Assessment of pharmaceutical waste management in Vhembe District, Limpopo Province, South Africa

By

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DECLARATION

I, **Mpho Bridget Malema**, hereby declare that this dissertation titled - **ASSESSMENT OF PHARMACEUTICAL WASTE MANAGEMENT IN VHEMBE DISTRICT, IN LIMPOPO PROVINCE SOUTH AFRICA** - submitted to the University of Venda, Limpopo, is my own independent work and has not been submitted to any institution by myself or any other person. All the references used are duly cited and compiled in a list of references.

23/02/2023

STUDENT SIGNATURE DATE

DEDICATION

I dedicate this research endeavour to God, the guiding force behind every step taken and every insight gained throughout this journey. Also, to my beloved three-year-old son, Kgosi, who despite his tender age, has been a driving force behind my achievements. His presence has been a constant reminder of my purpose and determination.

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ABSTRACT

Administering of pharmaceutical products is recognized as a crucial component of healthcare services, since these are used to treat, prevent, and cure diseases, however, rapid population growth has significantly increased the demand for pharmaceutical products, leading to a noticeable surge in their waste generation. This poses serious ecological and health risks if not properly managed, as pharmaceutical waste includes hazardous by-products that can contaminate various environmental spheres. Traces of pharmaceuticals have been detected in wastewater treatment plants, which often lack the necessary infrastructure to remove these compounds effectively. Consequently, the management of pharmaceutical waste is a critical concern for regional, national, and international communities, necessitating a thorough understanding of their management and potential eco-toxicological impacts to devise effective handling and containment strategies.

This study was designed to appraise the holistic management of pharmaceutical waste in Vhembe District, Limpopo Province, South Africa. To fulfil this objective, various data collection methods were employed, including questionnaires, on-site observations, and interviews with medical practitioners and waste management personnel. A checklist was used to evaluate compliance with regulatory frameworks, focusing on healthcare facilities and pharmaceutical outlets. Data from observations were analysed descriptively, supported by visual aids like photographs; the interviews were categorized, coded, and abbreviated for easier analysis, while the questionnaire data were processed using SPSS and other statistical tools to generate meaningful outputs.

The study's findings reveal significant deficiencies in pharmaceutical waste management within the Vhembe District. Inadequate waste management practices were observed, marked by the absence of source segregation and the use of suboptimal temporary storage containers chosen for convenience rather than efficacy. The infrastructure for waste storage within some of these facilities proved substandard, thereby, failing to meet regulatory requirements. Most facilities rely on municipal waste collection services and the sewer drainage systems, raising environmental and health concerns. The study also identified a significant gap in education and training regarding pharmaceutical waste management with healthcare professionals, who often perceive their responsibility as ending after writing a prescription. This lack of knowledge and preparedness to manage pharmaceutical waste, in line with legal requirements, is a major concern.

Additionally, the study revealed participants' challenges related to understanding waste categories and regulations, hence, emphasizing the need to sensitize healthcare professionals

about these regulations. The results showed that 71% of consumers were aware of pharmaceutical waste, but only 20.1% understood its associated environmental and health risks. Alarmingly, 71.8% consumers lacked essential information about the consequences of pharmaceutical waste, and 80% frequently had surplus medications due to practitioners' over-prescribing or discontinuation of treatment, contributing to waste accumulation. Furthermore, 86% of participants did not segregate pharmaceutical waste from general household waste. A significant 58.3% disposed of pharmaceutical waste in standard trash bins, leading to landfills and potential soil and water contamination through leaching and migration.

The study also highlighted the absence of dedicated regulatory measures addressing pharmaceutical waste; they are often categorised under the broader healthcare waste management framework. The existing framework suffers from a disconnect in policy development, implementation and enforcement, with regulations frequently formulated by different stakeholders who do not effectively collaborate. This lack of clarity makes it challenging for stakeholders to understand their separate roles and responsibilities, necessitating improved stakeholder engagement, education, and clear regulatory measures. Future efforts should focus on holistic approaches, proper stakeholder engagement, and stringent regulatory compliance to enhance proper pharmaceutical waste management and conserve the environment for future generations.

Keywords: Waste management, pharmaceutical waste, waste management, waste classification, health care facilities, waste management strategies.

ACRONYMS AND ABBREVIATIONS

ARVs	Antiretrovirals
DEA	Department of Environmental Affairs
DFFE	Department of Forestry Fisheries and Environment
DoH	Department of Health
DWS	Department of Water and Sanitation
EPA	Environmental Protection Agency
HCRW	Healthcare Risk Waste
HCRWM	Healthcare Risk Waste Management
HCW	Healthcare Waste
HPCSA	Healthcare Professional Council South Africa
HPW	Household Pharmaceutical Waste
HPWM	Household Pharmaceutical Waste Management
IDP	Integrated Development Plan
LEDET	Limpopo Economic Development Environment and Tourism
NEMA	Nation Environmental Management Act
PW	Pharmaceutical Waste
PWM	Pharmaceutical Waste Management
SAHPRA	South African Healthcare Pharmaceutical Regulatory Agency
SANS	South African National Standards
SPSS	Statistical Package for Social Science
USEPA	United States of Environmental Protection Agency
VDM	Vhembe District Municipality
WHO	World Health Organization

PUBLICATIONS

Anticipated papers

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Malema M.B., Edokpayi J.N. & Masindi V. 2024. A study on the assessment of Knowledge, Attitudes, and Perceptions of Healthcare Professionals Regarding Pharmaceutical Waste Management. Draft manuscript.

