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Disposal of unused medicines from households in Cape Town

By

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ABSTRACT

Evidence indicates that most South African households do not dispose of unused medicines in the manner prescribed by the medicine's regulatory authority. This trend is not unique to South Africa, but several developing nations have also lagged. An in-depth understanding of practices of disposal of unused as well as expired medicines is cardinal and critical to the development of an effective programme to reverse the situation. This study aimed to identify factors influencing the disposal practices of household unused and expired medicines, and the role of pharmacists in creating an efficient and robust system for proper disposal of unused medicine from households in the southern suburbs area of Cape Town.

A descriptive, cross-sectional study using a self-administered, semi-structured questionnaire was used to elicit responses from a convenience sample of the study population in the southern suburbs of Cape Town. An open-ended- semi-structured questionnaire was emailed online to registered pharmacists practising in hospital and community pharmacies in Cape Town, and hardcopy questionnaires were handed to both hospital and community pharmacists working within the southern suburb areas.

An average of 2.6 items per household of unused pharmaceuticals was reported, with painkillers, cold and flu, anti-allergy, anti-hypertensive, and antibiotics the most common category of items. Storage for future use (39%) was the most common reason for keeping unused medication, while the most common methods of disposal were via the drain (31%) and garbage bin (45%) which raises environmental concerns. Most of the (56.2 %) respondents demonstrated a lack of understanding of guidelines regarding the safe disposal of unused and expired medicines. Another striking outcome was the absence of a clear explanation to patients by pharmacists concerning the return to the pharmacy for safe disposal of unused and expired medicines. Ideas on how to improve the prevailing situation have also been captured such as designated collection points, patient education, intensified campaigns and advertisement educating the general public on safe disposal of expired and unused pharmaceuticals.

Keywords: Unused medicines, unused pharmaceuticals, improper disposal, proper disposal, households, pharmacists, pharmaceutical products, knowledge, awareness, medication.

DECLARATION OF AUTHORSHIP

I declare that this research has been undertaken by myself and that materials in this report including the results of the survey given herein were first obtained by me, where materials of other authors have been used, due acknowledgement has been given. Occasional brief phrases. Figures, quotation marks and diagrams used as well have been well-cited and credited to the original or primary sources of such materials.

I make this declaration in my own cognizant.

Signed: _____

Miriam Oluchi

Date: ……. /……./……

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Miriam Oluchi

LIST OF ABBREVIATIONS

SAPC –	South African Pharmacy Council
NEMA –	National Environmental Management Act
API-	Active Pharmaceutical ingredients
SPSS –	Statistical Package for Social Sciences
WHO –	World Health Organization
SAHPRA–	South Africa Health Products Regulatory Authority
GPP –	Good Pharmacy Practice
CHC –	Community Health Center
OTC –	Over the Counter
NSAID –	Non-Steroidal Anti-Inflammatory Disease
ARGs –	Antibiotic Resistance Genes
DUMP –	Disposal of Unwanted Medicines and Poisons
RUM –	Rational Use of Medicines
NEMA-	National Environmental Management Act
FMHACA –	Food, Medicines, Healthcare Administration and Control Authority
SIAPS -	Systems for Improved Access to Pharmaceutical and Services
SPS -	Strengthening Pharmaceuticals and Services
USAID –	United State Agency International Development
CPD -	Continous Professional Development

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CHAPTER ONE

1 INTRODUCTION

1.1 Background of the study

Pharmaceuticals are fundamental components of modern health systems. They contain active ingredients designed to perform pharmacological and physiochemical actions in a living organism. Such products must be safe, effective and are rationally used either for prophylactic, curative, or diagnostic purposes (WHO, 1998). In South Africa, pharmaceutical products can be obtained via a prescription or as over the counter medicines. Each pharmaceutical product is classified based on its active pharmaceutical ingredients and designated treatment purpose (SAHPRA, 2005). Most prescription-based pharmaceutical products are scheduled according to the level of regulatory control over the availability of the medicine or chemical, required to protect public health and safety (SAHPRA, 2003). Not all purchased pharmaceuticals are completely consumed before their expiration. Also, many other factors might be responsible for the accumulation of unused pharmaceuticals, including; non-adherence, death, side effects, or discontinuation due to health improvement (Maeng *et al.*, 2016).

When -pharmaceutical products are left or forgotten without being used in various households, they are described as unused. Most unused pharmaceuticals may no longer be in a suitable state for consumption after long storage. These are because they may not have been stored according to the manufacturer's requirements (light, humidity), or may have expired (Bound *et al.*, 2006). Therefore, those pharmaceuticals lose their potency to be effective and are wasted. Pharmaceutical waste includes expired, unused, leftover, or contaminated pharmaceutical products, medicines, vaccines, and sera that are no longer needed. Storage of these products in the community/household poses a high risk of accidental poisoning and encourages abuse (Beirens *et al.*, 2006; Franklin and Rodgers, 2008).

The World Health Organization (WHO) encourages consumers to remove any unused medication immediately after use to reduce the chances of intentional or unintentional misuse. The most

prominent factors which influence decisions on the storage of unused medications at various households include intentionally keeping them for emergency purposes and sharing with family members and neighbours with similar conditions (Fidora, 2017; Mashiane, 2017). While unintentional conditions such as a change in treatment due to disease deterioration, the appearance of side effects that could not be managed, thus require discontinuation and oversupply of medicines contribute to the accumulation of medicines in households (Sarah A. Angi'enda and Bukachi, 2016; Ayele and Mamu, 2018). The presence of unused pharmaceuticals in various households brings about disposal problems.

Proper disposal of pharmaceutical waste can only be through the pharmacy (Abahussain, Ball and Matowe, 2006), disposal companies or designated collection points for an individual consumer, except for twenty three highly dangerous and abused narcotic medications (such as morphine and fentanyl patch), that are meant to be flushed down the toilet immediately after use to minimize abuse, intentional misuse and accidental consumption by Food and Drug Administration (FDA, 2015). This concept has encouraged and led most of the patients to dispose of medicines in the manner at which they do today. The common and most convenient way used to dispose of expired or unused mediation is by flushing down the toilet/sink and dumping into the garbage bin (Peake and Braund, 2009). International publications have suggested that the volume of pharmaceuticals returned to the pharmacy or that are properly disposed of represents a small proportion compared to the medications that remain in the community unused (Jonathan P. Bound and Voulvoulis, 2005; Seehusen and Edwards, 2006)

Pharmaceutical products are produced and used in large quantities, with their increased usage diversifying every year (Bound and Voulvoulis, 2005; Kaiser*, 2010*). Hence, before pharmaceutical medicines or products can be disposed, they are required by South African pharmacy law to be sorted based on their schedules, dosage forms, active ingredients, etc., into different categories; creams, ointments and powders, solid dosage forms, ampoules and liquids (contained in glass), aerosols, radioactive drugs, cytostatic and cytotoxic drugs by the South African Pharmacy Council (SAPC, 2010). This allows for appropriate disposal methods, as the fate of pharmaceutical chemicals in sewage sludge is also of concern (Daughton and Ruhoy 2013, Kolpin *et al.*, 2002a). The increased use of pharmaceuticals in both human and animals may have

effects beyond the immediate consumer expectations as they may enter the environment directly via the sewage system (flushing down the sink/toilet) or indirectly (garbage bin) via improper disposal practices (Daughton and Ternes, 1999; Daughton and Ruhoy, 2013). For example, only 3% of the parent form of carbamazepine an anti-epileptic drug is excreted unchanged in the urine and the rest is excreted through faeces as a hydroxylase (Calamari *et al.*, 2003). This means that the processes of absorption, metabolism, and excretion of pharmaceuticals are variable and the degree to which a compound is changed in the body depends on its structure, mechanism of action, dosage and physiology of the individual. For many agents, significant quantities of metabolites are excreted in urine and/or in faeces without alteration or in altered but biologically active forms (Buxton, I.L.O., 2017). In addition to the excretion of administered pharmaceutical agents into the sewage system, pharmaceuticals may also enter the environment in unaltered form as a result of environmentally inappropriate disposal such as disposal via the trash bin (Daughton and Ternes, 1999; Bound and Voulvoulis, 2005). Sewage treatment systems are not generally designed specifically to remove pharmaceuticals from the effluent before discharge into receiving waters (Daughton and Ternes, 1999). Disposal of unused medicines into domestic waste may also lead to landfill leachate and create environmental problems (Jonathan, Bound and Voulvoulis, 2005).

The excretion of pharmaceutical compounds either through urine, faeces, and shedding from the skin during bathing is inevitable; however, the situation is further complicated by the substantial use of pharmaceuticals in agriculture through animal urine and faeces including land spreading of animal slurry. When pharmaceuticals enter the environment, complex biological and physical processes may result in the degradation of compounds at variable rates, depending on environmental conditions (Fent *et al.*, 2006). In some cases, pharmaceutical metabolites may be reactivated by conventional sewage treatment processes before discharge into the environmental (Daughton and Ternes, 1999; Ruhoy & Daughton, 2008).

Improper disposal of pharmaceutical products is now of global concern for both developing countries (such as Nigeria, Kenya, Ghana, Ethiopia, and South Africa) and developed countries in Europe, and the United States of America as reported in various studies conducted between the years 2000 and 2019. In the last decade, many studies have paid particular attention to inappropriate disposal of unused/expired pharmaceuticals from wastage of economic resources,

environmental and aquatic effects (Kolpin *et al.*, 2002b; Beirens *et al.*, 2006; Franklin and Rodgers, 2008; Ruhoy & Daughton, 2008; Braund, Peake and Shieffelbien, 2009; Kümmerer, 2009; Auta and Dafwang, 2010; Cook *et al.*, 2012; Sasu, Kümmerer and Kranert, 2012; Ang'ienda S., 2017). Consequently, the effect often leads to problems such as health risks (medicine resistance, ineffective treatment), increased morbidity and mortality, an excess expenditure of financial resources and in generally decreased quality of care by patients, healthcare professionals and the health care system (Peake and Braund, 2009).

South Africa is a developing country with a population of 57, 73 million people according to the mid-year statistical release by (Statistics South Africa.). In 2018 the country had a high burden of chronic conditions such as tuberculosis, diabetes, and HIV, which is now described as a cloud epidemic dominating the health landscape (Barron and Padarath; Health System Trust Report, 2017). This high burden of the disease results in polypharmacy, which could propagate poor adherence, and in turn, result in the accumulation of unused medicines and the problem of their disposal (Makki *et al.*, 2019).

Currently, the threat of pollution by pharmaceuticals to the South African environment has been confirmed by studies conducted by (Abahussain, Ball and Matowe, 2006; Matongo *et al.*, 2015) and the needs and usage of both prescription and over the counter pharmaceutical products are increasing every year due to increasing complexity of diseases and drugs needed to treat those diseases. This has resulted in a higher proportion of the population taking medicines for longer periods of their lives (Glasziou *et al.*, 2013). With the increase in the use of medications in households, comes the accumulation of unused, unwanted, stockpiled or expired medication and the attendant problem of their disposal. The accumulation of medication at households and the unsafe disposal of unwanted medicines could lead to inappropriate medicine sharing, accidental childhood poisonings, and diversion of medicines for illicit use (Ayele and Mamu, 2018). The main aim of proper disposal practices is to improve public safety, mitigate the irrational use of medicines, and increase awareness of the effects of improper disposal on the environment (Thobeli, 2015). Much confusion currently exists about the proper way in which medicines should be disposed of as many countries do not have standard medicines disposal protocols (Tong, Peake and Braund, 2011), this is true of South Africa from a patient's perspective as guidelines exist for

corporate, manufacturing companies and pharmacies, but limited information is available and accessible to the general public (Mashiane, 2017).

The problems of accumulated unused pharmaceuticals and its disposal are not an exception to Western Cape Province particularly Cape Town, which is confronted by waste management challenges driven by rapid population growth. According to an article published by Western Cape Government in 2015, 93 out of 164 landfills in the Western Cape had closed, having reached the end of their natural lifespan. The City of Cape Town continues with the struggle to address the large inequalities of poor waste and sanitation services imposed by apartheid spatial planning policies. The City of Cape Town is a large urban tourist attraction area with a high population density, an intense movement of people, goods and services, extensive development and multiple business districts and industrial areas. An audit found that, in 2015, 61% of waste management facilities it studied required "major improvements" (the Western Cape government, 2015). This is a major concern and rationale for this study to explore the exact medicine disposal issues that exist in the city of Cape Town, particularly, southern suburbs area.

1.2. Statement of the problem

Currently, South Africa is challenged with a complex burden of diseases including HIV/AIDS, tuberculosis and cardiovascular diseases which require complex and life-long treatment regimens. The usage of both prescription and over the counter (OTC) medications continues to increase resulting in commensurate increases in the volume of expired, unused and unwanted medications. Understanding the disposal practices of households and the factors influencing/determining the disposal practices of these medicines are important in designing practical and effective strategies to reduce environmental pollution with pharmaceuticals.

1.3. The rationale of the Study

A study conducted at Tygerberg poison information centre, Department of Medicine, Cape Town, revealed that accidental exposure to medicines and scheduled substances are more common (estimated at 65.2%) than intentional poisoning (34.8%), with medicines (including paracetamol,

antihistamines and benzodiazepines) causing 35.2% of the cases of ingested poisons (Veale, Wium, Muller, 2013). Accidental ingestion of medicines affects all ages but mostly children under 12 years when pharmaceutical products are stored unsafely in an easily accessible area. Paracetamol is readily available for sale in various supermarket shelves in the country, meaning a consumer can buy as much as desired which leads to the accumulation of household medicine. Also, the sale practice takes place in the absence of a healthcare professional to supervise, monitor and provide information on potential toxicity.

