Drug Waste

They are those medications purchased over the counter, the majority of which are bought without a prescription.

If placed in the trash, they contaminate landfills and when flushed, they disrupt the sewage treatment process and the microbial ecology of surface water. Leaving them carelessly could also cause injury, especially if misused by children or other illnesses if misused by adults. (Conserve Energy Future, ei pvm)

B. Non-hazardous Drug Waste

These include non-hazardous or non-controlled prescription medication, such as those used to treat diabetes, bacterial infections, and blood pressure.

They are dangerous if used by anyone other than those to whom they are prescribed or those who do not clinically need them. Despite them being classified as non-hazardous, they still pose a health risk to the environment, they should be sent back to a manufacturer or a medical facility for proper disposal through medical waste incineration. (Conserve Energy Future, ei pvm)

C. Hazardous Drug Waste

It refers to any waste that can potentially result in death or serious illness or such waste that poses significant hazards to human health or the environment if improperly stored, disposed of, transported, or treated. The characteristics of hazardous drug waste are: Ignitability, Corrosivity, Reactivity and Toxicity. (Conserve Energy Future, ei pvm)

D. Controlled Drug Waste

These are the drugs classified to require control as they are highly addictive, can be easily abused or are toxic if accidentally taken in high amounts. In most cases, they are collected in a satellite container onsite, consolidated, audited, packed, and transported before being treated and finally disposed of by a regulated substance disposal company or agency. (Conserve Energy Future, ei pvm)

E. Veterinary Use Pharmaceuticals

These are the drugs and pharmaceuticals given to or sprayed on domestic animals such as dogs, cats, and cattle. (Conserve Energy Future, ei pvm)

F. Agricultural Use Pharmaceuticals

These are the drugs sprayed on crops for the prevention of dangerous crop viruses, insects and other bacteria that would harm crops, either in the field or soon after harvest. (Conserve Energy Future, ei pvm)

2.3 Sources of Pharmaceutical Waste

2.3.1 Wastewater Treatment Plants (WWTPs)

Although these WWTPs focus on stopping waste from reaching the sources of water, they do not entirely remove all pharmaceutical waste in their treatment processes, because of a lack of proper design. (Conserve Energy Future, ei pvm)

2.3.2 Humans and Animals

After consumption of drugs for various purposes, they will have to get out of the body, through excreta and sweat. It means the pharmaceutical waste will be part of our urine and fecal matter, meaning it will eventually find its way into the environment. (Conserve Energy Future, ei pvm)

2.3.3 Pharmaceutical Waste Treatment Plants

They are the last stop and the responsible authority for dealing with pharmaceutical waste. They receive waste from hospitals and other institutions for proper disposal of the waste and they will care for it in the most appropriate way. (Conserve Energy Future, ei pvm)

2.3.4 Unused Drugs

Most prescriptions are taken in but end up remaining because a patient felt better. In the case of treating animals, the same applies and these drugs end up remaining. The most natural way for humans to dispose off these unused drugs is by throwing them away or flushing them. In doing so, they end up in the environment, or in the waterways, contributing to pharmaceutical pollution. (Conserve Energy Future, ei pvm)

2.3.5 Healthcare Institutions

Some hospitals take their unused drugs for disposal to the respective drug manufacturers or pharmaceutical waste treatment plants. However, nursing homes are notorious for

flushing medication down the drain especially if a patient dies or are transferred. (Conserve Energy Future, ei pvm)

2.3.6 Homes and Farms Where Food is Grown

When growing crops either at home or by large farms, they have to be sprayed with pesticides for the prevention of viral diseases, bacterial infections or insects that could affect the production. These pesticides are another source of pharmaceutical waste, especially if not all the drugs are used in the process. (Conserve Energy Future, ei pvm)

2.3.7 Personal Care Products

Not all pharmaceuticals refer to those drugs taken for illnesses, but it also includes personal care and beauty products like fragrances, and cosmetics. They are usually applied as creams and lotions and they are not absorbed in full by the body, in which case, the unabsorbed portions are washed off the body and end up in the environment. (Conserve Energy Future, ei pvm)

2.4 Methods of disposal of pharmaceutical waste

2.4.1 Return to donor or manufacturer

Wherever practical the possibility of returning unusable drugs for safe disposal by the manufacturer should be explored; particularly drugs which present disposal problems, such as antineoplastics.

2.4.2 Landfill

It is practiced widely to dispose solid waste. It is one of the oldest methods. It refers to placing waste at some disposal site without any prior treatment or preparation. Landfill can be done by:

A. Open uncontrolled non-engineered dump

A non-engineered dump is probably the most common land disposal method in developing countries. Untreated waste discharged into an uncontrolled, non-engineered open dump does not protect the local environment and should not be used. As a last resort, where it is not possible to immobilize the waste pharmaceuticals, then the untreated wastes must be covered rapidly with large quantities of municipal waste to prevent scavenging.

B. Engineered landfill

Engineering landfill is considered as the second-best method of disposing pharmaceutical wastes into a landfill. This process carried out by applying some features that prohibit the transfer of chemicals into the aquifer.

C. Highly engineered sanitary landfill

This refers to a properly constructed and operated landfill site which offers a relatively safe disposal route for municipal solid wastes, including waste pharmaceuticals. The top priority is protection of the aquifer. Each day's solid waste is compacted and covered with soil to maintain sanitary conditions. (Bulathsinhala, ei pvm)

2.4.3 Waste immobilization: encapsulation

This method is used to immobilize pharmaceuticals in a solid block within some plastic or steel drum. These drums are cleaned properly before use and it is always necessary to make sure that these drums were not used to store hazardous and explosive materials previously. 75% of the capacity of the containers are filled with solid and semi-solid pharmaceuticals. The remaining space of the container is filled with medium (such as, plastic foam, cement/lime mixture or bituminous sand. (K. Pratyusha*, 2012) (Muhammed Jaseem, 2017)

2.4.4 Waste immobilization: inertization

This is a variant of encapsulation in which the packaging materials, paper, cardboard and plastic from pharmaceuticals are removed. The pharmaceutical waste is grounded which is followed by the addition of water, cement and lime which form a homogenous paste. These pastes are transported to a landfill by a concrete mixer truck and finally decanted into normal urban waste. This process is comparatively cheap and can be carried out with simple equipment. (Muhammed Jaseem, 2017) (K. Pratyusha*, 2012)

2.4.5 Sewer

Liquid pharmaceuticals like syrups and intravenous (IV) fluids are diluted with water and flushed into the sewers in small amount for a long period of time without any serious public health or environmental effect in this method. (K. Pratyusha*, 2012) (Muhammed Jaseem, 2017)

2.4.6 Burning in open containers

Pharmaceuticals should not be destroyed by burning at low temperature in open containers, as toxic pollutants may be released into the air. Paper and cardboard packaging, if they are not to be recycled, may be burnt. Polyvinyl chloride (PVC) plastic however must not be burnt. It is strongly recommended that only very small quantities of waste pharmaceuticals be disposed of in this way. (Muhammed Jaseem, 2017) (K. Pratyusha*, 2012)

2.4.7 Medium temperature incineration

In many countries there are no high temperature, two-chamber incinerators designed to handle more than 1% halogenated compounds. Such incinerators meet strict emission control standards. Many older municipal solid waste incinerators are medium temperature incinerators, and the use of these facilities is encouraged as an interim measure, rather than less safe options, such as inadequate discharge to a landfill. Such incinerators

are not designed to incinerate halogenated compounds safely. The very low halogen content in most pharmaceuticals is likely to result in negligible halogen content in the combustion gases. (K. Pratyusha*, 2012) (Muhammed Jaseem, 2017)

