

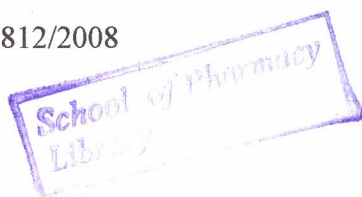


HANDLING OF PHARMACEUTICAL WASTE IN COMMUNITY PHARMACIES IN NAIROBI, KENYA

BY

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DECLARATION AND SUPERVISORS' APPROVAL

I hereby declare that this dissertation is my original work and has not been presented for any other degree in any university.

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DEDICATION

I dedicate this dissertation to all the special people in my life without whom I would never accomplish anything worthwhile. First to my family: my dad David and my mum Margaret for their undying, unconditional love and support and for always believing in me even when I doubt myself, for always being there for me and for their financial support; my closest friend and companion Purity for her encouragement and invaluable unconditional support and faith in my abilities; my older siblings Salome, Josphat and Fidelis, Grace and Joshua, Richard and Susan, and my dear sister Rachel for being good role models to me and my youngest brother Henry for being my best mentee, my nieces; Maggie, Marion, Teresia and Joan; my nephews Wycliff, Levi and Dan, for giving me hope in the future. My close and true friends: Fred, George, Lennox, Kevo, Rebecca, Carol and Selina for always tolerating my off-the-books character and all my classmates for always proving to me that even if it be that am the least, am the least among the best; and to all my University lecturers, primary school and high school teachers for always trying to bring me down by setting hard exams which I sometimes fail but I always pass.

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ABBREVIATIONS

ADHD – Attention Deficit Hyperactivity Disease

⁰C – Degrees Celsius

COMESA – Common Market for East and South African states

DEA – Drug Enforcement Agency

DHMT – District Health Management Team

EPA – Environmental Protection Agency

FIFO – First In First Out

IQ – Intelligence Quotient

IV – Intravenous

KNPP – Kenya National Pharmaceutical Policy

Kshs –Kenya shillings

Kgs - kilogrammes

LLHFs – Low Level Health Facilities

NHCWM – National Health Care Waste Management

PCBs – Polychlorinated Biphenyls

PPB – Pharmacy and Poisons Board

PVC – Polyvinyl chloride

UNEP – United Nations Environmental programme

RCRA- Resource conservation and recovery Act

UNIDO – United Nations Industrial Development Organization

USA - United States of America

US \$ - American Dollars

WHO – World Health Organization

WMT – Waste Management team

ABSTRACT

BACKGROUND

Pharmaceutical waste is waste consisting of/or containing pharmaceuticals which have expired or are no longer needed and their containers or items containing or contaminated with pharmaceuticals. Enforcing proper disposal of pharmaceutical waste is challenging because there are no direct benefits accrued, among other factors like unawareness to guidelines.

OBJECTIVES

To describe the generation, handling and disposal of pharmaceutical waste by community pharmacy outlets in Nairobi, Kenya.

STUDY DESIGN AND METHODS

This was a descriptive cross-sectional study. We randomly selected 25 community pharmacies from Hurlingham, Upperhill, downtown and the central business district areas within Nairobi and administered a predesigned questionnaire for filling. Twenty two filled in questionnaires. The data obtained was analyzed using Microsoft excel and results presented in tables, charts and graphs.

RESULTS

More than half of pharmaceutical waste generated in community pharmacy outlets comes from expired pharmaceuticals while a third of all wastes can be attributed to damaged, contaminated and spoilt pharmaceuticals. Environmentally hazardous methods of disposal such as open dumping, sewer disposal and burning in the open are still practiced. Most respondents are aware that their waste disposal methods pose a risk to the environment, humans, animals or aquatic life. Almost half of the respondents make effort towards minimizing potential threats of waste pharmaceuticals mainly by reducing amount of waste generated or using proper disposal methods.

CONCLUSION

Community pharmacy outlets in Nairobi generate a substantial amount of pharmaceutical waste from their day to day operations and most have multiple sources of wastes. Awareness of disposal policies, guidelines and methods is poor. The disposal methods used have potential threats not only to the environment but also to humans, animals and aquatic life.

CHAPTER ONE

1.0. INTRODUCTION AND LITERATURE REVIEW

1.1. INTRODUCTION

1.1.1. Pharmaceuticals

According to the Kenya National Pharmaceutical Policy (2008), the term pharmaceuticals is used most of the time synonymously to the term medicines which is defined in the Pharmacy and Poisons Act (CAP 244) as any medicinal substance, product, article or substance which is claimed to be useful for: treating, preventing or alleviating disease or symptoms of disease; diagnosing disease or ascertaining the existence, degree or extent of a physiological condition; preventing or interfering with the normal operation of a physiological function whether permanently or temporarily and whether by way of terminating, reducing, postponing or increasing or accelerating the operation of the function in human beings or animals. ^{1,2}

1.1.2. Pharmaceutical waste defined

The Kenya National Health Care Waste Management Plan 2008-2012 (KNHCWM) specifies pharmaceutical waste as waste consisting of or containing pharmaceuticals. This includes: pharmaceuticals which are expired or no longer needed, their containers and items contaminated with pharmaceuticals. ³

1.1.3. Handling of pharmaceutical waste

Enforcing proper disposal of pharmaceutical waste is mainly problematic because the parties involved do not accrue any direct monetary benefits by properly handling the wastes and any expenses incurred in waste disposal are viewed as unnecessary overhead costs. Sometimes the resources or equipment required for proper handling of pharmaceutical waste, e.g. special transport facilities, high temperature incinerators, engineered safety landfills, among others may be very costly and at times unavailable especially in resource poor settings such as in developing countries. ⁴

1.1.4. Regulation of pharmaceutical waste disposal

The Kenya National Chemicals Profile lists the Pharmacy and Poisons Board as the body established by the Pharmacy and Poisons Act (CAP 244) to control and regulate the practice of pharmacy in Kenya. It also lists National Environmental Management Agency (NEMA) as in charge of environmental management and setting up waste management regulations. For this reason PPB and NEMA are the regulatory bodies in charge of enforcing proper and environmentally friendly disposal of pharmaceutical waste.^{2,5}

In the past, efforts and resources have been concentrated on monitoring waste disposal in pharmaceutical industries as they are seen as high waste output centers with high potential for environmental pollution and regulatory authorities have over the years overlooked the impact of poorly disposed pharmaceutical wastes at wholesale and retail outlets because of their presumed low-waste-output.⁶

1.2. LITERATURE REVIEW

1.2.1. The Kenya pharmaceutical sector

The last decade has seen a rampant growth in the Kenyan pharmaceutical industry with an overall increase in pharmaceutical manufacturers, importers, exporters, wholesalers, distributors and retailers {Number of registered pharmaceutical manufacturers; 35 (2006), number of registered pharmacies including 208 wholesalers; 1,153 (2006)}. This has made the country a rich and coveted market for many local, regional and multinational pharmaceutical industries. The annual turnover for the pharmaceutical sector is now valued at hundreds of millions of dollars {US\$ 130 million (2004); 240 million (2008)}. This is due to both an increase in quantities {8000 tons in imports and 4000 tons in export (2004)} and in diversity of pharmaceutical products (more than 8500 products (2006)) marketed and consumed in the country.

Kenya therefore stands as one of the few developing countries in Africa with a highly developed and diverse pharmaceutical sector ranking second largest in Africa and the COMESA region after South Africa.⁷ This is an advantageous position both economically and socially particular because it has enabled accessibility to medication for a better part of the population.

1.2.2. Possible negative impact

This vibrant growth may have some demerits particularly because the policy formulation, control and regulatory agencies in charge of this sector have not grown at a proportional rate. Being a gigantic industry, the pharmaceutical sector undoubtedly produces a substantial amount of waste whose handling and disposal protocol especially at the wholesale and retail level is poorly monitored.³

1.2.3. Regulation of pharmaceutical waste disposal

The available pharmaceutical waste disposal policies are loosely adhered to and the pharmacy academic curriculum does not teach pharmacists or pharmaceutical technologists about proper pharmaceutical waste disposal while environmentalists have little if any understanding of pharmaceuticals and the possible effects of their poor disposal.⁸

The Pharmacy and Poisons Board being the major policy formulation and regulatory agency in the pharmaceutical sector has not been fully able to fulfill some of its duties such as controlling unqualified and unlicensed pharmacy operators (It's estimated that about 65% of pharmacy operators in Kenya are unqualified) and prevention of marketing of counterfeits.⁹ This has been blamed particularly on inadequate personnel, a poor operation system and inadequacy of laws and regulations. The unqualified operators are not only ignorant of the pharmaceutical sector regulations but also do not understand the basics about the dangers of mishandling pharmaceuticals and care less about how they handle pharmaceutical waste. This poor regulation and ignorance within the industry and inadequacy in the curriculum inadvertently results in pharmacy operators who are incompetent at handling pharmaceutical waste and are either unaware or ignorant of the dangers of mishandling pharmaceutical waste.¹⁰

1.2.4. A cumulative effect

Though daily pharmaceutical waste output from a single wholesale/retail outlet may appear too small to have significant impact, looking at the pharmaceutical sector in a city like Nairobi with hundreds of outlets holistically implies that, cumulatively a few days' pharmaceutical waste can be significantly catastrophic if handled inappropriately.