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CHAPTER ONE

INTRODUCTION

1.1 Background of pharmaceutical waste management

Pharmaceuticals are crucial elements in healthcare services because they play an essential role in assisting patients to effectively recover from illnesses and manage chronic conditions (Kadam et al., 2016). Rapid population growth has led to increased demand for healthcare services, this has consequently increased the amount and rate of medical waste generation (WHO, 2018). Pharmaceutical waste forms part of medical waste and can be defined as any waste that contains medicinal drugs that have expired and are unused, contaminated or ceased to be utilised (HPCSA, 2008). Sources of pharmaceutical waste are, but not limited to, healthcare facilities such as hospitals, clinics, over-the-counter drugstores, and pharmacies (Nyanga, 2020). Pharmaceutical waste is classified as “hazardous” due to its toxic nature and that it can have devastating consequences, if not properly stored, collected, managed, transported, or disposed of in a suitable manner (Dubey et al., 2017). HPCSA (2012) indicates that pharmaceutical waste must be segregated from other wastes and disposed in a proper manner to avoid access to and illegal use of discarded pharmaceuticals. Most high-income countries have developed regulations that adequately and effectively ensure that medical waste is managed in a safe and environmentally-viable manner, however low-middle income countries still encounter challenges regarding proper management of medical waste due to lack of funds, facilities, and policy enforcement to ensure that medical waste is managed in a proper and acceptable manner (Olaniyi, 2018).

Large quantities of healthcare waste in South Africa are not accounted for, which suggests that it is illegally dumped, buried, or burnt somewhere, thus affecting human health and the environment (Matlala, 2015). In the absence or lack of proper initiatives for the management of medical waste, many healthcare facilities use methods available to them for disposal which mainly comprise of landfilling, open burning, and incineration. These are popular methods used in low- and middle-income countries (LMICs). Dumping of pharmaceutical waste potentially expose people and the environment to pollution; for example, when unused pills are dumped during rain periods, they may be washed to water sources and contaminate surface and groundwater (Windfeld, 2015). Chemicals found in pharmaceutical waste may contain substances that are toxic, corrosive, flammable, reactive, explosive, and shock-sensitive when they find their way into the environment

(Lee et al. 2019). These substances are present in small quantities; however, they have detrimental effects on human health and may result in poisoning, either by acute or by chronic exposure, and injuries, including burns as a result of absorption of a chemical or pharmaceutical through the skin or the mucous membranes, or from inhalation or ingestion (Chamberlain, 2018).

A study conducted by Manvendra et al. (2019) has indicated that detection of pharmaceuticals and personal-care products (PPCPs) residues in wastewater suggests that pharmaceutical waste is being disposed in an inappropriate manner. Valdez (2020) indicated that the concentrations of Pharmaceutical Active Compound (PACs) in Africa, in wastewater, surface and groundwater, are extremely high and way above the maximum permitted concentrations as set by the United States Environmental Protection Agency (USEPA, 2016). Current methods of water purification are incapable of treating contaminated sources as traces of the compounds were still detected after full cycle of water treatment and purification. To mitigate the environmental and health risks posed by pharmaceuticals, it is essential to improve management strategies. This process includes evaluating current approaches to determine their impact on the concentration levels of pharmaceutical active compounds (PACs) in surface and groundwater. Some key studies (Qian et al., 2015; Asgar et al., 2018; Sharma et al., 2019) highlight the importance of assessing existing practices to enhance their effectiveness in safeguarding the environment and human health. This study is one of the few studies addressing pharmaceutical waste management and is designed to appraise the holistic management of pharmaceutical waste in Vhembe District, Limpopo Province, South Africa. Given the significant health and environmental risks associated with improper pharmaceutical waste management, this study aims to fill a crucial gap by providing a comprehensive evaluation of current practices in Vhembe District and coming up with recommendation to mitigate any challenges revealed.

1.2 Problem Statement

Pharmaceutical waste has become an environmental concern and has been declared a global emerging contaminant (Othman, et al., 2019). High-income countries have developed policies and invented technologies to deal with the environmental and human health risks associated with PACs (Yamini et al., 2016), however low-middle income countries are still far from making any progress in dealing with the management and impacts of pharmaceutical waste or overall medical waste management (Anne et al., 2019). The most common method for treating pharmaceutical waste is incinerators in healthcare facilities, however, the dominant method of disposal by consumers is to discard it with household waste which ends up in landfills or illegal dumpsites as indicated by Padmanabhan (2019). The second most used disposal practice for pharmaceutical

waste is through sewage system which results in surface and groundwater contamination affecting human health and aquatic life (Alazim et al., 2017).

The most common groups of pharmaceuticals compounds that are of major concern include - antibiotics, antiretrovirals (ARVs) drugs, steroids, hormones, anti-depressants, and cancer drugs - due to their resistant nature and being hazardous environmentally and to human health (Ngumba et al.,2016). Notable levels of pharmaceuticals in aquatic systems show ARVs, antibiotics, hormones, and analgesics as the most common groups (Madikizela et al., 2020, Yamini, 2016). Exposure to pharmaceutical waste, primarily through contaminated water and the consumption of aquatic organisms containing these residues, poses significant consequences for both aquatic organisms and humans (Truter, 2015). In the aquatic ecosystems, pharmaceutical waste can lead to bioaccumulation, disruption of endocrine systems, genotoxic effects, and changes in behavior and physiology among aquatic organisms (Smith et al., 2018; Jones & Brown, 2019). For humans, the consumption of water contaminated with pharmaceutical residues may result in adverse health effects, including the development of antibiotic-resistant microorganisms, hormonal imbalances, genetic mutations, and acute health issues (Ngwala & Muchesa, 2020; Johnson et al., 2017). The far-reaching impact of pharmaceutical waste underscores the urgent need for comprehensive waste management strategies and regulatory measures to safeguard both environmental and public health.