2.4.8 Novel high temperature incineration

Many countries do not possess and cannot justify economically, expensive, and sophisticated chemical waste disposal facilities, so the use of an industrial plant provides a viable and cheap alternative. During burning the cement raw materials reach temperatures of 1450°C while the combustion gases reach temperatures up to 2000°C. The gas residence time at these high temperatures is several seconds. In these conditions all organic waste components are effectively disintegrated. Some potentially dangerous or toxic combustion products become adsorbed into the cement clinker product or are removed in the heat exchange equipment. Pharmaceuticals should be introduced into the furnace as a reasonably small proportion of the total fuel feed. It may be necessary to remove packaging and/or to grind the pharmaceuticals to avoid clogging and blockage of the fuel feed mechanisms. (Muhammed Jaseem, 2017) (K. Pratyusha*, 2012)

2.4.9 Chemical decomposition

This method is not quite recommended but can be considered in the absence of an appropriate incinerator in accordance with the manufacturer's recommendations, followed by landfill. (K. Pratyusha*, 2012) (Muhammed Jaseem, 2017)

3 IMPORTANCE OF PHARMACEUTICAL WASTE MANAGEMENT

3.1 Pharmaceutical waste management in context of Nepal

Healthcare waste management guideline, 2071 has incorporated pharmaceutical waste and cytotoxic pharmaceutical waste as one of the Healthcare wastes requiring special attention on two different categories along with Human anatomical waste, Sharp waste, Blood, and body fluids waste. As per the guideline, pharmaceuticals include a multitude of active ingredients and types of preparations ranging from heavy metal containing disinfectants to highly specific medicines and also pharmaceuticals that have passed their recommended shelf life or pharmaceuticals that are unusable. Pharmaceutical wastes are again divided into three classes.

A. Non-hazardous pharmaceutical waste

This class includes chamomile tea, normal saline, dextrin, or cough syrup, etc. These pharmaceuticals are not considered hazardous and should be managed as non-risky HCW.

B. Potentially hazardous pharmaceutical waste

They are potential hazardous when used improperly by unauthorized persons. Their management must be done appropriately.

C. Hazardous pharmaceutical waste

This class contains heavy metal containing unidentifiable pharmaceuticals and also heavy metal containing disinfectants, which require special management and thus should be disposed appropriately.

D. Cytotoxic pharmaceutical waste

These pharmaceutical wastes are produced by use (administration to patients), manufacture and preparation of pharmaceuticals with a cytotoxic (antineoplastic) effect. These chemical substances are categorized into six main groups: alkylated substances, antimetabolites, antibiotics, plant alkaloids, hormones, and others.

The method of management of pharmaceutical waste explained in the guideline along with its different aspects is shown in a table below:

Table 1. Method of management of pharmaceutical waste with its different aspects.

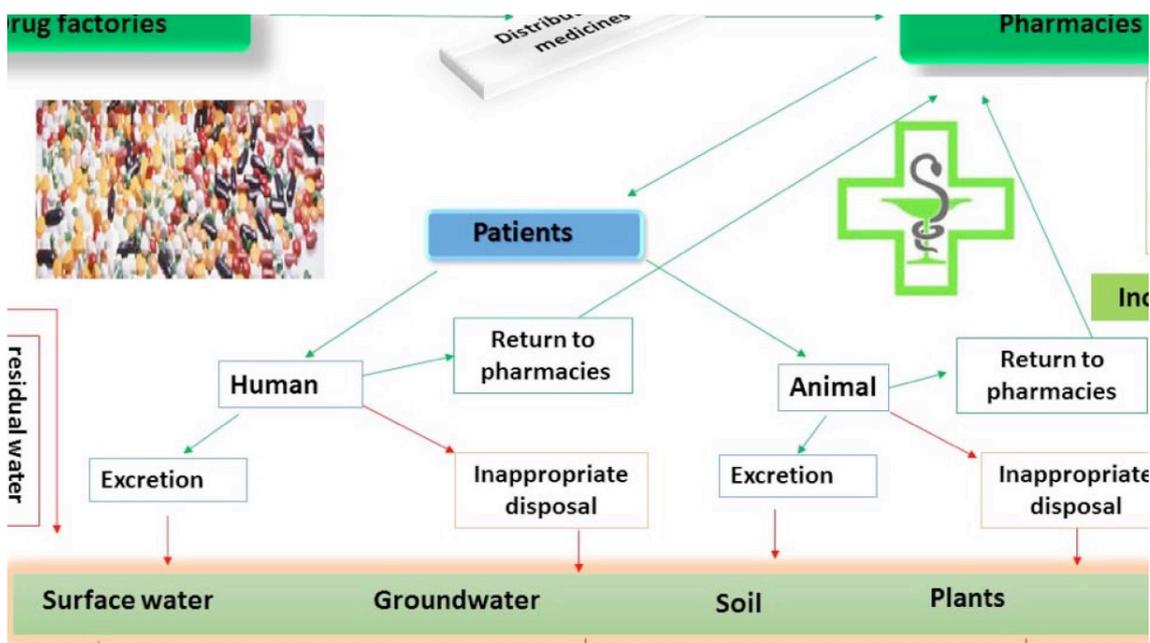
Types and Categories of HCW		Methods of management	Responsibility
HCW requiring special attention	Pharmaceutical waste like date expired, contaminated, and discarded medicines	Apply return back policy; return the waste to the store and from the store to the supplier OR Disposal in secured landfill after encapsulation	Storekeeper and authorized person
	Cytotoxic pharmaceutical waste such as post-expiration date cytotoxic pharmaceuticals, discernable liquid residues of cytotoxic concentrates	Applying return back policy; returning the waste to the store and from the store to the supplier OR Sanitary landfill followed by encapsulation.	

Pharmaceutical waste management has not been properly regulated as it should have been. The implementation of legislation, continuous monitoring, regular trainings, and updates, etc. have not been done. There is a vast gap in knowledge regarding the effect improper disposal of pharmaceutical products possess among general public. Since

there is a wide practice of use of over-the-counter drugs in Nepal, the general public are unknowingly putting their health as well as of the environment at risk by not disposing the unused, expired drugs properly.

The rapidly growing rate of pharmaceutical industry, private pharmacies, medical stores are not in proportion to the possibility of strict monitoring from concerned authorities. There is difficulty of regulating disposal of unused, expired, hazardous drugs in pharmacies/medical stores. Some workers working in those stores are not well trained, educated or experienced to dispose of the pharmaceutical products properly while some lack the resources and support from owners for carrying it out despite having the proper knowledge and training.

3.2 How does pharmaceutical waste contribute to environmental pollution?



(Bungau S, 2018)

Figure 2. Pharmaceutical waste contributes to environmental pollution.

The management of pharmaceutical waste remains unregulated although the negative impact of the production of pharmaceutical products on the natural environment is well known. Pharmaceutical products enter the environment at various stages of their life cycle, but particularly during the production phase. One of the main threats is that dis-

charging antibiotics into the environment can promote the natural development of antibiotic-resistant pathogens that are harder to treat. (Bungau S, 2018)

3.3 Consequences of improper pharmaceutical waste disposal in human health

The scope of human exposure to pharmaceuticals depends on many factors. Some of these factors include the density, types, and exposure of pharmaceuticals in the environment. Similarly, the nature of each drug and their structural transformation of the chemical compounds also determines the level of toxicity. Insufficient research of toxicity guidelines and their effects on human health in this matter has made it hard to figure out a proper dosage for water contaminated by pharmaceuticals. Health risk assessments have not been conducted to provide concrete evidence to link pharmaceutical contamination and adverse human health effects. At present, there is no concrete data on possibility of adverse end-result caused by the interactions or long-term exposures to these substances. Researchers have suggested the possibility of development of antibiotic resistance too. Higher antibiotic concentrations than the minimum inhibitory concentrations of a species of pathogenic bacteria, can exert a selective pressure promoting selective antibiotic resistance. In addition, transfer of genetic elements among bacteria under natural conditions in wastewater treatment plants has been observed. Antibiotic resistant bacteria in sewage sludge can enter the food chain if the sludge is not incinerated but used as fertilizer on agricultural land. (Nyagah, 2020)

3.4 Consequences of improper pharmaceutical waste disposal in the environment

Improper disposal of pharmaceutical waste poses many dangers to the environment, one of the major dangers being water pollution itself. A number of pharmaceuticals as well as components produced by their deterioration find their way into lakes and rivers from wastewater treatment plants. They end up in crop fields and livestock farms. They can even leech out from septic systems and landfills. In addition to deteriorating the normal flora and fauna in the water sources, the combination of various chemicals of pharmaceutical waste poses great risk to the livelihood of organisms.

