A SITUATIONAL ANALYSIS ON PHARMACEUTICAL WASTE MANAGEMENT IN NAIROBI COUNTY, KENYA

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A DISSERTATION SUBMITTED TO THE SCHOOL OF PUBLIC HEALTH, UNIVERSITY OF NAIROBI AS PART FULFILMENT OF THE REQUIREMENTS FOR THE AWARD OF MASTER OF PUBLIC HEALTH DEGREE

24th November 2015

UNIVERSITY OF NAIROBI

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ABSTRACT

Pharmaceutical waste (PW) includes pharmaceuticals that are no longer needed but it also includes containers and other used items that may contain remnants of pharmaceutical substances. Pharmaceutical waste management (PWM) is defined as all activities, both administrative and operational, for handling PW. Poor PWM may be deleterious to both human health and the environment. In the hospital set up, pharmaceutical waste is managed as part of healthcare waste (HCW) in accordance with the existing guidelines. Similar guidelines for PWM in community pharmacies are lacking.

The aim of this study was to describe the prevailing situation of PWM in Nairobi County, Kenya. A total of 477 community pharmacies were listed through mapping in 26 out of 85 wards, selected through cluster sampling. A self administered structured questionnaire was used for data collection among the selected participants. The response rate was 57%.

The respondents were categorized as either good or poor (adequate or inadequate) according to their respective scores. Chi square was used to determine associations. Over 70% of respondents were adequately qualified to practice sound PWM. About 62% of participating CPs had access to adequate disposal infrastructure. About 79% of the respondents had adequate knowledge of PWM while 66% of pharmacies had 'good practice'. However, the proportion of CPs with poor PWM practice was significant (34%). Knowledge of PWM was associated with manager qualification while practice was associated with both access to infrastructure and knowledge of PWM.

The situation of PWM was therefore generally good but there was room for improvement. It was recommended that the Pharmacy and Poisons enhances law enforcement to eliminate unqualified practitioners. Enlightenment of CP managers on PWM through continuous medical education (CME) was also recommended.

ACKNOWLEDGEMENTS

I would like to acknowledge the following people who contributed in different ways to the successful completion of this dissertation.

1. My two supervisors Ms. Mary Kinoti and Dr. Dismas Ongore both of who guided and encouraged me all the way.

2. All my lecturers who imparted me with the knowledge in class.

3. My ever supportive wife, Veronica Njeri Kimata, who not only took my role at home and work but also provided for me in many ways.

TABLE OF CONTENTS

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To whom it Concerns

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Thank you for your cooperation.

Yours Faithfully,
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LIST OF TABLES

LIST OF FIGURES

ABBREVIATIONS

APIs:	Active Pharmaceutical Ingredients
CME:	Continuing Medical Education
CP:	Community Pharmacy
DEA:	Drug Enforcement Authority
Deff:	Design effect
EE2:	Ethinylestradiol
EMCA:	The Environmental Management and Co-ordination Act
FEFO:	The first to expire – first out principal for inventory management
GPWR:	Global Pharmacy Workforce Report
HCW:	Health Care Waste
HCWM:	Health Care Waste Management
HFs:	Healthcare Facilities
ICF:	Informed Consent Form
ICRC:	International Committee of the Red Cross
IEBC:	Independent Electoral and Boundaries Commission
IFP:	International Pharmaceutical Federation
KNBS:	Kenya National Bureau of Statistics
KPA:	Kenya Pharmaceutical Association
MoH:	Ministry of Health
MSc:	Master of Science
NGO:	Non-governmental Organization

NMRQ:	Nicholson McBride Resilience Questionnaire
NRDC:	Natural Resources Defence Council
Pharm.D:	Doctor of Pharmacy
PhD:	Doctor of Philosophy
PI:	Principle Investigator
POPs:	Persistent Organic Pollutants
PPB:	Pharmacy and Poisons Board
PSK:	Pharmaceutical Society of Kenya
PSP4H:	Private Sector Innovation Programme for Health
PSU:	Primary Sampling Unit
PVC:	Polyvinyl Chloride
PW	Pharmaceutical Waste
PWM:	Pharmaceutical Waste Management
RA:	Research Assistant
SPSS:	Statistical Product and Service Solutions
SSU:	Secondary Sampling Unit
TFDA:	Tanzania Food and Medicines Authority
UK:	United Kingdom
UNEP:	United Nations Environment Programme
US:	United States
WHO:	World Health Organisation

DEFINITION OF OPERATIONAL TERMS

Community pharmacy: The term "community pharmacy" includes all those establishments that are privately owned and whose function, to varying degrees, is to serve societies' needs for both drug products and pharmaceutical services (Rakesh and Kumar, 2012).

Encapsulation: Immobilization of waste by stuffing containers with the waste, adding an immobilizing material, and sealing the containers (WHO).

Genotoxic waste: Cytotoxic waste containing substances with genotoxic properties (e.g. waste containing cytostatic drugs, often used in cancer therapy) (WHO).

Hazardous waste: Waste that poses a variety of environmental and/or health risks (WHO).

Healthcare waste: Health-care waste includes all the waste generated within health-care facilities, research centres and laboratories related to medical procedures. In addition, it includes the same types of waste originating from minor and scattered sources, including waste produced in the course of health care undertaken in the home (WHO).

Inertization: Immobilization of waste by mixing it with cement and other substances to make it stable and minimize migration of toxic substances into surface water or underground water (WHO).

Pharmaceutical waste: Pharmaceutical waste includes pharmaceuticals that are expired or no longer needed and/or items contaminated by or containing pharmaceuticals. Also includes genotoxic waste (WHO).

Waste management: The activities, administrative and operational, that are used in handling, packaging, treatment, conditioning, reducing, recycling, reusing, storage and disposal of waste [Environmental Management and Co-ordination (Waste Management) Regulations 2006].

CHAPTER ONE: INTRODUCTION

1.1 BACKGROUND

Pharmaceutical products are a group of chemical substances used for treatment, prevention and diagnosis of diseases and other health conditions in both humans and animals. The World Health Organization (WHO) definition of pharmaceutical waste (PW) includes pharmaceuticals that are expired or no longer needed and items contaminated by or containing pharmaceuticals (WHO, 2013). Pharmaceuticals can become unwanted due to expiry, spillage, contamination, damaged packaging, improper labelling or being obsolete. Household PW includes unused or leftover medicine stored at home after the user stops taking the dispensed regimen for one reason or another.

In the Environmental Management and Co-ordination (Waste Management) Regulations 2006, the term "waste management" is defined as the activities, administrative and operational, that are used in handling, packaging, treatment, conditioning, reducing, recycling, reusing, storage and disposal of waste. Therefore, pharmaceutical waste management (PWM) encompasses the pathway of PW from generation to final disposal. According to the United Nations Environmental programme (UNEP), sound waste management is that which goes beyond the mere safe disposal or recovery of wastes and seeks to address the root cause of the problem by attempting to change unsustainable patterns of production and consumption through the application of the integrated life cycle management concept (UNEP, 2013). This concept entails a cradle to cradle approach in which rather than ending up as waste, the materials in a product at the end of its use period begin a new life in a new cycle (UNEP, 2013).

The WHO publication titled 'Safe management of wastes from health-care activities' (referred to as the blue book), second edition, 2013 addresses issues surrounding the management of healthcare waste (HCW) in health care facilities. In this document, pharmaceutical waste is one of the categories of HCW. According to the blue book, healthcare waste management (HCWM) should ideally follow the waste management hierarchy (Figure 1.1). Good PWM is that which adheres to the hierarchy as much as possible. Preventing and reducing PW can be achieved through good inventory management. This may entail ordering of smaller quantities, checking expiry on receipt to avoid short expiry stocks, and practising the first to expire-first out (FEFO) principle. Reuse may involve redistribution or resale of unused pharmaceuticals which have been returned to the supplier but are still utilizable. However, this option is not recommended for pharmaceuticals that have been dispensed to patients because quality may no longer be guaranteed (WHO, 2013).

Recycling is less practical for pharmaceuticals except perhaps for the containers. Recovery may be possible for certain types of pharmaceuticals but it may be economically unviable. The last two options are treatment and safe disposal. The blue book recommends returning to the manufacturer as the first option. Where this is not possible, PW may be immobilized by encapsulation or inertization (treatment) and disposed of in a sanitary landfill. Chemical decomposition may be considered for small quantities of PW where the required equipment and chemicals are available. Some types of mild liquid and semi-solid preparations may be diluted with large volumes of water and poured into sewers (e.g. vitamin syrups, cough mixtures, intravenous fluids). Larger quantities of PW may be disposed of by encapsulation followed by land filling, or by high temperature incineration, or dilution followed by discharge into sewer for relatively harmless liquids (WHO, 2013).

The Natural Resources Defence Council (NRDC) white paper, 2009 addresses the problem of pharmaceutical contamination of the environment. The authors state that there are certain types of pharmaceuticals that should be considered as high priority in terms of environmental pollution. A pharmaceutical compound is considered high priority if it's volumes of production are high, or it is highly potent at low concentrations, or it is likely to persist or bioaccumulation in the environment. High volume pharmaceuticals are likely to be found in higher volumes in PW while highly potent pharmaceuticals may cause poisoning in low concentrations. Pharmaceuticals with bioaccumulation tendencies or persist in the environment may build up to environmentally harmful levels. Anti-microbial compounds are of particular concern because their production volumes are generally high and some of them have been shown to be persistent or to bio-accumulate in the environment (e.g. erythromycin both persists and bio-accumulates). Antibacterial compounds may also interfere with sewage treatment by killing beneficial bacteria.

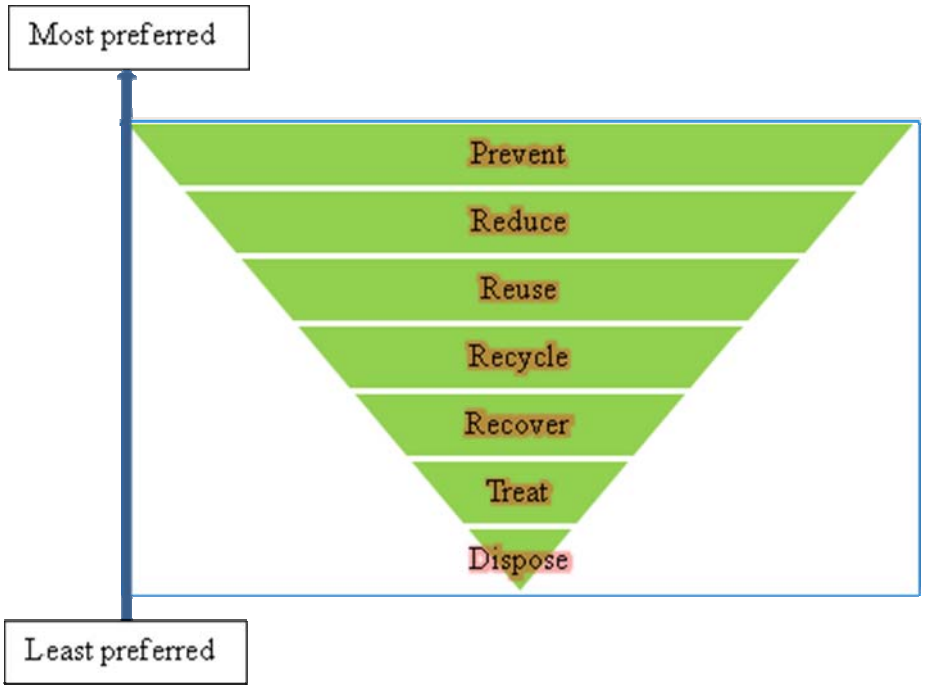

Figure 1.1: Waste management hierarchy (Modified from the WHO's 'Safe management of wastes from health-care activities' 2nd edition, 2013)

The other priority class of pharmaceutical compounds are hormones. Hormonal compounds are highly potent in low concentrations and have also been shown to bio-accumulate. A good example is ethinylestradiol (EE2) which has been found to be up to one million times higher concentration in fish than in the surrounding water (NRDC, 2009). Hormonal compounds are used in oral contraceptives, menopause treatment and hormone replacement therapy. Some types of PW such as cytotoxic drugs are considered hazardous waste due to their highly poisonous nature (WHO, 2013).

According to NRDC, opportunities for intervention exist at the product design stage, regulatory approval, production, consumption, and disposal stage. Product design should consider the aspects of persistence and bio-accumulation. Environmental impact can be considered at the approval stage. The process of manufacture can be made more efficient to reduce waste generation. At the use stage, the strategy is to reduce over-prescription for humans as well as overuse of antibiotics in animal health. At disposal stage, sound PWM should be practised.

In the United States of America (US), unsold pharmaceuticals are generally returned to the original suppliers either directly from healthcare institutions including community pharmacies (CPs) or through reverse distribution companies. The reverse distributors also offer hazardous waste handling and disposal services. Therefore, they deal appropriately with any non-returnable unsold pharmaceuticals (Musson et al 2007, Bound and Voulvoulis 2005; Gualtero 2005; NRDC 2009). In the United Kingdom (UK), PW in the pharmacies and other healthcare facilities is either land filled in designated hazardous waste landfills or incinerated (Bound and Voulvoulis, 2005). This is done through hazardous waste handling companies (which also handle other types of hazardous waste). Programmes for the collection of household PW from communities have been developed in several countries (Bellan et al, 2012). These include Canada, Australia, Italy, France

and Spain among others (Bellan et al, 2012). The latter two are said to have the largest reverse logistics programmes in Europe (Bellan et al, 2012).

Available literature suggests generally poor management of pharmaceutical waste in many developing countries (Tong et al, 2010; Abahussain et al, 2012; Matiko, 2012). A WHO assessment conducted in 22 developing countries in 2002 showed that HCW in general is poorly managed (WHO, 2009). According to this assessment, between 18% and 65% of healthcare facilities in these countries did not practice proper HCWM.

In Kenya, there are no official guidelines or national policy for regulation of PWM. The Environmental Management and Co-ordination Act (EMCA) No. 8 of 1999 gives the onus for hazardous waste management to the people or entities that generate the waste in the first place, or those dealing in hazardous materials. The Public Health Act, Chapter 242 of the Laws of Kenya, prohibits the accumulation of refuse of whatever nature that may be injurious or dangerous to health. The Pharmacy and Poisons Act (Cap 244, Laws of Kenya) regulates the business of pharmacy in general but includes no proviso for waste management.