1.2.5. Disposal of pharmaceutical waste and possible outcomes

In most pharmacy outlets and in homes, pharmaceutical waste is mostly collected in rubbish bins and disposed of like any other household wastes, burnt openly, flushed down the toilet or washed down the sink. Where garbage collection services exist, the waste in rubbish bins is ferried to dumping sites together with other wastes. Absent of these services, the waste is dumped in rubbish pits, backyards of pharmacy premises, drainage ditches or just left to litter in residential or commercial areas. These pharmaceuticals end up polluting the environment by creating unappealing sites or are washed away by rain water causing soil and water pollution.

This endangers both terrestrial and aquatic plants and animals and may even end up being consumed by humans in contaminated water or animal/plant products thus endangering human life. Pharmaceuticals that are flushed down the toilet or washed down the sinks may also end up in water sources especially in Kenya where untreated sewage and broken sewer effluents more often than not find their way into rivers, streams and dams that serve as water sources for people downstream or as sources of water for irrigation. This results in harm to plants, animals and humans. ¹⁰Expired drugs may find their way to the hands of ignorant children, street dwellers and drug addicts who may abuse or misuse them while others may be fed on by stray livestock. This may cause poisoning of the people or animals.

Some pharmaceutical products if burnt produce toxic fumes which pollute the air and may be hazardous if inhaled, contribute to greenhouse gases or cause acidic rains that corrode metallic and stone structures. ¹¹

1.2.6. Implications and possible solutions

It is therefore imperative that there is a dire need to monitor the handling of pharmaceutical waste in the numerous pharmaceutical outlets not only in Nairobi but in the whole country to ensure that we are not sitting on a time bomb which may in time not only cause catastrophic environmental pollution but may end up costing us the lives of innocent Kenyans. ¹² The regulatory agencies should be vigilant in enforcing existing policies and put in place systems that monitor adherence to these policies and bring to the book defaulters.

1.2.7. Classification of pharmaceutical waste

Pharmaceutical waste is not one single waste stream, but many distinct waste streams that reflect the complexity and diversity of the chemicals that comprise pharmaceuticals. Pharmaceutical waste is potentially generated through a wide variety of activities in a health care facility, including but not limited to intravenous (IV) preparation, general compounding, spills/breakage, partially used vials, syringes, and intravenous solutions, discontinued or unused preparations, unused unit dose repacks, patients' personal medications and outdated pharmaceuticals.^{6, 15}

The Kenya environmental management and co-ordination (waste management) regulations 2006 classifies pharmaceutical waste as biomedical waste category-4. It further specifies pharmaceutical waste, drugs and medicines as one of the categories of wastes considered hazardous (category Y₃).¹⁴

In the USA, drugs deemed hazardous by the Environmental Protection Agency (EPA) regulations are categorized as "P list," "U list," or "D-list/chemical characteristic." P-listed items are considered acutely toxic; both the drug and the container that held the drug are considered hazardous and must be disposed off in a resource conservation and recovery act (RCRA) approved container. U-listed items are considered toxic while items on the chemical characteristic "D" list are pharmaceuticals that cause wastes that are either; ignitable, corrosive, reactive or toxic. The diluents or preservative, rather than the active ingredient in a commercial or compounded drug may be the culprit in regard to RCRA regulations. Other pharmaceuticals are regarded as solid non-hazardous pharmaceutical waste.¹⁵

1.2.8. Sources of pharmaceutical waste in pharmacies

The major sources include; expiries, spillage, contamination, deterioration due to poor storage, breakages, returns from customers, recalls, damages due to poor handling or by pests among others.¹⁶

1.2.9. Guidelines on proper handling of waste pharmaceuticals in Kenya

The pharmacy and poisons board; “Guidelines for good distribution, wholesaling and retail practice for pharmaceuticals” require that premises be free of accumulated waste, dirt and debris. Waste should be sorted in different categories, collected in designated closed containers, stored in special quarantined areas before disposal and disposed at frequent intervals following a proper waste disposal system.¹⁷

The Kenya national pharmaceutical policy (KNPP) lists Proper pharmaceutical waste management as part of good dispensing practices. It states that the disposal methods should aim for safe, environmentally appropriate disposal of pharmaceutical waste in accordance with nationally and internationally acceptable standards.¹

The Kenya National Guidelines on Safe Disposal of Pharmaceutical Waste (2001) describe a series of steps that need to be followed in order to dispose unwanted pharmaceuticals. The steps required include; identification of pharmaceutical waste, sorting of pharmaceutical waste by category, filling the relevant forms to seek authority from the District Health Management Team (DHMT) and the Chief Pharmacist among other persons to dispose such waste. Upon obtaining all the relevant approvals, the disposal of the pharmaceutical waste shall be effected under the supervision of the local pharmaceutical waste disposal team or the Waste Management Team (WMT).¹⁸

The recommended methods for disposing unwanted pharmaceuticals include; The use of either medium temperatures incineration at a minimum of 850°C or high temperature incineration exceeding 1200°C with two chamber incinerator for solids, semi- solids and powders for controlled substances e.g. antineoplastics; Engineered sanitary landfill to be used for disposal of expired or unwanted pharmaceuticals; Sewer disposal for diluted liquids, syrups, intravenous fluids, small quantities of diluted disinfectants and antiseptics; and open air burning or municipal waste disposal of non-hazardous solid or semi-solid pharmaceutical waste.^{15,18}

1.2.10. Handling of pharmaceutical waste in the USA (developed country)

According to a pharmaceutical waste blue print suggested by Charlotte Smith, president of pharmecology associates; a company pushing for environmentally conservative handling of pharmaceutical waste in USA, pharmaceutical waste handling should entail: Management of regulated and non-regulated hazardous pharmaceutical waste applying best management practices; and minimization of pharmaceutical waste. While the first priority has to be the proper management of hazardous pharmaceutical waste, careful consideration should be given to the management of all pharmaceutical waste. Charlotte Smith suggests that as research data accumulates on the adverse impacts of waste pharmaceuticals on human health and the environment, applying the Precautionary Principle becomes increasingly relevant:

“When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically.” (The Precautionary Principle)⁴

According to South Dakota (USA) department of environment and water resources, a good pharmaceutical waste handling protocol should entail; **Identification:** Determine which pharmaceuticals are considered as hazardous waste and which are solid waste. **Quantification:** calculate the weight you have of each category. **Storage:** containers for hazardous waste pharmaceuticals must be compatible with the wastes, in good condition, not leaking, securely closed unless wastes are being added or removed and properly labeled. **Disposal:** Waste pharmaceuticals that are considered hazardous wastes need to be transported to a permitted hazardous waste storage, treatment or disposal facility while non-hazardous solid waste needs to be disposed at a permitted municipal solid waste facility. **Record** of identity, date and method of disposal should be maintained.¹⁹

1.2.11. Effects of waste pharmaceuticals on the environment

The term “chemical pollutants” most often calls to mind pesticides and industrial sewage, yet since the 1980s pharmaceuticals have increasingly been recognized as chemical environmental pollutants. Unfortunately, since pharmacists do not routinely receive instruction in environmental regulations, most are unaware of laws governing disposal of pharmaceutical wastes.