Different hazards caused from the pharmaceuticals are listed below:

- Toxic effect released by different micro-organisms can damage the environment.
- Some substances exposed to the environment for a long period of time may cause fatal effects.
- Bio-accumulative can affect the food-chain
- Manmade/Artificial disasters (e.g.- deforestation, forest fire, etc.) that occur in the process of development or operation of pharmaceutical industry can cause different catastrophes, mishaps, calamities, or grave occurrences. This also leads to contamination of water supplies for wildlife. The contamination of water sources by pharmaceutical waste impacts aquatic animals and mammals. Non-biodegradable antibiotics, disinfectants, or chemotherapy drugs/antineoplastic drugs that get mixed up in sewage systems can potentially kill bacteria necessary for sewage treatment. Antineoplastic drugs and disinfectants contaminate drinking water and endanger aquatic life.

Talking about the disposal of unused, expired drugs in households, many people tend to just forget about their prescription medication which leaves it available for children to find accidentally. However, others will casually throw away their drugs or flush them. The medication begins to dissolve and seep out dangerous chemicals which soon end up in waterways. The result of this can have an awful impact on the environment. (Chamberlain, 2019)

3.5 Pharmaceutical waste reduction and its benefits

Pharmaceutical waste cannot completely be terminated but the toxicity can be reduced and discarded. The target of various waste minimization techniques are usage of raw materials, water, and energy optimally. These methods are:

A. Reduce

Reduction refers to reducing the waste being generated. It is an important method of waste management. Repeated use (if usable), fixing the damaged items rather than purchasing new, producing reusable products are the ways to reduce waste.

B. Reuse

Re-use helps in avoiding the practice of discarding materials when their initial use has concluded. If possible, products should be transferred to the places that is preferable for reusing it.

C. Recycling

This involves the treating substances that can be transformed to their original state or intermediate state to decrease the consumption of more and more new products. It benefits the environment by minimizing the use of raw materials and is a way forward for sustainable development. Some of the benefits of recycling are listed below,

- i. Promotion of a good public image on environmental protection
- ii. There will be sufficient usage of different resources
- iii. Promotion of welfare of public and workers' health
- iv. Increase in manufacture, but still reduction of waste production
- v. Reduction of potential environmental liabilities (K. Pratyusha*, 2012)

3.6 Possible way forward

The following initiatives can be made to prevent pollution from pharmaceutical waste in the environment:

- Creating awareness among patients about the importance of proper unused drug disposal,
- Directing physicians and patients for proper drug disposal,
- Pharmaceutical industries should employ strategies for proper drug disposal
- Hospitals should practice better disposal methods of pharmaceutical waste.

The patients should be made aware pharmaceutical pollution and its hazardous effects on humans, animals and the environment. By doing this, further steps can be taken to prevent pharmaceutical waste being disposed in the environment. Customers should be sensitized to follow precautions before throwing out drugs in the trash or flushing them

down the sink or toilet. Community take-back programs can be initiated to set up for consumers. The pharmacies can even keep recycling bins for customers to return/bring back unused or expired medicines. A little push from physicians and patients and the environmental concern will help further reduce pharmaceutical waste. The hospitals need to focus on practicing effective ways of disposing hazardous waste which will prove to be beneficial. Likewise, data must be collected so as to measure the prevalence of different pharmaceutical levels in drinking water. Pharmaceutical industries/companies should be encouraged and supported to develop technology to extract pharmaceuticals from waterways. Since many of the pharmaceuticals pass through the human body unchanged, human excreta should not be mixed into waterways.

4 RECENT STUDIES IN PHARMACEUTICAL WASTE MANAGEMENT

The distinction of pharmaceutical waste from normal waste, different types and forms of pharmaceutical waste products produced during various steps and processes in pharmaceutical industries, hazardous and non-hazardous pharmaceutical waste, properties of hazardous waste, different methods of pharmaceutical waste management and disposal, hazardous waste management strategy, etc. were explained in the article titled “An overview of waste management in Pharmaceutical industry” published in 2017 in India. As explained in the literature, following waste products were produced:

- Drugs that are expired
- Personal medicines discarded by the patients
- Excessive drug containing materials such as syringes, IV bags, tubing, vials etc.
- Residues of chemotherapy drugs.
- Unusable drug containers
- Acute hazardous drug waste containers.
- Discarded drugs; and
- Garments, absorbents and spills that are contaminated.

The categorization of waste was made as: hazardous waste, non-hazardous waste and chemo waste. Hazardous waste was further categorized into: Listed waste and Characteristics waste. Hazardous properties of characteristic pharmaceutical waste like ignitability, corrosivity, reactivity and toxicity make it impossible to discard safely hence they need to be regulated. Wastes that do not have these properties can be considered solid waste and be discarded as per the existing regulations. Waste minimization, reuse and recycle were described as important Hazardous waste management strategy. The article stressed on the withstanding challenge for medical personnel in managing wastage effectively, the need for a modified classification of medical waste for ease of disposal and reduction of these waste by implementing effective strategies and regulations. (Muhammed Jaseem, 2017)

A similar study described different aspects of pharmaceutical waste formation, disposal and so on. It was written based on existing pharmaceutical regulations at that period.

Along with categorization of pharmaceutical waste as: hazardous waste, non-hazardous waste and chemo waste, chemo waste was briefly differentiated into:

A. Trace chemotherapy waste

The materials that are preferable for management as trace chemotherapy waste include:

- Vials, syringes, IV bags, and tubing.
- Materials that are used in routine operation, preparation and administration of chemotherapy (such as gowns, gloves, wipes etc.)
- Chemicals and wipes used for sanitization and cleaning of equipment used in chemotherapy.

B. Bulk chemotherapy waste

The following methods of pharmaceutical waste management and disposal were explained in the literature: Incineration, Autoclaving, Microwaving, Chemical disinfection, Deep burial, Secure land filling, Encapsulation, Inertization and Sewer. According to the literature, minimizing pharmaceutical waste is a must in today's world which can be done as follows:

1. Lifecycle Assessment should be considered before making purchases.
2. The use of opened chemotherapy vials should be maximized.
3. A sample policy should be implemented
4. Drugs that are used at home should be labeled properly
5. IV Lines should be flushed with Saline Solution
6. The size of the containers should be checked for relative use
7. Patient-Specific syringes should be brought into use instead of prepackaged unit dose liquids.
8. Controlled Substances
9. Delivering Chemotherapy Drugs
10. Dates on emergency syringes should be monitored
11. In order to reduce outdates, inventory controls should be reviewed
12. Other management options should be considered

13. Should be ready to adapt new techniques of management
14. Satellite accumulation areas should be located
15. Storage accumulation area must be evaluated in regular interval
16. Pilot programs should be conducted
17. Policies and procedures should be monitored

This problem demands for actions in policy level as well, so this article has also focused on the practical and effective layout of policies which are as follows:

- The approach to categorize the drugs and manage them as hazardous waste must be developed by the organization.
- The non-regulated drugs which can be managed as a hazardous waste should be determined.
- Proper labelling of drugs should be done in order to facilitate the segregation of hazardous waste.
- Waste streams should be properly segregated.
- Staffs should be trained and updated about the management of wastes.
- Storage accumulation areas and satellite accumulation should be established and managed.
- Manifests on hazardous waste should be maintained.
- determining their hazardous waste generation status. The status of hazardous waste production should be checked in regular intervals.
- The criteria for the selection of hazardous waste should be defined.(K. Pratyusha*, 2012)

Another literature primarily aimed to address the challenges associated with hazardous pharmaceutical waste. Not all pharmaceutical waste is hazardous. Warfarin, Physostigmine, Chemotherapeutic agents are some examples of hazardous waste. Listed wastes are those that are related to certain manufacturing processes, pharmaceutical wastes, and unused chemicals and are set apart from other hazardous wastes.