The National Health Sector Strategic Plan II (2005-2010), in the chapter on the development of a maintenance system, contains a clause on the provision of equipment, energy and water supply, and waste disposal tools in government health facilities. The National Healthcare Waste Management Plan, 2008-2012 reports a situation analysis sanctioned by the Ministry of Health (MoH), and carried out in 2007 to explore legislative, institutional and infrastructural challenges facing HCWM in the country. It discusses HCW and makes recommendations in the context of hospitals and other clinical settings. It also makes reference to a document titled Kenya National Guidelines on Safe Disposal of Pharmaceutical Waste, 2001. However, the existence of this document could not be

verified. A document of similar title but dated 2011 was in the process of development. Despite this lacuna in policy, PW continues to be generated in growing volumes.

One of the major challenges facing the CP sector in Kenya is the mushrooming of unlicensed pharmacies. According to some sources, illegal drug outlets outnumber legal ones in rural areas (Wafula, 2013). Although the Pharmacy and Poisons Board (PPB) is based in Nairobi County, the problem seems to persist, going by press reports. Another major challenge affecting the entire pharmaceutical sector is counterfeiting. Huge consignments of counterfeit products have been intercepted in the various ports of entry and widely reported in the media. Being the capital city and the regional transport hub, many of the counterfeits either pass through or are destined for Nairobi. Related to this is the illegal importation of unregistered pharmaceuticals of unknown quality. Cases of stolen drugs, including government stock seized in CPs, have also appeared in local media.

1.2 PROBLEM STATEMENT

Pharmaceutical waste management is of public health concern due to the various health and environmental risks posed by poorly managed PW. The first is possible development of bacterial resistance to antibiotics due to unintended low dose consumption. This occurs through consumption of water that is contaminated with antibacterial compounds as e result of poor PWM. The second is interference with sewerage treatment making it less effective, which is associated with antibiotics, antiseptics and disinfectants. This results from the killing of beneficial bacteria which normally help to decompose the waste. This can occur as a result of disposal through sewers (flushing down the toilet) or sinks. It can also occur through leakage of leachate from landfills or open dumps if the leachate finds its way into sewerage systems. The third concern is the negative effect on fish

reproduction associated with hormonal products. The risk of drug abuse and/or poisoning that may result from scavenging in open dumps as well as from stored household PW is another concern. The effect of long term low level exposure to active pharmaceutical ingredients (APIs) from water sources through drinking or bathing is largely unknown but cannot be entirely ignored in the absence of evidence (Jones et al, 2001). Incineration of PW, particularly waste containing polyvinyl chloride (PVC) at low incineration temperature may cause the release of substances that are deleterious to public health into the environment. These include persistent organic pollutants (POPs), such as dioxins and furans, some of which have been found to be carcinogenic (International Committee of the Red Cross-ICRC, 2011; WHO, 2013).

In Kenya, healthcare facility generated PW is managed as HCW along with the other types of HCW (sharps, body tissues, chemicals etc.). An official waste management plan had been developed for hospitals (the National Health Care Waste Management Plan 2008-2012). However, a similar management plan or guidelines for CPs had not been finalised at the time of writing this dissertation. To compound the matter, there is a general scarcity of information regarding PWM in CPs. The risks enumerated above show that PWM is of public health importance. The absence of official regulation of PW and the general scarcity of information on the subject are of major concern. This situation analysis of PWM in CPs is expected to inform future policy development on PWM among CPs in Nairobi and the country in general.

1.3 CONCEPTUAL FRAMEWORK

For any HFs to practice sound PWM, it needs three things are needed. One, the entity needs qualified personnel who are knowledgeable on PWM. Secondly, the knowledgeable persons need to be equipped with suitable infrastructure for PWM. Knowledgeable

persons need to have the right attitude. Finally, PWM guidelines are necessary to ensure compliance with existing law and enable monitoring and regulation. These are the major factors considered proximal to PWM. For them to be realized, policy environment must be conducive. PWM needs to be prioritized as potentially having an enormous impact on public health. Commensurate funding ought to be provided for all activities supporting sound PWM not only by government but also institutions and private businesses where PWM is generated.

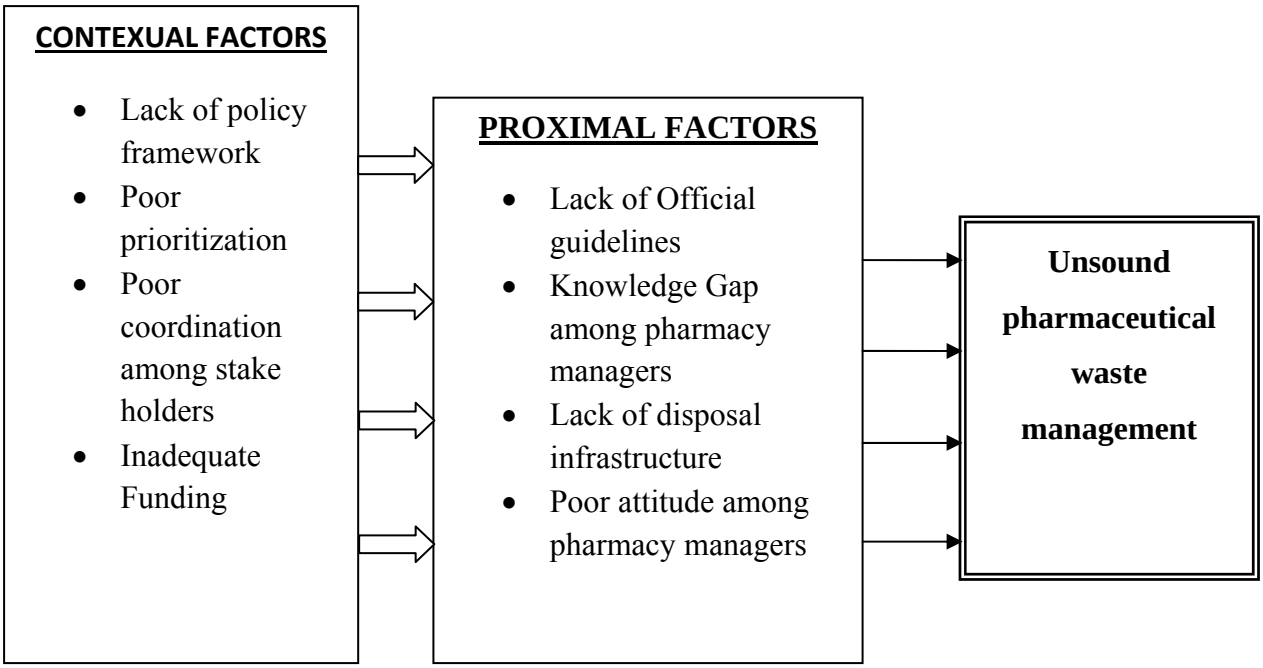

Figure 1.2: Factors likely to impact on PWM in community pharmacies

1.4 JUSTIFICATION

Haphazard disposal of pharmaceutical waste is a threat to human health and the ecosystem. Hospitals are usually equipped with disposal facilities with basic capacities for HCWM as part of their infrastructure. This is not the case for CPs. Efforts to streamline HCWM in HFs seem to have largely or completely overlooked CPs. The Kenyan MoH previously carried out an assessment of HCWM in hospitals and clinics and found the situation dire. Only 16.7% of the HFs had developed annual operation plans for HCW management

(National Healthcare Waste Management Plan, 2006-2015). This assessment however excluded the CP sector.

A thorough search showed there was one similar study carried out in Mombasa (Wepukhulu, 2011). However, both the study population and study design were different from those of the current study. This study aims at documenting the prevailing situation in terms of the competence of people managing CPs, access to PW disposal infrastructure, knowledge of PWM among CP managers, and the quality of practice of PWM among CPs in Nairobi County.

The CP sector has undergone tremendous growth over time. For this reason, the volume of PW generated in these facilities is similarly on the increase. In the absence of appropriate interventions, the problem may grow to crisis levels with the attendant public health and environmental consequences already alluded to. It is against this background that this situation analysis was carried out to document the prevailing state of PWM in CPs in Nairobi County. This information is expected to contribute to policy development for PWM. It is expected to inform future policy for streamlining PWM in the CP sector. It is also expected to be a useful source of information for stake holders in the pharmaceutical and medical sectors and also environmentalists. Finally, it is expected to create awareness among investors interested in waste management service provision.

1.5 OBJECTIVES AND HYPOTHESES

This section contains the statement of the study questions, objectives and hypotheses.

1.5.1 Study Questions

This study sought to answer the following questions.

1. Do community pharmacy managers have suitable qualifications to practice sound PWM?

2. Do community pharmacies in Nairobi County have access to infrastructure that supports sound PWM?
3. What is the proportion of community pharmacy managers with adequate knowledge of PWM?
4. What is the proportion of community pharmacies in which sound PWM is practised?

1.5.2 Objectives

The broad objective of this study was to establish the prevailing situation of pharmaceutical waste management among community pharmacies in Nairobi County. The specific objectives were:

1. To determine whether community pharmacy managers were suitably qualified to practice sound PWM.
2. To ascertain whether community pharmacies had access to infrastructure that supports sound pharmaceutical waste management.
3. To find out the proportion of community pharmacy managers with adequate knowledge of PWM.
4. To establish the proportion of community pharmacies in which sound PWM was practised.

1.5.3 Hypotheses

To determine the relationships between outcome and predictor variables, the following hypotheses were tested.

a) Knowledge of PWM among community pharmacy managers is associated with their levels of qualification.

b) The quality of practice of PWM in community pharmacies is associated with availability of infrastructure that supports sound PW disposal.

c) The quality of practice of PWM in community pharmacies is associated with knowledge of PWM among community pharmacy managers.

CHAPTER TWO: LITERATURE REVIEW

2.0 INTRODUCTION

A lot of the published literature on pharmaceuticals in the environment concerns the presence, concentration and possible effects of APIs on human health and the aqueous environment. Most of the studies have been carried out in North America and Europe. Much of the literature on the actual management of PW relates to household pharmaceutical waste. Others have demonstrated the presence of APIs in the environment. Musson and Townsend (2008) demonstrated the presence of APIs in municipal solid waste and measured their concentration using mathematical calculation and direct measurement methods. Only a few studies focussing on the management of PW generated at CP level were found.

One such study was carried out in New Zealand in 2011 (Tong et al, 2011). A few others have been carried out in Africa and the Middle East. However, there seems to be a general lack of literature on the subject. This chapter examines some of the information available under pharmacy manager qualification, disposal infrastructure availability, knowledge of PWM, and practice of PWM, which were the main variables in this study.

2.1 QUALIFICATION OF COMMUNITY PHARMACY MANAGERS

In Tanzania, a cross sectional survey found that pharmacists accounted for only 8% of medicine dispensers in CPs (Mugoyela *et al*, 2002), while 23% were pharmaceutical technologists. The rest consisted of clinical officers (15%), nurses (27%) and school leavers (27%). Another survey showed the situation in Pakistan was more desperate with almost half of CP attendants (45%) being at various stages of secondary school (Aslam *et al*, 2012). Only 9.5% had a pharmacy degree while another 16% had undergone a

dispensing course. In Saudi Arabia, a cross sectional survey showed virtually 100% of CP managers were educated to degree level including B. Pharm., Pharm. D, MSc and even PhD (Khojah *et al*, 2013).

To practice pharmacy legally in Kenya, one must be duly registered with the PPB. The PPB recognizes B. Pharm. degree (pharmacists) and pharmacy diploma holders (pharmaceutical technologists). According to the Global Pharmacy Workforce Report (GPWR, 2009), the training of pharmaceutical technologists in Kenya started in 1968. The aim was to complement the low numbers of pharmacists at the time, according to the Private Sector Innovation Programme for Health (PSP4H, 2014). On the other hand, training of pharmacists started in 1974 (GPWR, 2009). At the time of this study, there were six Kenyan universities accredited to train pharmacists compared to 25 colleges approved to train pharmaceutical technologists, according to the PPB website.

Pharmaceutical technologists were not being licensed to superintend pharmaceutical distribution business (PSP4H, 2014) and were thus mainly restricted to CP. There was also the effect of economic immigration of pharmacists. It was estimated that about twenty pharmacists applied for immigration annually to practice in Australia, Canada, US and UK (GPWR, 2009). A combination of these factors may have caused dominance of the CP sector by pharmaceutical technologists. However, unlicensed drug shops operating under unqualified personnel were said to be common in Kenya, particularly in rural areas (Wafula, 2013).

2.2 PW DISPOSAL INFRASTRUCTURE

As mentioned in chapter one, disposal is the last stage of waste management that comes into play after all other measures. The method of disposal of PW or any other type of waste depends on the available infrastructure among other considerations. In the case of

HF generated HCW, the institution concerned has the responsibility of treating the waste on site in the absence of suitable disposal infrastructure in the vicinity. This is according to recommendations by the ICRC, (ICRC, 2011). Harhay et al (2009) carried out a meta-analysis of available literature on HCWM around the world. They reported that incinerators, where present, were antiquated or dysfunctional in many cases, resulting in the disposal of HCW into municipal waste, open burning or simply burying within hospital compounds. In Tanzania, 40% of medical stores supervisors in government HFs in Dar-es-salaam cited lack of incinerators as one of the challenges facing PW disposal (Matiko, 2012) resulting in accumulation. However, this survey was specific to government owned institutions.

In Kenya, a government sponsored assessment in public and private HFs demonstrated a serious challenge with HCW disposal infrastructure (The National Healthcare Waste Management Plan, 2008-2012). While the majority of HFs relied exclusively on incinerators, about a quarter of them were dysfunctional; either under repair or in non-functional status. Only a handful of hospitals had alternative waste treatment infrastructure such as shredders. Since CPs were not assessed, it was not known whether they had access to PW disposal infrastructure.