Rapid population growth, and availability of inexpensive drugs along with upsurge of illnesses and other conditions and efforts to manage them, are the key drivers to the increased demand for pharmaceuticals products. This similarly increased pharmaceutical waste which then requires more facilities, funds, advancement in technology, and policy enforcement to ensure better management and safer disposal. Lack of knowledge and awareness regarding risks associated with pharmaceutical waste by consumers are some of the factors that contribute to the difficulty in managing it. Also, attitude, lack of accountability and non-segregation of medical waste at source, by medical practitioners do not make management any easier (Matlala, 2015). Compounding the prevailing challenges, lack of funds, non-prioritization, poor policy enforcement, non-accountability, and insufficient disposal facilities to ensure better and safer management of pharmaceutical waste at state level, also play a role in difficulty in ensuring that pharmaceutical waste is managed in a safer and sustainable manner. This issue is prevalent in low- and middle-income countries (LMICs) such as South Africa, hence this study will aid in identifying deficiencies in existing frameworks and come along with ways in which they could be reinforced. It is,

therefore, the primary objective of this study to appraise the management of pharmaceutical waste in Vhembe District, Limpopo Province, South Africa.

1.3 Motivation of the study

Incineration thermal treatment option, incorporated with emission control systems, are readily available to treat and manage pharmaceutical waste in high-income countries while low-middle income countries still face challenges with overall medical waste management (Thomas et al., 2016). Studies conducted by Zakiya (2016), and Wang (2017) suggest that environmental impacts and risks of pharmaceutical waste in low-middle income countries may be higher than that in high-income countries because there is limited information regarding pharmaceutical waste and its impacts on the environments and human health. Illegal disposal of pharmaceutical waste has been found in both developed and low-middle income countries, but it is more prevalent in low-middle income countries (Thomas et al., 2010). Low-middle income countries tend to use medical waste disposal methods based on convenience rather than regulations, the most popular method for all kinds of waste, pharmaceutical waste not being an exception, is the landfills which in most cases are poorly constructed, maintained and regulated (Daughton et al., 2017).

A study conducted by Ngqwala (2020) suggested that 70 to 80% of pharmaceutical waste is generated from households therefore consumers should be educated about risks associated with pharmaceutical waste. Pharmacists and other healthcare professionals are key role players in educating the consumers about the risks of pharmaceuticals that have ceased to be used if they land in wrong hands or are discarded inappropriately (HPCSA, 2015). A study conducted by Olaniyi (2018) revealed that there is poor management of medical waste in South Africa, and that - a lack of segregation at source, poor enforcement of medical waste regulatory frameworks and lack of means for proper management - were the major factors contributing to this poor management. More studies, hence, are required on pharmaceutical waste management given that it is regarded as a global emerging contaminant, as stated by Ohtman (2019). Research focusing specifically on pharmaceutical waste management in South Africa is limited compared to general medical waste management studies. Addressing this gap is crucial for proactive measures to mitigate environmental and health risks effectively and reduce associated costs. Studies conducted by Musić et al. (2018), Petrie et al. (2016), González-González et al. (2020), and Radjenović et al. (2009) have extensively examined the presence, levels, sources, and treatment efficiencies of Pharmaceutical Active Compounds (PhACs) in various water bodies and treatment strategies. This study will aid in understanding pharmaceutical waste management

practices from the point of generation to disposal in healthcare facilities, assess disposal practices of consumers and the effectiveness of current management practices. The study will also aid in assessing whether current management practices contribute to the alarming increment of PACs concentration in water and whether current regulatory frameworks are adhered to and are effective. This study will then use all the data obtained to draw a conclusion on whether the current management strategies are sustainable or whether better management strategies are required.

1.4 Research aim and objectives

1.4.1 Main Objective

The overall aim of this study was to assess pharmaceutical waste management practices in Vhembe District, Limpopo Province, South Africa.

1.4.2 Specific objectives

To fulfil the overall aim of this study, the following specific objectives were duly pursued:

- To identify and classify various types of pharmaceutical waste generated in facilities and their management practices.
- To assess the attitude, knowledge, and management strategies of consumers regarding pharmaceutical waste.
- To evaluate the knowledge, attitude, and perception of healthcare professionals towards pharmaceutical waste management.
- To evaluate compliance with existing pharmaceutical waste management regulatory frameworks, identify challenges and weaknesses, and develop an enhanced regulatory framework for pharmaceutical waste management.

1.5 Structure of the dissertation

Chapter 1: Introduction

This section initiated the dissertation by contextualizing pharmaceutical waste management which involves providing a comprehensive understanding of the background, significance, and current state of pharmaceutical waste management. It began with an overview of the global scenario, emphasizing the importance and relevance of addressing pharmaceutical waste. The chapter also discussed the motivations behind studying this issue, outlined specific problems to be addressed, and delineated the research aims, objectives, and scope.

Chapter 2: Literature Review

This chapter presents a comprehensive review of existing knowledge on pharmaceutical waste management. It covers various aspects, such as the classification of pharmaceutical waste, trends in its growth over time and their impacts on health and the environment, an analysis of policies governing its management, and an evaluation of current practices adopted in the waste stream.