It concluded that pharmaceutical products carry incredible benefits hence the people who need them should always have the opportunity to procure them. But this convenience and availability should not come at the cost of environmental and public health.

A review study aimed at examining the sources of pharmaceutical waste, expenses of disposal, reliable disposal processes, the results of improper disposal and the responsibility of pharmacists in disposal gathered related information by literature review. With the annual growth in pharmaceutical industry, the waste from these industries is increasing day-by-day too. Not only pharmaceutical products for humans, but the use of these products for livestock, ticks, mites, mosquitoes, etc. is rapidly increasing too. As a result, high concentration of these pharmaceutical waste products is being detected in rivers and industrial effluents. The sources of pharmaceutical waste production are: Production industries, health-care institutions and municipal wastewater treatment plants. Waste management settings such as landfills, agriculture, particularly intensive livestock and crop farming, aquaculture, septic tanks also emit significant amount of wastes. Point source (like wastewater treatment plants) and diffuse source (surface runoff and leaching of septic tanks) are the pathways of release of such pharmaceutical waste. The waste products were released into the environment via different methods like:

1. Waste from health-care facilities like hospitals and nursing homes
2. Disposal of unused or expired drugs directly to trash or flushing them to the sink or toilet
3. Excreta and urine
4. Waste disposed by the pharmacies
5. Disposals from relatively low-cost drug industries in under-developed countries.
6. Medicines and chemicals added to animal food disposed to the soil and water resources
7. Leaching from faulty landfills
8. Pest control drugs and chemical fertilizers used in farming
9. Residues from medicated/euthanized animal carcasses.
10. Extra drugs mixed to sewage or garbage from house-hold purposes.
11. Waste from dairy and slurries.
12. Sample drugs used in promotion that are unused or expired.

The literature also discusses the cost of pharmaceutical waste disposal in different countries using different methods. Similarly, the pharmaceuticals which are tough to dispose

like antineoplastics and unused/expired drugs can be sent back to the production companies and donors for proper disposal.

Improper disposal of pharmaceutical waste products during different processes like storage, handling and disposal creates adverse effects to the environment, economy, even human and animal life. Some of these consequences are:

- Water supplies for wildlife and domesticated animals get toxic.
- Unmanaged disposal of opioids can promote drug abuse.
- Accidental poisoning of children who come in contact with drugs that are not disposed properly.
- Possible threat of misuse by public and pets.
- Unmanaged disposal of wastes affects aquatic life
- Non-biodegradable disinfectants, antineoplastics, antibiotics kill bacteria required for sewage treatment affecting organic degradation processes, nitrification, and denitrification.
- Misuse and over-use can lead to the development of superbugs and antimicrobial resistance.

The constant use of these products has created a stage where they are accumulating in the environment at a rate higher than the rate at which they are being degraded. This serious issue on managing pharmaceutical waste is a global challenge more so because several countries are yet to acknowledge this problem at policy level. Irrational use of medicine among patients and lack of public awareness are significantly contributing to this issue. Pharmaceutical companies have deliberately focused on patient health, dosage, and effectiveness during clinical trials but not on environmental toxicity. The main focus of the pharmaceutical companies has been made on patient health, dosage of medicines and efficiency of clinical trials but not on environmental aspects. For better outcomes in long-term, following mitigation steps should be adopted: Cross-cutting, Design, Authorization, Production, Consumption, Collection and disposal, Wastewater treatment and finally Drinking water treatment. Another specific area this article has focused on is the role of pharmacist in managing pharmaceutical waste. Disposal of unused pharmaceuticals must be carried out under the supervision of a pharmacist. They

should be updated with the available disposal techniques in the area. They should discard the disposal in open dumpsites. Similarly, burning and destruction in poorly constructed/insecure landfills should be prohibited as these can be fatal to the public health. They should inform the competent authorities about disposal cost, availability of the disposal options, and preferable disposal services to outsource. Pharmacists should promote and track patient adherence and ensure that all prescribed drugs are used. Pharmacists play vital role in the ordering of supplies and prediction of the required number of products to escape overstocking. The standard procedures for the disposal of unused, outdated and low-quality pharmaceutical products should be done under the supervision of a pharmacist. Sufficient assessment, examination and monitoring by the health ministry, environmental agencies, waste-management authorities and Non-Government Organizations (NGOs) ensures the proper disposal of pharmaceutical wastes. (Nyagah, 2020)

A descriptive, cross-sectional study titled ‘Disposal practices of unused and expired pharmaceuticals among general public in Kabul’ was conducted in Kabul in 2016 with a sample size of 301 respondents. The participants were interviewed with pre-validated structured questionnaire. Majority of the respondents procured medicine based on prescription while some purchased medicine over the counter. The commonly purchased medicine were antibiotics, NSAIDS, antihypertensives and antidiabetics respectively. Also, majority of the respondents (97%) checked the expiry date of medicines while purchasing. Similarly, around half of the university graduates procured medicine on prescription. Most of the respondents (95.3%) on asking if they had any unused quantity of purchased medicine remaining at home, they replied positively. Out of all unused medicine at home, most of them were antibiotics. Some had no idea what was done with the unused medicine at home. Around half of the total respondents had kept their unused medicines at home until expiry. Many of them responded as government being the responsible agent, followed by pharmaceutical industries, public and pharmacists. The indispensable contribution pharmacists could contribute to this noble cause was sensitized by the study. (Bashaar, 2017)

Another literature discusses on the types, categories, sources of pharmaceutical waste, existing regulations to keep them in check, disposal methods in practice and so on. The

contents were described considering these existing regulatory bodies for 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 and Local Publicly Owned Treatment Works (POTW).

For proper handling of hazardous pharmaceutical waste, health care organizations most likely will need to create additional waste streams; the potential solution to which can be initiated through following approaches:

- a. Waste Management Team
- b. Inventory management
- c. Reverse distribution
- d. State and county activity
- e. Several benefits.

A comprehensive pharmaceutical waste management plan can be executed with these key points:

- a. Hazardous waste storage accumulation sites should be in the same locked area that houses mercury, xylene, formaldehyde, and other laboratory chemicals.
- b. The maximum storage time should be 90 or 180 days, as determined by the facility's waste generator status.
- c. Institutions should either contract with a hazardous waste broker or develop internal expertise in manifest preparation and land ban preparation (preparing those agents that cannot be disposed of in the landfill).
- d. Nonhazardous drugs should be segregated into non-red and non-yellow containers that are labeled
- e. "Nonhazardous Pharmaceutical Waste -Incinerate only" and are disposed of at a regular medical waste or
- f. municipal incinerator that is permitted to accept nonhazardous pharmaceutical waste.
- g. For the disposal of controlled substances, the practice of two health care professionals witnessing the waste should continue unchanged. (K. Sreekanth*, 2014)