There is minimal research in existence and scant data available concerning this topic and more importantly in Cape Town. Lack of compliance or failure to comply with guidelines on proper disposal of pharmaceuticals can have a devastating impact on the environment and consequently impact the economy of the nation through medicine wastage. The rationale behind this research work is to understand the social attitudes, and other factors influencing the disposal behaviour of Cape Town households. This is necessary for the design and implementation of possible prevention strategies concerning the improper disposal of unused pharmaceuticals.

1.4. Research Aim and Objectives

1.4. 1. Aim

"The purpose of this study was to understand factors influencing attitude, behaviour and knowledge of Cape Town households on disposal and practices of unused medicines".

1.4.1. Objectives

To achieve the principal goal highlighted above, the following objectives have been attended using a questionnaire-based survey:

1. Conduct an assessment of the unused medicines in households
2. Identify household's reasons for the accumulation of unused medicines
3. Determine household's method of unused medicine disposal

4. Identify factors influencing the disposal practice(s) used by households
5. Assess households' knowledge on proper disposal of unused medicines
6. Investigate pharmacists' role towards patient on proper disposal practice
7. Examine pharmacist opinions on current guidelines on disposal practices

1.5. Research Questions

The achievement of objectives outlined in section 1.4.2 enquires various interrogations:

1. Why are medications accumulated in households?
2. What methods are used for the disposal of unused/expired medicines?
3. What determines the method of disposal used by various households.
4. Are pharmacists aware of their role in proper disposal practices?
5. Are there guidelines or are patients informed of the disposal practices during their visits at the pharmacy?
6. What factors influence compliance with the return of medication to the pharmacy?

1.6. Scope of the study

A study on the disposal of unused medicines from households was recently conducted, where medicine disposal practices of residents of Johannesburg were evaluated (Mashiane M.M, 2017). This study identified the lack of awareness of proper disposal practices as well as the lack of disposal guidelines as factors influencing improper disposal practices. There are however not enough programs advocating for safe disposal practices in the country as a result, this aspect of pharmacy practice is lacking and requires further assessment.

An understanding of the general public on knowledge for proper disposal methods is fundamental in addressing improper disposal practices. Therefore, this study investigated disposal practices of unused medicines from households, and its geographical scope was restricted to the southern suburb area of Cape Town. The permission to collect data was granted by the Western Cape Health

Research Committee, Division of The National Health Research Database. Primary data were collected from patients attending Retreat Community Hospital, Private Hospital and pharmacies in the surrounding area of the southern suburb. Additional primary data was collected from the South African Pharmacy Council. The genre of unused medicines used comprised of over the counter and prescription medicines.

1.7. Delimitation

Due to the time and costs involved, data was only collected from Retreat CHC and southern suburb areas (Muizenberg, Kalk Bay, Stenberg, Tokai) and online. Therefore, these study results are limited to the southern suburb area and not the entire City of Cape Town.

1.8. Summary of the subsequent chapters

The current study comprises of four more chapters presented as follows:

Chapter two: This chapter captures the literature review on disposal of unused medicines / expired pharmaceuticals, the irrational use of medicines, their storage that leads to intentional or unintentional misuse or abuse as well as guidelines available and their challenges in other countries. The past investigation on disposal of unused medicines study was a general review and Johannesburg city-specific. The exact disposal issues and status for the City of Cape Town need to be understood to recommend a suitable approach to address the disposal needs in this study.

Chapter three: This chapter presents the investigational approaches, analytical procedures and the sampling methods used in this research. Pretested semi-structured close-ended questionnaires were used to collect data from participants as they are deemed easier to analyze and interpret than open-ended questions (Petersen, 2000). The questionnaire consisted of content questions used to measure the rationale of individual action on disposal practices from households and pharmacist's perspectives.

Chapter four: This chapter presents the results of the study. It gives a description and discussion of the data collected from participant's questionnaires that elucidated information on their demographics, disposal methods, knowledge of proper disposal, opinions on current disposal law,

perceived need to raise awareness. It also outlines the possible factors that could influence on the decision to adopt proper disposal practice for both patient and pharmacists perceptive.

Chapter five: this chapter presents discussion, conclusion, and recommendation about the study objectives from households and pharmacists perceptive.

CHAPTER TWO

2 LITERATURE REVIEW

2.1 Introduction

This chapter presents a review of the literature relevant to the research problem. The literature review is presented along with the following themes: Global perspective and practices for disposal of unused medicines, factors influencing behavioural attitude towards disposal practice, developing countries and the South African perspective on the disposal of unused medicines. Further, this chapter also discusses the theoretical framework for the study.

2.2. Global perspective

The improper disposal of pharmaceutical products is now of global concern for both developing and developed countries and these problems are well pronounced, yet there are still not enough guidelines or programs in place to address the problem. Consequently, the effect often leads to problems such as health risks, medicine resistance, ineffective treatment, patient non-compliance, increased morbidity and mortality, an excess expenditure of financial resources and in general a decreased quality of care for patients, healthcare professionals and the health care system (Daughton, 2003; Braund, Peake and Shieffelbien, 2009).

For decades, developed countries such as the United Kingdom and the United States of America's poison control centres approved disposing of unused or expired pharmaceuticals by flushing or rinsing down the drain as being suitable for a particular purpose; to prevent accidental or premeditated poisoning (Ortner, Mucullagh, 2010). For decades, the regulatory body thought that disposing of drugs immediately via the drain was the safest possible way. The consumers followed the disposal instructions because it was such a simple and convenient mode of disposal of unused pharmaceuticals. However, detection of measurable amounts of pharmaceutical substances in

water raised alarm about the consequences of pollution from pharmaceuticals on the environment and its potential effects on human health (Kotchen *et al.*, 2009; Kumar and Xagoraraki, 2010; Fatta-Kassinos, Meric and Nikolaou, 2011; WHO 2011; Blair *et al.*, 2013). The presence of trace quantities of pharmaceuticals and personal care products as environmental pollutants first gained attention in the 1980s when developments in analytical techniques allowed scientists to detect, quantify, and document trace amounts of pharmaceutical substances in wastewaters, sediments, groundwater, surface water, and even drinking water (Daughton, 2003; Bound and Voulvoulis, 2005; Kumar and Xagoraraki, 2010; Rodriguez-Moza and Weinberg, 2010b; Fatta-Kassinos, Meric and Nikolaou, 2011; de Cazes *et al.*, 2014).

Pharmaceuticals are unique among environmental pollutants in that they are designed to be bioactive. Numerous studies of water samples have detected antibiotics, anticonvulsants, analgesics, mood stabilizers, hormones, and chemotherapy agents (Bound and Voulvoulis, 2005; Corcoran, Winter, and Tyler, 2010; Ortner P, 2010; Uslu *et al.*, 2013). These substances have been linked with disruptions to aquatic life, such as genital abnormalities in fish, foot detachment in frogs, and, in some cases, the collapse of entire fish populations (De Cazes *et al.*, 2014; Kidd *et al.*, 2014). In 2011, the WHO formed a working group composed of experts in the fields of pharmacology, toxicology, water chemistry, water quality and health, water treatment, and water regulation and policy, who conducted an exhaustive detailed review of the existing literature and further reviewed scientific evidence, to report that trace concentrations of pharmaceutical substances in drinking water are low enough that they are unlikely to present risks to human health. At the same time, the same experts acknowledged the gap that limited understanding exists of the potential health risks associated with long-term exposure to low levels of pharmaceutical substances in drinking water or of the combined effects of mixtures of pharmaceutical compounds. Other experts raised the question of the potential effects of pharmaceutical exposure on sensitive populations such as pregnant women, children, the elderly, and individuals with compromised immune systems (Kumar and Xagoraraki, 2010).

The discovery of Antibiotic Resistance Genes (ARGs) in treated wastewater also raises the issue whether resistance might transfer to microbes capable of affecting human health as some metabolites tend to resist biodegradation (Segura *et al.*, 2009; Sahoo *et al.*, 2010; Fatta-Kassinos

et al., 2011; Marti, Jofre and Balcazar, 2013). With the increasing awareness of the effects of the improper disposal of pharmaceuticals on the environment, the WHO (2011) embraced strategies to minimize pharmaceutical contamination of water. These strategies include; guidelines and regulations, consumer education through public awareness campaigns, and drug take-back programs.

The White House Office of the National Drug Control Policy (ONDCP) published the first federal guidelines for proper disposal of medicines for consumers and health professionals in 2008. However, the set-out guidelines presented a barrier for the effective transition for the return of consumer drugs for proper disposal. This led to the enactment of the Secure and Responsible Drug Disposal Act of 2010 and the Safe Drug Disposal Act of 2010, thereby paving the way for drug take-back programs that allow for the return of controlled and uncontrolled substances. The policy was developed after, the Drug Enforcement Agency (DEA) in 2009, solicited public opinion on the issue of disposing of controlled substances dispensed to individual patients (Fass, 2011).

2.3. Practices in place for medication disposal (Policy and Practice)

Several countries, including Australia, France, Sweden, Portugal, Spain, the United Kingdom, and New Zealand, have for some time had formal programs to collect unused drugs (Ruhoy and Daughton, 2008). The acceptable practices for reverse logistics for unused pharmaceutical products are:

- Take-back program
- Drop-off program
- Mail or ship back program

According to the report by Health Canada (2009) and Tong *et al*, (2011), the WHO and European Union directives for environment and health require a member of states to have suitable collection systems in place for the return of unused medicines from individual consumers. As a result, formal guidelines were adopted to mitigate improper disposal by other developed countries. These programs include; Disposal of Unwanted Medication Properly (DUMP) campaign in New Zealand (Braund, Peake and Shieffelbien, 2009); ENVIRx disposal program in Canada (Segura *et al.*, 2009); and Return Unwanted Medicines Project in Australia, and a single government-owned

program called Apoteket B in Sweden. Apoteket B functions as an environmentally friendly program that is directed towards public awareness campaigns to teach and enlighten the general public about recycling and the adverse effects of flushing medications down the drain or dumping them into the trash (Persson, Sabelström and Gunnarsson, 2009). This focus on public awareness yielded over 70% of consumers returning unused pharmaceutical products to the pharmacy. The Spain Integrated Waste Management System also carries out intensive campaigns to raise public awareness, successfully producing large volumes of returned medications according to departmental performance report for 2009. (Fidora, 2017, Gagnon, E. 2009).

In contrast, some nations do not have official state guidelines or programs in place for the disposal of unused pharmaceuticals, while other nations have guidelines and programs in place, which are ineffective (Tong, Peake and Braund, 2011; Fayaz *et al.*, 2014). In Poland, environmental awareness is low, and consumers have few places to return unused pharmaceutical products, resulting in improper medication disposal (Rogowska *et al.*, 2019), while in the United States, pharmacy take-back programs are abundant, but ineffective due to complex laws on substance control.

A literature gap exists, as there are limited studies revealing relationships between consumers' knowledge, attitudes, and behaviours towards proper disposal practices. In the United States, the drug take-back program efficacy has not been completely evaluated, with only a few studies conducted in rural areas (Fidora, 2017).

Recognizing that discrepancies exist in disposal practices, raises vital questions about the perceptions and attitudes that different population groups may have towards what they assume to be appropriate and sensible disposal practices. This is demonstrated in research that shows that people from diverse backgrounds may experience similar levels of difficulty in varying ways (Fidora, 2017).

2.4. Factors influencing the accumulation of unused medicines in households

In the 1990s, there was a proliferation of studies documenting the presence of pharmaceuticals in the global community, environment and their effects on aquatic life; which suggested that the overall status of unused medication management was not satisfactory worldwide and the lack of established programs may have largely contributed to the poor standards in developing countries. Medication and scheduled substances may not be consumed (i.e. all dose units in a container are taken) - for many reasons including; an improvement in the medical condition of the patient, unclear instructions on medical labels, difficulty in adhering to instructions, the death of a patient, discontinuation by patients or a doctor due to side effects or lack of therapeutic effect, excess quantity supplied (Angi'enda S., 2017). These, therefore, remain in the patient's cupboard until it may eventually expire.

The pharmacy is one of the first access points used by most consumers to seek medical attention before authoritative validation and this plays a major role in reasons why pharmaceutical products accumulate in a household. Products purchased may be for example; for seasonal use and can inevitably expire before the next season. Besides, it may also be for recognized symptoms, which the body has developed antibodies against, meaning that they might not reoccur or occur with different effects needing a different treatment. The major causes for the generation of expired, leftover and unused products range from inefficiencies and certain practices by manufacturers, distributors, prescribers, dispensers and patients inclusively (Ruhoy & Daughton, 2008).

Patients are allowed by law to self-medicate, with a limit range of medications, to treat self-recognized symptoms. This practice opens an opportunity for medicines to accumulate as many diseases have similar symptoms and could lead to an improper diagnosis, hence incorrect treatment or the possibility of using out-of-date medicines from past ailments to treat new, undiagnosed symptoms. It also results in having a large number of medicines in the house which can contribute to confusion on the appropriate dosage, what medication to take, how and when to use them. Also, of concern is the purchase of more than the required amount of over the counter medication in certain pack sizes, this ultimately leads to left over medication and accumulation of unused medicine (Almanie and Holdford, 2015). Polypharmacy is another common practice in which

patients self-treat combining modern pharmaceuticals products with herbal medicines. These often result in a clash in achieving good therapeutic objectives and leads to the accumulation of pharmaceutical products in households (Braund, Peake and Shieffelbien, 2009; Valenza, P.L. *et al.*, 2017).