2.3 KNOWLEDGE OF PHARMACEUTICAL WASTE MANAGEMENT

There is a general scarcity of information regarding knowledge of PWM among community pharmacists and health care workers in general. In much of the developed world, regulatory frameworks and programmes are in place for reverse logistics and proper disposal of PW generated in pharmacies. In the US, there are reverse distribution companies which collect unused pharmaceuticals from pharmacies and other healthcare institutions and return it to the manufacturers on their behalf, or alternatively, dispose of it

in accordance with environmental regulations (Musson *et al* 2007, Bound and Voulvoulis 2005, Gualtero 2005, NRDC 2009). This arrangement seems to shift the responsibility of disposal from CPs. At the time of collection by reverse distributors, the pharmaceuticals have not yet been condemned and are not regarded as pharmaceutical waste. The manufacturers may pass credit to pharmacies for such returned goods provided their conditions for return of goods, which are manufacturer specific, are met (Musson et al 2007, Gualtero 2005, NRDC 2009). Those pharmaceuticals that fail to meet the criteria for return become PW in the possession of the reverse distributors, who dispose of it accordingly. However, controlled substances were an exemption since they cannot be returned through reverse distributors without breaking Drug Enforcement Authority's (DEA) regulations, which strictly regulate the transfer of controlled substances. They therefore have to be disposed of at the CP. An experimental study demonstrated that knowledge of the possible environmental impact of improper disposal of PW was low among US pharmacists (Jarvis *et al*, 2009). There were no specific guidelines for PWM in the US. Instead, PW was regulated under several different pieces of legislation (Musson et al, 2007). The interventional study mentioned above (Jarvis *et al*, 2009) concluded that an educational intervention in the form of a newsletter was effective in improving knowledge of PWM among pharmacists. However, the response rate was low (below 50%). Furthermore, the authors acknowledged that other experiences or events might have accounted for the recorded improvement in knowledge and attitude. Nevertheless, the study indicated a rather low percentage of respondents who were knowledgeable on PWM (< 50%). This is important because in the US, some types of PW, particularly that containing controlled substances are managed in the pharmacies (Gualtero, 2005).

Insufficiency of knowledge of PWM and the environmental risk it poses was a more serious concern in other countries. Tong *et al* (2011) recommended the creation of

awareness on the topic among community pharmacists in New Zealand, even though they did not specifically study knowledge of PWM. A similar recommendation was made in Kuwait (Abahussain *et al*, 2012) and Tanzania (Matiko, 2012). Abahussain *et al* (2012) made the conclusion after studying PW disposal habits among pharmacists working in government HFs. In the Tanzania study, 40% of medical store supervisors cited lack of sufficient pharmaceutical management skills as one of the causes of accumulation of PW in government HFs. Although these are only a few examples, the general scarcity of information may be a pointer to a widespread knowledge gap regarding sound PWM and the environmental consequences of unsound PWM. No literature on knowledge of PWM among CP practitioners in Kenya was found.

2.4 PRACTICE OF PHARMACEUTICAL WASTE MANAGEMENT

Globally, there was no standard procedure for dealing with pharmaceutical waste. In the US, there was variation among the different states in some aspects of PWM. Many states for instance allow some form of reuse or resale of returned pharmaceuticals considered to be safe but under varying conditions (Ballan *et al* 2005, Gualtero 2005). Reverse distribution companies handled PW originating from pharmacies, hospitals and clinics (Musson *et al,* 2007). This would therefore leave these facilities with only non-returnable PW, such as controlled substances to dispose of. A survey carried out in the 1990s in hospital and CPs in the US reported only 3% of the HFs studied not having PW disposal plans (Musson et al, 2007). Reverse distributors returned some of the PW to manufacturers and dispose of non-returnable items.

The arrangement in the UK is somewhat different. Institution-generated PW is regarded as clinical waste and is either incinerated or land filled by hazardous waste handlers (Bound and Voulvoulis, 2005). This means that the responsibility for waste management was

transferred from the healthcare facilities including CPs, to the waste handlers. The similarity between this model and the US model is that third parties managed and disposed of the bulk of PW on behalf of the HFs in both cases. The difference is that reverse distribution companies in the US collected both reusable and waste pharmaceuticals. In contrast, the hazardous waste handling companies in the UK collected only what was designated as waste and disposed of all the waste received. Figure 2.1 is an illustration of the US and UK models respectively.

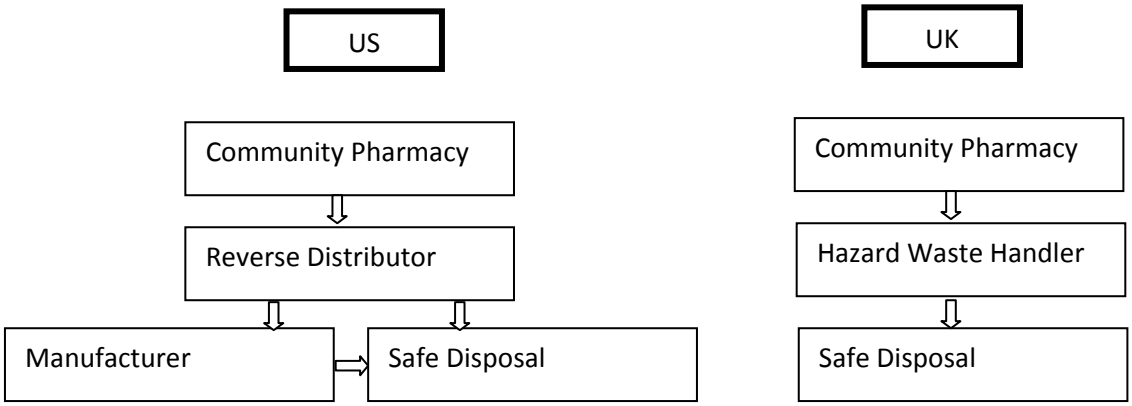

Figure 2.1: A Comparison of the US and UK Models for Disposal of Community Pharmacy Generated PW.

Reverse logistics for the collection of household pharmaceutical waste have been established in other developed countries such as Canada, Australia, Italy, France and Spain (Ballan *et al*, 2012). In New Zealand, patients were routinely advised to return unused pharmaceuticals to pharmacies but there was no sufficient data on pharmacy disposal practices (Tong *et al*, 2011). The study's aim was to assess the disposal practices among community pharmacists in New Zealand. According to the results, the most common disposal methods among the respondents were not environmentally sound. However, only 53% of the initial study sample took part in the study. The authors acknowledged this as a possible source of bias since those who responded may have consisted of people who were

more interested in the subject. In Kuwait, which is described as a developing country, government pharmacies were required to send their PW to the central medical stores, which then performed disposal under the environmental agency's supervision (Abahussain *et al*, 2012). The major concern of this study however was the role of the government pharmacists in collection and disposal of household PW.

Information on PWM in African is scarce. Tanzania is one of the African countries where guidelines for PWM were available (titled "Guidelines for disposal of unfit medicines and cosmetic products, First Edition, 2009"). The guidelines were developed by the Tanzania Food and Medicines Authority (TFDA), which is the equivalent of the Kenyan PPB. However, enforcement and compliance with the guidelines was poor, even for government HFs (Matiko, 2012). This study reported that 72.4% of the respondents buried their PW at the Dar es Salaam dumpsite while 31% burned their PW. Only 37.9% mentioned incineration as one of the options for PW disposal. This practice was at variance with the TFDA guidelines which required PW to be either land-filled or incinerated save for a few specified exceptions. The author stated that copies of the guidelines were not present in most of the facilities studied. However, some of the lower level facilities were not responsible for disposal of their own PW, which was expected to be collected by regional pharmacists for disposal in larger facilities. It is also noted that the institutions studied lacked homogeneity in terms of size and personnel, making comparison difficult. A major limitation of this study was the failure to include private HFs for comparison with public institutions.

The literature reviewed showed a generally poor state of PWM in developing countries (Matiko 2012, National Healthcare Waste Management Plan-2008, Mugoyela & Ally 2002, Wafula 2013).. Policy guidelines were lacking in many countries. Where present, the guidelines are seldom followed. PWM is a fairly recently recognized and evolving

environmental concern. In the absence of policy guidelines, pharmacy practitioners were left to their own devices in trying to deal with PW. It was therefore imperative to study and document the existing practice to demonstrate the nature of current practice and the prevailing circumstances.

CHAPTER THREE: STUDY DESIGN AND METHODOLOGY

3.1 STUDY DESIGN

This is an analytic cross-sectional study, employing a quantitative method to meet the specific objectives. It is observational since there was no intervention involved, and cross-sectional because both predictive and outcome variables were measured at the same time. It is also analytical because it examines associations between predictor and outcome variables although no causality relationships may be derived.

3.2 STUDY AREA

The study was undertaken in Nairobi County. Nairobi is the capital city of Kenya; located on latitude 1017'S longitude 36049'E. The total area of the county is 694.85 Sq Km. The population was 3,138,369 as of 2009 (Kenya National Bureau of Statistics-KNBS). Electorally, Nairobi County is subdivided into 17 constituencies which are further subdivided into 85 wards (Independent Electoral and Boundaries Commission [IEBC] website, accessed on 12/10/2013). The socio-economic circumstances vary widely in different areas. There are many slum areas without adequate provision of amenities such as water, sewerage connection and lighting. There are also some highly affluent areas inhabited by the well to do. The CPs are widely varied in terms of premises size, inventory size and inventory variety depending on owners' capabilities and local economic circumstances. Those located in the city centre or shopping malls typically stock more expensive brands than those located in or near slum areas.

3.3 STUDY POPULATION AND SAMPLING FRAME

3.3.1 Study Population

The study population was defined as managers of CPs located within Nairobi County. For the purposes of this study, a pharmacy manager was the person responsible for the day to day management of the pharmacy, regardless of their legal or educational status. The sampling frame consisted of all CPs located within the borders of Nairobi County. Each pharmacy constituted one unit of the study population.

3.3.2 Inclusion Criteria

To be included in the study sample, a pharmacy outlet had to meet two criteria. The first was to be a privately owned CP providing retail pharmacy services to the community. The second was to be located within the boundaries of Nairobi County.

3.3.3 Exclusion Criteria

Any facility that met the inclusion criteria was excluded if the CP manager was unwilling or unavailable to take part in the study; or the CP was closed during the period of the study.

3.4 SAMPLE SIZE AND SAMPLING TECHNIQUE

3.4.1 Sample Size

Each CP which was located within the study area and met the inclusion criteria constituted a single unit of the study population. The sample size was calculated using the formula for a single population proportion as shown below.

$n = \pi (1-\pi) Z^2/e^2$ (Bound and Voulvoulis, 2005); where

n = the desired sample size

Z= the two-sided value of the standardized normal deviate for the required level of confidence (1.96)

π = the preliminary estimate of the proportion of managers who practice sound pharmaceutical waste management (0.25)

e = the desired level of precision, in this case 0.05.

A study carried out in Dar es Salaam, Tanzania (Mugoyela and Ally, 2002) studied a similar population of CPs. The results indicated that 66.7% practiced unsound PWM (dumping and draining down the sink). The rest (33.3%) used more acceptable disposal methods. The Kuwaiti study (Abahussain et al, 2012) found only 16% of government pharmacists adhered to official guidelines. Hence P was taken to be 0.25 (average of the two results) for the purpose of sample size calculation.

Hence calculated sample size, $n^1= (1.96)^2(0.25x0.75)/ (0.05)^2=288$

The final sample size was adjusted for non-response by a factor of 15%.

Hence the final sample size was $n = 1.15n^1=288x1.15=332$.

3.4.2 Sampling Method

The required sample was obtained using simple two-stage cluster sampling method. This method was preferred over simple random sampling for two main reasons. The first is cost efficiency since the study area was fairly expansive. Secondly, a complete sampling frame of all the secondary sampling units (SSUs), which are CPs, was not easily available. The primary sampling unit (PSU) or cluster was an electoral ward. A ward rather than a district or constituency was chosen as the PSU in order to minimize design effect (deff) since a bigger cluster size implies a greater value of deff. As mentioned in 3.2 above, Nairobi County is divided into 85 electoral wards. The PPB list of all licensed premises

contained a total of 1307 premises (as of September, 2013). This figure included pharmaceutical manufacturers, distributors and even hospitals licensed by PPB to offer pharmacy services. By perusing the list, it was determined that roughly 1100 of these were CPs. Using this figure as the estimated number of SSUs, the minimum number of PSUs to obtain the required sample was calculated. No. of PSUs = (332/1100) x 85 which yielded 26 PSUs (electoral wards). The 26 PSUs were selected by simple random sampling using MS excel. A mapping exercise was carried out to obtain the full list SSUs within the 26 selected PSUs. This yielded a total of 477 SSUs which formed the final study sample.

3.5 DATA PROCESSING

The data were analysed using the Statistical Product and Service Solutions (SPSS) version 22 and presented using tables, figures and statements. In order to obtain a uniform measure of infrastructure availability, each participating pharmacy was awarded scores corresponding to the availability of infrastructure necessary for PW disposal (part II of questionnaire). Adapting the Nicholson McBride Resilience Questionnaire (NMRQ) principle, each favourable response was allocated a score of 2, making the maximum total score for any given respondent 18. Any pharmacy with a total score of 10 and above was categorized as having "adequate infrastructure". Those scoring below 10 were categorized as having "inadequate infrastructure".

Knowledge of PWM was measured through a test consisting of ten questions on the subject (part III of questionnaire). Using an adaptation of the NMRQ tool, each correct response was allocated a score of 2 while wrong responses were awarded zero score. The maximum score was 20 and the minimum was zero. The expected correct responses were, starting from question 1: yes, yes, yes, yes, yes, yes, no, yes, yes, and yes (see

questionnaire, appendix 2). The scores were classified into either "adequate knowledge" (score ≥14) or "inadequate knowledge" (score <14).

Practice of PWM was measured using part IV of the questionnaire. Again adopting the NMRQ questionnaire method, each favourable response was awarded a score of two while undesired responses were awarded zero. The favourable responses were, beginning with question 1: yes, yes, no, no, no, no, yes, no, no, and no (appendix 2). The maximum total score for a respondent whose responses were all favourable was 20. Practice scores were categorized into either "good practice" or "poor practice" with the cut off for "good practice" set at 14. Hypothesis testing to determine associations between outcome and predictor variables was done using chi square statistics.

Data presentation started with socio-demographic characteristics of the respondents, followed by the characteristics of the participating pharmacies. Qualification of CP managers, access to PW disposal infrastructure, knowledge categories and practice of PWM categories followed in that order. The final part contained associations between predictor and outcome variables.

3.6 RECRUITMENT AND CONSENTING PROCEDURES

The first stage of data collection was the mapping exercise in which all SSUs in the selected PSUs were listed. To do this, it was necessary to locate the ward boundaries, which were obtained from IEBC, local administration offices and informants on the ground.

The second and final stage of data collection was the administration of the questionnaire. Recruitment of participants was done concurrently with data collection. The list of pharmacies in each PSU was provided to the researcher allocated that particular PSU. For logistical reasons, each researcher was allocated PSUs as near to each other as was

practically possible for any given day. Repeat visits were only made where necessary. The procedure for recruitment was as follows. The researcher enters pharmacy and greets those present at the counter. He/she requests to speak to the manager. If the manager was absent, the researcher would attempt to book an appointment. He/she introduces him/herself to the manager and explains the purpose of the visit. If the manager was ready for the interview, the researcher gives him/her a copy of the informed consent form (ICF) and explains the contents. The researcher answers any questions asked by the prospective participant. Once the participant was satisfied and willing to take part, he/she was requested to sign the consent form, a copy of which he/she retained. If the potential participant declined, the researcher moved on to the next SSU.