A study was conducted by Bungau S et al in 2018 in Romania. The objective of the study was to identify the elements that could have an effect on the efficiency of pharmacies in the collection and disposal of the pharmaceutical waste of the population in order to develop appropriate strategies and policies. Data was collected among 521 pharmacists in the country through phone and online methods (email, social networks). The response rate was over 95%. An Opinion enquiry based on a questionnaire with 20 items was addressed to pharmacists. Since each pharmacist in this study worked in a different pharmacy, the sample were representative of the whole population. The sample constituted of pharmacists and pharmacy assistants from both urban and rural areas with the age group ranging from 35 to 50 years of age. In this study, 75% pharmacists reported that they are directly responsible or share with other persons the responsibility of taking decisions regarding the collection of expired/unused medicines from the citizens while 16% do not collect unused/expired medicines from the population. Very few of the pharmacies (2%) were required to provide the services of collected medical waste daily while some were asked less than a month to collect unused/expired medication. Likewise, regarding the costs of this service, majority (92%) of respondents believed that these costs should not be supported by pharmacies but rather by: patients, local authorities, Ministry of Health, Ministry of the Environment, others (NAMMD, Government, manufacturer or supplier, drug-issuing pharmacy, authorized ecological unit). Over 36% of the pharmacists responded that they were not at all satisfied with the collection procedure at the pharmacies where they worked and about 14% said they were extremely satisfied. This shows a significant percentage of dissatisfaction regarding the collection procedure of unused/expired medicine among the pharmacists. Around 65% of the respondents said they were dissatisfied with the current procedure and had at least one suggestion. Nearly 33% of the investigated pharmacists have refused the take-up of unused medicinal products from citizens at least once. The most important reasons behind this were a lack of procedure, incomplete legislation, exceeding the amount contracted with the operators and high costs. More than half of the pharmacists (53.6%) consider themselves sufficiently informed about the waste disposal legislation, only 19.3% consider themselves highly informed and almost 9% believe they are little informed or not at all. More than 40% of the investigated pharmacists consider current legislation as being incomplete, about 20% considered the law to be ambiguous, while 12.86% believed that the law is clear and easy to apply. Varieties of suggestions given

by pharmacists to improve the current procedure were placement of special containers in pharmacies where citizens can directly put unused medicines, setting up a nationwide service, creation of collection centers, taking the unused medicines by distribution companies and selling them to manufacturers, collective collection from pharmacies respectively. Majority of the respondents considered themselves informed on this topic and also most participants in this study considered it extremely important to inform patients about the correct way to dispose of unused medications. This study suggested possible outlets to the issue raised by employing efficient strategy for pharmaceutical waste disposal with a specific and comprehensive legislation with clear responsibilities, awareness campaign for both staff and the general public, removal of the financial burden of waste disposal from pharmacies, simplifying the collection of medical wastes through the implementation of special containers in pharmacies and other sites, participation of all concerned parties in the health system. (Bungau S, 2018)

A study was conducted to monitor the disposal practices of unused and expired medicines among the general population in Bandung, Indonesia. Out of all respondents (497), most of them were females, the age group ranged from 18 to 30 years old, more than half of them completed secondary education about a third were university graduates. Most of the respondents (95.5%) had at least one unused medication in their home. The majority of the respondents revealed that the reason for medicines non-usage was patients improved medical condition, followed by the drugs were expired and alterations in prescription. Few respondents had unused medicines due to non-adherence, adverse events and unsure of medication purpose. NSAIDs were the most common medicines left unused followed by vitamins and nutritional supplements and antibiotics. The findings also showed that the respondents used to check the expiration date of drugs before buying them. A significant proportion of the respondents kept the unused medicines at their home until they got expired. The most common disposal method of expired medicines was disposal in the household garbage, followed by flushing the medication to the toilet or sink. About 8% of the respondents did not know what to do with their expired medicines. Almost all of the respondents considered that education on the proper medication disposal method was necessary. An environmentally unsafe disposal method was used by the majority of the respondents, indicating a very poor awareness of pharmaceutical waste management issues. A high rate of medication disposal through house-

hold waste was observed in this study. Over half of the respondents were unaware about the negative impacts caused by the improperly disposed medicines to the environment and human health which is very alarming. Poor awareness of the harms associated with inappropriate disposal practice was observed. Government and health-care professionals should be more proactive in educating the public about the appropriate use, storage, and disposal of pharmaceutical products. Furthermore, conducting relevant training and continuous education for health-care professionals, as well as medical, pharmacy, and nursing students, are strongly encouraged as per the findings of the study. (Widya N. Insani, 2020)

Felicity Thomas has examined the rise in medicine use and considered the existing knowledge of pharmaceutical waste in the environment. According to the literature, the use of pharmaceutical compounds has significantly grown in WHO European region. The data gives an idea that more than half of the medicines are not prescribed, dispensed and disposed properly. The impact caused can only be imagined. This has resulted in costly resource waste, significant adverse fluctuations on wildlife and ecosystem. The benefits of drugs are countless ranging from health benefits to even economic benefits, but in addition to this, pharmaceutical waste is increasingly affecting the ecosystem, when the unused medicines are not disposed and discarded appropriately. The article also discusses on the serious issue of water sources being polluted with pharmaceutical waste. Significant amount of pharmaceuticals have been found mainly on the surface of water resources such as lakes and rivers. Similarly, groundwater, soil, manure and even drinking water are found to be contaminated by pharmaceuticals. Active pharmaceutical ingredients enter the environment through two main routes; urine or feces and disposal of unused medicines to sink or toilet. These medical pharmaceuticals finally get mixed up in the sewage treatment plants which are not designed to eliminate such pollutants from wastewater in general. Coming to the main basis of this paper, the author puts forward how cultural perspective can help understand why geographical and social variations exist in rates of medicine prescribing, across Europe, which can offer on discrepancies in the frequency of antibiotic-resistant infections over the past years. Besides popular media, advertisements and excessive access to the internet have played a vital role in increment of use of pharmaceuticals in day-to-day life. At the same time, public expectations can be influenced by health policy which is also an interesting fac-

tor brought into light by this article. The articles conclude with how the ongoing rise in pharmaceutical use and misuse, will be exacerbating in coming years without significant intervention. There are several innovative technological responses that deal with pharmaceutical waste are prevalent. These techniques are complex and expensive and do not address the prevalent sources which when we critically think about are actually simple cause-effect relationships. Adapting a cultural point of view and inspecting this within the circumstances of extensive social, economic and political aspects, can be very helpful not only to understand the possibility of proper disposal and consumption of medicines within a particular group of population but also plays vital role in formulation of new ideas and techniques to tackle the root cause of the issue. It is also important to recognize that the complicate relationship between the changing natural environment and changing human lifestyles promote cultures of co-operation between health and environmental policymaking. (Thomas, 2017)

A descriptive, cross-sectional survey was conducted exploring the knowledge, attitudes and practice regarding drug disposal by pharmacists in North India. The main objective of the study was to understand the knowledge, attitudes and practice of pharmacists about the disposal of medications and their perception on possible environmental effects caused by improper disposal of drugs. Simple random sampling was used to recruit a cohort of pharmacists working in pharmacies in an urban town in North India. The response rate was 56% only. Sample population comprised mostly of males (98%) aged between 28 and 67 years. Regarding qualification of the pharmacists, majority of them held a diploma in pharmacy and were experienced in practice of pharmacy. As per the findings of the study, most of the leftover drugs were returned to the distributor, irrespective of dosage form. The pharmacists reported that they had adopted a systematic management strategy at their worksites to take stock of leftover drugs. One-fourth of pharmacists accepted that they throw the solid dosage forms, especially if the quantity was less. Most of the pharmacists (90%) had a system of regularly removing the expired drugs from inventory. Many of the pharmacists stated that they were not educated about proper drug disposal methods in pharmacy schools. The expired and unused drugs at the pharmacy comprised of those expired at pharmacy (72%), returned drugs that were unsuitable to the patients leading to change of medication by the doctor (25%) or belonging to deceased relative (3%). The patients' frequency of enquiry about advice on drug

disposal was never (98%), sometimes (2%), always (0%), which is an alarming finding. The pharmacists thought (72%, n = 60) pharmacies in government hospitals to be most suitable location for returning medications. Other places suggested were pharmacies in private hospitals or clinics (13%), supermarket (24%) and others (6%). On asking questions related to frequency and methods of getting updated on latest trends, policy, guidelines, etc. most of the pharmacists took references from journals or workshops to get the information. There was inadequate knowledge about drug disposal and environmental impact of pharmaceutical waste. Only 58% responded that drug disposal was linked to environmental pollution. Only 69% of them agreed that incineration was the best way to dispose unused/expired drugs. The authors concluded that environmental pollution by improperly disposed pharmaceuticals is increasingly being recognized as a major threat to ecosystems worldwide. Since pharmacists are accountable for pharmaceutical waste management in their pharmacy; they should be updated about recommended drug disposal techniques, trained, made accountable and responsible. They have also focused on the need for national guidelines and a formalized protocol for disposal and destruction of unused and expired medications to minimize their potential impact on the environment. (Suruchi Aditya, 2014)

5 RESEARCH METHODOLOGY

5.1 Research design

A descriptive cross-sectional study was conducted in Kathmandu, Nepal. This method was employed since the study was aimed at retrieving the aspects of pharmaceutical waste management in pharmacies of given research setting at given point of time.