For many years, pharmacists have been primarily concerned with ensuring that waste drugs were rendered unrecoverable through sewage disposal or incinerating. The focus was on ensuring that children did not gain access to such drugs or that illegal diversion did not occur. ⁽⁶⁾Increased awareness around the presence of pharmaceuticals in drinking water and the discovery of a variety of pharmaceuticals in surface, ground, and drinking waters in countries like the USA, Germany and Nigeria has raised concerns about the potentially adverse environmental consequences of these contaminants and has resulted in closer scrutiny and increased regulatory oversight of pharmaceutical waste. Evidence of feminization of fish raised a red flag and resulted in more studies, closer scrutiny and concern for human health and the environment. ⁸

Dumping healthcare waste in open uncontrolled areas is a practice that can have major adverse effects on the population and can have a direct environmental effect by contaminating soils and underground water. During incineration, under some circumstances, including when some wastes such as plastics that contain polyvinyl chloride (PVC) are incinerated at low temperatures, dioxins and furans and other toxic air pollutants may be produced as emissions and if no proper filtering of gases is done, air can be polluted causing illnesses to the nearby populations. Exposure to dioxins, furans and co-planar Polychlorinated Biphenyls (PCBs) may lead to adverse health effects. ¹⁰ This has to be taken into consideration when choosing a treatment or a disposal method by carrying out a rapid environmental impact assessment. ^{4, 10}

At the level of natural systems the interaction between waste handling procedures and public health conditions is influenced by climatic conditions and characteristics of local, natural and ecological systems. The degree to which uncontrolled waste dump sites become breeding ground for insects, rodents and other disease vectors and a gathering place for dogs, wild animals and poisonous reptiles depends largely on prevailing climatic and natural conditions. These factors determine the frequency with which waste collection points must be serviced in order to limit negative environmental consequences. ^{10, 20} At the level of the built environment, the size and structure of a settlement have an important influence on the character and urgency of waste management needs. In urban areas, the physical characteristics of a settlement including such factors as density, width and condition of roads, topography, etc., need to be considered when selecting and/or designing waste collection procedures and equipment such as containers and vehicles. ²⁰

1.2.12. Studies on the environmental impact of waste pharmaceuticals

1.2.12.1 Studies in the USA

In a New Jersey study, 90 percent of the pharmaceuticals found within a water treatment system came from human waste while 10 percent came from medicines flushed down the drain. It was concluded that there is need to take actions to minimize the amount of pharmaceuticals getting into water supplies. Such actions include ensuring unwanted and non-narcotic pharmaceuticals are disposed of in accordance with the country's solid and hazardous waste requirements. Narcotics need to be handled in accordance with the state requirements specific to that category of drugs or in accordance with drug enforcement agency (DEA) guidelines.¹²

In 2002, Colin et al reported that of 139 streams sampled in 30 states across the USA, 80% contained one or more organic wastewater contaminants (OWCs). The study tested for 95 OWCs, including pharmaceuticals. Most (82) of the OWCs were found in at least one stream sample, and 13% of the streams contained more than 20 OWCs. Many of the OWCs were pharmaceuticals from common prescription and nonprescription products.

Similarly, in a U.S. Geological Survey study of Minnesota wastewater, surface, ground, and drinking waters, OWCs were found in 90% of the samples. The highest levels detected were from nonprescription drugs, antibiotics, and prescription drugs, respectively.²¹

1.2.12.2. Studies in Africa

In Africa, a study of waste disposal by Nigerian pharmaceutical industries revealed that most generators of hazardous waste are not aware of the health and environmental implications of improper disposal and so public awareness and training are imperative. Such training should be done for the staff of the regulatory authorities, the key players in the public and private sectors, industrial and health workers.²²

In Tanzania, a study on handling of medical waste in (LLHFs) low level health facilities revealed that; most of the facilities have no specific disposal sites. Most of the health facilities burn wastes in poorly designed incinerators, open pits or on the ground while many of the facilities bury wastes in the pits. More than half of the disposal sites surveyed were not fenced and were in

close proximity to human settlements. Most incinerators in the surveyed facilities were not in good working conditions, about half of them were low capacity and some parts were missing, e.g., chimneys, ash pits, covers for waste loading and ash removing doors. Transportation of wastes to the disposal sites was by hands or use of wheelbarrows. Waste segregation and color coding are poorly adhered to while most of the storage areas are too small and record keeping is poor. It was concluded that, the medical waste management in LLHFs is still poor and awareness should be raised among LLHFs workers on proper management of the medical wastes. (4, 23) In Africa, the situation of poor medical waste management was found to be similar in South Africa, Mozambique, Swaziland, Kenya and Tanzania. Illegal dumping is a serious problem in most developing countries. Almost all the countries recognized poverty as a basic factor that dwarfed the success of African efforts in the area of environmentally sound management of hazardous waste. ²³

1.2.12.3. Studies in Kenya

Local studies on handling of pharmaceutical waste in Kenya are not readily available, they have either not been done or are not published. A rapid assessment of health care waste management in Kenya was conducted in four of the eight provinces in Kenya namely; Nairobi, Central, Rift Valley and Western involving 24 hospitals. The study concluded that it was clearly evident there was lack of targeted resources necessary to put in place the required infrastructure for health care waste management at the national level, facility level and at home in the case of home based care.

It was found that most facilities dispose their waste on site mainly through incineration, open dumping and open burning. Most facilities dispose waste in waste pits, open dump sites or bury waste in trenches. It was also evident that most incinerators were not in good working condition and incineration was being done below required temperatures which could lead to harmful by-products. Open dumping was common in most facilities and waste storage areas had poorly regulated access and some were not fenced. Transport and segregation were not as per set guidelines and there was poor documentation of the entire waste handling and disposal process. ³

1.2.13. Health effects of waste pharmaceuticals

Although pharmaceutical contaminants have not been found at therapeutic levels, they have potential adverse consequences, including water quality degradation, endocrine disruption (which translates into problems with physical, mental, and sexual development), antibiotic resistance, and negative public perception regarding water cleanliness. The environmental and physical consequences of improper pharmaceutical waste management are serious. Human male sperm counts have dropped 50% on average since 1939, and there have been increases in infertility, genital defects, cancers caused by hormones (breast and prostate), and neurological disorders in children. Endocrine disrupters found in U.S. waterways could have effects on future generations; they interfere with normal functioning of the endocrine system (thyroid, adrenals, ovaries, and testicles), mimic hormones, and affect reproduction, development, and behavior.

In addition, antibiotic resistance is on the rise; ampicillin-resistant bacteria were found in every U.S. river tested in 1999.^{6, 8, 12} In a 2000 study, all samples taken from the Ohio River contained *Escherichia coli* with some resistance to penicillin, tetracycline, and vancomycin. Samples containing the highest levels of antibiotics also contained bacteria with the greatest resistance.

Scientists have also warned that fetal exposure to toxic substances may cause fetal programming up to the 2nd and 3rd generations and may result in lifelong effects such as, obesity, diabetes, cancers, attention disorders (ADHD), low IQ, parkinsonism, Alzheimer's, and immune suppression.⁶ Studies on effect of selective serotonin re-uptake inhibitors on aquatic life show they cause developmental delays in forelimb formation, tail resorption and increased metamorphosis time and mortality in tadpoles; other studies have showed feminizing effects of estrogens in fish.²⁴

1.3. PROBLEM STATEMENT

1.3.1. Poor regulation, monitoring and training

Handling of pharmaceutical waste in community pharmacies in Kenya is poorly regulated and unmonitored. Policies on handling of such waste are unknown to the majority of pharmacy operators and where such policies are known they are either not followed adequately or are totally ignored. Regulatory agencies in the country are either not vigilant enough at ensuring adherence to policies regarding handling of pharmaceutical waste or have inadequate personnel and resources to satisfactorily monitor and regulate the pharmaceutical sector.⁷ Most pharmacy operators are ignorant of the effects of inappropriate disposal of pharmaceutical waste and environmental impact is a thing of little note to them. There is also poor coverage of the subject on proper disposal of pharmaceutical waste in the universities and colleges that train pharmacists and pharmaceutical technologists thus even the trained personnel have very little understanding of this subject and few if any pharmacy outlets carry out staff trainings on this subject.

1.3.2. Unavailability of waste processing facilities

Some pharmaceuticals require special disposal facilities such as high temperature incinerators and engineered safety landfills. These are expensive to set up and are rarely available or located very far from the outlets thus high transport costs and need for special transport facilities.⁴

1.3.3. Effects of improper disposal of pharmaceuticals

Poorly disposed pharmaceuticals cause water, air, soil and environmental pollution. Consumption of these products by humans or animals may cause poisoning which may be lethal and life threatening.^{10,12}

1.4. STUDY JUSTIFICATION

The study aims to find out if community pharmacy outlets have well established and documented guidelines and procedures for handling and disposing of pharmaceutical waste. It also intends to determine existence or not of written plans or inventory as regards, sorting, handling, storing, transportation and disposal of pharmaceutical waste and whether or not the waste disposal is different from that of general household waste.