Chapter 3: Research Methodology

This chapter offers insights into the methods utilized during the research phase. It introduces the research context, elucidates the chosen methodology, details the techniques employed for data collection, sampling methods, data analysis approaches, and acknowledges any encountered limitations throughout the research process.

Chapter 4: Results and discussions

This chapter discusses the findings of the pharmaceutical waste management, thoroughly presenting and discussing results for each specified objective.

Chapter 5: Conclusions and recommendations

The final chapter syntheses the key findings obtained from the research. It summarizes the research outcomes, offers recommendations, and proposes potential solutions to effectively manage pharmaceutical waste. Focus is placed on the importance of addressing this issue and suggests potential directions for future research in the field of pharmaceutical waste management.

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

This literature review comprehensively explored pharmaceutical waste, covering its generation, management, disposal practices, and regulatory frameworks. By synthesizing a diverse range of scholarly articles, reports, and studies, the review aims to provide a detailed understanding of current pharmaceutical waste management.

2.2 Pharmaceutical products and pharmaceutical waste

Pharmaceutical products are used in health care facilities to save millions of lives by preventing and treating diseases as well as to improve the quality of life of the human population (Muhammed et al., 2021). Pharmaceuticals products are often used interchangeably with medication, with the latter defined as a chemical or chemicals used to diagnose, manage, control, prevent and cure diseases (WHO, 2016). Pharmaceuticals are manufactured by pharmaceutical companies in different forms, such as liquids, tablets, capsules, ointments, drops, inhalers, and injections or implants and delivered to healthcare facilities such as hospitals, clinics, and pharmaceutical outlets, (pharmacies and private health care centres) (Drug Society, 2014). Medication is then accessed by public through prescriptions from medical practitioners given to patients and over-the-counter outlets HPCSA (2009). Pharmaceutical products can be systematically classified into various ways. One of numerous ways to classify pharmaceutical products is through a schedule number which range from 0-8 and is allocated to a pharmaceutical product based on its benefits and drawbacks; the lower the number, the lower the risk. These schedules are rated between 0 and 8, each of which describes a group of pharmaceutical products and their prescription condition as guided by Section 22A (15) of the Medicines and Related Substances Act (101 of 1965) and described by the Standard Treatment Guidelines as well as Essential Medicines List of the Department of Health (DOH) (see Table 2 below).

Table 2.1: Medication schedule number (Source: Innovative Pharmaceutical Association of South Africa, 2016)

Schedule Numbery	Available	Example
0	General shop, e.g. supermarket.	Simple analgesics (e.g. Aspirin, small doses of paracetamol).
1	Over the counter in a pharmacy.	Antibacterial and antifungal skin creams.
2	Over the counter in a pharmacy. Sale record must be kept.	Cough and cold preparations.
3	Prescription only – allowed to repeat for 6 months. Available from the dispensary in the pharmacy.	Medicines for hypertension and diabetes.
4	Prescription only, allowed to repeat for 6 months. Available from the dispensary in the pharmacy.	Anti-infectives (e.g. antibiotics, antivirals, antifungals).
5	Prescription only, repeats stipulated. Available from the dispensary in the pharmacy.	Psycho-active medicines (e.g. sedatives and antidepressants).
6	Prescription only, therapeutic narcotics.	Narcotic painkillers.
7	Controlled substance	Cannabis, methaqualone (also known as mandrax) and heroin.
8	Strictly controlled substances	There are only three of these: amphetamine, dexamphetamine and nabilone.

Schedule 0 products can be purchased over the counter and in supermarkets without a prescription; schedule 1 and 2 substances can only be purchased without a prescription from a pharmacy, however, with the pharmacist's advice. Schedule 2 substances are subject to dispensing control and demand the pharmacist to keep a schedule 2 register and schedules 3 - 5 substances may be purchased from a pharmacy only, with a doctor's prescription.

Another way of classifying pharmaceuticals is using dosage type, referring to the specific form or presentation in which medications are administered to patients. Dosage types encompass a variety of formulations tailored to meet different patient needs and medical requirements. According to the "British National Formulary" (BNF) (Joint Formulary Committee, 2022), dosage types include solid oral forms such as tablets and capsules; liquid formulations like solutions and syrups; injections administered through various routes; topical preparations for skin application; inhalation devices for respiratory conditions; suppositories for rectal or vaginal insertion; powders, as well as implants for sustained release. Each dosage type serves a distinct purpose, addressing

factors such as patient preferences, the nature of the medical condition, and the pharmacokinetics of the drug (WHO, 2019), for instance, tablets and capsules are convenient for oral administration, while injections provide rapid and precise delivery for certain medications. This classification aids healthcare professionals in prescribing and administering pharmaceuticals in the most effective and patient-friendly manner (FDA, 2015). Figure 2.1 below illustrates the different types of pharmaceutical products.

Figure 2.1**:** Pharmaceutical dosage type: source: adopted from Stericycle (2010)

Pharmaceuticals can also be classified based on type and function which provides valuable insights into the therapeutic purposes and roles of each product within the healthcare ecosystem, contributing to a more nuanced understanding of their applications (Smith et al., 2020; Johnson & Williams, 2019). This approach allows healthcare professionals to categorize pharmaceuticals based on their specific characteristics and intended therapeutic effects; for example, medications may be grouped by their functions, such as antipyretics, analgesics, or antihypertensives, providing a clear framework for understanding their functions in treating fever, pain, or high blood pressure, respectively (Brown et al., 2021). Additionally, this classification helps in tailoring treatment plans to individual patient needs, ensuring that the right medication is chosen for a particular medical condition. Table 2.2 below shows a summary of different categories of pharmaceutical products found in facilities.