5.2 Research setting

This study was conducted in private pharmacies/companies operating in Kathmandu, Nepal.

5.3 Sampling

A purposive sampling was used targeting to recruit 5 private pharmacies/pharmaceutical companies operating in the research setting. They were approached purposively based on vicinity to the data collector and objective of the study.

5.4 Type of instrument

A structured questionnaire was developed to find out different aspects of pharmaceutical waste management prevalent. The validity of the instrument was ensured by pretesting it in two pharmacies as well as extensive literature review. After pretesting, necessary changes were made. The pharmacies included in pretesting were later excluded in the actual study.

5.5 Data collection procedure

After approaching the pharmacy/pharmaceutical company, the objectives of the study were clearly explained to the parties involved. A written consent was obtained from the participants. The questionnaire was given to one main responsible person working in there. Their queries were cleared (if any). After the respondents had finished filling the

questionnaire, it was checked for completeness and then collected. The respondents were thanked for their time and effort.

5.6 Data analysis

Data was analyzed using descriptive statistics.

5.7 Ethical considerations

Privacy and confidentiality were maintained during and throughout the study. The right of the participants to refuse to take part in the study was considered.

6 RESULTS

6.1 Socio-demographic characteristics

The socio-demographic characteristics of respondents is shown in the table below:

Table 2. Socio-demographic characteristics of respondents.

S.N.	Characteristics		Frequency	Percentage (%)
1	Gender	Male	4	80
		Female	1	20
2	Age	30 to 40 years	3	60
		40 to 50 years	2	40
3	Educational Level	Bachelor's degree	1	20
		Master's degree	4	80
4	Operating time of industry	15 to 20 years	1	20
		20 to 25 years	2	40
		25 to 30 years	2	40
5	Working experience	Less than 5 years	2	40
		5 to 10 years	1	20
		10 to 15 years	1	20
		16 to 20 years	1	20
6	Trained	Yes	4	80
		No	1	20

Among 5 companies recruited for this study, proportion of male respondents was more than females. The age group ranged from a minimum of 33 years to a maximum of 50 years old. Majority of the respondents (80%) had completed educational level of master's level in pharmacy followed by bachelor's degree. Regarding the time duration the pharmacy/pharmaceutical companies have been operating for, only one had been operating for a less time, the time being 16 years while the rest of the companies had been operating for more than 20 years (the maximum time of operation being 30 years). Similarly, regarding the working experience of respondents, the respondents working

for duration of less than 5 years were 40% (one had been working for 2 years while one for 3 years). Likewise, all other respondents had been working there for more than five years. One of them had been working for as long as 16 years. Out of all respondents, 80% had acquired some training on pharmaceutical waste management during their professional years of working. (Appendix 1)

6.2 Knowledge regarding pharmaceutical waste management

Table 3. Dumping pharmaceutical waste into the environment.

a. Is it acceptable to dump pharmaceutical waste into the environment?		
Responses	Frequency	Percentage (%)
Yes	0	0
No	5	100

All the participating respondents had correct knowledge regarding disposal of pharmaceutical waste into the environment.

Table 4. Returning unsold pharmaceuticals to the supplier.

b. Do you think returning of unsold pharmaceuticals to the suppliers is a good way of minimizing pharmaceutical waste?		
Responses	Frequency	Percentage (%)
Yes	5	100
No	0	0

All the respondents knew that returning of unsold pharmaceuticals to the suppliers is a good way of minimizing pharmaceutical waste.

Table 5. Burning pharmaceutical waste.

c. Is burning of pharmaceutical waste a good way of disposal?		
Responses	Frequency	Percentage (%)
Yes	0	0
No	5	100

All respondents agreed that pharmaceutical waste should not be disposed by burning.

Table 6. Burying pharmaceutical waste.

d. Does burying of pharmaceutical waste prevents it from being mixed into the water sources?		
Responses	Frequency	Percentage (%)
Yes	0	0
No	5	100

All respondents thought that burying of pharmaceutical waste does not prevent it from being mixed into the water sources.

Table 7. Encapsulation.

e. Is encapsulation necessary before adopting landfilling method for pharmaceutical waste disposal?		
Responses	Frequency	Percentage (%)
Yes	4	80
No	1	20

Majority of the respondents agreed that encapsulation should be done before adopting landfilling method for pharmaceutical waste disposal.

Table 8. Inertization.

f. Does inertization reduces or delays the pharmaceutical compounds into the environment?		
Responses	Frequency	Percentage (%)
Yes	4	80
No	1	20

Most of the respondents said that inertization reduces or delays the pharmaceutical compounds into the environment. (Appendix 2)

6.3 Comparing correct responses to different methods of pharmaceutical waste management

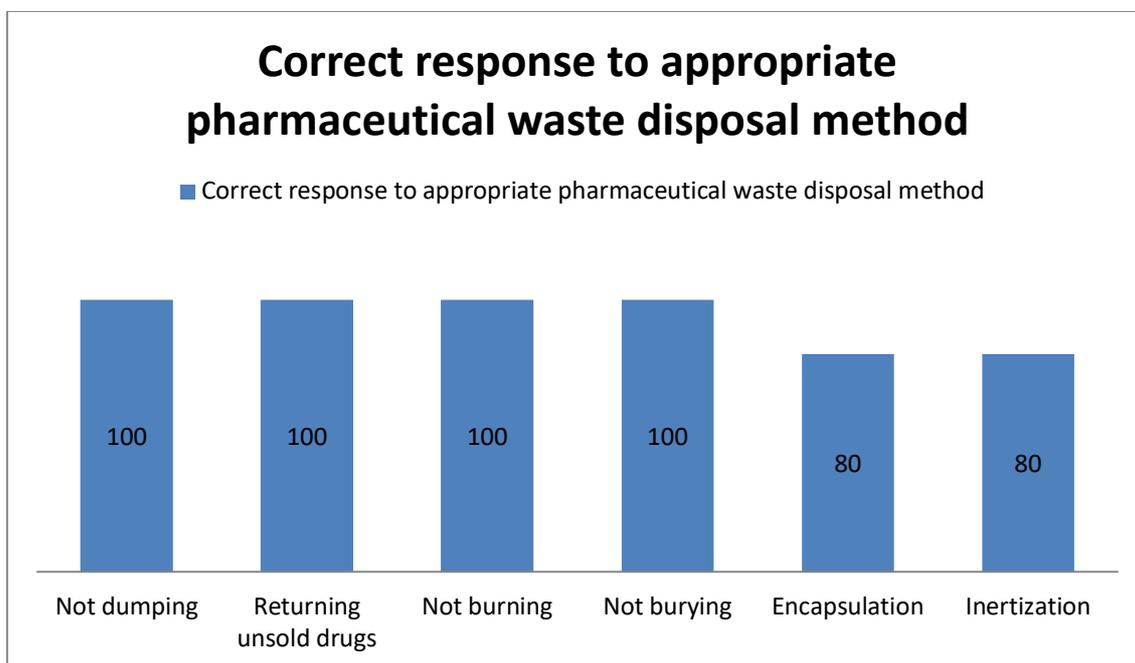


Figure 3. Comparison of different methods of pharmaceutical waste management.

Overall, the knowledge regarding different methods of pharmaceutical waste management, their appropriateness seems to be adequate among the respondents. Despite this finding, the respondents were not familiar with the current pharmaceutical waste management guideline. Only 20% of them were not familiar with the pharmaceutical waste management guideline prevalent at the present context. However, all the respondents were aware of the significance of proper pharmaceutical waste management to effective sewage treatment in the environment. (Appendix 2)

6.4 Prevalent practices on pharmaceutical waste management

Adopting guideline/policy/protocol for pharmaceutical waste management

The following results were obtained on asking about the practice of using guideline/policy/protocol for pharmaceutical waste management:

Table 9. Guideline/policy/protocol for pharmaceutical waste management.