If not properly disposed, this waste may end up in dumping sites or in sewers and eventually in soil or water bodies. Pharmaceuticals within the soil may take many years to decompose and may affect plant growth and crop productivity. In water bodies they may cause death of aquatic life or cause genetic deformities and extinction of aquatic life. If they find their way to water sources and are consumed by humans they may cause life threatening toxic, teratogenic, mutagenic and carcinogenic effects, immunological sensitization, antimicrobial resistance and can at high levels and some at low doses cause death. Where pharmaceuticals are burnt, some may generate toxic fumes, greenhouse gases or gases which result in acidic rains that destroy structures and buildings.¹²

Considering the many wholesale and retail outlets in operation in Kenya today; more than 700 wholesale and around 1300 retail; most of which are in urban areas,¹³ it is very possible that these outlets could collectively and cumulatively generate large amounts of pharmaceutical wastes. If these outlets are centralized in one relatively small geographical area such as they are in a city like Nairobi, then improper handling of pharmaceutical waste from these outlets could definitely have significant negative environmental, ecological, socio-economic and health impact.

A study on handling of pharmaceutical waste in pharmacy outlets in Nairobi will therefore paint a clear picture of the actual handling of such waste in our city. The results can be extrapolated to other towns and urban centers in the country thus giving a nationwide view of existing or potential environmental pollution by pharmaceutical waste from community pharmacy outlets. The results of the study if properly implemented can act as a platform on deciding the way forward regarding either control of existent pollution or avoiding possible development of pollution by pharmaceutical waste.

1.5. OBJECTIVES

1.5.1. Broad objectives

To carry out a study on how community pharmacy outlets in Nairobi handle and dispose of pharmaceutical waste.

1.5.2. Specific objectives

1. To find out the specific pharmaceutical wastes generated in pharmaceutical outlets in Nairobi.
2. To find out the specific waste disposal methods used in pharmacy outlets in Nairobi.
3. To find out the awareness of policies and guidelines on disposal of pharmaceutical waste by pharmacy operators in Nairobi.
4. To find out the possible impact of inappropriately disposed pharmaceuticals on the environment, ecological systems and human life.

CHAPTER TWO

2.0. METHODOLOGY

2.1. Study area and sample size

The study was undertaken in twenty two community pharmacy outlets in and around Nairobi central business district, twelve of which were the pharmacies in which the 2012 fourth year Bachelor of Pharmacy students from the University of Nairobi did their community pharmacy electives rotation between 9th January and 2nd March 2012. The other ten were selected randomly from among the other community pharmacies within the Nairobi central business district. The community pharmacies selected included both wholesalers and retailers.

2.2. Data collection

A questionnaire (Appendix: 1) was prepared and distributed to the selected pharmacies and constituted of open and close ended questions which the respondents responded to by writing/ticking on the provided space.

The filled questionnaires were collected and the data obtained analyzed.

2.3. Data analysis and presentation

The raw data obtained was analyzed using Microsoft excel and results presented in tables, charts and graphs.

2.4. Ethical considerations

An introductory letter granting permission to undertake the study was obtained from the Office of The Dean, School of Pharmacy, University of Nairobi (see attached).The respondents were assured of anonymity and all information provided was used for academic purposes only. Respondents filled in the questionnaires at will.

CHAPTER THREE

3.0. RESULTS

3.1. Characteristics of Pharmacy outlets

Twenty five questionnaires were issued to 25 community pharmacies of which twenty two filled in questionnaires. Categories of the respondent community pharmacies are shown in Table 1 below.

Table 1: Categories of the Community Pharmacies

Category	Number of respondents
Wholesale	1
Retail	18
Wholesale and retail	3
Total	22

Most of the responders were retail pharmaceutical outlets.

3.2. Waste generation

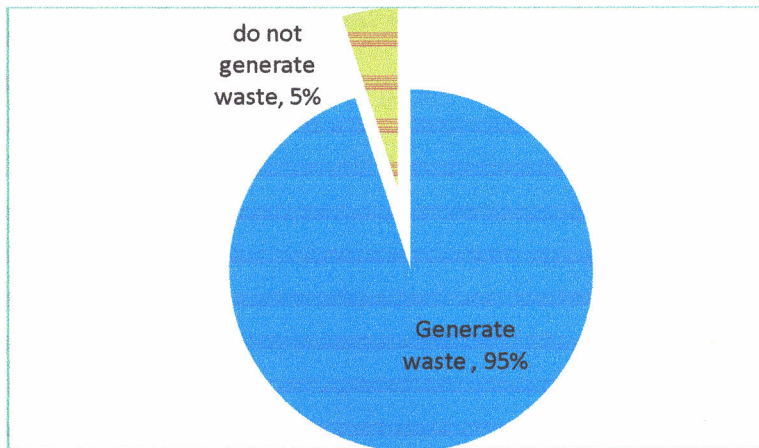


Figure 1: Proportion of community pharmacy outlets that generate pharmaceutical waste.

A majority of outlets (95%) reported that they definitely generate pharmaceutical waste.

3.3. Sources of waste

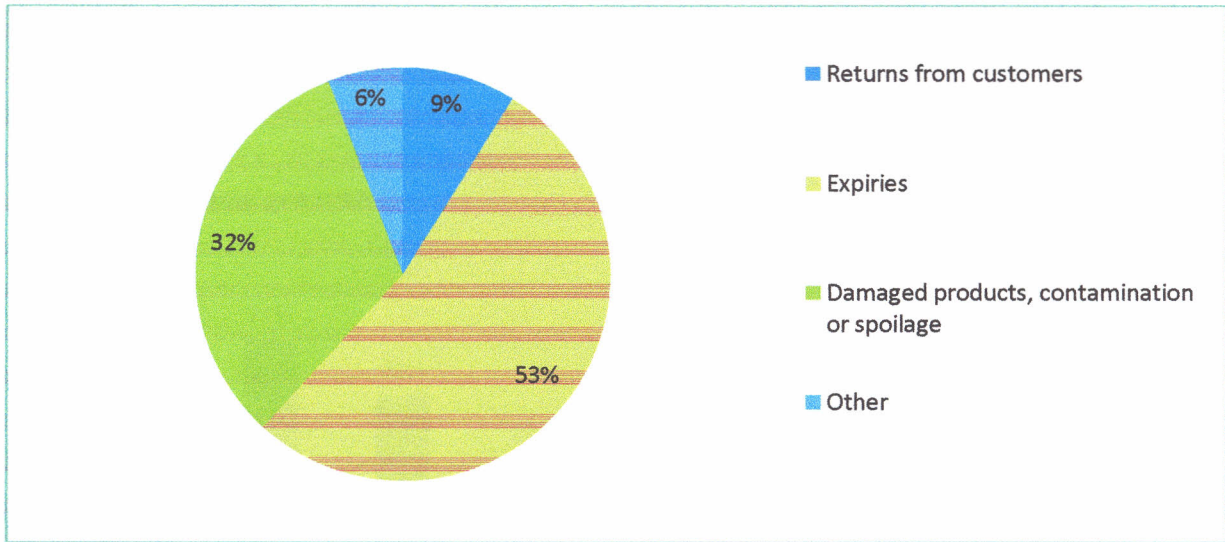


Figure 2: Proportion of pharmaceutical waste generated by various sources of wastes.

More than half of pharmaceutical waste generated in community pharmacy outlets in Nairobi comes from expired pharmaceuticals while almost a third of all waste is attributed to damage, contamination and spoilage of pharmaceuticals.

3.4. Amount of waste generated

Table 2: Amount of waste generated

	Respondents	Category of outlet			Average (Kgs)	Monthly average (Kgs)	Annual average (Kgs)
		retail	wholesale	Both			
Daily	1	1	-	-	3	84	1092
Weekly	4	2	-	2	4.25	17	221
Monthly	5	4	1	-	3.6	3.6	46.8
Annually	3	3	-	-	12.7	1.1	12.7
Average (Kgs)						26.4	343.2
Did not know	8						
Total	22					370	4804

The amount of waste generated varies highly from one outlet to the other with the highest generating 3 kilogrammes daily and the lowest generating 1 kilogramme annually. Thirty six per cent (36%) of outlets do not weigh their wastes and could not estimate how much waste they generate.