Table 2.2: Summary of distinct types of pharmaceutical drugs and their functions: source (Drug Society, 2016)

Types of pharmaceutical	Function	Examples
Anti-inflammatory drugs	Therapeutic drug which contains agents to block certain substances in the body that cause inflammation. They are used to relieve or reduces pain, inflammation, fever, and prevents blood clots.	Aspirin, ibuprofen, diclofenac etc.
Anti-biotics drugs	Medication is used to treat and prevent bacterial infections in humans and animals. Functions by releasing agents that acts against bacteria in the body.	Penicillin, amoxicillin, cephalexin, ciprofloxacin, clindamycin, metronidazole Azithromycin
Anti-viral drugs	Medication used to treat and prevent viral infections by inhibiting and suppressing their growth.	Antiretrovirals (ARVs), Zanamivir, peramivir, and oseltamivir
Hormonal drugs	Medication that functions to stop, block, add or remove hormones. It is often used to establish balance or enhance hormonal performance in the body.	Contraceptives and steroids
Anti-analgesics (Pain Killers)	Drugs used to manage and relieve pain, also known as 'pain killers'. These drugs contain agents that blocks pain in the body and often contain anti-inflammatory agents as well.	Compral, ibuprofen, panado,
mins\supplements	Substances taken to correct deficiencies in the system, often called 'immune boosters'	Multivitamins, thiamin, riboflavin,niacin, pantothenic acid, biotin, vitamin B6, vitamin B12, and folate/folic acid).
Anti-pyrectics	Medication used to reduce fever and treat flu/cough	Paracetamol, Aspirin, metamizole, nebumetone, nimesulide, phenazone, rodinal (para-amino phenol)
Personal care products	Products used for personal hygiene and may at times be prescribed to treat and manage a particular issue with the body, such as skin. They are mostly for external use and often accessed over the counter.	Creams, ointments, soaps, hair products and cosmetics.

After pharmaceutical products are received and used, various types of waste can be generated. This includes partially used or unused dosage, personal medications of patients, expired drugs in dispensaries and hospitals, and wastage due to inappropriate donations or inadequate stock management and distribution (Sui, et al., 2016). According to Environmental Protection Agency (EPA, 2016) pharmaceutical waste is defined as any unused, expired, or leftover chemical or biological product medicine that is aimed for use in the - diagnosis, cure, mitigation, care, treatment, or prevention of disease or injury, of humans or animals. These products include, but not limited to - drugs, vaccines, sera, and discarded items - used in the handling of pharmaceuticals, such as bottles, boxes, gloves, masks, connecting tubing, and drug vials that are no longer required (Tabash et al., 2016). Pharmaceutical waste may be classified by circumstances of use, quantity, or concentration inherent in the physical, chemical, or toxicological characteristics (this could significantly pose adverse effect on public health and the environment) (Bungau et al., 2018). Pharmaceutical waste cannot be recycled and reused as general waste, thus it is important to minimise its generation (Lee et al., 2016).

2.3 Types and sources of pharmaceutical waste

Pharmaceutical waste exhibits diverse types and originates from various sources within healthcare systems and beyond (Kusturica et al., 2012; Khan et al., 2017). For instance, primary sources contributing to pharmaceutical waste, include healthcare facilities, pharmacies, manufacturing units, households, and veterinary care facilities (Khan et al., 2017; Corcoran et al., 2010). Each source generates specific types of waste, such as expired drugs from healthcare facilities and unused or partially-used medications from households and pharmacies (Volkow et al., 2019).

Pharmaceutical waste extends beyond human healthcare settings, incorporating veterinary care facilities and agricultural practices (Shah et al., 2011; Tong et al., 2011). Veterinary care facilities and farms contribute to this waste stream through medications used for animal health, disease prevention, and productivity enhancement. Agricultural sectors utilize pharmaceuticals for crop protection and enhancement, leading to the generation of specific types of waste, including pesticides, herbicides, and growth-promoting agents (Zuccato et al., 2010). These sources collectively contribute to the heterogeneous nature of pharmaceutical waste, as they contain various active pharmaceutical ingredients (APIs), chemicals, and potentially hazardous compounds (World Health Organisation, 2018; Bound & Voulvoulis, 2005). Figure 2.1 below illustrates different types of pharmaceutical waste.

Figure 2.2: Distinct types of pharmaceutical wastes (Source adopted from: National Pharmaceutical Returns, 2019.)

2.4 Pharmaceutical waste management strategies

Effective pharmaceutical waste management is imperative to mitigate the environmental and health risks associated with inappropriate disposal.. Various organizations, including the World Health Organization (2012), National Institute for Occupational Safety and Health (2016), and Environmental Protection Agency (2016), have established comprehensive guidelines for healthcare and medical waste management, specifically addressing pharmaceutical waste. These guidelines outline a systematic approach from waste generation to disposal, encompassing crucial stages such as segregation, labelling, packaging, transportation or collection, treatment, and final disposal.

2.4.1 Segregation Practices

The Occupational Safety and Health Administration (OSHA) emphasizes the importance of segregating medical waste to ensure the safety of healthcare personnel (OSHA, 2015). In the broader context, effective healthcare waste management, including pharmaceutical waste segregation, is crucial for protecting both healthcare workers and the environment, while also mitigating public health risks (Smith et al., 2019). Numerous studies, including those conducted by Garcia et al. (2023), Smith and Brown (2022), and Johnson et al. (2017), have consistently underscored the crucial significance of proper waste segregation practices within healthcare facilities. Notably, Figure 2.2 serves as a visual representation, illustrating how waste can be effectively segregated and sorted, highlighting the urgency of precise identification in this process.