3.7 DATA COLLECTION PROCEDURES

Once the informed consent form had been signed by the participant and the researcher, data collection followed the procedure described below. The participant was given the questionnaire to fill in. If the participant embarked on filling in the questionnaire, the researcher waited for the exercise to be completed and collected the completed questionnaire. If the participant needed more time to fill in the questionnaire, the researcher requested to collect it later and proceeded to another SSU. On getting the completed questionnaire, the researcher was to thank the participant and make their exit. Completed questionnaires were handed in to the principal investigator (PI) at the end of each day.

3.8 PILOT TEST

A pilot test was carried out prior to the actual data collection. This involved the PI and all four research assistants (RAs) who were to take part in the actual data collection later. The four RAs included a Nutrition graduate, a college student and two employees of a research

organization both having secondary school level education coupled with data collection experience. It was carried out in Korogocho and Kawangware wards in an exercise lasting one day. These are electoral wards located within the study area but which were not selected for actual data collection. This process served to pre-test the questionnaire as well as to estimate the amount of time required for data collection. The data collected were processed and taken through analysis. The questionnaire and method of analysis were found suitable for the study. It was determined that one researcher could collect data in 12 SSUs in a day on average. It was therefore estimated that 5 people would take about six days to complete data collection. The actual exercise involved 5 people (the PI and 4 RAs) and was completed within 5 days from 24th to 28th November, 2014.

3.9 VARIABLES

The predictor variables included manager qualification and access to PW disposal infrastructure. The indicators for manager qualification were level of education, PPB registration status, professional body membership status and continuing medical education (CME) attendance status. The PW disposal infrastructure of interest included piped water, municipal sewer, septic tank, landfill, waste water drainage, incineration facility, private burial site, public burial site and pit latrine. The outcome variables were knowledge of PWM and practice of PWM.

3.10 TRAINING PROCEDURE

Upon recruitment, the RAs were taken through a short training programme by the PI lasting one day. The purpose was to familiarize them with the data collection tool, the informed consent form, the recruitment of participants and data collection procedures. The principal investigator conducted the training.

3.11 QUALITY ASSURANCE PROCEDURES

Upon receiving completed questionnaires, the principal investigator read through each questionnaire to confirm completeness. The PI undertook to contact some of the respondents to ensure they were actually visited by the RAs. Wherever necessary and practicable, participants were revisited to obtain missing information or to seek clarifications.

3.12 DATA COLLECTION INSTRUMENT

A self-administered, structured questionnaire in English language was administered to the respondents. The first part of the questionnaire was tailored to capture some personal details of the participants and relevant contextual issues surrounding CP practice. The second part contained a series of questions to gauge knowledge of PWM. The final part is a number of questions regarding PW disposal methods employed by the participants for their pharmaceutical waste. The full questionnaire is included in appendix 2.

3.13 MINIMIZATION OF ERRORS AND BIASES

To help minimize errors and biases, the RAs were trained so that they understood the data collection tool and procedures to make the exercise as uniform as possible. Data collection was closely supervised by the PI. Secondly, a pilot test was undertaken prior to actual data collection to identify and correct any ambiguities in the data collection tool. All the persons assigned data collection took part in the pilot test exercise. Filled questionnaires were reviewed daily to ensure completeness and minimize spoilt questionnaires as much as possible. Clarifications were sought whenever possible, if necessary. Finally, the mapping exercise undertaken to identify the study subjects enabled the researcher to include pharmacies which were not in the PPB register at the time including illegal ones, which would otherwise have been omitted even though they were relevant to the study.

This allowed the study to improve its scope of coverage of the situation prevailing on the ground.

3.14 ETHICAL CONSIDERATIONS

This study was non-clinical and data collection did not expose the participants to any risk of harm. The study findings were expected to be beneficial to the communities and the participants by contributing to improvement in pharmaceutical waste management. The participants were allowed to opt freely to participate or not without being coerced. They reserved the right to withdraw at any stage without incurring any consequences. Full disclosure of the nature of the study was made to potential participants including the title, introduction, objectives and expected benefits. Informed consent was sought and only participants who signed the consent form were included in the study. Strict confidentiality and anonymity of the data was maintained.

Ethical approval was sought and obtained from the Kenyatta National Hospital-University of Nairobi ethics and research committee (appendix 5). Endorsement was sought from and granted by the Pharmaceutical Society of Kenya (PSK). A commitment was made to provide feedback by sharing the report with the ethics committee, the PPB, PSK as well as other stake holders. The main study findings would be published in a recognized scientific journal. The ICF used in the study is included in appendix 1.

3.15 STUDY LIMITATIONS

Some factors may have restricted the ability of the study to achieve its objectives. First, the mapping exercise was hampered by the failure of a considerable number of CPs to display their names. In addition, some of them declined to provide names on request due to suspicion. Some pharmacy names were common to several pharmacies making it difficult to distinguish them. Also, some pharmacy managers were unavailable during the

data collection period while a few others declined to take part, a factor which may have caused selection bias, possibly affecting the representativeness of the final sample. Some CPs were closed during the duration of data collection. This was experienced particularly during the final days of data collection in some areas because PPB inspectors were said to have been carrying out impromptu inspections. Since some areas were affected disproportionately, this may have affected sample representativeness and therefore, internal validity. Similarly, it is possible that the potential participants who declined to take part were more likely to have inadequate knowledge of PWM, poor practice of PWM or both. Finally, the study was limited to Nairobi County. It would be inappropriate to generalize the findings to other counties without empirical data from those counties.

CHAPTER FOUR: DATA ANALYSIS AND PRESENTATION

4.0 INTRODUCTION

This chapter contains analysis and presentation of the study findings. Data analysis was done using the Statistical Product and Service Solutions programme (SPSS) version 22. The SPSS output is included in appendix 5. The data were presented using tables, figures, and statistical statements by each objective. All computations were based on 95% level of confidence. The response rate was 57.4% (274 out of an initial sample of 477). However, this represents 82% of the calculated sample size (332).

4.1 Socio-demographic Characteristics of the Respondents

Respondents' background information included age category, sex, highest level of schooling, pharmacy working experience, and pharmacy business ownership status. Almost half of the respondents (49.3%) were aged below 30 years while another 43.8% were aged between 30 and 44 years (Fig. 4.1). Only 7% were above 44 years of age. The difference in proportions was statistically significant at p= 0.000.

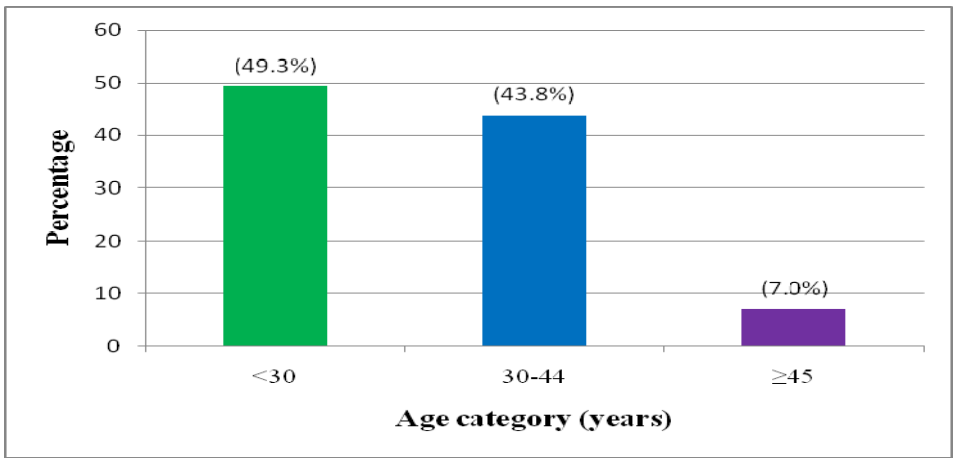

Figure 4.1: Distribution of respondents by age category (n=274)

Slightly more than half of the respondents (53%) were males (Fig. 4.2). The difference in proportions of the age categories was statistically significant at p=0.004.

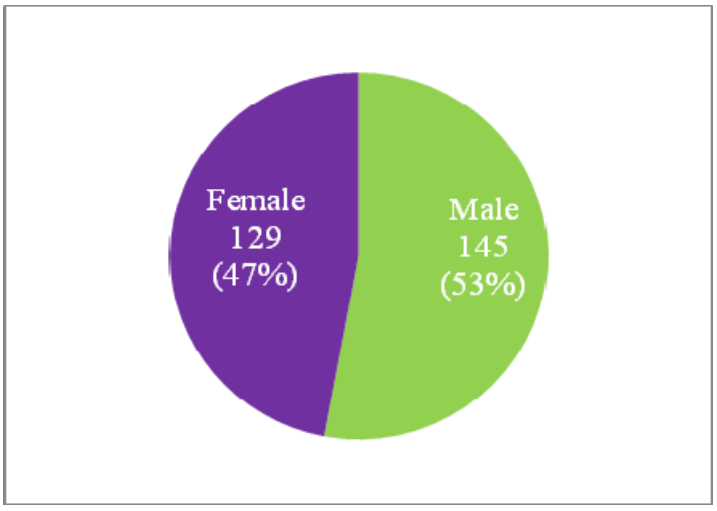

Figure 4.2: Distribution of respondents by sex (n=274)

Over 62% of respondents had schooled up to diploma level while degree holders among the respondents were only 18.6% (Fig. 4.3). The remaining 19% had levels qualification lower than diploma. The difference in proportions was statistically significant at p=0.000.

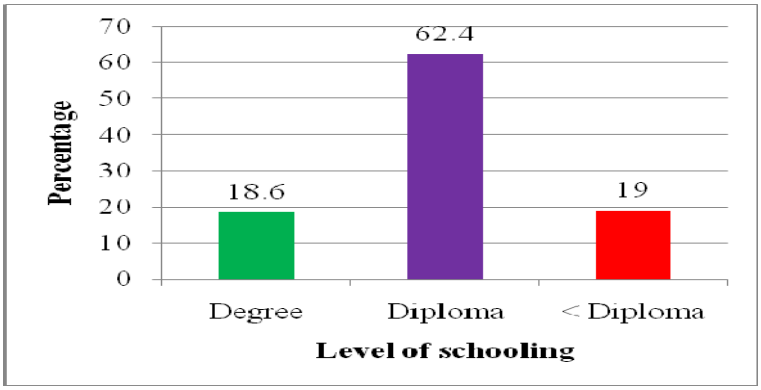

Figure 4.3: Distribution of respondents by highest level of schooling (n=270)

About 19.7% of respondents had less than 2 years experience while 46% had between 2 and 5 years. Thus the proportion of respondents with up to 5 years pharmacy experience was almost two thirds (65.7%). Those with 6 to 10 years experience represented 29.2% of respondents while those with experience over ten years were on 4.7% (Fig.4.4). The difference in proportions was statistically significant at p=0.000.

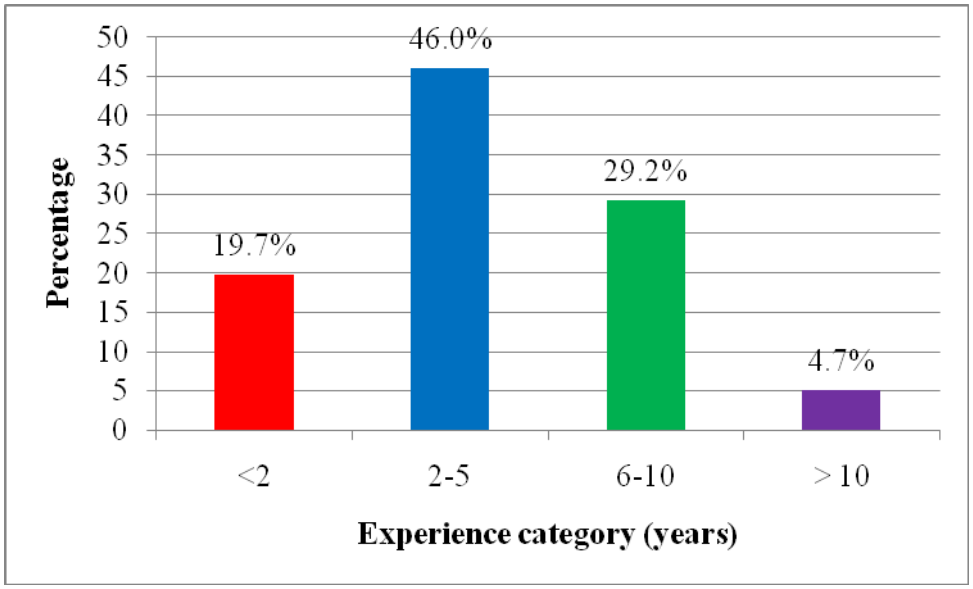

Figure 4.4: Distribution of respondents by pharmacy experience (n=274)

Out of 272 participants who responded to the question, 55 (20.2%) owned the pharmacies in which they worked. Another 43 (18.8%) were in partnership while 64% were employees (Fig. 4.5). The difference in proportions was statistically significant at p=0.000.

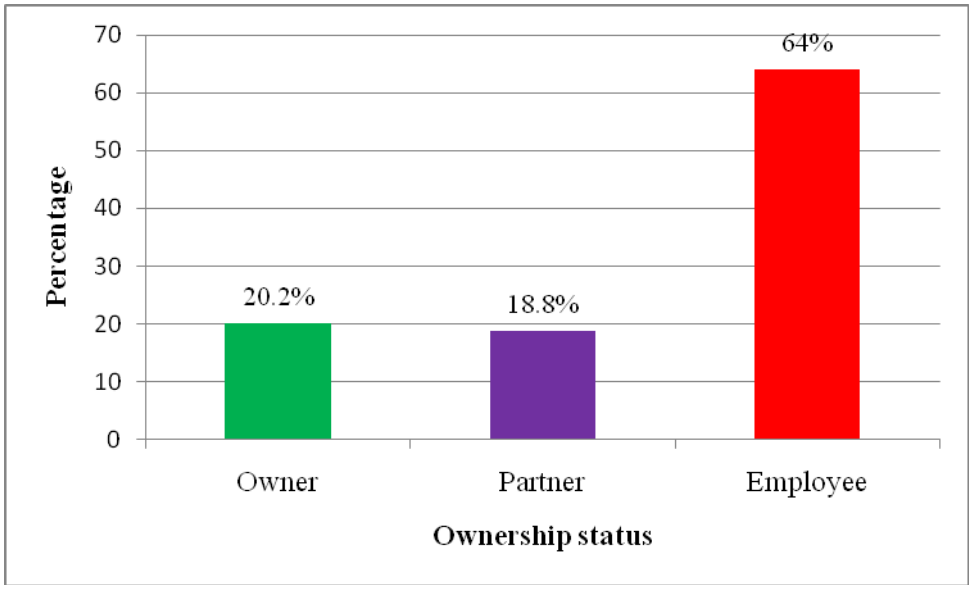

Figure 4.5: Extent of manager's involvement in pharmacy ownership (n=272)

4.2 Characteristics of the Community Pharmacies

The characteristics of the CPs studied included the number of years since establishment of pharmacy, connection to piped water, connection to municipal sewer, connection to septic tank, presence (or otherwise) of pit latrine and the type of drainage for waste water. Test of significance was done using chi square statistic.