Do you have guideline/policy/protocol for pharmaceutical waste management in your pharmacy?		
Responses	Frequency	Percentage (%)
Yes	4	80
No	1	20

Out of all the pharmacies/pharmaceutical companies in the study, only 20% did not have regular adherence to some guideline/policy/protocol for pharmaceutical waste management. Remaining pharmacies/pharmaceutical companies practiced pharmaceutical waste management adhering to some guideline/policy/protocol on the basis of past experience, learning from seniors, observations and recommendations from others.

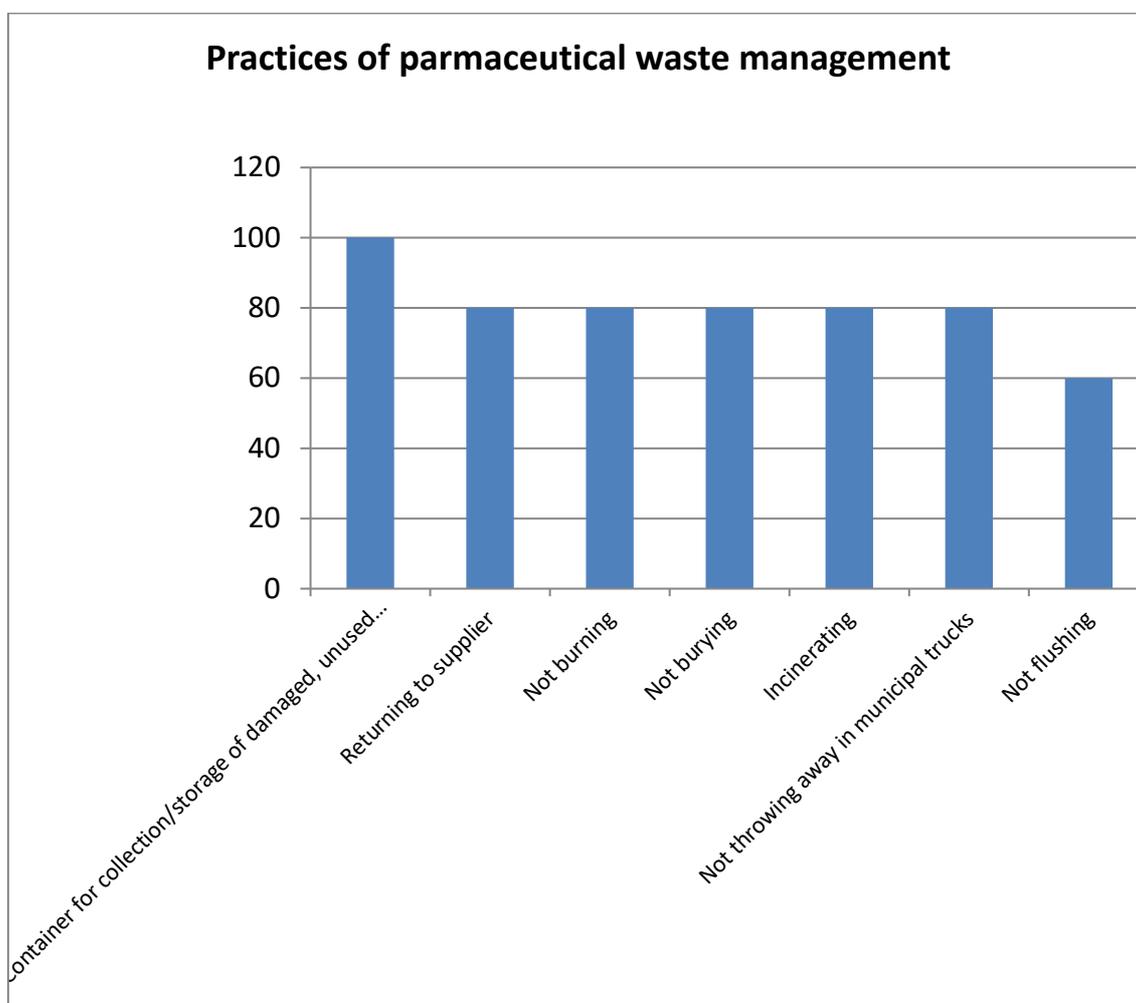


Figure 4. Comparing the practice of correct pharmaceutical waste management.

The overall practice of pharmaceutical waste management seems good. However, some simple, easy yet extremely important practices were likely neglected. All of the pharmacies/pharmaceutical companies practiced container for storage of unused, damaged, expired drugs. 80% practiced returning the unused damaged, expired drugs to the manufacturer. About 20% of the pharmacies/pharmaceutical companies still burned drugs, 20% buried them, 20% did not practice incineration, 20% threw away the drugs in municipal trucks and 40% flushed them in sinks/toilets. (Appendix 3)

6.5 Other methods of pharmaceutical waste management practiced

The respondents were asked about different methods of pharmaceutical waste management practiced in their settings other than returning unused, damaged, expired drugs to the suppliers/manufacturers, collecting/storing them in containers, incinerating, encapsulation, inertization, landfilling after adopting other measures. The common response was treating chemically, physically and biologically using Effluent Treatment Plant (ETP). The waste was treated by dilution method before collecting in the effluent treatment plant (ETP). Some even managed them by using various safe and effective techniques which can preserve our environment like vermicomposting. (Appendix 3)

6.6 Measures to improve pharmaceutical waste management practices

On asking the respondents from the participating pharmacies/pharmaceutical companies about the possible measures to adopt for improving pharmaceutical waste management practices:

- Raising awareness among the general public about how improper disposal of pharmaceutical waste can cause harmful effects on the environment
 - Disposing off pharmaceutical waste only under the supervision of a trained pharmacist or environment specialist
 - In-service education and trainings, workshops, conferences should be organized timely to impart knowledge on guidelines for safe disposal of pharmaceutical waste
- Strict legislation for pharmaceutical waste management

- Implementation of the existing laws, rules and regulations effectively
- Exploration of new sustainable technologies
- New system implementation regarding effluent treatment
- Strong regulations by national regulatory body
- While prescribing medicines or selling them, the consumers should be sensitized with the thought of what they should do with the unused drugs
- Health education to admitted patients by hospitals
- Advocacy, campaigns by environmentalists
- Strong supervision, monitoring and guidance by government authorities. (Appendix 3)

7 DISCUSSION AND CONCLUSION

The knowledge and practices of pharmaceutical waste management were explored in this study. Although the overall knowledge was found good, the knowledge regarding individual aspects of pharmaceutical waste management and their practices was not quite appreciative.

In a similar study conducted in North India, the knowledge regarding pharmaceutical waste management was found inadequate, which is similar to the findings of this study. Sample population comprised mostly of males (67%) aged between 28 and 67 years while in our study, sample population consisted of 80% males, age range of 33 to 50 years old. Regarding qualification of the pharmacists, majority of them held a master's degree in pharmacy and were experienced in practice of pharmacy which is similar to findings of our study. Likewise, most of the leftover drugs were returned to the distributor, irrespective of dosage form which is in line with the findings of our study. One-fourth of pharmacists admitted that they trashed the solid dosage forms, especially if the quantity was less, which is found to have been practiced in our setting too. Only 58% responded that drug disposal was linked to environmental pollution in this study while in our study, all the respondents agreed that it is not acceptable to dump pharmaceutical waste into the environment. (Aditya, 2014)

Pros and cons of some disposal methods that were found being practiced in this study are given below: (Lamb, 2012)

Table 10. Pros and cons of some disposal methods that were found being practiced in this study.