Figure 2.3: Medical waste segregation (Source: Seranya, 2021)

There are numerous ongoing efforts in waste management, however, challenges in persist, marked by the lack of standardised guidelines and inconsistent segregation practices (Villanueva et al., 2020). Notably, Olanyi's 2018 investigation in South Africa revealed that poor segregation at the source significantly contributes to inadequate medical waste management which include pharmaceutical waste. This sentiment is echoed by Smith and Jones (2019), whose research identified deficiencies in the segregation of medical waste, emphasizing the urgency for enhanced practices at the source to improve overall waste management's efficiency. A study by Rodriguez et al. (2020) further underscored concerns about insufficient segregation practices, hence, the necessity for targeted interventions to address these issues. The lack of consistency in segregation practices poses a significant risk, as it may lead to the inadvertent mixing of hazardous pharmaceuticals with general waste, thereby increasing environmental hazards. Figure 2.3 below provides a visual representation of non-segregated pharmaceutical waste.

Figure 2.4**:** Non-segregated pharmaceutical waste (Source: Tribune India, 2021)

2.4.2 Packaging and labelling

Proper packaging and labelling are pivotal components for effective waste management strategies aimed at safeguarding public health and the environment (World Health Organization [WHO], 2019). Regulatory guidelines for pharmaceutical waste management vary, but certain universally-recognized principles are commonly adhered to.

Labels on pharmaceutical waste containers play a vital role in proper waste identification and management. These labels should include information about the type of waste, potential hazards, and any specific handling instructions. The goal is to provide clear and concise information that facilitates safe handling and disposal of pharmaceutical waste. Additionally, the use of symbols and pictograms can enhance communication, especially in diverse healthcare environments where multiple languages may be spoken (WHO, 2018). Pharmaceutical waste must be segregated from other medical waste to prevent cross-contamination (WHO,2015). Containers, such as, labelled bins or bags, should be utilised to ensure effective containment, labels indicating their attributes, like - leak-proof, puncture-resistant, and securely closable designs - to minimise the risk of spills and exposure (U.S. Environmental Protection Agency [EPA], 2016). Color-coding of pharmaceutical waste containers is another crucial aspect of effective packaging. This practice aids in easy identification and segregation, aligning with established standards and guidelines.

The use of specific colours for different waste categories enhances safety and reduces the likelihood of errors during waste management processes (EPA, 2016).).

2.4.3 Collection and transportation of pharmaceutical waste

The transport and collection of medical waste, particularly pharmaceutical waste, are critical phases in the waste management process, demanding meticulous attention to regulatory standards, containerization, and transportation methods (U.S. Department of Transportation, 2021; EPA, 2016). Adhering to stringent regulatory guidelines is paramount to ensure the safety of healthcare workers, the public, and the environment. Proper containerization involves securely containing pharmaceutical waste in leak-proof, puncture-resistant, and appropriately labelled containers, with color-coding aiding in easy identification and separation from other waste types (EPA, 2016).

Dedicated transportation methods, utilising specialized vehicles equipped with safety features, are employed to minimise the risk of spills, leaks, and exposure during transit (DOT, 2021; EPA, 2016). Compliance with transportation guidelines, including route planning and emergency response protocols, is imperative to prevent accidents and ensure the secure delivery of waste to disposal facilities. Providing continuous training and awareness initiatives for healthcare personnel involved in pharmaceutical waste transport and collection, are essential (World Health Organisation [WHO], 2019). Regular training programs should cover proper handling procedures, loading and unloading protocols, and emergency response measures; these processes contribute to a safer working environment and reduce potential risks. Accurate documentation is crucial throughout the transportation and collection process. Comprehensive record-keeping, including details on the types and quantities of waste transported and any incidents or accidents, facilitates traceability, regulatory compliance, and the identification of areas for improvement (DOT, 2021; EPA, 2016).

The collection and transport methods for pharmaceutical waste exhibit significant variation globally, with high-income countries implementing specialised services and stringent regulations (Carter et al., 2021). In contrast, developing regions face challenges such as inadequate infrastructure and limited collection services, leading to improper disposal practices (Chigudu et al., 2020). Disparities in waste collection infrastructure, particularly in resource-constrained settings, underscore the need for targeted interventions to improve waste management practices (Miller & Johnson, 2018). The World Bank (2019) emphasizes the necessity of comprehensive waste management systems in low-income countries to mitigate environmental and public health risks associated with improper disposal.

2.4.3 Treatment options for pharmaceutical waste

The treatment of pharmaceutical waste encompasses diverse methods, including incineration, chemical treatment, and advanced oxidation processes as indicated in Table 2.3 below. Incineration has historically been a widely adopted method, valued for its efficacy in destroying hazardous compounds, however, concerns have arisen regarding potential air pollution resulting from emissions generated during the incineration process (Brunner et al., 2021). In pursuit of more sustainable alternatives, chemical treatment and advanced oxidation processes have emerged as promising methods for neutralising pharmaceutical compounds in waste, however, despite their potential benefits, debates persist regarding the scalability and cost-effectiveness of these alternatives (Wang et al., 2022).