As shown on Fig. 4.6, about half (52.8%) of the CPs studied were started five or less years prior to the date of study. A further 94 (34.9%) pharmacies were established between 6 and 10 years before the study. That makes a total of 87.7% established within the 10 years preceding data collection. Some 21 pharmacies (7.8%) were established 11-15 years prior to the study while 12 pharmacies (4.5%) had been in operation for 16 or more years. The difference in proportions was statistically significant (p=0.000).

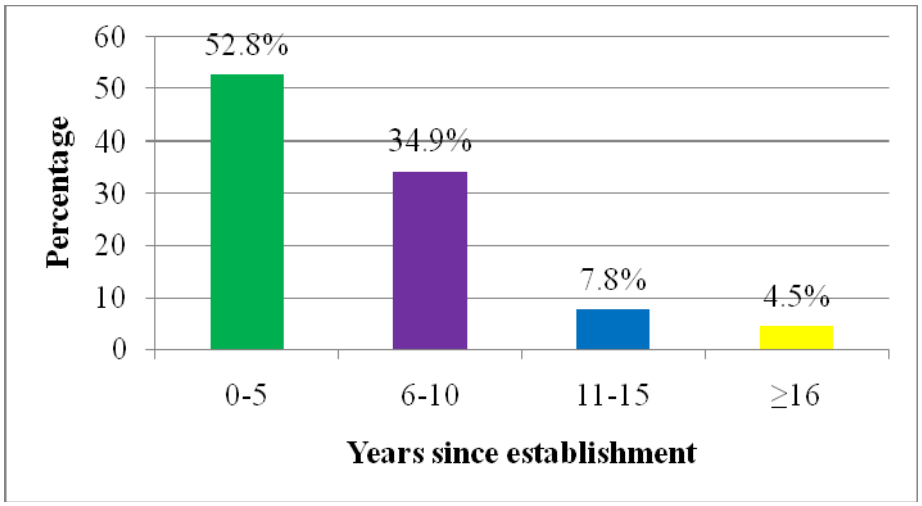

Figure 4.6: Distribution of community pharmacies by number of years since establishment (n=269)

Table 4.1 shows the distribution of pharmacies according to their access to piped water connection, municipal sewer, septic tank and pit latrine. Out of 272 pharmacies, 226 (83.1%) had piped water connection, which was unavailable in the other 16.9%. The difference in proportions was statistically significant (p=0.000). Out of 272 pharmacy managers, majority (79%) had access to municipal sewer connection while the remaining 21% did not. The difference in proportions was statistically significant (p=0.000). Out of 266 respondents, 178 (66.9%) indicated they had connection to a septic tank while the remaining 88, or 33.1% did not. The difference in proportions was statistically significant (p=0.000). The percentage of respondents with access to a pit latrine were 40% (n=270). The other 60% of pharmacies did not have access to a pit latrine. The difference in proportions was statistically significant (p=0.001).

Table 4.1: Distribution of respondents by pharmacy characteristics

Pharmacy Characteristic	Response		P value
	Yes (%)	No (%)	
Piped water (n=272)	83.1	16.9	0.000
Municipal sewer (n=272)	79	21	0.000
Septic tank (n=266)	66.9	33.1	0.000
Pit latrine (n=270)	40	60	0.001

About 70% of the pharmacies drain their waste water into municipal sewerage systems, 13% drain into soak pits while 17% discharge waste water into open drains (Fig. 4.7). The difference in proportions was statistically significant (p=0.000).

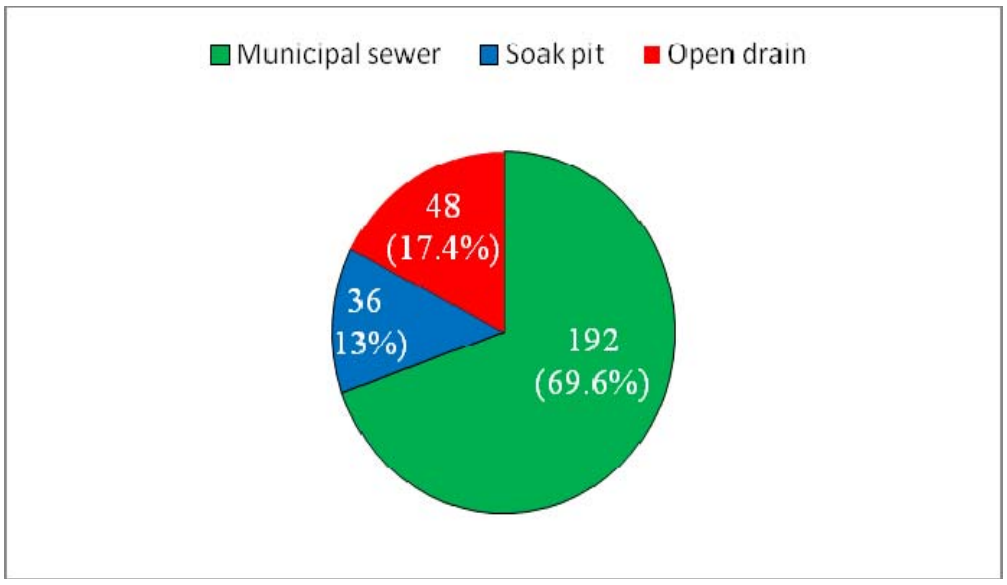

Figure 4.7: Routes of discharge for waste water (n=273)

4.3 QUALIFICATION OF COMMUNITY PHARMACY MANAGERS

This section presents the findings related to the participants' qualification as CP practitioners. The criteria for manager qualification included pharmacy training status, Pharmacy and Poisons Board registration status, professional body membership status, and continuous medical education attendance status. The distribution of respondents according to the main qualification factors is summarized on table 4.2. Out of 272 respondents, 251 (92.3%) were trained in the pharmacy profession while 7.7% had no pharmacy training. The difference in proportion was statistically significant (p=0.000). Of those with pharmacy training, 16% were pharmacy degree holders, 68% were pharmacy diploma holders while another 16% were pharmacy certificates holders (Fig. 4.8). A certificate in pharmacy is not legally recognized, hence the proportion of respondents qualified to legally run a pharmacy was 77.3%. The difference in proportions was statistically significant (p=0.000).

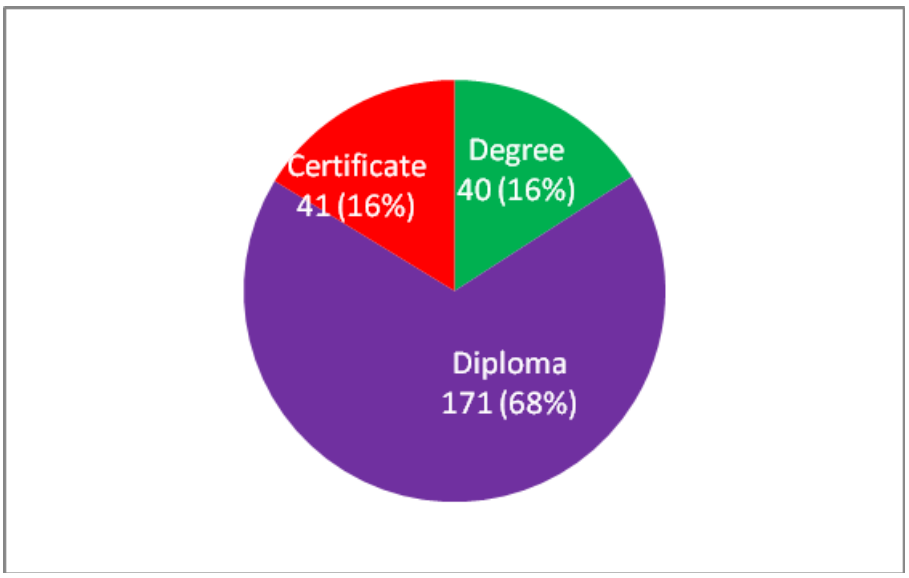

Figure 4.8: Distribution of respondents with professional training according to level of training (n=252)

The majority of respondents (77.2%) indicated they had PPB registration compared with 22.8% who did not. The difference in proportions was statistically significant. (p=0.000).

Out of the 264 respondents, 184 (69.7%) belonged to a professional body while 80 (30.3%) did not. The difference in proportions was statistically significant. (p=0.000). The difference in proportions was statistically significant (p=0.000). Out of 268 respondents, 72.8% regularly attended CME. The remaining 73 respondents (27.2%) did not regularly attend CME. The difference in proportions was statistically significant (p=0.000).

Table 4.2: Distribution of respondents according to the main qualification criteria

Qualification Criterion	Response		P value
	Yes (%)	No (%)	
Pharmacy Training (n=272)	92.3	7.7	0.000
PPB Registration (n=267)	77.2	22.8	0.000
Professional Body (n=264)	69.7	30.3	0.000
CME Attendance (n=268)	72.8	27.2	0.000

Out of the 184 who were affiliated to professional bodies, PSK members were 52 (28.3%), Kenya Pharmaceutical Association (KPA) members were 125 (67.9%), and 7 respondents (3.8%) belonged to other professional bodies (Fig. 4.9).

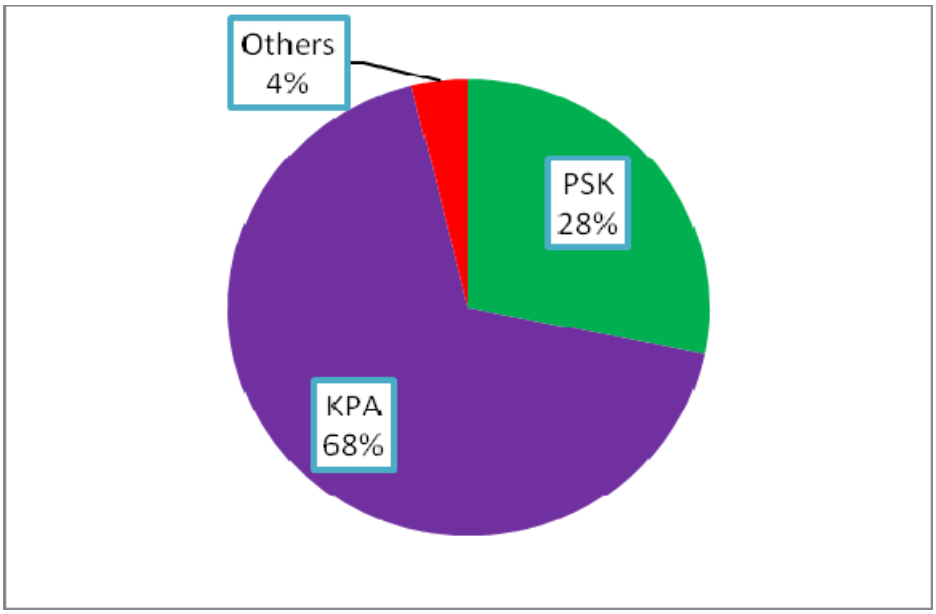

Figure 4.9: Distribution of respondents by professional body affiliation (n=184)

4.4 PHARMACEUTICAL WASTE DISPOSAL INFRASTRUCTURE

This section presents the findings on infrastructure necessary for sound PW disposal. The infrastructure of interest included access to regulated landfill, access to incineration facility, access to private burial site, access to public burial site, engagement of a licensed hazardous waste handler, and membership to an association providing hazardous waste disposal services.

4.4.1 Key waste disposal infrastructure

Figure 4.10 shows the distribution of pharmacies according to their access to key pharmaceutical waste disposal infrastructure. About half (51.9%) of the participating pharmacies had access to a landfill while 48.1% did not have. The difference in proportions was not statistically significant (p=0.543). Regarding incineration facilities, 54.8% had access while 45.2% didn't. The difference in proportions was not statistically significant (p=0.123). The proportion of respondents who had access to private burial sites was 24.4% compared to 75.6% who didn't have. The difference in proportion was statistically significant (p=0.000). About 61% of respondents had no access to a public

burial site for hazardous waste. The difference in proportion was statistically significant (p=0.000). Those who had contracted a hazardous waste handler were 63.3% of respondents. The other 36.7% didn't have this arrangement. The difference in proportion was statistically significant (p=0.000). About 60% of respondents were members of associations that provided PW disposal services for members. The difference in proportion was statistically significant (p=0.001).

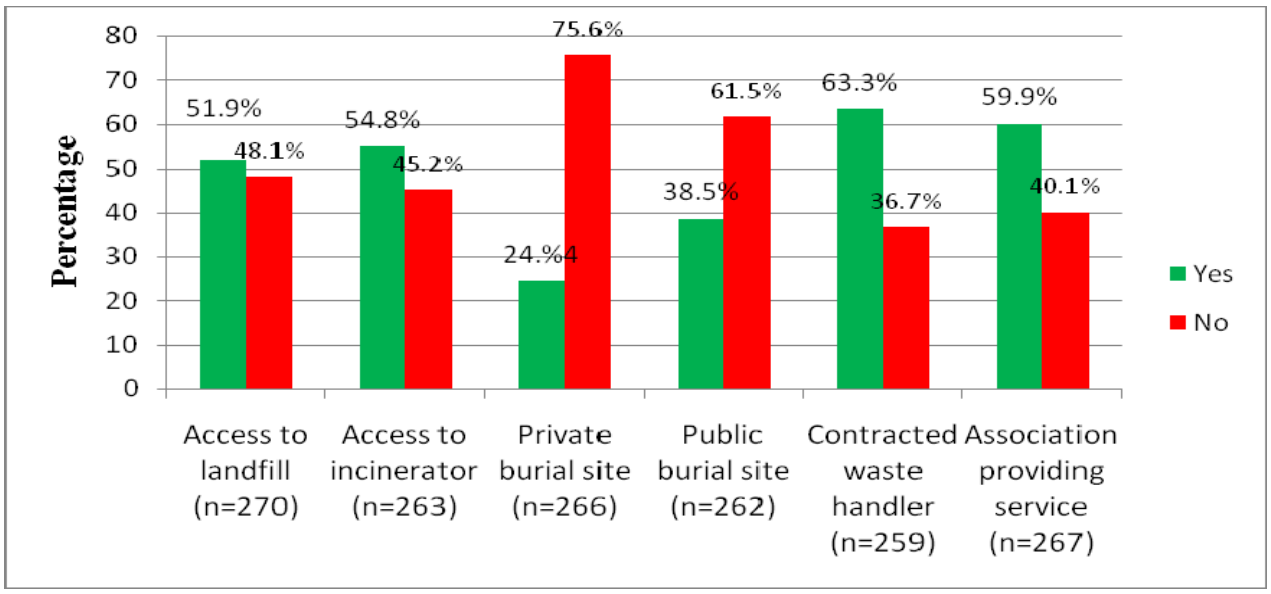

Figure 4.10: Access to key PW disposal infrastructure

4.4.2 Categorization of pharmacies by infrastructure score

Out of 274 respondents, 171 or 62.4% had "adequate waste disposal infrastructure" while 37.6% had "inadequate waste disposal infrastructure" (Fig. 4.11). The difference in proportion was statistically significant (p=0.001).