3.5. Types of waste generated

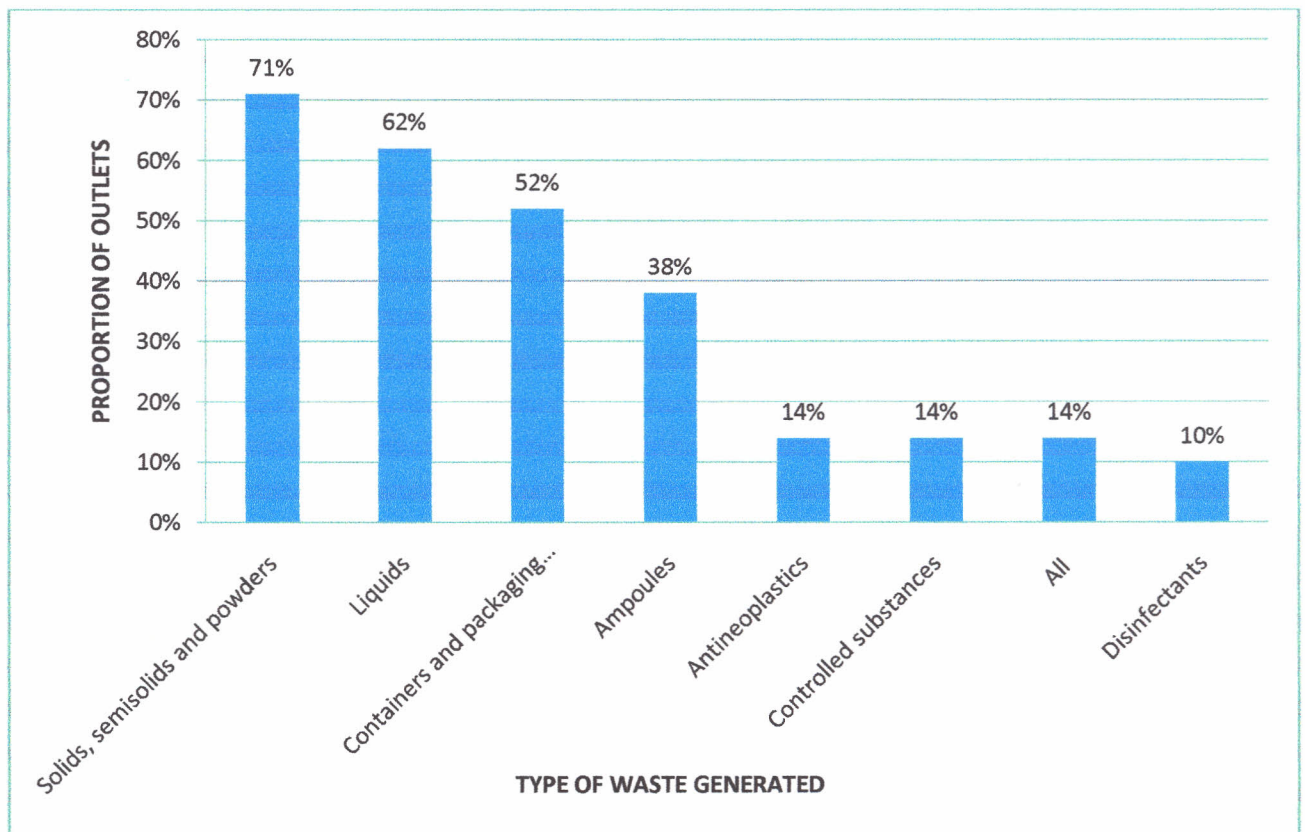


Figure 3: Proportion of pharmacy outlets that generate different types of wastes.

Solids, semisolids and powders are generated as pharmaceutical waste in 71% of community pharmacy outlets, liquid wastes in 62% of outlets, containers and packaging materials are constituents of pharmaceutical waste in about half of all outlets and injection ampoules in about 38% while disinfectants, controlled substances and antineoplastics are generated as waste in less than 15% of outlets.

3.6. Storage of pharmaceutical waste

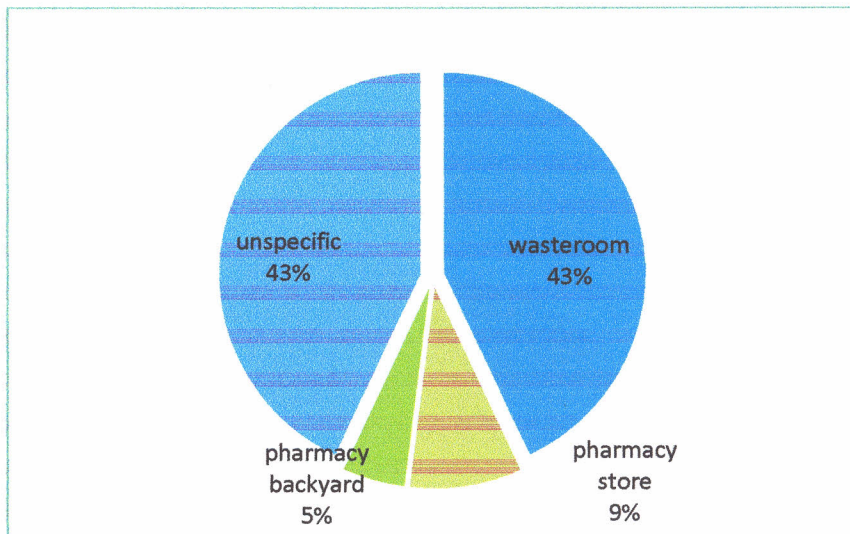


Figure 4: Areas for storage of pharmaceutical waste in community pharmacy outlets

Most of the respondents have some form of waste containers such as cartons, paper bags, dustbins or boxes for putting pharmaceutical waste. Almost half of the respondents keep these waste containers in a segregated waste room, and almost half (43%) have no specific place where they keep waste.

3.7. Frequency of waste disposal

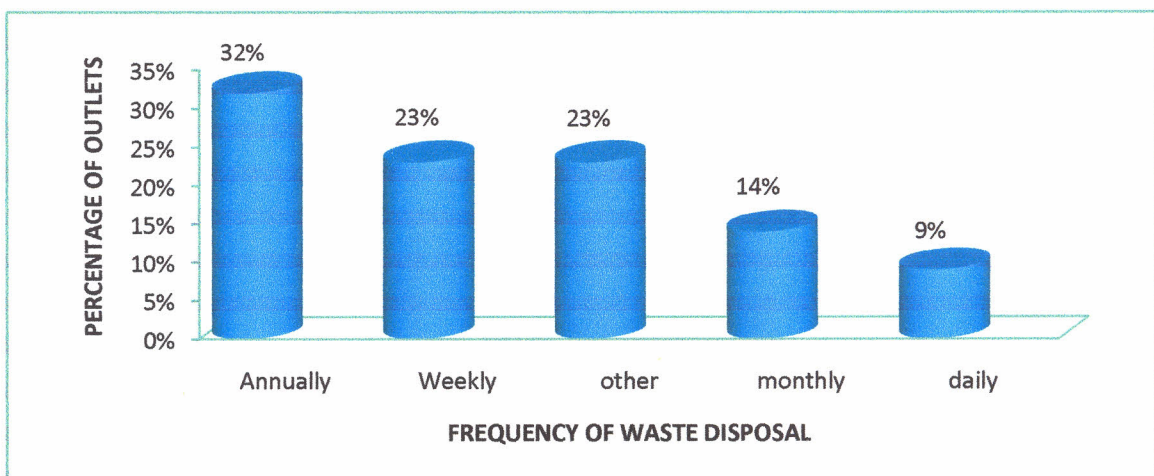


Figure 5: Frequency of disposal of pharmaceutical waste.

Most outlets dispose waste annually. Very few outlets dispose their waste daily, 23% do it on a weekly basis, 14% do it monthly while another 23% dispose either when necessary, quarterly or half yearly.

3.8. Waste disposal site

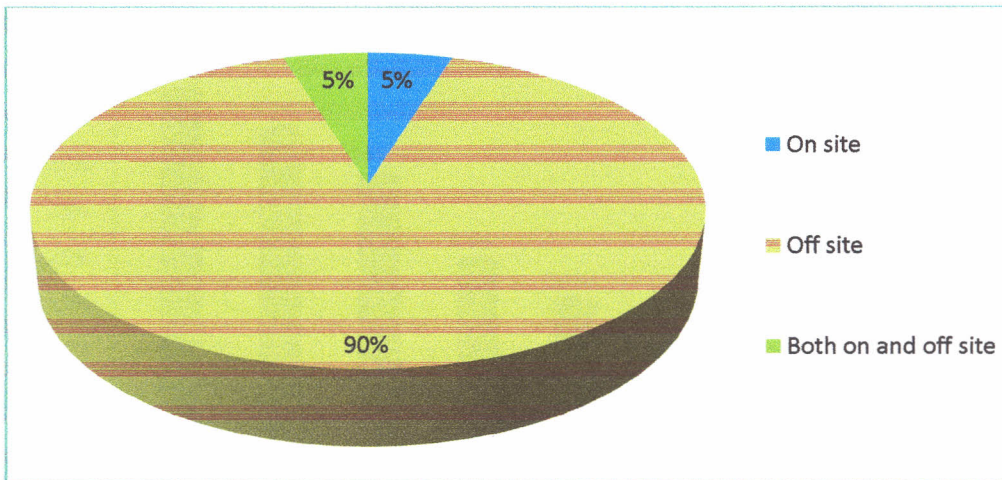


Figure 6: Sites of waste disposal site

Most outlets dispose their waste at a disposal site located away from the outlet (off-site), 5% dispose their waste within the pharmacy environ (on-site) while another 5% dispose some wastes on-site and other wastes off-site.