2.5. Factors influencing the disposal decisions of accumulated medicines

In the early to mid-2000s, a few studies emerged in the United States and other countries examining consumers' medication disposal knowledge and attitudes. At the time, the outpatient pharmacy at Madigan Army Medical Center at Fort Lewis in Washington State had a policy that allowed patients to return unused or expired medication, which would be disposed of as medical waste (Seehusen and Edwards, 2006). Controlled substances were excluded from the program. Information about the policy was clearly stated on the instruction sheets that patients received when they received medication, specifying that this was the preferred mode of medication disposal. However, the issue remains that patients routinely do not read the label or simply ignore instructions (Bound and Voulvoulis, 2005). Besides, patients also had the option to return unused or expired drugs to a provider.

In another study aimed at gaining insight into hospital patient practices for disposing of medication and their beliefs about medication disposal techniques, most participants reported taking no more than five medications or having more than five medications at home (Seehusen and Edwards, 2006). Less than 20% of participants had received any guidance from a health professional about the proper disposal of medication. Given the time of the study and lack of professional advice, it is unsurprising that more than half the participants kept unused or expired drugs at home, and a similar proportion flushed drugs down the toilet. Slightly more than one-third rinsed drugs down the drain, with only 14% returning unused drugs to a health care provider, and 23% returned drugs to a pharmacy which suggests slight awareness amongst people, although the percentage rate can be accepted as poor considering the effects of improper disposal. A marked contrast was reported between participants' beliefs about drug disposal and their behaviour (Seehusen and Edwards, 2006). This could be since most of the studies conducted, focused on health professionals and not

on patients who are generally the most users and defaulters of proper disposal of unused pharmaceuticals (Fidora, 2017).

In the United Kingdom, Bound and Voulvoulis (2005) examined household practices in the disposal of unused and expired medication in a general population survey of 400 respondents in southeastern England. Virtually all respondents had some medication at home, with most households (60.2%) keeping a combination of prescription and OTC drugs at home. Most respondents reported using all the painkillers they purchased or were prescribed (80%). However, the figure for antibiotics was striking, as only 16% of respondents consumed all the antibiotics they had acquired.

Patterns between frequent pharmacy visits, dispensing more prescribed drugs, and returning unused drugs, suggested patients were advised on medicine disposal when they returned for new medications (Seehusen and Edwards, 2006). Seehusen and Edwards (2006) strongly advocated patient education and proposed that health professionals and pharmacy staff should discuss medicine disposal with patients and that patients could be provided written information when receiving medications or medication labels or pill bottles could display information about disposal. Seehusen and Edwards (2006) asserted that persuading patients to believe it is desirable to return medicines to a health professional or pharmacy is a prerequisite for getting them to carry out the behaviour. However, their findings revealed a gap between beliefs and behaviours. Even pharmacists (Abahussain, Waheedi, and Koshy, 2012) and nurses (Ortner P, 2010) do not always act in accordance with their knowledge of proper medicine disposal. The decision of behaviour change relies on need recognition that education is paramount, but not enough to change behavioural attitude (Fidora, 2017).

A study comparison by Bound and Voulvoulis (2005) for the United States and Great Britain showed a striking revelation. The United States had a negligible 1.4% of the respondents that returned unused pharmaceuticals to the pharmacy versus 21.8% of the Britain respondents. Only 2% of the respondents used all their medications in the United States. The researchers guessed that this result might have echoed the difference in the regulatory guidelines between the two countries. U.S. residents were instructed to dispose of unused meds down the drain, and at the time of the

survey, few available locations existed for returning unused medicines (Fidora, 2017). The presence of leftover prescription drugs beyond antibiotics suggested that many respondents were not adhering to their medication as prescribed. The researchers concluded, since 1.4% returned unused meds and 2 % used it all, then a substantial amount of pharmaceuticals were finding their way into the environment.

Replacing the act of flushing medications down the drain with that of returning them to the pharmacy reflects recognition of the harmful effects of pharmaceuticals in the natural environment and their potentially harmful effects on human life, but the emphasis on awareness campaigns is on the hazards of keeping unused medications in the home. That may be advantageous to changing behaviour in that it emphasizes the more immediate threat (poisoning) over the more distant threat (pollution). At the same time, environmental protection is a powerful motivator for many participants at take-back events (Gray and Hagemeier, 2012). For health care facilities that have large quantities of unused pharmaceuticals, protecting the environment is a major issue**.**

2.6. Developing Countries perspective

Most developing nations, especially in Africa, undoubtedly are recipients of pharmaceutical donations (Van Dijk *et al*., 2011, Khare AK., 1998). Some of these medicines may not match the demographic disease patterns in the recipient countries and end up increasing medicines accumulation which ultimately finds their way to numerous households (Van Dijk et al., 2011, Khare AK., 1998). Several developing Nations have no clear policy and guidelines regarding the safe disposal of unused medicines. Again, inappropriate waste management due to lack of resources also take the major blame for the set-back (Fayaz *et al.*, 2014).

Most households in Africa commonly dispose of their unused medications either by throwing them into the sink/toilet or the garbage bin and ignorance with lack of established unused medicines protocols and standard sanitation guidelines are a huge challenge in most developing nations (WHO, 2018).

2.6.1. Nigeria

A study conducted by (Auta and Dafwang, 2010) in Jos city, Nigeria showed that 94.1% of households had unused medicines. Two thousand nine hundred and four unused medicine items were found in households representing a mean of 6.8 items per household. A total of 41.7% and 58.3% of the unused medicines were obtained on prescription and self-medication, respectively. The community pharmacies (52.1%) and patent medicine vendors (33.3%) were the common sources of these medicines. About 0.7% of the medicines found in households were expired and 15.6% were unlabeled. The common types of medicines kept in households were analgesics (18.6%), antibiotics (16.8%), and nutrition/blood preparations (14.9%). All respondents of households reported that they dispose of their medicines in the dustbin/trash can. Basic education on the appropriate disposal of medicines is lacking in Nigeria. Unused/expired medications are not returned to pharmacies for appropriate disposal as obtainable in developed countries (Auta and Dafwang, 2010). The accumulations of pharmaceuticals in the soil, groundwater, and drinking water have been reported, and these compounds are likely accumulating in the environment since they are mostly disposed of in refuse dumps.

2.6.2. Kenya

A study conducted by (Sarah A Angi'enda and Bukachi, 2016) in Nairobi County in Kenya which focused on households' perceptions and practices of disposal patterns of unused medicines in Nairobi City found that household's knowledge on disposal practices of unused medicines is relatively weak, and attributed this to a lack of public outreach and awareness campaigns, laxity on the side of medical and healthcare professionals to provide disposal guidance at hospitals and pharmacies, unclear disposal instructions on medicines packages and negligence to read the disposal instructions. The study also reported about 31.77% of respondents "strongly agreed" regarding the extent to which they believe that unused medicines present potential risks and or negative consequences at home. Further 32.32% of the respondents also "strongly agreed" that children are more at danger with unused medicines while 89.02% of the respondents also "strongly agreed" that lack of adequate information on safe disposal practices is a precursor to the risks and negative consequences of unused medicines. None of the respondents "strongly agreed" that there is adequate advice by doctors and healthcare professionals on safe disposal practices with only 29.88% strongly agreeing that mandatory take-back programs as a disposal practice can help in

addressing the potential risks and dangers associated with keeping unused medicines at home. On the contrary, there were respondents (21.34%) who "strongly disagreed" that unused medicines present potential risks at home with a further 19.51% and 31.10% "strongly disagreeing that children are more vulnerable to the risks of unused medicines and mandatory take-back programs as a disposal practice should be initiated" respectively.

2.6.3. Ghana

Ghana is one of the African countries located in the Western region where the safe disposal of unused medicines awareness exists amongst the general public and the government. Ghanaian initiatives include the Rational Use of Medicines (RUM) program by healthcare providers, a take-back program that sensitizes the public to take back unused medicines to the hospitals and pharmacies through the Disposal of Unused Medicines Program (DUMP) (Angi'enda and Bukachi, 2016). Currently, there are two quasi-governmental hospitals and their subsidiary clinics with a comprehensive drug return programs and pharmaceutical waste separation program. However, according to the study conducted in 2012, the disposal program is not popularly known as about 80% of the participants were not aware or never heard about drug return program in the country (Sasu, Kümmerer and Kranert, 2012).

2.6.4. Ethiopia

Ethiopia, a country in the north-eastern part of Africa, also experiences problems with the accumulation of pharmaceutical waste management like other African developing countries (Ayele and Mamu, 2018). This is because either there are not enough disposal programs advocating for the safe disposal of unused medicines or that public awareness is still limited. The lack of clear directives and guidelines before 2011 in many of the public and private health facilities also compounds the situation (Ayele and Mamu, 2018).

In response to this challenge and to address it, Medicines Waste Management and Disposal directives were established in 2011 by the Food, Medicines and Healthcare Administration and Control Authority (FMHACA). The success of the policy was achieved with the effective implementation from Strengthening Pharmaceuticals Systems (SPS) and Systems for Improved Access to Pharmaceuticals and Services (SIAPS) funded by the US Agency for International

Development (USAID) (Ejigu and Tadeg, 2012). The provided policy noticeably defined how a safe disposal system should function and be utilized in Ethiopia.

According to the study conducted by Ayele and Mamu in 2018, the researchers reported the existence of available disposal and drug take-back programs and a majority of the survey respondents (72.9%) knew about medication waste. However, a large portion of the respondents (66.9%) did not know about the drug-take-back system. This revelation was after seven years the policy and guidelines were established could imply two factors; the disposal facility that meets the required standards are not enough or maybe limited, or the provided disposal guidelines are not enough to initiate behavioural change for proper disposal practice. More attention needs to be drawn towards creating awareness for the general public and it is important to note that the efforts in place involved the pharmaceutical sectors.

2.6.5. South African perspective

South Africa, like many other developing nations with a myriad of medical health-related issues, also suffers from this problem. Some recognized factors including malnutrition, poor lifestyle choices, socio-economic and cultural factors and the high prevalence of self-medication and polypharmacy are contributors to the accumulation of unused pharmaceuticals in households and the attendant improper disposal. In a pilot study conducted by Amod *et al* (2008) on a random sample of 200 adults, 17% disposed of unused meds via the toilet while 6.5% used the sink, all of which increases the accumulation of pharmaceutical compounds in the wastewater system, 62.5% disposed of in the garbage bins, which increases potential risks of accidental exposure and ingestion by children, pets, wildlife, and scavengers which play a significant role to the high percentage toll of medicinal poisoning (Kolpin *et al.*, 2002b; Glassmeyer *et al.*, 2009).

The South African healthcare system is divided into two sectors: the public and the private sector. Only 16% of country's patient population obtain their medical treatment through the private health sector in which money is paid for all the services rendered, while the remaining 84% of the population access healthcare services through government-run clinics and hospitals at either a minimal cost based on their income or at no cost at all (Whittaker *et al.*, 2011). Furthermore, no

cost billed for medications prescribed and dispensed in the public health pharmacy, possibly encourages poor compliance to treatment regimens, frequent visiting's resulting in an unnecessary/overprescribing by health professionals (Ekedahl, 2006; Lindberg *et al.*, 2008). Discarding medicinal products with their original labels intact promotes medicine abuse as well as medicine and personal profile information theft. It is an important issue and a further concern that affects the elderly as they might have difficulty with the removal of labels and patients with chronic diseases, who mostly are the biggest consumers of prescribed medicines to support degenerating health due to age and progression of disease state (Glassmeyer *et al.*, 2009).

The South African Bill of Rights of the Constitution, clause 24 states "everyone has the right to an environment that is not harmful to their health and wellbeing". Therefore, approval and sanctioning of disposal of Pharmaceutical Waste in South Africa are governed by this legislation; The South African Constitution (Act 108 of 1996), The Pharmacy Act 53 of 1974 as amended, Medicines & Related Substances Act 101of 1965 as amended, Good Pharmacy Practice 2012, National Environmental Management Act 107 of 1998 (NEMA) and National Environmental Management: Waste Act 59 of 2008. All these regulations and Acts of parliament give directive on safe disposal of unused medicines in South Africa. The purposes of the promulgated laws are to ensure that medicines and scheduled substances are not disposed into the sewerage system, rather through the pharmacy in a manner that is safe and cannot allow any retrieval of substances to minimize the risk of causing harm either to the environment or human health/ animals (SAHPRA, 2003). However, the effectiveness of these laws is questionable with regards to patient's perspectives who are the biggest culprits to improper disposal practices.

The proper disposal of pharmaceutical waste can only be through the pharmacy for an individual consumer, except for few selections of highly abused narcotic medications like morphine, and a fentanyl patch, which is proposed to flush down the toilet immediately after use to minimize abuse, intentional misuse and accidental consumption as stipulated in the guide by WHO 2011. This concept has encouraged and led the majority of patients to dispose of medicines in the manner at which they do today. Hence, the common and most convenient way to dispose of expired or unused mediation is by flushing down the toilet or sink and dumping into the garbage bin (Ruhoy & Daughton, 2008)

Private community pharmacies are mostly transactional oriented which often puts pharmacists in an invidious position where "cost" is placed before moral, ethical and professional considerations (Bothma & Clack, 2009). Prescriptions and repeat scripts are filled without assessing the amount at hand, sale of large pack sizes and quick advice offered to patients at complaints of medication side effects which are also of serious concern. Published research suggests that medication wastages may not only be an effect of excessive and unnecessary dispensing of prescription medications to patients without restrictions in community pharmacies, but unnecessary prescribing by doctors is also of a major concern that compounds the problem as it also leads to increase in the quantity of leftover pharmaceutical medicines and scheduled substances by the patient (Ekedahl, 2006).