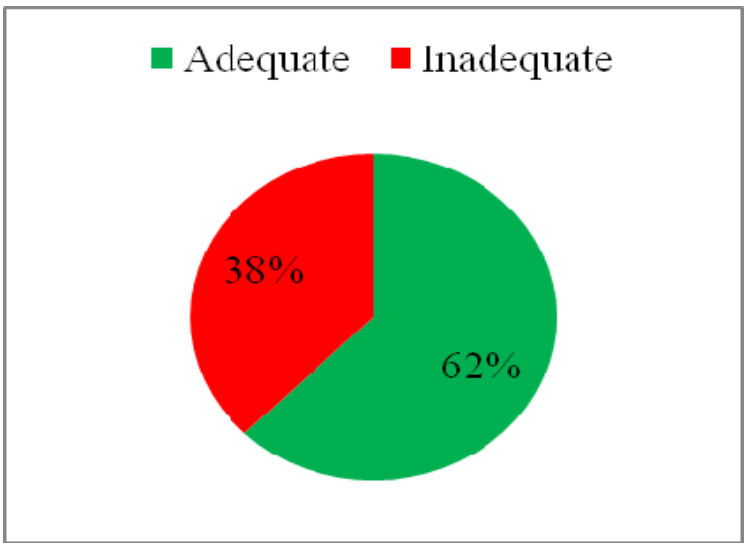

Figure 4.11: Distribution of pharmacies by PW disposal infrastructure category (n=274)

4.5 KNOWLEDGE OF PHARMACEUTICAL WASTE MANAGEMENT

Majority of the respondents (78.7%) demonstrated "adequate knowledge" of PWM compared to 21.3% who demonstrated "inadequate knowledge" of PWM (Fig. 4.12). The difference in proportion was statistically significant (p=0.000).

4.6 PRACTICE OF PHARMACEUTICAL WASTE MANAGEMENT

The percentage of respondents falling in the category of "good practice" of PWM was 66.1% (Fig. 4.13). The remaining 33.9% (93 out of 274 pharmacies) were categorized as having "poor practice" of PWM. The difference in proportion was statistically significant (p=0.000).

4.7 ASSOCIATIONS BETWEEN VARIABLES

This section presents associations of the various predictor variables and the outcome variables. The statistical test used was chi square. The outcome variables were knowledge of PWM (knowledge category) and practice of PWM (practice category). The predictor

variables were subdivided into respondents' socio-demographic characteristics, respondents' qualification indicators and pharmacy characteristics.

4.7.1 Association of knowledge and socio-demographic factors of respondents

Socio-demographic factors of respondents included age category, sex and level of schooling (Table 4.3). The statistics showed no association between knowledge category and respondent's age category (p=0.074). Knowledge was associated with sex of the respondents (p=0.019). Knowledge was also found to be associated with the highest level of formal schooling (p=000).

Table 4.3: Association of knowledge and respondents' socio-demographic factors

Manager Characteristic		Knowledge Category		Number of respondents (n)	p value
		Adequate (%)	Inadequate (%)		
Age Category: n=272	< 30	73.1	26.9	134	p=0.074
	30-44	83.2	16.8	119	
	≥ 45	89.5	10.5	19	
Sex: n=272	Male	84.1	15.9	145	p=0.019
	Female	72.4	27.6	127	
Highest level of schooling: n=268	Degree	92.2	7.8	51	p=0.000
	Diploma	81.2	18.8	170	
	< Diploma	53.2	46.8	47	

4.7.2 Association of knowledge and pharmacy manager qualification factors

The main manager qualification factors were professional training status, PPB registration status, professional body membership status and CME attendance status. Secondary

qualification factors were level of professional training, pharmacy experience and professional body identity. Table 4.4 is a summary of associations of knowledge with the main qualification factors. The statistics showed association between knowledge category and professional training status (p=0.002). PPB registration status was also associated with knowledge category (p=0.001). Knowledge was associated with professional body membership status (p=0.000). Similarly, knowledge was associated with the respondents' CME attendance status (p=0.004).

Table 4.4: Association of knowledge of PWM and the main qualification factors

Qualification factor		Knowledge Category		Number of respondents (n)	p value
		Adequate (%)	Inadequate (%)		
Professional training status:	Trained	81.1	18.9	249	p=0.002
	Untrained	52.4	47.6	21	
	Total			270	
PPB registration status:	Yes	83.9	16.1	205	p=0.001
	No	63.3	36.7	60	
	Total			265	
Professional body membership status:	Yes	87.4	12.6	183	p=0.000
	No	62.5	37.5	80	
	Total			263	
CME attendance status:	Yes	83.4	16.6	193	p=0.004
	No	67.1	32.9	73	
	Total			266	

As depicted on Table 4.5, the level of pharmacy training was associated with knowledge category (p=0.001). Knowledge was not associated with either pharmacy experience (p=0.246) or professional body identity (p=0.390).

Table 4.5: Association between knowledge of PWM and secondary qualification factors

Qualification factor		Knowledge Category		Number of respondents (n)	p value
		Adequate (%)	Inadequate (%)		
Level of training:	Degree	95	5	40	p=0.001
	Diploma	82.4	17.6	170	
	Certificate	62.5	37.5	40	
	Total			250	
Pharmacy experience:	< 2 years	70.4	29.6	54	p=0.246
	2 – 5 years	78.2	21.8	124	
	6 – 10 years	85	15	80	
	≥ 10 years	78.6	21.4	14	
	Total			272	
Professional body identity:	PSK	92.3	7.7	52	p=0.390
	KPA	84.6	15.4	124	
	Others	85.7	14.3	7	
	Total			183	

4.7.3 Association between practice of PWM and socio-demographic factors

This sub-section describes the association between practice of PWM and the respondents' socio-demographic factors (Table 4.6). The socio-demographic factors included age category, sex and level of schooling. Practice was not associated with respondent's age category (p=0.180) or sex of respondent (p=0.281). The respondents' level of schooling was associated with practice (p=0.000).

Table 4.6: Association of practice of PWM and respondents' socio-demographic factors

Manager Characteristic		Practice Category		Number of respondents (n)	p value
		Good (%)	Poor (%)		
Age Category:	< 30	60.7	39.3	135	p=0.180
	30-44	71.7	28.3	120	
	≥ 45	68.4	31.6	19	
	Total			274	
Sex:	Male	69	31	145	p=0.281
	Female	62.8	37.2	129	
	Total			274	
Level of schooling:	Degree	72.5	27.5	51	p=0.000
	Diploma	70.8	29.2	171	
	< Diploma	41.7	58.3	48	
	Total			270	

4.7.4 Association of practice of PWM and the respondents' main qualification factors

The association of practice and the main manager qualification factors is summarized on Table 4.7. The respondents' professional training status was associated with practice category (p=001). PPB registration status was similarly associated with practice category (p=0.000). Practice category was also associated with professional body membership status (p=0.002). Practice category was similarly associated with CME attendance status (p=0.000).

Table 4.7: Association between practice of PWM and the main qualification factors

Qualification factor		Practice Category		Number of respondents (n)	p value
		Good (%)	Poor (%)		
Professional training status	Trained	68.9	31.1	251	p=0.001
	Untrained	33.3	66.7	21	
	Total			272	
PPB registration status	Registered	73.3	26.7	206	p=0.000
	Not registered	49.2	50.8	61	
	Total			267	
Professional body membership status	Member	72.8	27.2	184	p=0.002
	None	53.8	46.2	80	
	Total			264	
Regular CME attendance	Yes	75.4	24.6	195	p=0.000
	No	43.8	56.2	73	
	Total			268	

Table 4.8 shows the association between practice and other qualification factors. The level of professional training was not associated with practice of PWM (p=0.063). Similarly, there was no association between practice of PWM and the respondents' experience (p=0.131). Practice was associated with the identity of professional body at p=0.004. The null hypothesis stated there was no association between knowledge of PWM and the degree of qualification of the pharmacy manager. The null hypothesis was therefore rejected since all the major qualification factors showed association with knowledge of PWM.

Table 4.8: Association of practice of PWM and secondary qualification factors

Manager Characteristic		Practice Category		Number of respondents (n)	P value
		Good (%)	Poor (%)		
Level of training:	Degree	70	30	40	p=0.063
	Diploma	72.5	27.5	171	
	Certificate	53.7	46.3	41	
	Total			252	
Pharmacy experience:	< 2 years	53.7	46.3	54	p=0.131
	2 – 5 years	66.7	33.3	126	
	6 – 10 years	71.3	28.7	80	
	> 10 years	78.6	21.4	14	
	Total			274	
Professional body identity:	PSK	59.6	40.4	52	p=0.004
	KPA	80.0	20.0	125	
	Others	42.9	57.1	7	
	Total			184	

4.7.5 Association of practice of PWM and pharmacy characteristics

Pharmacy characteristics included the number of years since establishment of pharmacy, access to running water, access to municipal sewer, access to septic tank, access to pit latrine and type of waste water drainage. As shown on Table 4.9, the length of time (years) since establishment of pharmacy was not associated with practice of PWM (p=0.432). Connection to piped water was associated with practice of PWM (p=0.001) and so was connection to municipal sewer (p=0.000). Connection to septic tank was similarly associated with practice of PWM (p=0.014). Practice of PWM was also associated with access to a pit latrine (p=0.000) and so was the type of waste water drainage (p=0.000).

Table 4.9: Association of practice of PWM and pharmacy characteristics

Pharmacy related factor		Practice Category		Number of respondents (n)	P value
		Adequate (%)	Inadequate (%)		
Years since establishment:	0-5 years	64.1	35.9	142	P=0.432
	6–10 years	66.7	33.3	93	
	11-15 years	77.3	22.7	22	
	> 15 years	66.7	33.3	12	
	Total			269	
Piped water:	Yes	70.4	29.6	226	P=0.001
	No	45.7	54.3	46	
	Total			272	
Municipal sewer:	Yes	72.1	27.9	215	p=0.000
	No	45.6	54.4	57	
	Total			272	
Septic tank:	Yes	71.9	28.1	178	P=0.014
	No	56.8	43.2	88	
	Total			266	
Pit latrine:	Yes	45.4	54.6	108	P=0.000
	No	80.2	19.8	162	
	Total			270	
Waste water drainage:	Sewer	75.5	14.5	192	P=0.000
	Soak pit	52.8	47.2	36	
	Open drain	35.6	64.4	45	
	Total			273	

4.7.6 Association of practice of PWM and access to PW disposal infrastructure

Table 4.10 presents a summary of associations between practice of PWM and access to PW disposal infrastructure. Access to a landfill and access to an incinerator were both associated with practice of PWM (p=0.001 and 0.000 respectively). In contrast, practice of

PWM was not associated with either access to a private burial site (p=0.998) or access to a public burial site (p=0.082). There was association between practice of PWM and access to contracted waste handlers (p=0.000). The same was true of practice of PWM and access to associations that provided PW waste disposal services (p=0.000). The null hypothesis stated there is no association between practice of PWM and availability of infrastructure that supports sound PWM. Cross tabulation of practice of PWM and infrastructure category showed there was association (p=0.002). Thus the null hypothesis was rejected.

Table 4.10: Association of practice of PWM and access to PW disposal infrastructure

PW disposal infrastructure		Practice Category (%)		Number of respondents (n)	p value
		Adequate (%)	Inadequate (%)		
Land fill: n=270	Yes	75.7	24.3	140	P=0.001
	No	56.2	43.8	130	
Incinerator: n=263	Yes	79.8	20.2	144	P=0.000
	No	50.4	49.6	119	
Private burial site: n=266	Yes	66.2	33.8	65	P=0.998
	No	66.2	33.8	201	
Public burial site: n=262	Yes	60.4	39.6	101	P=0.082
	No	70.8	29.2	161	
Waste handler: n=259	Yes	75.6	24.4	164	P=0.000
	No	50.5	49.5	95	
Ass. providing services: n=267	Yes	75	25	160	P=0.000
	No	52.3	47.7	107	

4.7.7 Association of practice of PWM and knowledge of PWM

The null hypothesis was that the quality of practice of PWM is not associated with knowledge of PWM. The statistical test showed that practice of PWM was associated with knowledge of PWM (p=0.000). The null hypothesis was therefore rejected.

CHAPTER FIVE: DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

5.1 DISCUSSION

The main objective of this study was to describe the prevailing situation of PWM among CPs in Nairobi. This was to be achieved by measuring manager qualification, access to infrastructure, knowledge of PWM and practice of PWM.

The results indicate that the majority of CP managers in Nairobi County were adequately qualified to practice sound PWM. The proportion of managers with the relevant professional training (77%) contrasts with the situation in Tanzania, where only 31% of medicine dispensers in Dar-es-Salaam had the relevant training i.e. pharmacists and pharmaceutical technologists (Mugoyela and Ally, 2002). However, the difference in study populations and long time lapse mean that direct comparison with the current study is inappropriate. In Pakistan, 55% of CP attendants had only secondary school education while only 9.5% were educated to degree level (Aslam et al, 2012). However, it is noted that the study populations were differently defined in both cases. Elsewhere in more developed economies, the majority of CP managers were highly qualified. A case in point is Saudi Arabia, where 96% of community pharmacists had a Bachelor of Science degree; over 2% had Doctor of Pharmacy (Pharm. D), over 1% Master of Science and about 0.6% had Doctor of Philosophy degrees (Khojah et al, 2013). With this in mind and remembering that pharmacy practice imparts directly on human health, it is fair to state that the current situation is far from perfect.