Disposal methods	Positive outcome	Negative outcome
Flushing	Quick disposal (Avoids potential poisoning and diversion) Cost-efficient	Contamination of water sources, water pollution, harm to aquatic habitats
Throwing in trash	Quick disposal (Avoids potential poisoning and diversion)	Potential for wildlife, children, pets, or others to ingest medication

	Cost-efficient	Leaching from landfill to groundwater, mixing with sources of water
Crushing and adding to another substance	Quick disposal (Avoids potential poisoning and diversion) Cost-efficient	Leaching from landfill to groundwater, mixing with sources of water
Returning to manufacturer	Gets the unnecessary medicine out of home Disposal is environmentally sound Cost-efficient for consumer	Can be expensive and more work for pharmacies

The practice of the newer and correct methods of pharmaceutical waste management adopted by the pharmacy, pharmaceutical companies like incineration, encapsulation, inertization, landfilling after inertization, collection containers, returning unused drugs to the supplier, adherence to existing guidelines, adopting protocols, etc. were impressive but since the traditional and unscientific practices like burning, burying, throwing away like any other common waste, flushing in toilet, dumping in different sites were still prevalent, these are of serious concerns. In this era of 21st century where the advancement of science and technology has reached to different horizons, millions of dollars are being invested in production, manufacturing and sales of pharmaceutical products, number of research studies are being done regarding different aspects of pharmaceutical industry, the domain of pharmaceutical waste management is still in the dark. This is simple logic if people pay even a little attention to it, the drugs are composed of different chemicals, they cause different physiological reactions on our body, it is not a new thing that they would behave the same way when they reach the bodies of different animals similarly different plants and ultimately the environment. They could affect worse since there is no proper mechanism of check and control over it. The environment is in the verge of more harm with every new prescription that goes on.

On one hand, the responsible parties for safely disposing the pharmaceutical waste like pharmacies / pharmaceutical companies are not following the correct methods of pharmaceutical waste management due to different factors like carelessness, low educational

level of workers, non-adherence to pharmaceutical waste management guidelines/protocols, insufficient infrastructures, non-implementation of legislation, lack of proper rules and regulations, lack of educational trainings and programs for pharmacists, no support from concerned authorities, the voices of advocating environmentalists not being heard by upper authorities and regulating organizations. On the other hand, the unused, damaged and expired drugs at homes are being disposed improperly since the common public are not aware of how those drugs should be handled, disposed. They are not even aware how they are putting the environment at risk by these improper practices. Another important factor to consider is the waste produced during production of pharmaceutical products. These are the major cause of environmental debilitation.

The acts like burning, burying, flushing and dumping pharmaceutical waste by educated manpower is unacceptable. These activities are not directly seen as acts harming the ecosystem balance but actually these are causing more harm to the environment. Burning of drugs mixes air with different chemicals that may cause many respiratory diseases, aggravate air pollution, get mixed with other pollutants and cause many more adverse effects. When these chemicals get mixed into the sewage, they ultimately reach the water sources, this creates imbalance in aquatic as well terrestrial habitats, genetic changes, contamination of drinking water sources, mixing of different hazardous chemicals causing different dangerous reactions. Cytotoxic drugs are hazardous and if not disposed of properly embark greater risks. Likewise, the haphazard disposal of antibiotics contributes to development of antimicrobial resistance which is a burning issue of today's medicine. If this current trend of improper and unscientific pharmaceutical waste management practices continues at this devastating rate, the impact on our environment will be dreadful making it hard to fight back for us and sadly we might not be able to recover.

With the growing problems of today's era of poverty, global warming, climate change, terrorism, non-communicable diseases (NCDs), etc. we might be falling back on protecting the environment where we live and destroy the homes of our future generation. Countries in the west have realized the urgent need to safeguard the environment by managing the pharmaceutical waste wisely but this issue has not been realized in the context of Nepal, it seems. The seriousness of this issue should be realized soon by the

government and pharmaceutical industries now. Hence, the accurate knowledge regarding pharmaceutical waste management should be imparted, expanded and updated timely, the use of correct practices should be encouraged, monitored, supervised; the impact on environment should be explored and measures should be adopted to protect and preserve the environment.

8 RECOMMENDATIONS

Different studies can be conducted to explore the status of pharmaceutical waste management in production companies, government as well as private hospitals, clinics, laboratories. An observational study can be conducted to observe the practice of pharmaceutical waste management in pharmaceutical industries, pharmacies, hospitals. The impact of improper pharmaceutical waste management in environment can be observed and studied by longitudinal observational studies. The interventions being done by different governmental and non-governmental agencies, environmental specialist, advocates can be explored. Other similar studies can also be conducted by involving different workers working in the companies or pharmacies. Also, the pharmacies can collaborate with other pharmacies, pharmaceutical companies for waste disposal, they can share their experiences for better outcomes.

The Government of Nepal should make strict legislation regarding pharmaceutical waste management and implement the same. The government authorities should regularly monitor, supervise the pharmacies, pharmaceutical companies. The guidelines should be updated regularly, protocols should be made compulsory for practicing pharmaceutical waste management, there should be provisions of continuous medical education, Inservice education, workshops, trainings, conferences for the pharmacists, punishment and fines should be instated by government to those who do not follow the rules and dispose pharmaceutical waste haphazardly.

Since there is no way of exactly knowing how much the environment has been affected by acts of improper waste management, this topic should be brought into the general public, so they also get sensitized and become aware of the risks. While prescribing or selling drugs, the consumers should be taught about how to dispose the unused or expired drugs, they should be encouraged to return the unused drugs to the pharmacies itself and this should be made easy and accessible for the general public.

The sewage and waste treatment plants should be made advanced and regulated as well. The drainage system of pharmaceutical companies should be monitored to ensure that

the chemicals are not being drained. The newer technological advancements in pharmaceutical waste management should be explored, encouraged, and adopted.

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APPENDICES

Questionnaire

1) Socio-demographic status

a. Name of pharmacy:

.....

b. Gender of pharmacist:

.....

c. Age of pharmacist: (in completed years)

.....

d. Education level of pharmacist:

.....

e. How long has the pharmacy been operating? (in years)

.....

f. How long has the respondent been working in the pharmacy? (in years)

.....

g. Has the respondent been trained on pharmaceutical waste management?

i. Yes

ii. No

2) Knowledge regarding pharmaceutical waste management

a. Is it acceptable to dump pharmaceutical waste into the environment?

i. Yes

ii. No

b. Do you think returning of unsold pharmaceuticals to the suppliers is a good way of minimizing pharmaceutical waste?

i. Yes

ii. No

c. Is burning of pharmaceutical waste a good way of disposal?

i. Yes

ii. No

d. Does burying of pharmaceutical waste prevents it from being mixed into the water sources?

- i. Yes
 - ii. No
- e. Is encapsulation necessary before adopting landfilling method for pharmaceutical waste disposal?
 - i. Yes
 - ii. No
- f. Does inertization reduces or delays the pharmaceutical compounds into the environment?
 - i. Yes
 - ii. No
- g. Are you familiar with the current pharmaceutical waste management guideline?
 - i. Yes
 - ii. No
- h. Is there any effect of pharmaceutical waste to effective sewage treatment in the environment?
 - i. Yes
 - ii. No

3) Practices on pharmaceutical waste management

- a. Do you have guideline/policy/protocol for pharmaceutical waste management in your pharmacy?
 - i. Yes
 - ii. No
- b. Is their provision of maintaining a container for damaged or expired drugs in your pharmacy?
 - i. Yes
 - ii. No
- c. Do you regularly return unused/expired medicine to the supplier?
 - i. Yes
 - ii. No
 - iii.
- d. Do you burn pharmaceutical waste in your pharmacy?
 - i. Yes

- ii. No
- e. Do you bury pharmaceutical waste in your pharmacy?
 - i. Yes
 - ii. No
- f. Do you incinerate pharmaceutical waste in your pharmacy?
 - i. Yes
 - ii. No
- g. Do you throw away pharmaceutical waste in municipal trucks?
 - i. Yes
 - ii. No
- h. Do you flush pharmaceutical waste down the toilet?
 - i. Yes
 - ii. No
- i. What other methods of pharmaceutical waste disposal do you use?
.....
- j. What do you think should be done to improve pharmaceutical waste management practices?
.....