The study conducted by Ruhoy and Daughton (2008), suggests that a physician might agree with a patient to prescribe medication for a longer period to reduce the frequency of visit by a patient. This practice increases the possibility of unused pharmaceuticals as the physician might neglect professional responsibility towards a patient to review general health and previous prescription before issuing another. The medical file of the patient might be misfiled leading to incorrect records about a patient, especially for offices without a proper or full computer recording system in place.

According to the guidelines provided by the South African Pharmacy Council (SAPC) in the Good Professional Practice (GPP) for pharmacist and pharmacies, before pharmaceutical medicines or its products, can be disposed of, they are required by law to be sorted by a pharmacist based on their schedules, forms, dosage, active ingredients, etc. into six different categories; creams, ointments and powders, Solid dosage form, ampoules and liquids (contained in glass), aerosols, radioactive drugs, cytostatic and cytotoxic drugs. This will allow for appropriate methods required for the disposal as the fate of pharmaceutical chemicals in sewage sludge is also of concern even though it aims to minimize accidental ingestions and minimize recovery (Kolpin *et al.*, 2002b; Barnes *et al.*, 2004). Currently, there are guidelines on disposal practices available only for Corporate, Governmental and Pharmaceuticals Manufacturers with vivid, limited information and guidelines for the general public.

2.7. Summary of chapter two

Globally in developed countries, various studies exist which capture the impact of improper disposal of unused pharmaceuticals and since have established programs that encourage proper disposal practice among its citizens. In contrast to developing African countries like South Africa, these problems are still at large as that knowledge gap exists with regards to the extent of the un-attendant problem of improper disposal, which poses to be financially substantial for households and detrimental for the community and the environment at large.

Lack of research towards knowledge, attitudes, and behaviour of the general public toward proper disposal of practices of unused pharmaceuticals begs for the need for better management of pharmaceutical waste from households in Cape Town, and South Africa as a country.
However, the literature reviewed in this chapter showed these gaps:

- Proper disposal practices of unused medicines exist in some developing countries, but the lack of awareness programs amongst the public limits the effectiveness of the program.
- The role to create awareness requires pharmacists to be at the forefront as custodians of medicines, while the unanimous effort is needed from the government and pharmaceutical manufactural industries to effect disposal practices for any country.
- The disposal of unused pharmaceuticals may be associated with a slight cost that limits their application for both individuals and corporate bodies.

Although these identified gaps are centred on household awareness programs, the behavioural factors linked to unused medications and its accumulation problems need to be overcome to expect success in improper disposal practices. For instance, in 2007, a study conducted in the United Kingdom by Mackridge and Marriott recommended the reuse of returned medications by patients as many might still be in a suitable condition. This was considered after checking the significance of financial and environmental costs incurred by the disposal of expired and unused products.

Nevertheless, the alarming presence of pharmaceuticals being detected in the South African environment and tap water as confirmed with studies conducted by (Amod *et al.*, 2008), headlines on Sunday Times newspapers in 2015, and the state of water crises and drought condition. The

need for proper disposal goes beyond the cost and reuse of medicines recommendations. Therefore, the ultimate objective of this study is to create awareness for proper disposal programs to curb the effects of improper disposal practices in various households in Cape Town.

CHAPTER THREE

3 METHODOLOGY

3.1 Introduction

This chapter describes the methods used to investigate the disposal practice of unused medicines or pharmaceuticals from households in Cape Town, the role of pharmacists in advocating for a proper disposal approach, and to examine the opinion of the pharmacist on the current law for disposal. The synopsis includes; research design, population size, sampling, method of data collection, data analysis, study limitations and the ethical consideration associated with this research.

3.2 Research design

The research design is a descriptive, cross-sectional design that involved qualitative data collection approach, that is aimed to determine the disposal practices of unused pharmaceuticals among the general public and pharmacist in the southern suburb area of Cape Town. The study design also looked at factors influencing attitude, behaviour, knowledge and the role of pharmacists towards disposal and practice of unused medicines.

3.3 Study site description

This survey was conducted in the City of Cape Town. The City is a metropolitan municipality with a population of 4004,793 million people and has a high literacy rate of 90.5% (City of Cape Town report, 2016). Cape Town is sub-divided into a mostly Afrikaans speaking northern suburbs, mainly English-speaking southern suburbs and the Cape flats area to the South-East comprising

mostly non-white residents who are low-income earners. The City is one of the most multicultural cities with ethnicity and racial composition of 42.4% coloured, 38.6% Black African, 15.7% white, 1, 4% Asian and 1.9% others (Statistics South Africa Census, 2011).

The southern suburb area was chosen as an area of interest because, it has a true representation of South Africa in terms of race, income, and language. The Retreat CHC is the only facility in the southern suburbs with 24-hour emergency service and caters for all aspect of care, including a baby, Human Immunodeficiency Virus (HIV) and Tuberculosis (TB) clinic. The patient catchment area for this hospital includes the surrounding southern suburbs of Retreat, Steenberg, Tokai, Lavender Hills, Muizenberg, and Kalk Bay. The South African Pharmacy Council (SAPC) was contacted for access to the register of both community and hospital pharmacists who are registered and are working in Cape Town.

3.4 Participants selection / sampling

The study participants were randomly recruited using a convenience sampling approach, from households in the southern suburb area, Retreat Community Health Centre and pharmacists registered with the South African Pharmacy Council in Western Cape.

The participants who were waiting in the outpatient waiting area of Retreat Community Health Center or the waiting area of community pharmacies in the area were approached with the information leaflet and consent form (appendix 3&4), and participants who met the inclusion criteria and were willing to participate in the study were given the self-administered survey questionnaire (appendix 5).

The pharmacists who are registered in the public/private hospital and community pharmacy sector as indicated in the SAPC register were contacted electronically with the online semi-structured questionnaire (appendix 3, 4 & 6). Pharmacists working within the southern suburbs area (Claremont, Retreat, Muizenberg, Wynberg, Plumstead) were approached with a hardcopy version of the same questionnaire.

3.5 Inclusion criteria

Participants in this study had to be; a resident of Cape Town, aged 18 years or older, and had to be a previous or current user of prescription or over-the-counter medication to receive the households' participant survey pool to receive the household questionnaire**.** Pharmacists who were registered with the South African Pharmacy Council and working at either a hospital or community pharmacy were recruited for the pharmacist participant survey pool to receive the pharmacist questionnaire.

3.6 Exclusion criteria

Individuals who were aged below 18 years or were not resident in Cape Town or had never used medication were excluded from the households' participant survey pool, while pharmacists who were not registered with the South African Pharmacy Council or were not currently working in a hospital or community pharmacy in Cape Town were excluded from the pharmacist participant survey pool.

3.7 Sample size

The Raosoft® online software calculator was used to compute the sample size using a 95% confidence interval, a 7% margin of error and assuming a 50% response rate. The calculated minimum sample size for households' survey was 184 based on a population of 2875, and 185 for the pharmacist survey based on a population of 3153 registered pharmacists in either private/public community or hospital pharmacy sector in the Western Cape.

3.8 Data collection procedures

3.8.1 Qualitative research-structured questionnaire for households

A pre-tested, self-administered, semi-structured questionnaire was used to collect data from selected participants. The study questions were adopted from (Mashiane, 2017), and slightly modified to suit the study objectives and answer research questions. The questionnaire contained

19 questions that comprised mostly of multiple-choice closed-ended questions and few open-ended questions framed from a combination of literature models on the disposal of unused pharmaceuticals globally. The questionnaire was used to collect information on; demography (age, residence area, educational level), types of medications used, reasons for the presence of unused medicines in the household, and methods used to dispose of unused medicines from the respondents. The questionnaire also elicited information on the knowledge of proper disposal methods and the willingness to adhere to programs for proper disposal of medicines, and factors that could influence their actions towards proper disposal practices.

A semi-structured questionnaire (appendix 5) was administered to 200 patients in the waiting area at Retreat Community hospitals by the researcher. The questionnaire was written in English and transcribed to Afrikaans as the community is mainly Afrikaans speaking population. Steps that were taken in the waiting area where household participants were waiting to be seen by a doctor:

- Self-introduction with a brief explanation of what the study was about
- Copies of the participant leaflet and consent letter were handed out
- Allowed participants time to go through the leaflet and consent form
- Explained the information contained in the consent form and why it should be signed if the participant agrees to be part of the survey
- Allowed time for questions; which were answered by the researcher
- Distributed questionnaires only to those who were willing to participate in the study
- Allowed time for clarity on any question that was not clear on the questionnaire
- Once the questionnaires were completed, it was collected from the participants by the researcher

Participants who were unable to or had difficulty with reading and writing were assisted by the researcher's assistant who spoke both English and Afrikaans.

3.8.2 Qualitative research structured questionnaire for Pharmacists

A pre-tested, self-administered, open-ended- semi-structured questionnaire was emailed online to pharmacists in hospital and community pharmacy registered in Western Cape, and hardcopy questionnaires were handed to both hospital and community pharmacists working within the

southern suburb areas. The questionnaire was accompanied by a participant information leaflet and consent form (appendix 3&4) and was designed to access knowledge on the disposal practices of unused pharmaceuticals and the role of the pharmacist with regards to information on the disposal of medicines provided to patients during a consultation or dispensing.

An open-ended- semi-structured questionnaire, same as in 3.7.2 (appendix 6), was used to interview persons responsible for medicines and their disposal at Retreat Community Hospital facility, but additional questions on the actual disposal procedure and records were asked. The interview was conducted in a relaxed and convenient atmosphere at the facility office to reduce context bias. The objective of this method was to expose more detailed issues concerning improper disposal and management of unused medicines from households and not to collect general notions. To achieve this, my focus was on specific questions and topics such as the actual disposal process used by the pharmacy, if unused medications are accepted from households and any incidence about unused medicines recorded by the pharmacy."

3.9 Data analysis

All data collected from the participants were manually sorted, to ensure all records had enough, accurate information and was verified, coded and entered into Microsoft excel sheet. Statistical Package for the Social Sciences (SPSS) version 24 was used to analyze the data. Descriptive statistics (means, frequencies, percentages) were used to aggregate data and Chi-square, analysis of variance and correlation was used to test for significant associations between education level, area of residency, suburb, and having unused medicine at home for households. A correlation test was also checked for an association between guidelines received by a pharmacist, disposal programs offered at pharmacies, pharmacist's opinion of the current law and advising patients during their visits to the pharmacy.

3.10 Data reduction strategies

Questionnaires with over 80% of the questions answered were included in data analysis, while questionnaires with less than 80% of the questions answered were excluded from the analyzed data.

3.11 Ethical Considerations

Ethical approval for this study was obtained from the Humanities and Social Science Research Ethics Committee of the University of the Western Cape "HS17/8/8" (appendix 1). Permission for Data Collection from Retreat Community Health Centre was sought and granted by Health Impact assessment – Health research sub-directorate of Western Cape "WC_201804_026" (appendix 2). The participation in this study was voluntarily as no incentives were offered. Eligible participants were provided with a Participant Information leaflet describing the research aims and objectives, before giving informed consent. The researcher maintained confidentiality, by ensuring the survey was completed anonymously throughout the duration of the study, for the semi-structured interviews were removed from the data before data analysis. This study was carried out according to the Declaration of Helsinki.

CHAPTER FOUR

4 RESULTS AND FINDINGS

4.1 Introduction

This chapter presents the results and findings of both semi-structured survey questionnaires in two sections. Section **4.2** presents the findings of the household survey while section **4.3** presents the findings of the pharmacist survey.

4.2 Household survey questionnaire

4.2.1 Response Rate

A total of 200 household questionnaires were distributed to study participants, and 162 of these questionnaires completed with over 80% accuracy were included in the study data, giving an 81% response rate. This response rate according to Lyons and Doueck (2010), is enough to ensure the validity and reliability of the study findings.

4.2.2 Demographic characteristics of household participants

The majority of the respondents (32.1%) were aged 56 years old and above, 30.9% were aged 41 – 55 years, 28.4% were aged 26 – 40 years and 8.6% were aged 18 -25 years old. Concerning residence, 65.4% of the respondents surveyed lived in a suburban area (Retreat, Lavender Hills, Steenberg), 19.8% lived in an urban area (St James, Kalk Bay, Muizenberg), while 14.8% lived in a location / Township (Vrygrond). Most of the respondents (43.8%) had up to a grade 8 education, 34.6% had a Matric certificate, while the smallest percentage (6.8%) had a postgraduate qualification (table).

Table 1: Demographic characteristics of respondents (n=162)

Variables	Frequency	Percentage (%)
Age		
18-28	14	8.6
26-40	46	28.4
41-55	50	30.9
≥56	52	32.1
Educational level		
Up to grade 8	71	43.8
Matric	56	34.6
Tertiary (University, Colleges, Technicon)	24	14.8
Postgraduate (Masters, PhD)	11	6.8
Area of Residence		
Retreat	77	47.5
Lavender Hill	16	9.9
Steenberg	2	1.2
Other (Muizenberg, Vryground, Kalk Bay)	66	40.7
Area of description		
Urban	32	19.8
Suburban	106	65.4
Location /Township	24	14.8

4.2.3 Evaluation of unused medicines in households

Of the 162 respondents, only 12 respondents did not have unused medicines at home while over 90% of the respondents reported having unused medicines at home. Unused medicines included both prescribed and over the counter items, with painkillers (64.2%) the most common item and contraceptives (3%) the least common unused medications in households (figure 2). The mean number of medications per household was 2.6. Community/government hospitals (54%) was the most common source of unused medicines, while private hospitals (1%) were the least common source of unused medicines. The pharmacy (26%) and doctor (19%) were also reported as sources of unused medicines.