The finding that 77% of respondents were registered with PPB was inconsistent with existing literature. There was a reported high incidence of informal CPs in Kenya, particularly in rural areas (PSP4H, 2014). In fact unlicensed pharmacies were said to

outnumber licensed ones in the rural areas (Wafula, 2013). However, Nairobi County is mainly urban. It also hosts the PPB headquarters. These factors probably make enforcement of regulations easier than in other counties. But it is likely that slum areas are probably as bad as or worse than rural areas in this respect. As the largest city in Kenya, Nairobi hosts some of the biggest slums in the region. Secondly, it is possible that unlicensed pharmacy managers or managers of illegal pharmacies were more reluctant to take part in the study due to fear of PPB inspectors.

The proportion of respondents who were members of professional bodies (70%) is comparable to the proportion of those regularly attending CME (73%). Indeed 87% of those with membership to professional bodies regularly attended CME compared to 40.5% of those who were not members of professional bodies. This is not surprising since professional bodies usually oversee most of the CMEs. Educative intervention was found to improve the knowledge of pharmacists regarding PWM in the US (Jarvis et al, 2009). This was a before-after experimental study involving a single educative newsletter in the US. It would be expected that regular CMEs with relevant content would be more effective as an educational intervention than a one off intervention.

Over 62% of participating pharmacies had adequate PW disposal infrastructure as measured in this study. It was however not determined whether the available infrastructure was of the required standards. About 52% of the respondents had access to landfills. In Tanzania, 72% of public health facilities in Dar es Salaam buried their PW at the city's public dumpsite (Matiko, 2011), perhaps due to the lack of sanitary landfills. The Tanzania study had no mention of landfills. In the current study, about 45% of participating pharmacies had no access to incinerators. This compares favourably with Tanzania where 46% of government HFs in Dar es Salaam cited lack of incinerators as one of the major barriers to proper disposal of PW (Matiko, 2012) even though PW disposal

infrastructure was not specifically measured as a variable. About 60 % of respondents had contracted waste handlers, an option that seemed more popular in New Zealand, where over 80% of solid PW and over 60% of liquid PW from CPs was disposed of by this mode (Tong et al, 2011). The same mode was widely used in the US and parts of Europe as mentioned in the literature review. It is a potentially good alternative in the absence of adequate PW disposal infrastructure or reverse logistics. But the waste handlers themselves must be closely supervised to ensure they practice sound waste management.

About 79% of the respondents in this study demonstrated 'adequate knowledge' of PWM. This was similar to Kuwait where over 80% of public sector pharmacists were aware of the environmental impact of unsafe disposal of PW (Abahussain et al, 2012). But the Kuwait study differed with the current study in the definition of study population. In the US, the proportion of pharmacists taking part in an interventional study who perceived inappropriate disposal of PW to be an environmental hazard increased from 47% to 57% following a one-off educational intervention (Jarvis et al, 2009). Again, the type of study and the contextual factors were entirely different from those obtained in the current study. Even though the majority of respondents had adequate knowledge of PWM, some of the questions proved difficult. About 76% for instance incorrectly answered that burying PW could prevent pollution of water sources. It is also noteworthy that higher levels of pharmacy training improved the probability of having adequate knowledge of PWM. Among pharmacy degree holders, 95% had adequate knowledge of PWM compared to 82% of pharmacy diploma holders. This suggests that increasing the numbers of highly qualified CP managers and eliminating unqualified ones from the business can improve the situation significantly.

About 66% of participating pharmacies were categorized as having 'good practice' of PWM. But a significant 36% of respondents burned their PW compared to New Zealand,

where less that 1% of CPs burned their PW (Tong et al, 2011). In Tanzania, 31% of HFs in Dar es Salaam burned their PW (Matiko, 2012). This compares more closely with the finding of the current study even though the study units were different. This suggests that this method is practiced more commonly in poorer countries. Secondly, 21% of respondents discarded PW into garbage dumps while 23% gave it to informal waste-collectors. A similar situation obtained in Tanzania where about two thirds of private pharmacies in Dar es Salaam either dumped PW or drained it through the sink (Mugoyela and Ally, 2002). However, it contrasts with New Zealand where 3.9% and 24.6% disposed of solid and semi-solid PW respectively with regular rubbish (Tong et al, 2011).

Knowledge of PWM was associated with all the main manager qualification indices. Pharmacy managers with professional training and duly registered with PPB, who belonged to professional bodies and who regularly attended CME were more likely to demonstrate adequate knowledge of PWM. Furthermore, a higher level of schooling and also a higher level of professional training were also associated with adequate knowledge of PWM. This implies that ensuring that CPs are managed only by qualified and registered professionals would enhance the proportion of pharmacy managers with adequate knowledge of PWM.

Similarly, practice of PWM was associated with all the main manager qualification indices. In addition, practice was associated with professional body identity, implying that the different professional bodies had different levels of influence on knowledge of PWM. There was no association between practice of PWM and the level of professional training. This is probably because knowledge of PWM was not obtained from the classroom but rather in other educative forums.

5.2 CONCLUSIONS

The majority of CP managers in Nairobi County, Kenya were adequately qualified to practice sound PWM.

Although well over half of CPs in Nairobi County had access to adequate waste disposal infrastructure, there was room for improvement. Considering the importance of PWM to public health, the proportion of CPs with inadequate PW disposal infrastructure was significant

The majority of CP managers were adequately knowledgeable on PWM. Knowledge of PWM was associated with the main indicators of manager qualification which were professional training status, PPB registration status, professional body membership status and CME attendance status.

Practice of PWM was good in 66% of CPs in Nairobi County. However, unsound methods of PW disposal such as discarding with municipal waste or through informal waste collectors and also burning of PW were being practiced in some pharmacies. Quality of practice of PWM can be improved by improving access to PW disposal infrastructure and knowledge of PWM among CP managers.

5.3 RECOMMENDATIONS

5.3.1 Policy

The PPB should enhance law enforcement to ensure that only suitably qualified persons are allowed to superintend CPs. Secondly, the PPB should discourage the establishment of CPs before verifying the PW disposal infrastructure available to them. This requirement should be a prerequisite for pharmacy licensing. PWM guidelines which were being developed by PPB should define the types of PWM infrastructure acceptable for CPs.

The PSK and KPA should explore ways of encouraging suitably qualified CP managers to take membership in order to improve learning opportunities for them. Secondly, they should strive to organize CMEs with PWM content for their members on a regular basis.

5.3.2 Further Research

A national study is recommended to investigate the magnitude of environmental pollution with PW in Kenya.

Another important area of study is the presence and concentration of APIs in municipal waste, sewage and drinking water.

A research study is recommended to study the consequences of exposure to low concentrations of APIs through drinking, bathing or otherwise coming into contact with water.

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APPENDICES

APPENDIX 1: INFORMED CONSENT FORM (ICF)

ICF FOR COMMUNITY PHARMACY MANAGERS

Study Title:	A situation analysis on pharmaceutical waste management in Nairobi County
Name of Principal Investigator:	John R. Mugumura
	P.O. BOX 10542-00100 NAIROBI
Institution:	University of Nairobi
	P.O. BOX 30197-00100 NAIROBI

PART 1: INFORMATION SHEET

1. Introduction: My name is John Mugumura, a Master of Public Health student at the University of Nairobi. I am carrying out research on pharmaceutical waste management in Nairobi County. I am inviting you to take part in this research study which will form part of my assessment for award of the MPH degree. Please feel free to seek clarification on any aspect of the study at any stage.
2. Objective of Research: This research study aims at describing the current situation of pharmaceutical waste management among community pharmacies in Nairobi County. We believe that the information gathered will help the stake holders in developing solutions for pharmaceutical waste management.
3. Benefits: This study is expected to benefit the community in general by contributing to safe management of pharmaceutical waste. It is also expected to benefit community pharmacies by creating awareness on the subject. The information generated should also benefit the Pharmacy and Poisons Board in policy development.
4. Risks: This research study is nonclinical and we do not foresee any risks.
5. Participant Selection: You have been selected to take part in this study in a random selection process. However, the decision to participate or decline is absolutely yours.
6. Confidentiality: Your personal details and those of your pharmacy will be handled with strict confidentiality. The information you provide will be identified by a number rather than name.
7. Duration: The study will be conducted within a period of three weeks. During this time, we may revisit you to seek any clarifications if necessary.

8. Contact Person: You may ask questions now or later. If you need to ask questions later, you may contact the principal investigator using the following contact details.

   John Mugumura
   Tel: 0722 777 381
   Email: jonmugumura@gmail.com

This proposal has been reviewed and approved by the Kenyatta National Hospital/University of Nairobi Ethics and Research Committee (KNH/UON, ERC), a committee whose task it is to make sure that research participants are protected from harm. To find out more about the clearance of this proposal by the KNH/UON, ERC, you may contact the committee secretary, P.O. Box 20723, 00202 Nairobi; or telephone +254202726300-19.

PART 2: CONSENT STATEMENT BY THE PARTICIPANT

I have read the foregoing information. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction. I consent voluntarily to be a participant in this study.

Name of Participant_____

Signature _____

Date _____ dd/mm/yyyy

Statement by the researcher

I have provided the information sheet to the potential participant, and to the best of my ability made sure that the participant understands the contents. I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.
A copy of this ICF has been provided to the participant.

Name of Researcher taking the consent _____

Signature of Researcher taking the consent_____

Date _____ dd/mm/yyyy

APPENDIX 2: QUESTIONNAIRE FOR PHARMACY MANAGERS

Questionnaire ID_____

Please respond to all the questions.

Part I

1. Please indicate your age category. <30 ☐ 30-44 ☐ 45-59 ☐ ☐ ≥60
2. Please indicate your gender. Male ☐ Female ☐
3. For how many years have you worked in a pharmacy? Please tick the applicable choice. ☐ ☐ ☐ ☐ ☐

   <2 2-5 6-10 10-20 >20
4. Are you trained in the pharmacy profession? Yes ☐ No ☐
5. If the answer to 4 is yes, please indicate your level of training.

   Pharmacy degree ☐ Pharmacy diploma ☐

   Pharmacy certificate ☐ Other (Specify) _____
6. Are you registered or enrolled as a pharmacy professional with the Pharmacy and Poisons Board?

   Yes ☐ No ☐
7. How many years have passed since you completed secondary school education? Please tick the applicable choice.

   Less than 10 ☐ 10 or more ☐
8. What is your highest level of schooling? Degree ☐ Diploma ☐ Certificate ☐ Secondary School ☐ Other (Specify) _____
9. Are you the person responsible for licensing compliance in your pharmacy?

   Yes ☐ No ☐
10. Do you regularly attend continuous medical education? Yes ☐ No ☐
11. Do you belong to a professional body? Yes ☐ No ☐
12. If the answer to 11 is yes, please indicate which professional body?

    PSK ☐ KPA ☐ Other (Specify) _____
13. Are you in the ownership structure of your pharmacy?

    Owner ☐ Partner ☐ Employee ☐

Part II

1. How many years ago was your pharmacy established?
   0-5 ☐ 6-10 ☐ 11-15 ☐ 16-20 ☐ 21-30 ☐ >30 ☐
2. Is your premises connected to running piped water? Yes ☐ No ☐
3. Is your premises connected to a municipal sewerage system? Yes ☐ No ☐
4. Does your pharmacy have access to a regulated landfill for hazardous waste?
   Yes ☐ No ☐
5. Do you belong to any association that provides or procures hazardous waste disposal services for members?
   Yes ☐ No ☐
6. What type of drainage is available for waste water in your pharmacy?
   Municipal sewer ☐ Soak pit ☐ Open drain ☐
7. Is your premises connected to a septic tank? Yes ☐ No ☐
8. Does your pharmacy have access to an incineration facility? Yes ☐ No ☐
9. Do you have access to a private burial site for hazardous waste? Yes ☐ No ☐
10. Is a pit latrine available as a form of sanitation for your premises? Yes ☐ No ☐
11. Do you have access to a public burial site for hazardous waste? Yes ☐ No ☐
12. Have you engaged the services of a licensed hazardous waste handler?
    Yes ☐ No ☐

Part III

1. Do you consider dumped pharmaceuticals to be an environmental hazard?
   Yes ☐ No ☐ Not sure ☐
2. Do you consider it necessary to separate expired pharmaceuticals from sellable stock?
   Yes ☐ No ☐ Not sure ☐
3. Do you think development of resistance to anti-bacterial compounds can result from unsound management of pharmacy waste?
   Yes ☐ No ☐ Not sure ☐
4. Do you consider pharmaceutical waste in the environment to be a threat to effective sewage treatment?
   Yes ☐ No ☐ Not sure ☐

5. Do you consider inventory management to be an important phase of sound waste management?

   Yes ☐ No ☐ Not sure ☐

6. Do you consider return of unsold pharmaceuticals to the manufacturer a good way of minimizing pharmaceutical waste?

   Yes ☐ No ☐ Not sure ☐

7. Burying pharmaceutical waste prevents pollution of water sources with pharmaceutical compounds. Do you agree?

   Yes ☐ No ☐ Not sure ☐

8. Burning of pharmaceutical waste may lead to production of harmful persistent organic pollutants (POPs). Do you agree?

   Yes ☐ No ☐ Not sure ☐

9. Encapsulation of pharmaceutical waste is a method of disposal that precedes land filling. Do you agree?

   Yes ☐ No ☐ Not sure ☐

10. Inertization ensures that release of active pharmaceutical compounds into the aqueous environment is reduced and/or delayed. Do you agree?

    Yes ☐ No ☐ Not sure ☐

Part IV

1. Do you have a separate receptacle for storage of expired or damaged pharmaceuticals in your pharmacy?

   Yes ☐ No ☐

2. Do you regularly return unsold stocks to your suppliers? Yes ☐ No ☐
3. Do you usually dispose of waste containing pharmaceuticals by burning it?

   Yes ☐ No ☐

4. Do you usually dispose of pharmaceutical waste in a garbage dump?

   Yes ☐ No ☐

5. Do you usually dispose of pharmaceutical waste through informal waste collectors?

   Yes ☐ No ☐

6. Do you usually deposit pharmaceutical waste in a pit latrine? Yes ☐ No ☐

7. Do you regularly dispose of pharmaceutical waste by incinerating it?

   Yes ☐ No ☐

8. Do you regularly dispose of pharmaceutical waste by burying it? Yes ☐ No ☐

9. Do you regularly dispose of liquid pharmaceutical waste by flushing it down the toilet?

   Yes ☐ No ☐

10. Do you normally dispose of unwanted liquid pharmaceuticals by pouring them into the sink?

    Yes ☐ No ☐

End of questionnaire, thank you.