Table 2.3: Pharmaceutical waste treatment methods

Treatment Method	Description
Incineration	Combustion of pharmaceutical waste at high temperatures to destroy hazardous compounds.
Chemical Treatment	Use of reactive substances to neutralize or transform pharmaceutical compounds, reducing their harmfulness.
Advanced Oxidation Processes	Implementation of chemical reactions, often involving powerful oxidizing agents, to break down pharmaceutical compounds in waste.
Encapsulation	Embedding pharmaceutical waste in materials to immobilise contaminants, preventing their release into the environment.
Non-Incineration On-Site Treatment	On-site treatment methods excluding incineration, including autoclaving, microbial treatment, and thermal methods.
High-Temperature Steam Sterilization	Utilising high-temperature steam to sterilize pharmaceutical waste, reducing microbial load and infection risks associated with the waste.

Source Adopted from EPA (2011)

2.4.5 Disposal methods

Disposal practices significantly impact the environment and public health. WHO (2016) has provided guidelines on various methods which should be employed by healthcare facilities and anyone in possession of pharmaceutical waste to ensure proper disposal for the various types of pharmaceutical waste. Below is a list of methods for pharmaceutical waste disposal according to WHO (2011). Table 3 below presents several pharmaceutical waste disposal methods employed in various facilities.

Table 2.4: Pharmaceutical waste disposal methods

Disposal Method	Description
Return to manufacture or facility	A method whereby consumers are encouraged to return unused, expired and partially used pharmaceutical waste to facilities for proper disposal.
Encapsulation	Encapsulation involves immobilising the pharmaceuticals in a solid block within a plastic or steel drum. Drums should be cleaned prior to use and should not have contained explosive or hazardous materials previously
Landfilling	This is the method where waste is buried in a shallow pit. Properly constructed and operated landfill sites offer a relatively safe disposal route for municipal solid wastes, including pharmaceutical waste.
Incineration	The process of using high temperatures to destroy microorganisms present in waste through combustion, ensuring that the waste is completely oxidized. Pharmaceutical waste should only be incinerated in incinerators operating at temperatures of 820°C or higher to ensure complete destruction of hazardous substances.
Sewer	A method whereby waste is dissolved and drained into a sink and discharged into a sewage. Some liquid pharmaceuticals, e.g. syrups and intravenous (IV) fluids, can be diluted with water and flushed into the sewers in small quantities over a period of time without serious public health or environmental affect.

Source Adopted from EPA (2011)

Landfilling is the predominant and commonly used method for the disposal of pharmaceutical waste, despite its associated environmental risks. Deng et al. (2020) emphasize that pharmaceutical waste, including expired or unused medications, is often directed to landfills, posing significant concerns about potential leaching and contamination of soil and water sources.

While landfilling has been the conventional method, recent discussions in literature, such as the work of Benson et al. (2023), highlight a shifting away from landscape with a growing interest in exploring sustainable disposal methods that incorporate energy recovery through waste-to-energy processes. , Landfilling remains deeply ingrained in waste management practice, despite this emerging trend, due to many factors including convenience, familiarity, feasibility, and cost effectiveness (Larsson, 2018; Daughton, 2010).

2.5 Risks and impacts of pharmaceutical waste

Pharmaceutical chemicals pose a severe threat to both the environment and public health, due to their ability to permeate the ecosystems through multiple pathways (Andrew et al., 2011). The disposal of pharmaceutical waste into the environment presents a concerning issue, with potential consequences for waterways and beyond (Moges et al., 2014). Hazards associated with pharmaceutical waste span their entire lifecycle, involving the stages of - collection, handling, storage, transportation, treatment, and disposal. Significant contributors to environmental contamination are the improper disposal of unused or expired medications by consumers, pharmaceutical production companies and pharmaceutical outlets, which include healthcare facilities and retailers such as pharmacies, whether through flushing them down toilets or discarding them inappropriately (Bound and Voulvoulis, 2016). This practice leads to the direct release of pharmaceutical compounds into wastewater treatment systems or landfills, ultimately contaminating water bodies and soil, thereby, posing a threat on the environment and public health (Banwat et al., 2018). Figure 2.5 below illustrates the pathway of pharmaceutical waste in the environment.

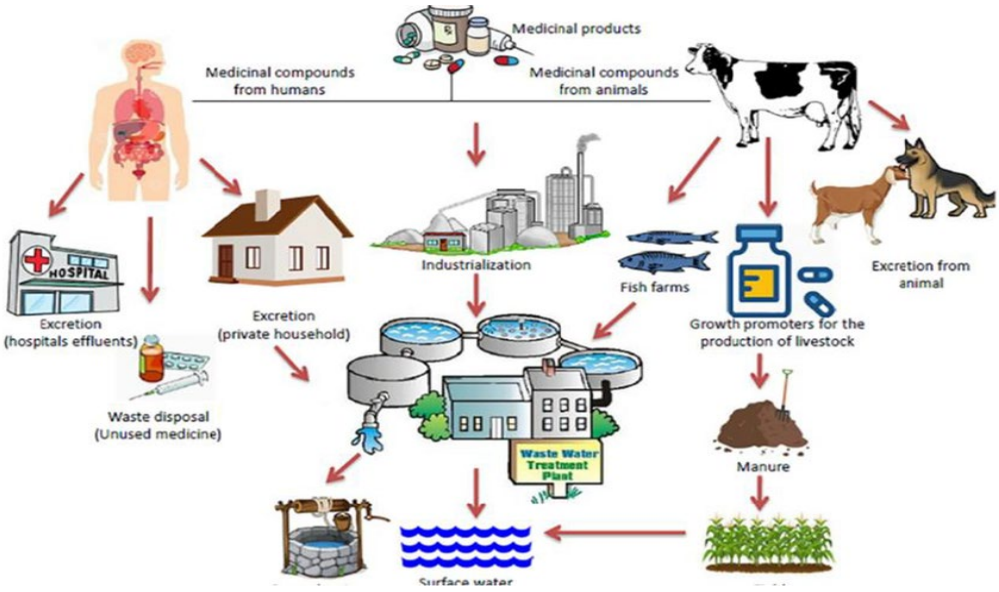

Figure 2.5: Pathway of pharmaceutical waste pollution (Kumar et al., 2019)