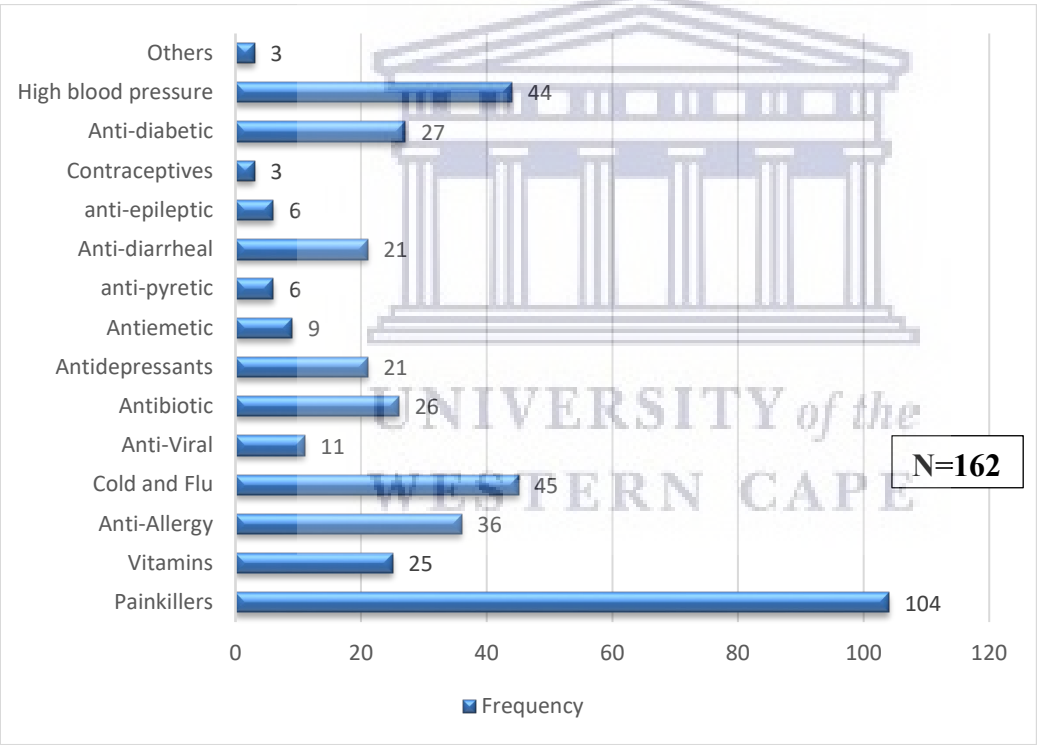

Figure 1: Types of unused medicines in the home of respondents

4.2.4 Factors influencing the retention of unused medicines in households

Reasons for retaining medications in the households included for future emergency use (58%), patients felt better and discontinued treatment (19%), medicines had expired (7%), patients received an excess supply of medication (6%), patients discontinued treatments due to side effects (6%) and there was a change of treatment (4%) Figure 2.

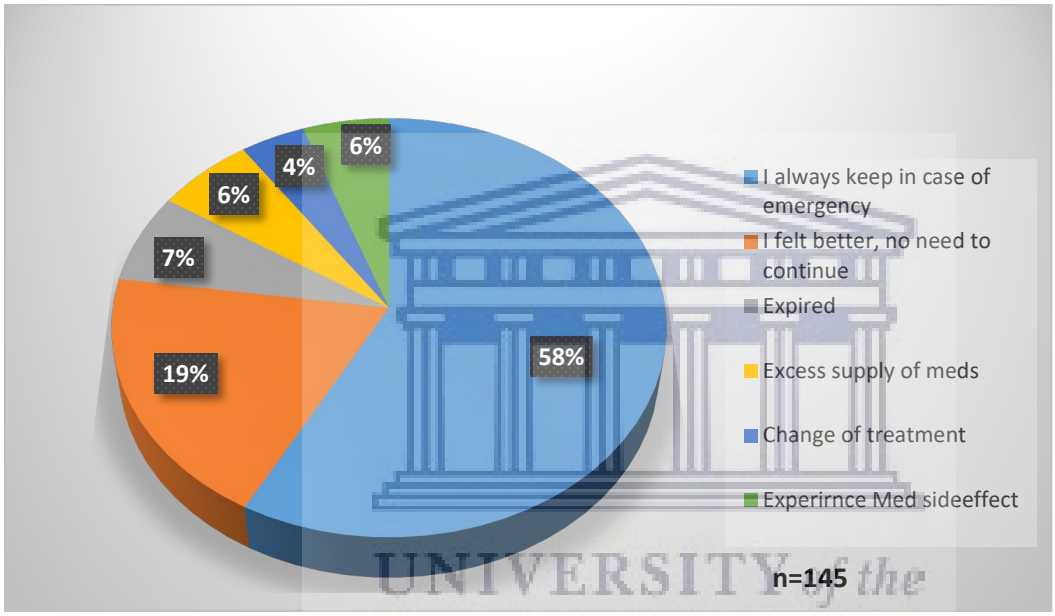

Figure 2: Respondents' reason for having unused medicines at home

4.2.5 Evaluation of participants unused medicine disposal practice

In response to the reasons for the accumulation of unused medications, 39.0% of the respondents indicated this was for future use, only 25% indicated to be returned to the pharmacy at a later date, while, 14% gave the medicines to someone with a similar health condition and 22% dispose of medications. The preferred method for the unused medication was the trash bin (45%), followed by flushing down the drain (31%) (Figure 3). Only 21% of the respondents used the pharmacy as the method of disposal.

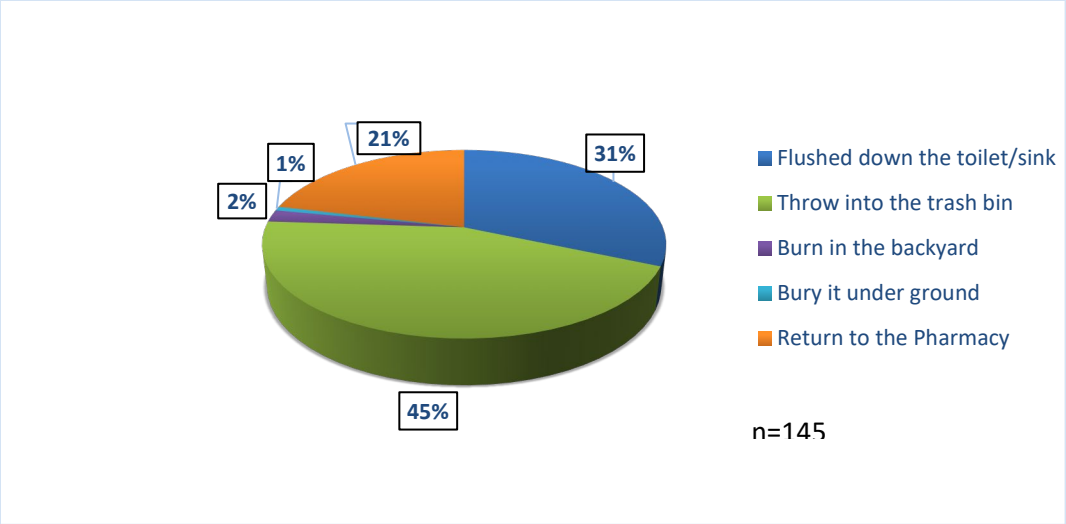

Figure 3: Households' methods for the disposal of unused medicines

4.2.6 Participants knowledge of proper disposal of unused medicines

Concerning their knowledge of the proper methods for the disposal of unused medicines, only 43% indicated being knowledgeable of proper disposal methods, while the majority of the respondents (56.2%) indicated that they did not know the proper methods of disposal. The study found that only 61% of the respondents were aware of the package inserts and this number, only 27% always read the package insert. The majority (46%) never read package inserts while 28% read the package insert sometimes (Figure 4).

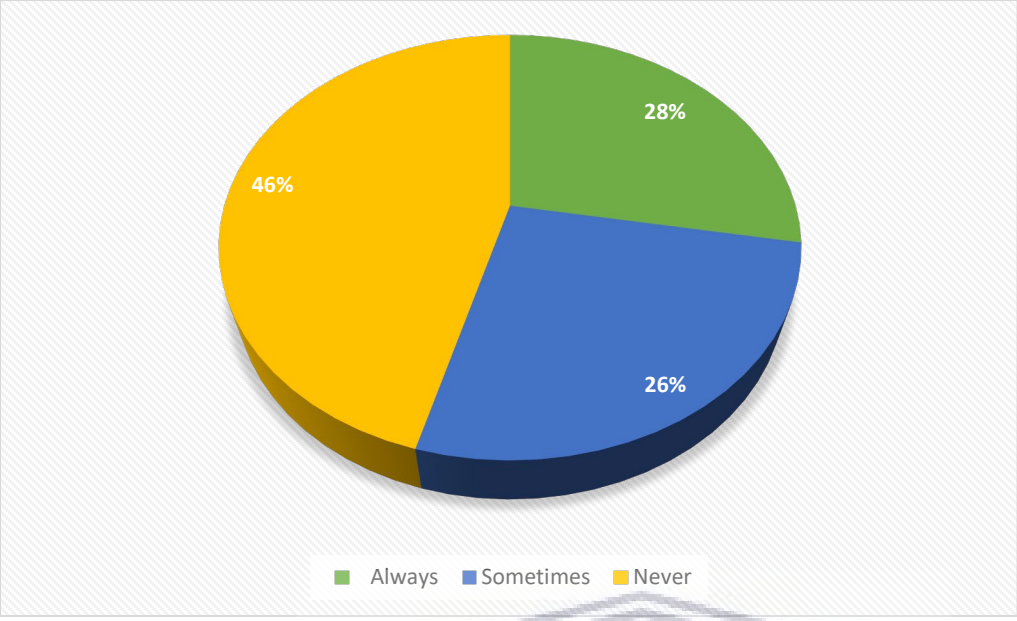

Figure 4: Respondents frequency of reading the package insert

4.2.7 Information on disposal of medicines given by pharmacists

Of the respondents, the majority (67.9%) indicated that have never been given information on the proper disposal methods by a pharmacist during dispensing. Of the 52 respondents (32%) who indicated they have received information on the disposal of medicines from a pharmacist, only 17 (33%) indicated that this was a regular occurrence while the majority (67%) reported this as occasional.

4.2.8 Household willingness to follow proper disposal practices

Concerning the willingness of participants to return unused medicines to the pharmacy for proper disposal, the majority of the respondents (76.5%) indicated a willingness while 12.3% indicated an unwillingness to practice proper disposal methods and 4.3% would ignore either to return unused medicines or fellow proper disposal method. Of those who indicated that they would ignore the request to return unused medication, the main reason was their lack of understanding of the reason for the return to the pharmacy (Table 2).

The study further interrogated possible reasons that can influence or hamper appropriate decision to practice safe disposal from household participants, (33.3%) indicated the time as the main barrier while (15.4%) indicated cost as the main barrier. A significant proportion (21.4%) indicated their retention for possible future use as the main factor influencing decision regarding safe disposal practices (table 2).

Table 2: Participants attitude to medicine disposal programs

	Frequency	**Percent (%)**
Action, if asked to return unused medication		
Yes, I will return medication	124	76.5
No, I will keep medication	20	12.3
No, I will ignore	7	4.3
Reasons that could influence safe disposal practice		
The time it will take to return	54	33.3
Cost it will incur to return	25	15.4
I am keeping for future use	35	21.6
Reason for Ignoring		
it is not important	11	6.8
I don't know why I have to return	21	13.0

In this study, results show that there was no significant relationship between possession of unused medicine at home and level of education ($r = 2.154^{a}$, $P = 0.541$) or with a residential area ($r = 1.750^{a}$, $P = 0.626$) of respondents. The level of respondent's education did not affect their knowledge of proper disposal of unused medicines ($r = 6.973^{a}$, $P = 0.073$) or the actions are undertaken to dispose of medicines ($r = 8.729^{a}$, $P = 0.726$). There was an association between knowledge of proper disposal and receiving advice from a pharmacist during visits to the pharmacy ($r = 51.397^{a}$, $P = 0.001$), as well as those who read package ($r = 11.662^{a}$, $P = 0.003$).

4.3 Pharmacists' survey questionnaire findings

4.3.1 Response Rate

A total of 3153 electronic questionnaires were sent out to the registered pharmacists in Western Cape for which 1880 was to community pharmacists, 270 private hospital pharmacists, and 1003 public hospital pharmacists. There was a zero percent response rate for data sent out online as no feedback was received. A total of 50 questionnaires were then sent out and was collected via face-to-face using hardcopy from pharmacists working in the community and private pharmacies within the southern suburb area of Cape Town. Of the 50 questionnaires completed, only 41 was completed with 80% accuracy and were accepted for this study. Only the persons responsible for medicines and its disposal was interviewed at Retreat CHC and is included in the data. The response rate of 82% was achieved for the pharmacist survey which is enough to ensure validity and but not enough for reliability as the required sample size population was not obtained.