APPENDIX 3: BUDGET

ITEM	UNIT COST (KSh)	NUMBER REQUIRED	TOTAL COST (KSh)
Allowances for RAs	800 per RA per day	10 x 10 days	80000
Document Holders	100	10	1000
Printing costs	10 per page	Approx. 1000	10000
Photocopying	2 per page	Approx.4000	8000
Travel costs for RAs	300 per RA per day	10 RAs x 10 days	30000
Transport for PI	1000 per day	10	10000
Data Analysis			50000
Allowance for PI			40000
Miscellaneous (5 %)			11450
Subtotal			240450
Contingency (10%)			24045
Grand Total			**264495**

APPENDIX 4: STATISTICAL TESTING OUTPUT

Frequency Distributions of Socio-demographic characteristics

	Age category	Sex	Highest level of schooling	Experience category	Participant ownership status
Chi-Square	87.161	.934	109.400	96.628	115.684
df	2	1	2	3	2
p value.	.000	.334	.000	.000	.000

Frequency Distributions of community pharmacy characteristics

	Years since established	Connection to piped water	Connection to municipal sewerage	Connection to septic tank	Access to pit latrine	Type of waste water drainage
Chi-Square	168.784	119.118	91.779	30.451	10.800	168.593
df	3	1	1	1	1	2
p value	.000	.000	.000	.000	.001	.000

Frequency distribution of manager qualification factors

	Prof. training status	PPB registration status	Prof. body membership status	CME attendance status	Level of prof. training	Years since est.	Prof. body identity
Chi-Square	197.882	78.745	40.970	55.537	135.167	96.628	115.641
df	1	1	1	1	2	3	2
p value.	.000	.000	.000	.000	.000	.000	.000

Frequency distribution of pharmacies by access to PW disposal infrastructure

	Access to landfill	Access to incineration facility	Access to private burial site	Access to public burial site	Services of hazardous waste handler	Association providing disposal services
Chi-Square	.370	2.376	69.534	13.740	18.382	10.521
df	1	1	1	1	1	1
p value	.543	.123	.000	.000	.000	.001

Distribution of respondents by access to infrastructure, knowledge and practice

	Infrastructure Category	Knowledge Category	practice Category
Chi-Square	7.036	89.471	28.263
df	2	1	1
p value	.030	.000	.000

Cross-tabulation statistics for knowledge and age category

	Value	df	p value (2-sided)
Pearson Chi-Square	5.221	2	.074
Likelihood Ratio	5.398	2	.067
Linear-by-Linear Association	5.111	1	.024
N of Valid Cases	272		

Cross-tabulation statistics for knowledge and sex of respondent

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	5.521	1	.019		
Continuity Correction(a)	4.846	1	.028		
Likelihood Ratio	5.528	1	.019		
Fisher's Exact Test				.026	.014
Linear-by-Linear Association	5.501	1	.019		
N of Valid Cases	272				

Cross-tabulation statistics for knowledge and respondents' level of schooling

	Value	df	p value (2-sided)
Pearson Chi-Square	25.476	3	.000
Likelihood Ratio	23.480	3	.000
Linear-by-Linear Association	23.604	1	.000
N of Valid Cases	268		

Cross-tabulation statistics for knowledge and respondents' experience

	Value	df	p value (2-sided)
Pearson Chi-Square	4.143	3	.246
Likelihood Ratio	4.134	3	.247
Linear-by-Linear Association	2.999	1	.083
N of Valid Cases	272		

Cross-tabulation statistics for knowledge and respondents' ownership status

	Value	df	p value (2-sided)
Pearson Chi-Square	5.718(a)	2	.057
Likelihood Ratio	6.594	2	.037
Linear-by-Linear Association	4.929	1	.026
N of Valid Cases	270		

Cross-tabulation statistics for knowledge and professional training status

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	10.824	1	.001		
Continuity Correction(a)	9.032	1	.003		
Likelihood Ratio	8.949	1	.003		
Fisher's Exact Test				.003	.003
Linear-by-Linear Association	10.784	1	.001		
N of Valid Cases	270				

Cross-tabulation statistics for knowledge and PPB registration status

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	11.940	1	.001		
Continuity Correction(a)	10.722	1	.001		
Likelihood Ratio	10.880	1	.001		
Fisher's Exact Test				.001	.001
Linear-by-Linear Association	11.895	1	.001		
N of Valid Cases	265				

Cross-tabulation statistics for knowledge and professional body membership status

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	21.503	1	.000		
Continuity Correction(a)	19.982	1	.000		
Likelihood Ratio	20.083	1	.000		
Fisher's Exact Test				.000	.000
Linear-by-Linear Association	21.422	1	.000		
N of Valid Cases	263				

Cross-tabulation statistics for knowledge and CME attendance status

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	8.463	1	.004		
Continuity Correction(a)	7.511	1	.006		
Likelihood Ratio	7.954	1	.005		
Fisher's Exact Test				.006	.004
Linear-by-Linear Association	8.431	1	.004		
N of Valid Cases	266				

Cross-tabulation statistics for knowledge and level of professional training

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	14.301	2	.001
Likelihood Ratio	14.409	2	.001
Linear-by-Linear Association	13.783	1	.000
N of Valid Cases	250		

Cross-tabulation statistics for knowledge and managers' experience

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	4.143(a)	3	.246
Likelihood Ratio	4.134	3	.247
Linear-by-Linear Association	2.999	1	.083
N of Valid Cases	272		

Cross-tabulation statistics for knowledge and professional body identity

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	1.881(a)	2	.390
Likelihood Ratio	2.059	2	.357
Linear-by-Linear Association	1.533	1	.216
N of Valid Cases	183		

Cross-tabulation statistics for practice and age category

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	3.433(a)	2	.180
Likelihood Ratio	3.447	2	.178
Linear-by-Linear Association	2.465	1	.116
N of Valid Cases	274		

Cross-tabulation statistics for practice and sex of respondent

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	1.161(b)	1	.281		
Continuity Correction(a)	.902	1	.342		
Likelihood Ratio	1.160	1	.281		
Fisher's Exact Test				.308	.171
Linear-by-Linear Association	1.157	1	.282		
N of Valid Cases	274				

Cross-tabulation statistics for practice and respondents' level of schooling

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	15.350	2	.000
Likelihood Ratio	14.611	2	.001
Linear-by-Linear Association	10.113	1	.001
N of Valid Cases	270		

Cross-tabulation statistics for practice and respondents' experience

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	5.636	3	.131
Likelihood Ratio	5.578	3	.134
Linear-by-Linear Association	5.087	1	.024
N of Valid Cases	274		

Cross-tabulation statistics for practice and respondents' pharmacy ownership status

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	3.985	2	.136
Likelihood Ratio	3.858	2	.145
Linear-by-Linear Association	.983	1	.322
N of Valid Cases	272		

Cross-tabulation statistics for practice and number of years since pharmacy establishment

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	1.499	3	.683
Likelihood Ratio	1.581	3	.664
Linear-by-Linear Association	.764	1	.382
N of Valid Cases	269		

Cross-tabulation statistics for practice and access to piped water

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	10.419	1	.001		
Continuity Correction	9.345	1	.002		
Likelihood Ratio	9.920	1	.002		
Fisher's Exact Test				.002	.001
Linear-by-Linear Association	10.381	1	.001		
N of Valid Cases	272				

Cross-tabulation statistics for practice and access to municipal sewer

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	14.189	1	.000		
Continuity Correction	13.025	1	.000		
Likelihood Ratio	13.553	1	.000		
Fisher's Exact Test				.000	.000
Linear-by-Linear Association	14.137	1	.000		
N of Valid Cases	272				

Cross-tabulation statistics for practice and access to septic tank

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	6.059	1	.014		
Continuity Correction	5.396	1	.020		
Likelihood Ratio	5.948	1	.015		
Fisher's Exact Test				.018	.011
Linear-by-Linear Association	6.036	1	.014		
N of Valid Cases	266				

Cross-tabulation statistics for practice and access to pit latrine

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	35.276	1	.000		
Continuity Correction	33.732	1	.000		
Likelihood Ratio	35.280	1	.000		
Fisher's Exact Test				.000	.000
Linear-by-Linear Association	35.145	1	.000		
N of Valid Cases	270				

Cross-tabulation statistics for practice and type of waste water drainage

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	29.120	2	.000
Likelihood Ratio	28.163	2	.000
Linear-by-Linear Association	28.915	1	.000
N of Valid Cases	273		

Cross-tabulation statistics for practice and access to landfill

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	11.542	1	.001		
Continuity Correction	10.684	1	.001		
Likelihood Ratio	11.625	1	.001		
Fisher's Exact Test				.001	.001
Linear-by-Linear Association	11.500	1	.001		
N of Valid Cases	270				

Cross-tabulation statistics for practice and access to incineration facility

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	25.366	1	.000		
Continuity Correction	24.061	1	.000		
Likelihood Ratio	25.637	1	.000		
Fisher's Exact Test				.000	.000
Linear-by-Linear Association	25.269	1	.000		
N of Valid Cases	263				

Cross-tabulation statistics for practice and access to prove burial site

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	.000	1	.998		
Continuity Correction	.000	1	1.000		
Likelihood Ratio	.000	1	.998		
Fisher's Exact Test				1.000	.556
Linear-by-Linear Association	.000	1	.998		
N of Valid Cases	266				

Cross-tabulation statistics for practice and access to public burial site

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	3.033	1	.082		
Continuity Correction	2.582	1	.108		
Likelihood Ratio	3.007	1	.083		
Fisher's Exact Test				.106	.054
Linear-by-Linear Association	3.022	1	.082		
N of Valid Cases	262				

Cross-tabulation statistics for practice and access to services of hazardous waste handler

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	16.967	1	.000		
Continuity Correction	15.861	1	.000		
Likelihood Ratio	16.727	1	.000		
Fisher's Exact Test				.000	.000
Linear-by-Linear Association	16.901	1	.000		
N of Valid Cases	259				

Cross-tabulation statistics for practice and membership to association providing PW disposal services

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	14.659	1	.000		
Continuity Correction	13.668	1	.000		
Likelihood Ratio	14.557	1	.000		
Fisher's Exact Test				.000	.000
Linear-by-Linear Association	14.605	1	.000		
N of Valid Cases	267				

Cross-tabulation statistics for practice and infrastructure category

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	17.545	2	.000
Likelihood Ratio	17.536	2	.000
Linear-by-Linear Association	15.531	1	.000
N of Valid Cases	274		

Cross-tabulation statistics for practice and knowledge of PWM

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	23.166	1	.000		
Continuity Correction	21.684	1	.000		
Likelihood Ratio	22.110	1	.000		
Fisher's Exact Test				.000	.000
Linear-by-Linear Association	23.081	1	.000		
N of Valid Cases	272				

APPENDIX 5: ETHICAL APPROVAL

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
(254-020) 2726300 Ext 44355

KNH/UON-ERC
Email: uonknh_erc@uonbi.ac.ke
Website: www.uonbi.ac.ke

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

10 SEP 2014

Ref: KNH-ERC/A/316 Link:www.uonbi.ac.ke/activities/KNHUoN 10th September 2014

John R. Mugumura
School of Public Health
College of Health Sciences
University of Nairobi

Dear John

Research proposal : A situation analysis on pharmaceutical waste management in Nairobi county, Kenya (P456/07/2014)

This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and **approved** your above proposal. The approval periods are 10th September 2014 to 9th September 2015.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH/UoN ERC before implementation.
c) Death and life threatening problems and severe adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH/UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH/UoN ERC within 72 hours.
e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
f) Clearance for export of biological specimens must be obtained from KNH/UoN-Ethics & Research Committee for each batch of shipment.
g) Submission of an *executive summary* report within 90 days upon completion of the study This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/or plagiarism.

For more details consult the KNH/UoN ERC website **www.uonbi.ac.ke/activities/KNHUoN.**

Protect to Discover

Yours sincerely

PROF.M.L. CHINDIA
SECRETARY, KNH/UON-ERC

c.c. The Principal, College of Health Sciences, UoN
The Deputy Director CS, KNH
The Chair, KNH/UoN-ERC
The Assistant Director, Health Information, KNH
The Director, School of Public Health, UoN
Supervisors: Ms. Mary Kinoti, Dr.Dismas Ongore

APPENDIX 6: PSK ENDORSEMENT

Pharmaceutical Society of Kenya

Hurlingham, Woodlands Rd, Opp. DOD
P. O. Box 44290 - 00100, GPO, Nairobi-Kenya
Tel: 020 2738364/18, Mobile: +254-0722 817264/0723 310942
Website: www.pskenya.org, Email:pskkenya@yahoo.com

Our Ref: 2314/PSK/CHR/007

23th September 2014

To whom it Concerns

Dr John Rukungu Mugumura – Pharmacist of Reg.No.1175

The above named is a masters student at the University of Nairobi and is carrying out a study on Pharmaceutical waste management. He therefore needs to collect information from community pharmacies. Kindly assist him as necessary.

Thank you for your cooperation.

Yours Faithfully,
Pharmaceutical Society of Kenya

Pharmaceutical Society of Kenya
P O Box 44290-00100
GPO Nairobi Kenya

Dr Paul Mwaniki
President

National Executive Council Members: Dr. Paul Mwaniki (Chairman), Dr. Samuel Nyariki (Vice Chairman), Dr. Michael Kabiru (Treasurer), Dr. Juliet Konje (Hon. Secretary)

APPENDIX 7: U.O.N. SPH INTRODUCTION LETTER

UNIVERSITY OF NAIROBI

College of Health Sciences
School of Public Health

Kenyatta National Hospital
P.O. BOX 19676-00202,
NAIROBI, KENYA.

Tel: Nairobi 2726300 Ext. 43481
Telegrams: 22095, Medken Nairobi
Direct line: 2724639
Fax: 2724639

Date: 23rd September, 2014

TO WHOM IT MAY CONCERN

DR. JOHN RUKUNGU MUGUMURA – H57/79384/2012

This is to confirm that Dr. Mugumura is a postgraduate student pursuing a Masters of Public Health degree at the School of Public Health. His research is titled: "A Situation Analysis on Pharmaceutical Waste Management in Nairobi County, Kenya". The data collection will be carried out in community pharmacies in Nairobi County, Kenya

Please accord him the necessary assistance.

SCHOOL OF PUBLIC HEALTH
COLLEGE OF HEALTH SCIENCES
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UNIVERSITY OF NAIROBI

Dr. Dismas Ongore
DIRECTOR
SCHOOL OF PUBLIC HEALTH