3.9. Responsibility for waste disposal

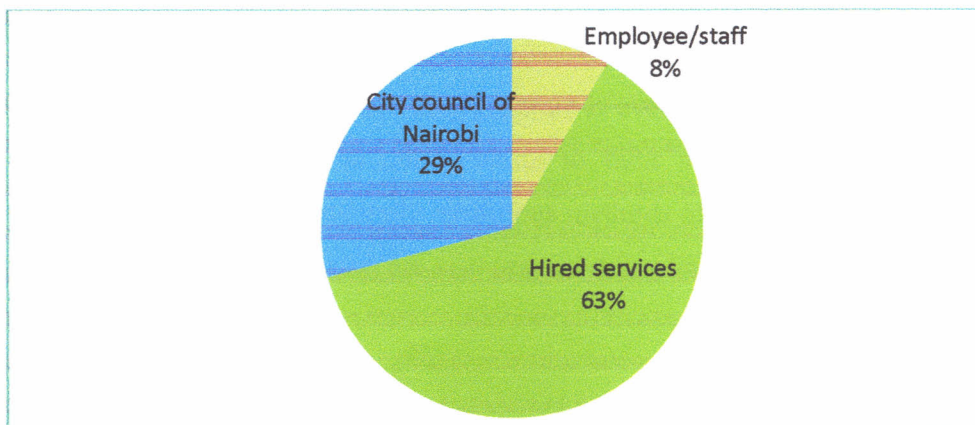


Figure 7: Party responsible for waste disposal.

Most outlets hire waste disposal services to take their waste to the disposal site, 29% have their waste disposed by the city council while in 8% of outlets disposal is done by a pharmacy employee.

3.10. Methods of waste disposal

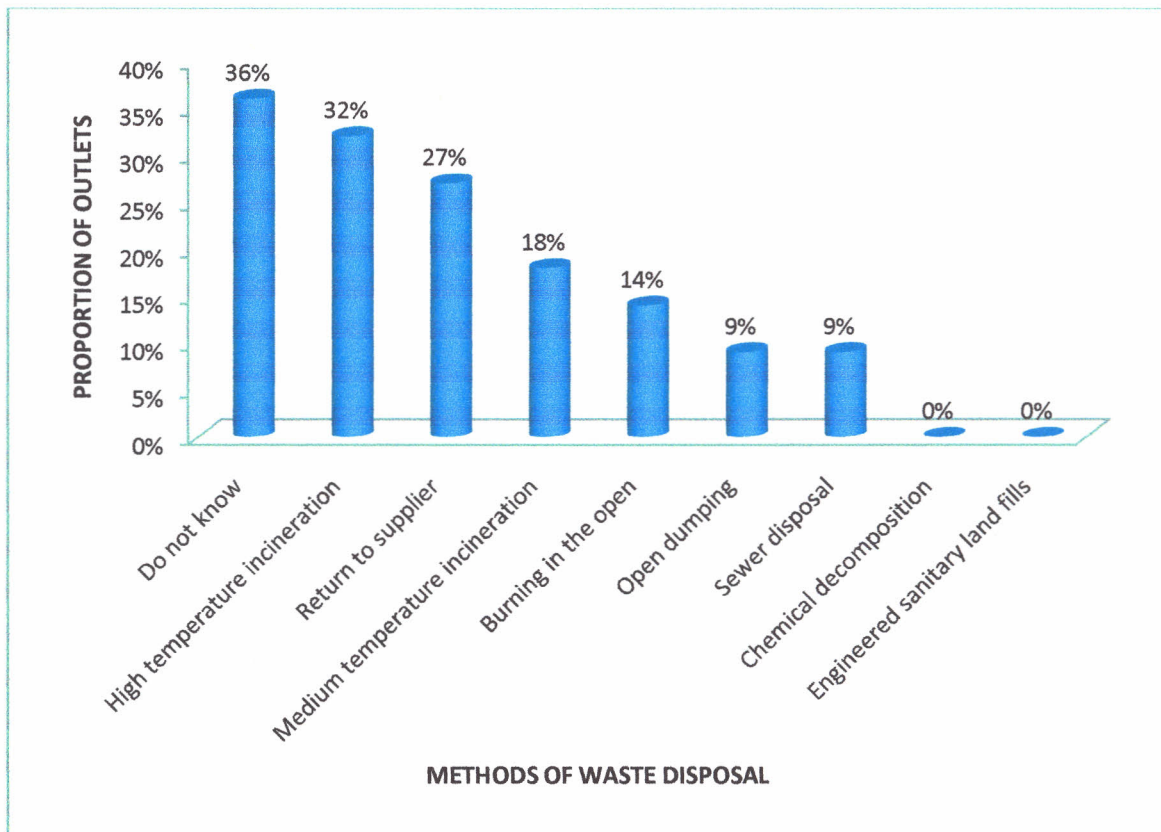


Figure 8: Methods of disposal and proportion of outlets that use each of them.

Most outlets do not know how the waste they generate is eventually disposed. A third dispose by high temperature incineration, 27% return waste to their supplier while 18% do medium temperature incineration. Environmentally hazardous methods of disposal such as open dumping, sewer disposal and burning in the open are also practiced in a third of the respondents.

3.11. Cost of waste disposal

Table 3: Estimated Monthly Cost of Waste Disposal for Different Outlets

Cost per month in Kshs.	N
less than 200	2
200	1
400	1
500	2
1000	2
2000	2
3000	1
5000	2
Don't know	9
Total	22

The cost of waste disposal was highly variable with the highest cost being Kshs. 5000 per month and the lowest being less than Kshs. 200. The average cost of disposal was Ksh.1,152. Some outlets do not know how much it costs to dispose their waste while others pay waste disposal charges as part of rent.

3.12. Government agency in charge of waste pharmaceutical disposal

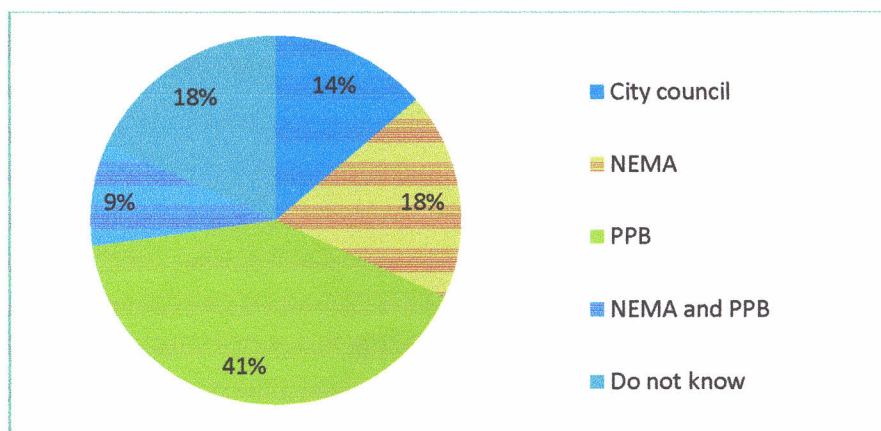


Figure9: Agencies which respondents think is in charge of waste disposal.

Most respondents believe that PPB is responsible for disposal of pharmaceuticals waste; some think National Environmental Management Authority (NEMA) is the responsible body while 18% do not know who is responsible. A few think it's a joint responsibility of PPB and NEMA.