4.3.2 Pharmacist demographic characteristics

Of the pharmacist's respondents (N=41), 63.4% were females while 36.6% were males. A Bachelor of Science degree (75.6%) was the highest education level held by the majority, followed by masters in pharmacy (17.1%), while none of the participants had PhD degrees. The highest working experience was 6 -10 years (46.3%) and 1 – 5 years (39.0%) the second highest, while only 4.9% had work experience above 11 years. The majority were pharmacists registered in the community pharmacy sector (78.0%), while 22.0% were pharmacists registered in the hospital sector (table 3).

Table 3: Pharmacist demographic characteristics (N=41)

Variables	Frequency	Percentage (%)
Gender		
Male	15	36.6
Female	26	63.4
Educational level		
B.Sc. Pharm	31	76.6
MPharm	7	17.1
Hon/Msc	3	7.3
PhD	-	-
Pharmaceutical sector		
Community Pharmacy	33	78.0
Hospital pharmacy	9	22.0
Years of working experience		
1-5	16	39.0
6-10	19	46.3
11-15	2	4.9
16-20	2	4.9
20 and above	2	4.9

4.3.3 Pharmacist knowledge of proper disposal of unused medicines

Concerning knowledge for proper disposal of unused pharmaceuticals, the majority (61%) of the pharmacists indicated to have formally received formal disposal guidelines, while 39.0% indicated not to have received formal guidelines. Of those who had received formal guidelines, 51.2% had

received guidelines during job training, 46.3% had received guidelines from the university during undergraduate studies and 2.4% during continuous professional program shown (figure 5).

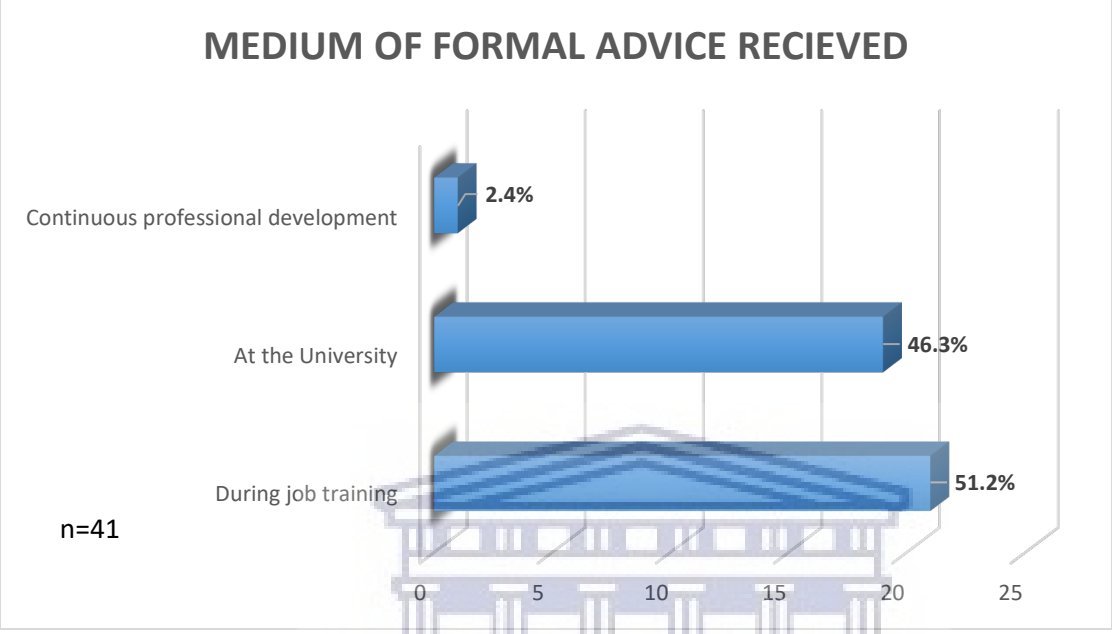

Figure 5: Pharmacists' responses to the medium of formal guidelines received

4.3.4 Pharmacist factors influencing household disposal practices

Concerning disposal programs provided by the pharmacy, only 29% responded to have disposal programs offered to the public, while 71% indicated not to have any available program on proper disposal in the pharmacy. In response to the disposal program, the study further asked pharmacists; what is their opinion about the present law on disposal practices of unused medicines, since the guideline available on GPP only indicated roles and how the process should be carried out for pharmacies and pharmacists. The findings reported 53.7% of the pharmacists indicated that the current law needs attention, while 19.5% indicated it is not effective and 26.8% indicated it was effective. Pharmacists indicated that the South African Pharmacy Council (51.2%), The Department of Health (36.8%) or both organizations (12.2%) should be responsible for managing disposal programs (table 4).

Table 4: Pharmacist opinion on the management of medicine disposal program

	Frequency	Percentage (%)
Is there a need to initiate medication disposal programmes at Pharmacies?		
Yes	17	41.2
No	24	58.8
What is your opinion about the present law on disposal practices of unused medicines?		
Effective	11	26.8
Not effective	8	19.5
Need attention	22	53.7
In your opinion, who should be responsible to manage and enforce such programs?		
The South African Pharmacy Council	21	51.2
The ministry of Health	15	36.8
Both (SAPC and Ministry of Health)	5	12.2

4.3.5 Pharmacists opinion on factors that can affect the disposal program

To understand their perception, pharmacists were asked for their opinions on what could hamper the implementation and effectiveness of a medicine disposal program in South Africa. The study findings showed the extra workload for disposal procedures (31.7%), the time it will take to accept and record (26.8%), and the cost of disposal (7.3%) as the main factors hampering the implementation of a disposal program (table 5).

Table 5: Factors negatively influencing the effectiveness of the disposal program

Factor	Frequency	Percent (%)
Cost	3	7.3
Time	11	26.8
Extra workload	13	31.7
All above (Cost, Time, Extra workload)	14	34.1

Regardless of the workload, pharmacist acknowledged the need to raise awareness disposal programs (90.2%) to the public. Furthermore, the pharmacist highlighted the reasons why no disposal advice is currently offered to the public at their facilities in Table 6 below.

Table 6: Reasons for not offering disposal advice to patients (N = 21)

Responses	**Frequency (%)**
Never been instructed or advised to do so	3 (14.3%)
Do not realize it's one important role to remind clients	2 (9.5%)
Assume that medication would be used up	3 (14.3%)
Am usually more concerned with proper use of medicine than its disposal after use	1 (4.8%)
Assume they know to bring it back to the pharmacy	2 (9.5%)
Only when asked by patients	2 (9.5%)
Long queues and patients waiting (Time)	6 (28.6%)
It doesn't come to mind; I think we just forget	2 (9.5%)

Findings from this study indicate that there was no relationship between a pharmacist receiving a formal guideline and giving advice to patients during dispensing ($r = 0.170^{a}$, $P < 0.680$). Neither does having a disposal program offered to the public in the pharmacy and providing advice during dispensing ($r = 2.364^{a}$, $P < 0.124$), have a significant association. The scope of practice for a pharmacists includes distribution and control of medicines. Ensure correct record keeping of purchase, sale, possession, storage, safe-keeping and return of medicines with limited emphasis on the provision of guidelines to the general public. Hence responsibility for guiding the public was neglected as indicated in their responses. The negligence by pharmaceutical statutory body towards disposal programs were prevalent with the responses indicated by pharmacists receiving formal guidelines ($r = 1.447^{a}$, $P < 0.004$). This signifies the role and responsibility of the Ministry of

Health and the South African Pharmacy Council towards health professionals and disposal practice.

4.4 Chapter four summary

The findings presented in this chapter were from the captured data from the household and pharmacist's questionnaires on their knowledge, behaviour, and perception with unused pharmaceuticals and their disposal practices. In the next chapter, these findings are discussed about the study objectives.

CHAPTER FIVE

5 DISCUSSION AND CONCLUSION

5.1 Introduction

In this chapter, the study findings are analysed and discussed concerning the study objectives and literature from previous similar studies. The chapter ends with a conclusion of the study findings and recommendations.

5.2. Discussion

In the assessment of the presence of unused medicines, the behavioural approach for its accumulation, and the disposal by respondents' resident in the southern suburb area, this study found that there was minimal awareness or knowledge of environmental effects and health impact of improper disposal of unused medicines. This is similar to reports from other studies across the world, and especially in Africa (Tomas, Sabo and Paut Kusturica, 2016). Even though several factors play a role in determining the behavioural approach to the disposal of unused medicines, the lack of an existing disposal program had the greatest impact, irrespective of individual's educational level of the participants.

The data revealed that the highest education level completed of the household participants ranged from primary to university level with (43.8%) up to grade 8, (34.6%) matric, and (14.8%) college /university qualification. These figures correlate with statistics that the City of Cape Town has a high literacy level of 90.5% according to (City of Cape Town, 2016). Although the inclusion age range for the study was from 18 years and above, respondents aged 41and above had the highest amounts of unused medicines at home. This is expected as the older patients tend to have more acute and chronic conditions and thus typically need to use more medicines. A previous study conducted by Abruquah, Drewry and Taylor (2014) also indicated the same age range as chronic medicine users.

The study observed that 92.6% of the household participants had unused pharmaceuticals at home and the mean average of medicine per household was 2.6 of which painkillers (64.2%) and anti-allergy (22.2%) were among the medicines found in various households in high quantities, which increases the probability of accidental poison possibility in various homes, more especially for children. Painkillers were generalized in the survey questionnaire for easy understanding, but they include drugs like ibuprofen, aspirin, diclofenac, and paracetamol/Panadol which has been proven to cause kidney failure when exposed to animals in a study by Rodriguez-Moza and Weinberg (2010b). Moreover, conditions like cold, are self-limiting, therefore do not require treatment continuation of full course completion. As such, these drugs are expected to remain at various households for re-use in the event of self-recognized similar conditions. The study findings were in line with a similar study conducted in Johannesburg which reported painkillers, cold and flu medicines among many unused medicines by various households (Mashiane, 2017). This accumulation, however, poses an increased risk of abuse, the error of taking an expired or impotent drug that may have been incorrectly stored.

The direct risk of improper medicine disposal has also been identified as a health problem as it often results in unhealthy medication sharing amongst the community (Abahussain and Ball, 2007). A study conducted at the Tygerberg poison information centre, Department of Medicine, Cape Town, revealed that accidental exposure to medicines and scheduled substances are more common (estimated at 65.2%) than intentional poisoning (34.8%), with medicines such as paracetamol and antihistamines the highest abused drugs (Veale and Wium, 2013). Painkillers, vitamins, cold and flu, and anti-allergy medication are essential drugs for regular use and are scheduled 0, 1 and 2 according to Medicines and Related Substances Act of 1965. This schedule code makes them available for purchase without a prescription from either a pharmacy or supermarket. This means that these pharmaceuticals are readily available and accessible for purchase in the desired quantity without any advice from a health professional for supermarket sales in South Africa and could account for the high percentage of its unused aspect.

Self-medication drugs such as paracetamol are useful for conditions that do not require a visit to the hospital or pharmacy, and as such having some supply in the household is necessary. However, high quantities of antihypertensive, antidiabetics and antibiotics, obtained only on prescription

were found as part of unused medication in various households in this study. This may be due to the increasing complexity of the diseases and the need to treat other symptoms that usually accompany disease deterioration, as reported in a study by Braund, Yuen, and Jung (2007). The treatment of other symptoms by the patient-user population increases the need for self-medication, which in turn results in inappropriate drug use, especially with antibiotics. One of the effects of antibiotic misuse is antimicrobial resistance, leading to increased ill-health with the high possibility of drug interactions for a patient. The results of this study was in line with the data collected for City of Johannesburg by (Mashiane, 2017) which reported that 37% participants had OTC items, 18% had prescription drugs and 47% had a mixture of both (prescription and OTC) as unused pharmaceutical at various households suggesting high non-compliance rate.

This study suggests that the source of medication may contribute to non-compliance by its users. Medicines kept at various households by the study respondents were obtained from both public/private hospitals, clinics, doctors and pharmacies. The participants who sourced their medication from a government facility (54%) had the highest number of unused medicines, compared to the minority who sourced medicines from a private facility (1%). Apart from the waiting time at a government facility, little or no money is paid for services received, the ease of access may contribute to non-compliance which in turn results in the accumulation of medicines, verses at the private facility in which fees are charged for all services rendered. These could be to a greater extent, the reason for non-compliance and suggests that the socioeconomic status of an individual could enforce the decision to keep unused pharmaceuticals at home. This finding is supported by the study conducted amongst South African community by Peltzer K. (2008), where the survey reported 29% of the ill-health episodes experienced in the past 1 year, were treated utilizing medication received in the past either hospital or pharmacy. With a high prevalence of self-medication practice, the pharmacy remains the first access point for many South Africans who seek information or solution for ill-health before going to a doctor or hospital for authoritative validation.

This study also observed that minimal high amount of unused medicine was sourced from the pharmacy (26%), and the doctor (19%). Now, why do households still end up with unused medicines, as fees are paid sourcing pharmaceuticals via these media? The unethical business

approach by certain health professionals where "cost" is placed before moral 'need' attitude cannot be ignored (Bothma & Clack, 2009), and therefore, suggest that excess prescribing and supply may also be the reason behind the high percentages as reported by a study conducted by Ruhuy and Daughton (2008).

Over the years, the production of pharmaceuticals has increased due to increased access to pharmaceuticals, their diversified usage (human, animal) and the number of people needing health care in South Africa. As a result, the number of pharmaceutical waste in various households and its contamination to the environment continues to increase globally (Rogowska *et al.*, 2019). The lack of adequate information, guidelines, and clear instructions for households as well as ignorance of the knowledge of the effects of improper disposal methods on the environment continue to impede proper disposal practices. In South Africa, legislative guidelines exist for proper disposal of unused pharmaceuticals, but there are limited or not accessible to the general public (Abahussain, Ball and Matowe, 2006). According to the health belief model used to predict a variety of health-related behaviours, 'the cue to take action depends on an individual's perception of danger'. It is, therefore, understandable that more than half of the study population in this research had no knowledge about the proper disposal of medicines and so felt no need to take appropriate action. It is natural for an individual to take informed action about proper disposal practice if they are made aware of the detriments to the environment.

The South African Bill of Rights of the Constitution, clause 24 states "everyone has the right to an environment that is not harmful to their health and wellbeing". The indirect entrance of pharmaceuticals into the sewage is unfortunately inevitable via excretion processes, however, the direct disposal of unused pharmaceuticals into the sewage system will forever contradict the achievement for a safe environment by the same population that needs it, if not re-addressed. The main objective of this study is to reveal the actual disposal practice of unused medicines from households in Cape Town. The survey had 162 household participant, for which the (n=17) (10.5%) responded not to have unused medicines at home, the remaining (n=145), (31%) flushed the unused pharmaceutical down the drain (toilet/sink), (45%) used the trash bin and (21%) returned to the pharmacy. These studies (Braund *et al*, 2009; Seehusen and Edward, 2006) which

identified the pattern of disposal by patients reported similar findings, which indicates it's a universal problem.

The WHO, recommends flushing down the drain for a certain class of highly abused narcotics like Morphine which are intended to minimize unintentional consumption/abuse, thus is a direct input of pharmaceutical into the effluent/aquatic environment. Therefore, the predominant action of flushing down the drain, maybe as a result of a misconception of what is the right disposal method. Even though, there is a recommended procedure (removing drugs from its original containers, mix with an unpalatable substance like cat food), but how many individuals are aware of it nor adhere to it. These recommendations further endanger the lives of animals and microorganisms in the environment. Moreover, the effluent sewage system is not structured to eliminate such chemicals, hence traces of pharmaceutical contents find their way back into clean water sources for reuse (Aschenbrenner, 2015). The disposal using the trash bin or drain may be a matter of convenience, since there may not be an appropriate disposal procedure or program available to the public. If the trash is incinerated, it may be environmentally safe, but Cape Town city utilizes a landfill system which only delays the entry of unused pharmaceutical into affluent and thereafter, the water sources. The study conducted by the City of Cape Town management (2015) indicated landfill site issues with ill-management processes which further intensifies disposal problems with even more health impact for the City. In the study conducted in the United States (2014), the author reported 20-30% of the study participants disposed of unused pharmaceutical utilizing the drain as the preferred method (Kotchen *et al.*, 2009). This suggests that improper disposal exists even in developed countries and are not limited to Cape Town.

The South African Health Products Regulatory Authority (SAHPRA), the regulatory body responsible for all pharmaceutical regulatory affairs for the country, instructs all the manufacturers to include patient information leaflet/instruction on each container /packet of pharmaceuticals. The package inserts for every pharmaceutical are designated to convey information for use as well as their appropriate disposal method as instructed by the manufacturer. However, a third of the respondent's participants for this study had no knowledge about package inserts, while only about half of those who were aware of package inserts had read them, while the remainder of the participants never read package inserts. This finding was similar to that reported by Mashiane

(2017) with over 50% of respondents in Johannesburg unaware of package inserts. These results suggest that the achievement of a safe environment as desired by the Bill of Rights depends solely on proper behaviour by patients which are primarily dependent; on their knowledge of proper disposal practice, awareness of environmental and health impacts of improper disposal of unused pharmaceuticals.

The Wood *et al* (2015) study was amongst the first study to confirm the presence of pharmaceuticals in the South African environment and linked it to a low level of public awareness to proper disposal practices. In 2019, this study found that only 43% of the study population are knowledgeable about proper disposal, while 56.2% lacked knowledge. This may be as a result of a lack of a standardized method for proper disposal available to the public. The return of unused medicines to the pharmacy is the only appropriate method as recommended by Abahussian, Ball and Matowe (2006). Therefore, the public is to be made aware of such practices by their healthcare professionals during their visits. The findings for his study found the majority of the study respondents indicated they do not receive any advice during their visits for medication collection, particularly from the pharmacist. These findings were compared with the recent study conducted in Johannesburg which reported (72.4%) of the study respondents did not receive advice during their visits. This suggests a low level of awareness as stipulated by Wood et al, 2015. The safe disposal of unused pharmaceuticals will require the involvement of pharmacists who are the custodian of medicines and are in the health sector where households access more frequently to get health information (Ruhoy & Daughton, 2008).

The pharmacy profession is an evolving profession that requires pharmacists to be at the forefront in all aspects of a pharmaceutical life cycle, starting from production down to its disposal. Again, they are in strategic positions with the significance of easy accessibility without appointment nor consultation fees (Gilbert, 1998). Hence, the concept of the seven-star pharmacist was introduced by WHO and taken up by FIP in 2000 to break the existing knowledge gap in aspects of pharmacy practice (Wiedenmayer, 2006). The necessity of further education leads to the addition of one more star (research), making it eight stars. Two of the eight stars of a South African qualified pharmacist is to be a life-long learner and researcher. But with the poor record in further education among

pharmacists, it suggests that once a degree is achieved, there seems to be no need or lack of interest in furthering education and developing professionally.

In the past decades, there is a paradigm shift in the role of a pharmacist which has evolved from a compounder/dispenser to a patient-oriented pharmaceutical caregiver with an emphasis on meeting the need of the community and the environment at large (Gilbert, 1998). However, the lack of effective disposal guidelines from a patient perspective in South Africa might be the reason pharmacists feel un-obliged by law to offer effective disposal services as it not stipulated in the Pharmacy Act 53 of (1974) scope of practice for a pharmacist. In this study, only 29% of the pharmacists surveyed indicated their pharmacy offered disposal programs to the public. However, the findings from a similar study in Johannesburg contrasted with this study, the author reported that the majority of pharmacies offered a disposal program (Mashiane, 2017). The Abahussian et al (2012) study which looked at pharmacist attitude towards the return of unused medicine, reported most pharmacists to receive unused medicine at their workplace but, only 16% utilized proper disposal practices. This suggests that the decision to adhere to proper practice might also be an individual attitude irrespective of any law.

The scope of practice of a pharmacist States "evaluation, selection, dispensing and providing information for use, excluding providing information on disposal of unused" pharmaceuticals to the general public according to Section 35A of the Pharmacy Act stipulated in the Good Pharmacy Practice (The *Good Pharmacy Practice In South Africa*, 2010). Although some regulatory guidelines exist such as; Medicines & Related Substances Act 101of 1965 as amended, Good Pharmacy Practice 2012, National Environmental Management Act 107 of 1998 (NEMA) and National Environmental Management: Waste Act 59 of 2008, but can be said to be limited in regards to awareness of its existence to the general public. This suggests the lack of attention towards proper disposal aspect of pharmacy practice from a regulatory and statutory body perspective. This study found that 61% of the pharmacist has received formal disposal guidelines, while 39.0% had not formally received the guidelines. Pharmacists are the custodian of medicines and their role in healthcare service delivery evolves in the community and hospital environments, as well as academia, research, and regulation. Therefore, their important roles in healthcare are beyond procurement, a supply of pharmaceutical care services, and the sale of medicines.

According to a study on Chandigarh Indian pharmacists, 89% reported they were not taught the disposal of unused medicine at school (Aditya and Rattan, 2014). The Fass, (2011) study stipulated and stressed the need for pharmacy students who are the future of the pharmacy profession to be deeply involved in disposal practices and be prepared with adequate attitude and knowledge to assist the general public.

In many developed countries according to literature, drug-take-back programs are already functioning, and are open to the general public for acceptance of unused pharmaceuticals. Most of the programs are managed by the government, with a joined effort from pharmaceutical companies in some regions. For example, in New Zealand, unused medicines are returned to the local pharmacy and they have designated collection points (Braund, Peake and Shieffelbien, 2009) and these programs are effective. However, other studies have reported existing disposal programs that are not effective, for example; in Ghana. They have a program called DUMP, but 80% of the population is not aware of the program (Sasu, Kümmerer and Kranert, 2012). In Serbia, the government introduced pharmaceutical waste legislation in 2010 that forces pharmacies to accept unused medicines. The legislation did not specify responsibility on disposal cost, therefore puts the halt on the effectiveness of the program (Kusturica *et al.*, 2012). In Ireland, an awareness campaign for the return of unused medication to the pharmacy is very high. However, the pharmacies are equally not obligated to accept unused pharmaceuticals from the public (Vellinga *et al.*, 2014).

In South Africa, drug take-back programs are limited and there are no designated collection point and pharmacies are not obliged to accept unused medicines. The law guiding disposal practices for pharmacies and pharmacists are provided by SAHPRA and in the Good Pharmacy Practice (GPP) by the South African Pharmacy Council made provision for procedures and steps for unused medicines disposal. The majority of pharmacists in this study felt that the South African Pharmacy Council should manage medicine disposal programs. Thus, to orient the community on proper and standard disposal practices, it is important to increase awareness and undertake training interventions among the public by the government, pharmacists, and pharmaceutical industries. It is also important that the manufacturing sector assumes a role towards proper disposal practices as

they manufacture the product, hence they are in a better position to ascertain the best safe disposal process and at a minimal cost.

In the studies by Kusturica *et al*., (2012) and Vellinga *et al*., (2014), they reported cost as the major factor behind unacceptance of unused pharmaceutical by pharmacies. There were contrasts between the handling of unused medicines between the government-run facility and private pharmacies. Retreat Community Health Center Pharmacy accepts unused and expired medicines from members of the public, with the cost of disposal borne by the government, whereas private pharmacies would only accept unused medicines if purchased from that pharmacy. This is obviously due to the costs incurred by the pharmacy in disposing of the unused medication. A study conducted in Romania by Bungau *et al.,* (2018), reported 16% pharmacies do not accept unused pharmaceutical, while 33% pharmacies refused to accept unused medicine from the public because of the cost of accepting unused pharmaceuticals from households and cost of disposal by disposal companies. However, the study conducted in the Republic of Serbia by Manojlović *et al.,* (2015), reported 76.5% of unused medicines were collected from households for appropriate disposal. This might be due to effective disposal police, none/limited cost for disposal and standardized collection and disposal program run by the government.

A significant role is expected to be played by pharmacists in the community or hospital pharmacy sector since they are on the forefront as custodians of medicines. To provide information on the use of medicines, providing proper education and awareness to the community on the disposal of unused medicine should take place during the dispensing process. To understand their perception; pharmacists were asked of their opinion on what could hamper disposal program in South Africa. The study findings showed 7.3% indicated cost it will incur to dispose of, 26.8% indicated time it will take, 31.7% indicated extra workload added to the already stretched work especially for those in the hospital sector, 34.1% indicated all the 3 (cost, time, extra workload) factors could hamper the progress. Pharmacist's perception and mindset towards their role for patients should change and this begs for intervention training to re-enforce safe disposal practice and effectiveness.
The return of unused pharmaceuticals to the pharmacy is the recommended approach according to literature by Abahussain et al., (2006; 2012). The need to familiarize the community on appropriate and standard disposal practices directs the importance to increase awareness which will involve

the government, pharmacists, other healthcare professionals and pharmaceutical industries. The lack of knowledge on the appropriate method for proper disposal by the majority of the households' participants poses a major limitation, as knowledge of improper disposal effects to the environment remains an important factor that will stimulate proper disposal attitude amongst the general public. From this study observation, households are willing to follow proper disposal practice, only if they are aware of what right method to use, which highlights that environmental awareness may impact the behavioural decision.

To confirm, this study queried possible reasons that can influence or hamper appropriate decision to practice safe disposal from household participants, 33.3% suggested time it will take to return, 15.4% suggested cost it will impose on them because some pharmacies charge a minimal fee, while 21.4% indicated they will keep for future use. The lack of established programs and designated collection points may have been the major contributing factor to poor knowledge and increased improper disposal practice amongst communities in Cape Town. These study findings were similar to the results of the study conducted in the city of Johannesburg by Mashiane (2017) in which 79% of the study participants indicated to be willing to adopt appropriate disposal practices. The study by (Kotchen *et al.*, 2009), reported the study participant's willingness to pay for the disposal of unused pharmaceuticals. Although, this approach may not be accepted by the South African community, 80% population of the country access healthcare via government facility in which no cost is paid based on their income. The success of the move will depend on individual behaviour and attitude towards change.

5.3. Conclusion

The main conclusion and findings obtained by this study are that most respondents demonstrated a lack of understanding of guidelines regarding the safe disposal of unused and expired medicines. Another striking outcome is the absence of an unclear explanation to patients by pharmacists concerning return to the pharmacy for safe disposal of unused and expired medicines. Ideas on how to improve the prevailing situation have also been captured such as designated collection points, education, intensified campaigns and advertisement educating the general public on safe disposal of expired and unused pharmaceuticals.