3.13. Fulfillment of some requirements related to disposal of pharmaceutical waste

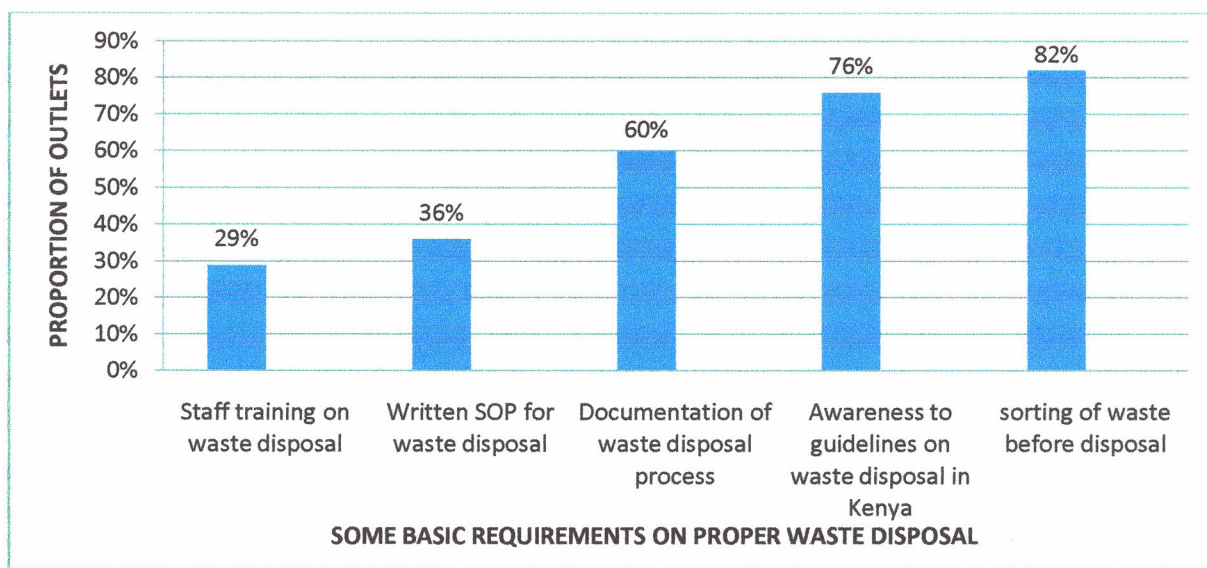


Figure 10: Proportion of outlets that fulfill some basic requirements on proper pharmaceutical waste disposal.

Majority of the respondents (82 %) reported that they sort their pharmaceutical waste into different categories before disposal. About three quarters of the respondents are aware of the existence of guidelines on pharmaceutical waste disposal. Slightly more than half document their waste disposal process and about a third have written standard operating procedures for waste disposal. However, staff training on disposal of pharmaceutical waste is very low at 29%.

3.14. Potential threat of disposed waste on: humans, animals, aquatic life and/or environment.

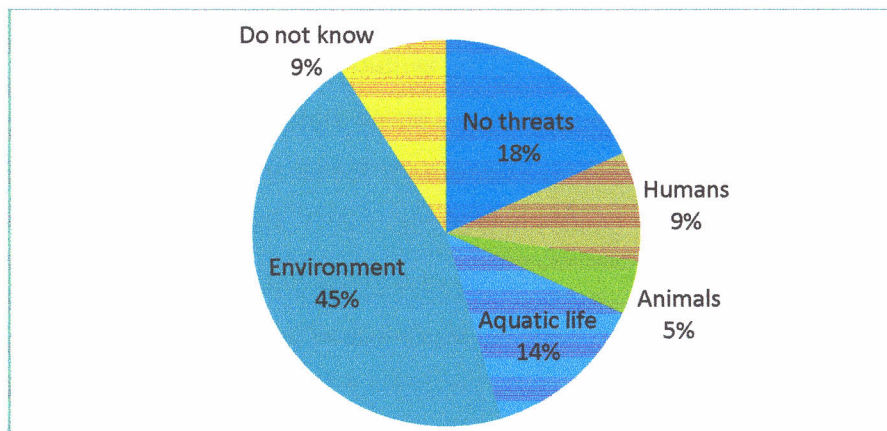


Figure 11: Proportion of respondents that think their waste disposal methods pose some risks to humans, animals, aquatic life or the environment.

Most respondents think that their waste disposal methods pose a risk to the environment; 14% think there is potential risk to aquatic life, few think their method poses risk to humans or animals, 9% do not know while 18% believe their disposal methods are completely safe.

Table 4: Examples of threats posed by waste pharmaceuticals

Type of threat	Examples of threats
Humans and Animals	Toxicity or physical harm e.g. by broken bottles or spilled drugs
Aquatic life	Sewer disposal of drugs may kill fish and other aquatic life.
Environment	Open dumping of non-biodegradable drugs, plastics and polythene containers is environmentally hazardous and destroys the environment; air pollution from fumes after burning or incineration; pollution

Sixty three per cent (63%) of respondents did not give any examples of threats posed by their waste to humans, animals, aquatic life or environment upon disposal. Forty-five percent (45%) of the respondents make effort towards minimizing potential threats of waste pharmaceuticals.

CHAPTER FOUR

4.0. DISCUSSION

Most (95%) of community pharmacy outlets in Nairobi generate pharmaceutical waste. The small percentage that does not generate waste (5%) attribute this mainly to their highly efficient stock tracking system that enables detect short expiry products which they exchange for longer expiry products from the suppliers. Other factors that reduce waste generation include avoiding over stocking, careful handling and storage to avoid breakages and preventing contamination. This implies that most community pharmacies do not have proper and efficient commodity chain management systems.

The biggest source of pharmaceutical waste is expiries with 82% of respondents listing it as a source. Damage, contamination and deterioration are the second commonest being sources of waste in 50% of outlets. Ten (45%) of the respondents had more than one source of waste. Of those with one source, 82% stated expiries as the source while 18% attributed their waste to; damage, contamination and/or spoilage. This implies that proper stock tracking and use of first-in-first-out or earliest-expiry-earliest-out protocols and proper handling and storage could greatly reduce pharmaceutical waste generation in community pharmacies.

The most common type of waste in community pharmacies is; solids, semisolids and powders being generated in 72% of outlets, liquids are second at 62% of outlets, containers and packaging materials are waste in 52% of outlets, ampoules 38%. This could be due to the fact that, most of the pharmaceuticals come as either solid, semisolid or liquid dosage forms.

The amount of waste generated differs greatly from one outlet to another probably due to differences in size, scope of operation, handling and storage of products, among other factors. Most outlets do not weigh their waste and 8 (38%) had no idea of how much waste they generate while most of the others could only give approximate quantities. For the 13 outlets (62%) with known or approximate quantities the total weight of waste was approximately 350 Kgs per month. This implies that the outlets collectively generate a large quantity of pharmaceutical waste (approximately 5 tonnes per year) which if not properly disposed may have a lot of negative impact on the environment, humans, animals, plants and aquatic life among others.

Most of the outlets dispose their waste on an annual basis (32%) or weekly (23%) while only 9% dispose their waste daily. Most outlets (95%) dispose their waste off-site and 71% of the pharmacies hire waste disposal services. Majority of the outlets (36%) do not know the method of disposal used by their hired waste disposal services provider. This implies a need to follow up on the waste disposal service providers to find out their methods of final disposal. The most used method of disposal is high temperature incineration being used by 32% of outlets. Therefore, only 32% of pharmacy outlets use a method of disposal with low negative impact (high temperature incineration), the rest 68% use potentially hazardous disposal methods.

The cost of waste disposal varies highly depending on type and amount of waste, who disposes the waste and the disposal method used. On average the cost is approximately Kshs.1150 per month. Most outlets opt to use cheaper methods of disposal most of which are not in accordance to pharmaceutical waste disposal guidelines because some of the recommended methods are too expensive with some disposal companies charging up to Ksh.2000 to 3000 per Kg of waste.

In 76% of outlets, pharmacy staff is aware of the existence of guidelines on disposal of pharmaceutical waste. 41% of the staff think that PPB alone is the body regulating disposal of waste pharmaceuticals, 18% think it's NEMA, 14% say it's the city council, 9% think that it is a collective responsibility of both PPB and NEMA while 18% do not know the responsible agency. Most of the respondents (82%) sort their waste into different categories before disposal. Only 43% of the outlets have designated waste storage areas, 36% have written SOPs on waste disposal, 60% documentation the waste disposal process/schedule while only 29% train their staff on waste disposal. This shows considerable non-adherence to basic guidelines on pharmaceutical waste disposal.

Most of the outlets (80%) despite knowing the potential dangers of their disposal methods, to the environment, humans, animals or aquatic life still use them which implies carelessness on their side.

Some ways used by the respondents to minimize potential threats of waste pharmaceuticals include:

- Segregation and disposing of pharmaceutical waste separately from other wastes.
- Following of proper disposal procedures.
- Outsourcing waste disposal services to companies professionally specialized in pharmaceutical waste disposal.
- Use of incineration for flammable products.
- Recycling of packaging materials and reusable containers.
- Efficient stock tracking and returning of short-expiry products and exchanging them for long-expiry ones.
- Use of first in first out protocol to minimize expiries.
- Disposal away from animals and humans.
- Avoid overstocking and stocking long-expiry products.
- Proper handling of products to avoid breakages.

Suggestions by respondents for easing, facilitating and ensuring safe and proper disposal of pharmaceutical waste include;

- The government and responsible agency should provide containers for waste storage and collect them on a monthly basis.
- Proper training and continuous education on waste disposal for pharmacy staff and garbage collectors.
- Government should take charge of waste disposal and lower charges for the same.
- Provision of SOPs and guidelines on disposal of pharmaceutical waste from the government agency in charge.
- Cheaper and affordable ways of disposal.
- Ensure sorting of wastes and appropriate disposal of each category.
- Use of bio-degradable packaging materials in place of plastics and polythene bags.
- There should be a government agency solely in charge of waste handling.
- PPB should be keen and follow up on waste disposal.

4.1. Study Limitations

1. Unwilling or unfriendly respondents.
2. Inconsistency of some information provided.
3. Suspicion of being a regulatory agency official.
4. The study involved a lot of commuting.
5. Unavailability of data on similar studies in other countries.

CHAPTER FIVE

5.0 CONCLUSION AND RECOMMENDATIONS

5.1. Conclusion

Community pharmacy outlets in Nairobi generate a substantial amount of pharmaceutical waste from their day to day operations and most have multiple sources of wastes. Expiries, damages, contamination and deterioration are the biggest sources of pharmaceutical waste. Solids, semi-solids, powders, liquids, injection ampoules and packaging materials/containers are the commonest constituents of pharmaceutical waste generated in Nairobi's community pharmacy outlets.

Most outlets out-source waste disposal services. Majority of the outlets do not know the method of waste disposal used by their hired waste-disposal-service-provider. A big proportion of outlets return generated waste to their suppliers. The most commonly used method of disposal is high temperature incineration but medium temperature incineration, open burning, open dumping and sewer disposal combined are used more than high temperature incineration alone. Thus the majority of waste disposal methods used have potential for negative effects.

Awareness to policies and guidelines on disposal of pharmaceutical waste by pharmacy operators in Nairobi is high with only a small but substantial proportion (24%) being unaware of their existence. However, adherence to these regulations is low with improper storage, absence of SOPs on waste disposal, poor or no documentation of waste disposal and inadequate training of pharmacy staff on proper waste disposal being prevalent in a majority of outlets. Most pharmacy operators do not know which government agency regulates the disposal of pharmaceutical waste. The disposal methods used have potential threats mostly to the environment but also to humans, animals and aquatic life. They cause environmental pollution, kill aquatic life and some are potentially injurious or toxic to animals and humans. Only a small proportion of community pharmacy outlets are doing something to reduce these negative effects of pharmaceutical waste.

5.2.Recommendations

Most of the suggested recommendations for improving the handling of pharmaceutical waste focused on reduction of waste generation from the major sources namely; expiries, damages, contamination and deterioration. This can be done through proper stock tracking, avoiding over stocking, proper handling and maintaining conducive storage conditions.

To improve adherence to guidelines, there is need for proper training and continued education of pharmacy staff on policies and guidelines relating to handling of pharmaceutical waste. Such guidelines should be made available on the regulatory authorities' websites to ease access. There is also need for clarity on the government agency responsible for regulation of the handling of pharmaceutical waste and this body should follow up and ensure adherence to set guidelines on proper disposal.

There is need for a government body in-charge of waste disposal which should provide colour coded containers for storage of different categories of wastes, collect wastes from the pharmacies regularly, charge lower and affordable fees for waste disposal services and ensure each category of pharmaceutical waste is disposed by the appropriate method to minimize possible negative effects.

Related studies in future should involve the waste disposal service providers who do the final disposal to find out the specific/definitive methods they use to dispose pharmaceutical waste.

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APPENDICES

Appendix 1; Questionnaire

HANDLING OF WASTE IN COMMUNITY PHARMACIES IN NAIROBI, KENYA.

My name is Mburu Julius Njenga .Am a fourth year student at the University of Nairobi; School of Pharmacy (Adm No: U29/2812/2008). Am doing this research entitled “**Handling of pharmaceutical waste in community pharmacy outlets in Nairobi**” as part of my academic project. I humbly seek your assistance to please fill in this questionnaire as honestly as possible to enable capture the real situation on the ground. The results of the study will be of great use in the future for informing policy on safe, proper, cost effective and sustainable methods and plans for disposal of pharmaceutical waste. All confidentiality is promised and assured. All information provided shall be used for academic purposes only. Thank you in advance for your invaluable assistance and for your time.

Please tick in the appropriate box or answer in the provided space.

1. Please specify your scope of operation.
 - a. Wholesale
 - b. Distributor
 - c. Retailer
 - d. Other

2. Does your premises generate pharmaceutical waste?
Yes No

3. What are your sources of pharmaceutical wastes?
 - a. Returns from customers
 - b. Expiries
 - c. Damaged products, contamination or deterioration
 - d. Other: specify

4. Approximately how much waste in kilograms do you generate;
 - a. DailyKgs
 - b. WeeklyKgs
 - c. MonthlyKgs
 - d. Yearly.....kgs

5. What kind of wastes do you generate?
- a. Solids, semi-solids and powders
 - b. Liquids
 - c. Ampoules
 - d. Controlled substances
 - e. Antineoplastics
 - f. Disinfectants
 - g. Containers and packaging materials
 - h. All the above
6. Do you sort your pharmaceutical waste before disposal? {E.g. as per above (No.5) categories?}
- Yes No
7. Where and how do you store waste before disposal?
-
-
-
8. How often do you dispose of pharmaceutical waste?
- Daily Weekly Monthly Yearly Other
9. Where do you dispose of the waste?
- On site off site
10. Who disposes off your waste?
- Personally Employees /staff Hired waste disposal services
- City council of Nairobi
11. How do you or your hired services dispose of the waste?
- a. Return to manufacturer, distributor or wholesaler
 - b. Engineered sanitary landfills
 - c. Sewer disposal
 - d. Burning in the open
 - e. Medium temperature incineration
 - f. High temperature incineration
 - g. Chemical decomposition
 - h. Open dumping
 - i. Do not know
12. On average how much money in Kshs per month does it cost you to dispose of pharmaceutical waste? Kshs

13. Do you have a written standard operating procedure for waste disposal?

Yes

No

14. Do you document your waste disposal schedules, protocols and processes?

Yes

No

15. Are you aware of any guidelines on pharmaceutical waste disposal in Kenya?

Yes

No

16. Which government agency regulates the disposal of pharmaceutical waste?

NEMA

City council

PPB

Do not know

17. Do you carry out any staff training on pharmaceutical waste disposal?

Yes

No

18. Do you think your disposal methods pose any threats to:

Humans

Animals

Aquatic life

Environment

19. If any threats to animals, humans, environment, aquatic life please list:

- a.
- b.
- c.
- d.

20. What are you doing to minimize these threats?

- a.
- b.
- c.
- d.

21. What are your recommendations for ensuring, facilitating or easing disposal of pharmaceutical waste?

- a.
- b.

Appendix 2: Budget and Time Frame

Budget

Item	Cost (Kshs)
Printing	1500
Binding	500
Transport	300
Total	2300

Time frame

Time interval	Activity
June to July 2012	Proposal writing and approval
August to September 2012	Data collection and analysis
October 2012	Writing of dissertation and Project presentation

Appendix 3: Introductory letter



UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
SCHOOL OF PHARMACY

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Our Ref: UON/CHS/SOP/4/5

16 July 2012

TO WHOM IT MAY CONCERN

MBURU JULIUS NJENGA - U29/2812/2008

This is to request you to allow the above named Bachelor of Pharmacy final year student to administer a questionnaire in your institution with a view of carrying out research entitled "Handling of Pharmaceutical Waste in Community Pharmacy Outlets in Nairobi" as part of his academic project.

This is part of their final year student's projects. The data collected is solely for academic purpose and utmost confidentiality will be observed.

Hereby attached is the questionnaire to be administered.

Your assistance will be highly appreciated.

Yours faithfully,

P.N. Mwangi
Assistant Registrar, School of Pharmacy

Encs

PNM/jnn