5.4. Study limitation

The weakness of this study includes: the study population for households was recruited based on convenience sampling which may not be the true representative of the population under study and the study population is limited to the southern suburb area of Cape Town. Therefore, may not be generalized to the whole city as suggested by the study title. The response rate was low, especially for the pharmacist participants. An accurate data collection was difficult, as the pharmacists were extremely busy, at the time of data collection, so a response may be subjected to a bias of convenience rather than actual practice. Another limitation of this study is sector exclusion of the pharmaceutical manufacturing industry and government (Ministry of health and SAPC). More detailed studies are needed that will involve the excluded sector.

5.5. Recommendations

Many studies conducted in different geographical areas globally suggests a lack of knowledge and the effects of improper disposal (Tomas, Sabo, and Kusturica, 2016). This current study confirms the statement true as 56.2% of household participants lacked knowledge about proper disposal, package insert and the pharmacies around them do not offer any program. This begs for the need for an extensive awareness program to educate the public on proper disposal practice, designated collection point easily accessible to the public to be in place and adequate monitoring for irrational use of medicines. This study recommends more research studies, to further understand the underlying factor for improper disposal problems for the City of Cape Town, South Africa.

The return of unused pharmaceuticals to the pharmacy is the only appropriate method of disposal for an individual as recommended by Abahussian et al. (2006; 2012). Therefore, the pharmacist's participants for this study suggested; posters to be displayed in every pharmacy, information leaflets in strategic positions for consumers, information to be displayed on television monitors at a pharmacy while patients wait in line, and compulsory CPD's training for pharmacists. Some of the pharmacists stated, they do not advise while dispensing because they are not aware it is a responsibility, which means a lack of knowledge. Therefore, there is an important need to educate

practising pharmacists, to include and intensify disposal education for pharmacy students in every institution, which will ensure better disposal knowledge that will mitigate environmental safety.

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APPENDIX 1:
Ethical approval by University of Western cape

UNIVERSITY of the WESTERN CAPE

OFFICE OF THE DIRECTOR: RESEARCH
RESEARCH AND INNOVATION DIVISION

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23 April 2018

Mrs M Okonwho Ihebe
School of Pharmacy
Faculty of Natural Sciences

Ethics Reference Number: HS17/8/8

Project Title: The disposal practices of unused medicines from households in Cape Town.

Approval Period: 18 April 2018 – 18 April 2019

I hereby certify that the Humanities and Social Science Research Ethics Committee of the University of the Western Cape approved the methodology and ethics of the above mentioned research project.

Any amendments, extension or other modifications to the protocol must be submitted to the Ethics Committee for approval.

Please remember to submit a progress report in good time for annual renewal.

The Committee must be informed of any serious adverse event and/or termination of the study.

Ms Patricia Josias
Research Ethics Committee Officer
University of the Western Cape

PROVISIONAL REC NUMBER - 130416-049

APPENDIX 2:
Ethical approval for Retreat Community Health center by Health research Sub-directorate (Health impact assessment)

Western Cape Government
Health

Health impact assessment
Health research sub-directorate
Health.Research@westerncape.gov.za
tel: +27 21 483 0866: fax: +27 21 483 9895
5th Floor, Norton Rose House, 8 Riebeek Street, Cape Town, 8001
www.capegateway.gov.za)

REFERENCE: WC_201804_026
ENQUIRIES: Dr Sabela Petros

University of Western Cape

Robert Sobukwe Road

Bellville

Cape Town

7305

For attention: Mrs Miriam Oluchi Okonkwo Ihebe

Re: **Disposal of Unused Medicines from Households in Cape Town.**

Thank you for submitting your proposal to undertake the above-mentioned study. We are pleased to inform you that the department has granted you approval for your research.

Please contact the following person to assist you with any further enquiries in accessing the following sites:

Retreat CHC	**Mr Henry Lemmetjies**	**021 713 9741**

Kindly ensure that the following are adhered to:

1. Arrangements can be made with managers, providing that normal activities at requested facilities are not interrupted.
2. By being granted access to provincial health facilities, you are expressing consent to provide the department with an electronic copy of the final feedback (**annexure 9**) within six months of completion of your project. This can be submitted to the provincial Research Co-ordinator (Health.Research@westerncape.gov.za).

3. In the event where the research project goes beyond the *estimated completion* date which was submitted, researchers are expected to complete and submit a progress report (**Annexure 8**) to the provincial Research Co-ordinator (Health.Research@westerncape.gov.za).

4. The reference number above should be quoted in all future correspondence.

Yours sincerely

pp **DR J EVANS**

ACTING DIRECTOR: HEALTH IMPACT ASSESSMENT

DATE: 2018/08/21

Appendix 3

Participant information leaflet and invitation letter

TITLE: Disposal of Unused Medicine from Households in Cape Town

PRINCIPAL INVESTIGATOR'S NAME: Miriam Oluchi Ihebe

You are invited to take part in a survey. Please read the information provided below carefully before you decide whether or not you wish to take part in this survey. You are not obliged to take part in this study, participation is purely voluntary.

WHY IS THE STUDY IMPORTANT?

This study is to understand for the City of Cape Town how and what unused medicines accumulate; why they accumulate and where they are disposed. Improperly disposed medicines pose a health risk to the environment, aquatic world, and human beings especially children who are likely to ingest them leading to poisoning accidents. The study aims to raise awareness on proper disposal practice of unused medicines by establishing a partnership between the public and pharmacists.

WHO IS ORGANISING AND FUNDING THIS STUDY?

This research is being conducted in fulfillment of the requirement for a master's degree in pharmacy from the University of Western Cape. The study is self-funded by the researcher.

HOW THE STUDY WILL BE CARRIED OUT?

The study involves survey questionnaires that will be distributed to, selected household participants, part-time/full time registered pharmacists' residents/ working in Cape Town. Each participant will receive one survey and the feedback collected from the survey will be analyzed and submitted in the final thesis.

HAS THE STUDY RECEIVED ETHICS APPROVAL?

This study has received written approval from the Research Ethics Review Committee of the University of Western Cape, Natural science facility. A copy of the approval letter can be obtained from the researcher if you so wish.

WHAT WILL HAPPEN IF I AGREE TO TAKE PART?

No personal information will be requested, and all your information collected from the survey will be treated with respect and confidentiality.

CONFIDENTIALITY

The data collected from this survey will be anonymous and will only be shared with academic personnel at the University of Western Cape in pursuance of the qualification as stated above.

By participating in this survey, I confirm that I understand the objectives of the study and give my consent for my response to be used as outlined in the participant information leaflet and invitation letter.

RISK OF THE STUDY

There are no anticipated risks of participating in this study. The study design is structured with minimal or no risk as the survey is questionnaire-based, and are there no requirements for personal details. All questions used are not of sensitive nature and responses provided will be coded, hence participation remains anonymous.

FOR ADDITIONAL INFORMATION, PLEASE CONTACT:

Name: MIRIAM IHEBE

Email: Miriam.ihebe@gmail.com

Appendix 4

Participant consent form

Title: Disposal of unused medicine from households in Cape Town

Principal Investigator's Name: MIRIAM OLUCHI IHEBE

Principal Investigator's Title: MISSES

The study you are about to participate in is a survey on the disposal of unused medicines. It is conducted to understand trends for which Cape Town residents deal with unused medicines and reasons why households end up with unused medicines. The study employs standard principles for the questionnaire survey as approved by the Research Ethics Committee of the University of Western Cape that has no potential harm to its participants. Should you agree to be part of the study, you will be asked to fill out questionnaires by simply ticking the appropriate answer of your choice and providing responses as it concerns you and your opinion.

All data collected from you will be coded in order to protect your identity; therefore, there will be no way to connect your name with your data. Any additional information about the study result will be provided to you at its conclusion or upon request.

You are free to withdraw from the study at any time, should you agree to participate. Please, sign below, indicating that you have read and understood the nature of the study, and that all inquiries concerning the study have been explained to satisfaction.

Signature of the participant and date ……

Appendix 5

Household voluntary survey

This voluntary survey has 19 questions and should take about 15-20 minutes to answer.

1. I have read and understood the participant information leaflet and invitation letter

   ☐ Yes

   ☐ NO

2. What is your age?
   ☐ 18 -25
   ☐ 26 -40
   ☐ 41 -55
   ☐ 56 or older

3. What is the highest level of education you have completed?
   ☐ Up to grade 8
   ☐ Matric
   ☐ Post / tertiary (University, Colleges, Technicon)
   ☐ Postgraduate (Masters, Ph.D.)

4. In which suburb do you currently reside?

   _____

5. Which of the following best describes the area you live in?

   ☐ Urban
   ☐ Suburban
   ☐ Locations / township

6. Have you currently or in the past had any type of unused/expired medication at home?
   - ☐ Yes
   - ☐ No

7. The unused / expired medicine you have at home was gotten from?
   - ☐ Pharmacy
   - ☐ Doctor
   - ☐ Community Hospital / Clinic (Government Sector)
   - ☐ Private Hospital

8. The unused medicine in my household are for: **(you can choose more than one)**
   - ☐ Painkillers
   - ☐ Vitamins – (drugs to support my body to be strong)
   - ☐ Anti-Allergy – (drugs that relieve seasonal sickness)
   - ☐ Cold and flu
   - ☐ Anti- viral – (drugs that control virus growth)
   - ☐ Antibiotics – (drugs that kill germ)
   - ☐ Antidepressants – (drugs that relieve depression)
   - ☐ Antiemetic – (drugs for vomiting)
   - ☐ Anti- pyretic – (drugs that stop fever)
   - ☐ Anti- diarrheal – (drugs that stop loose watery stool)
   - ☐ Anti – epileptic – (drugs that prevent seizures)
   - ☐ Contraceptive – (drugs that prevent pregnancy)
   - ☐ Anti-diabetic – (drugs that control sugar in the blood)
   - ☐ High blood pressure
   - ☐ Others (please specify) _____

9. The unused medicines in my household are because;
   - ☐ I always keep in case of emergency
   - ☐ I felt better, so no need to continue
   - ☐ Expired
   - ☐ Excess supply of medicine
   - ☐ Change of treatment
   - ☐ Experience of medicine side effects

   Others (please specify) _____

10. What do you do with the unused medicines in your household?

☐ Store it – For future use

☐ Give it away – to someone with a similar condition

☐ Throw it away – No need for use

☐ Keep it to return to the Pharmacy / Doctor

11. If you throw it away, how do you dispose of your unused medicines?

☐ Flush down the toilet / sink

☐ Throw into the trash

☐ Burn in the back yard

☐ Bury it under ground

☐ Return to the pharmacy / Doctor

Other (please specify) _____

12. Do you know the proper way to dispose of your medicine?

☐ Yes

☐ No

13. Have you ever been advised by your pharmacist on the proper disposal of medicine?

☐ Yes

☐ No

If yes, how often?

☐ Sometimes

☐ Always

14. Are you aware that every medicine has a package insert and they contain information on how to use and dispose of the medicine?

☐ Yes
☐ No

If yes, do you read it?

☐ Always
☐ Sometimes

☐ Never

15. Does your community pharmacy accept unused medicine returned for disposal?

☐ Yes

☐ No

☐ I have no idea

16. Have you ever returned any unused/expired medicine to the pharmacy

☐ Yes

☐ No

If yes, where?

☐ Private pharmacy/ hospital

☐ Government pharmacy / clinic

17. If the medication was returned, was it accepted?

☐ Yes

☐ No

If no, what was the reason for rejection? _____

18. If you are asked to return every unused medicine from your household, will you?

☐ Yes, I will return the medication

☐ No I will keep the medication
☐ No I will ignore

19. If you will keep the medication, what will be your reason?
☐ Time it will take to return
☐ Cost it will incur to return
☐ I am keeping for future use

If you ignore, reason?

☐ It is not important

☐ I don't know why I have to return

Other (please specify) _____

Appendix 6

Voluntary Survey for Community and Hospital Pharmacists in Cape Town

DEMOGRAPHIC INFORMATION

Date: …...../……/……. Code...

Please tick as appropriate

1. **Gender:** Male ☐ Female ☐
2. **What is your highest level of education?**

   (a) BSc Pharm ☐ (b)M.Pharm ☐ (c) Hon/MSc(e) PhD ☐
3. **Which of these Pharmaceutical industry sectors best describes your work?**

   (a) Community Pharmacy ☐ (b) Hospital Pharmacy ☐
4. **How many years of working experience do you have?**

   (a)1-5 ☐ (b)6-10 ☐ (c)11-15 ☐ (d)16-20 ☐ (e)21and above ☐
5. **Have you formally received guidelines on proper disposal of unused medicine?**
   Yes ☐ No ☐
6. **If you have received training in the disposal of unused medicines, specify through which medium you received your training?**

   ☐During job training
   ☐At the university
   ☐Continuous professional development
   Other (please specify) ☐
7. **Does your community/Hospital pharmacy offer programs to the public on the return of unused medicine?**

   ☐Yes
   ☐No
8. **What is your opinion about the present law on disposal practices of unused medicines?**

☐Effective
☐Not effective
☐Needs more attention

9. During dispensing, do you advise patients on proper disposal of unused medicine?

☐Yes
☐No
If No, Why? _____

10. Do you think there is a need for a pharmacist to raise awareness to improve on proper disposal practices?

☐Yes
☐No

11. Do you think there is a need to initiate programs for disposal practices at pharmacies?

☐Yes
☐No

12. If yes, what strategies do you think can be implemented at your workplace to achieve this goal?

_____

13. In your opinion, who should be responsible to manage and enforce such programs?

☐ The South African Pharmacy Council
☐ The Department of Health

Other (please specify) _____

14. What do you think could hamper the effectiveness of the program?

☐Cost
☐Time
☐Extra workload

Please comment any other factors

……
……