2.5.1 Environmental Risks Associated with Pharmaceutical Waste

Pharmaceutical waste poses significant environmental risks due to the presence of active compounds and chemicals. Improper disposal, such as flushing unused medications or discharging them into wastewater systems, leads to contamination of water bodies (Du et al., 2019). This contamination can affect aquatic ecosystems, disrupting the balance of flora and fauna and leading to bioaccumulation in aquatic organisms. Studies have shown adverse effects on fish, altering their reproductive systems and behaviour due to exposure to pharmaceutical residues in water bodies (Ortiz de Garcia et al., 2020).

The introduction of hormonal pharmaceuticals, particularly contraceptives, into aquatic ecosystems poses a significant threat to aquatic life and further exemplifies how pharmaceutical waste permeates the environment. Hormonal compounds can disrupt the endocrine systems of aquatic organisms, affecting their reproductive and developmental processes. Additionally, the persistence of pharmaceutical compounds in the environment contributes to long-term ecological risks, impacting biodiversity and ecosystem stability. Soil is also susceptible to contamination from pharmaceutical waste. Land application of bio-solids containing pharmaceutical residues from wastewater treatment plants, leads to soil pollution, affecting microbial communities and potentially entering the food chain through plants (Liu et al., 2021). This contamination not only poses risks to agricultural productivity but also raises concerns about human exposure to pharmaceutical residues via food consumption. Figure 2.6 below illustrates pharmaceutical waste found in different receiving mediums of the environment.

Figure 2.6: Pharmaceutical waste found in the environment. (Source: James Ashworth 2022; US Bioclean, 2019)

2.5.2 Human Health Risks Associated with Pharmaceutical Waste

The presence of pharmaceutical residues in the environment poses potential health risks to human populations. Contaminated water sources serve as a primary route of exposure, with studies linking the presence of pharmaceuticals in drinking water to adverse health effects (Jia et al., 2020). Prolonged exposure to low concentrations of pharmaceuticals has been associated with endocrine disruption, reproductive issues, and the development of antibiotic-resistant bacteria in humans (González-Pleiter et al., 2019). Vulnerable populations, such as pregnant women and children, face increased risks due to their heightened susceptibility to the effects of these chemicals, therefore, pharmaceutical waste mismanagement contributes to occupational health risks among waste handlers and workers in healthcare facilities. Improper handling and lack of protective measures can lead to direct exposure to potent pharmaceuticals, potentially causing acute health effects or long-term complications (Papaspiliou et al., 2022). Inhalation of fumes from incineration of pharmaceutical waste and skin contact during handling are significant concerns as they lead to potential health issues among workers.

Research, of Larsson (2018) and Kümmerer (2009), underscores the link between the release of pharmaceuticals into the environment and the development of antibiotic resistance. This poses a serious risk to the effectiveness of this crucial medications, leading to increased healthcare costs as alternative treatments for resistant infections become more expensive and resource-intensive (Larsson, 2018; Rizzo et al., 2013).

Beyond individual health impacts, the societal consequences of pharmaceutical waste are profound. Improper disposal results in environmental contamination, creating a complex challenge that affects communities and healthcare systems globally (Larsson, 2018; Glassmeyer et al., 2008). The ramifications from this are particularly pronounced in regions with limited resources and infrastructure, where the social and economic burdens of addressing environmental contamination and health issues related to pharmaceutical waste, are significant. This underscores the urgent need for comprehensive strategies to manage pharmaceutical waste and mitigate its associated societal impacts.

The socioeconomic dimensions of pharmaceutical waste emphasize the broader implications for communities and healthcare systems. The inadequate treatment of pharmaceutical wastewater

strains both individual communities and larger healthcare infrastructures, particularly in regions with limited resources, exacerbating existing social and economic disparities (Larsson, 2018; Daughton, 2010). Effectively addressing pharmaceutical waste, hence, is not only crucial for safeguarding public health but also for promoting social equity and sustainability on a global scale.

Effluents generated from pharmaceutical manufacturing, especially in processes like antibiotic formulation, are recognised as containing persistent and challenging compounds. The necessity for adopting appropriate technology in treating pharmaceutical wastewaters is underscored by stringent water quality regulations aimed at environmental protection (Deegan et al., 2011). Traditional wastewater treatment methods, such as activated sludge, have proven inadequate in completely removing active pharmaceutical ingredients and other constituents present in industrial waters (Mudri, 1968).

The impacts of inadequately treated pharmaceutical wastewater are manifold. Firstly, the release of untreated or poorly-treated effluents can result in environmental contamination, posing risks to aquatic ecosystems and potentially affecting human health through the contamination of water sources (Ruhí et al., 2019). Secondly, the presence of pharmaceutical residues in water bodies contributes to the escalating problem of antibiotic resistance, a significant global health concern (Larsson, 2018), therefore, addressing the treatment and management of pharmaceutical wastewater is imperative to protect both environmental and public health.

2.6 Status of pharmaceutical waste management

Diseases have no political or geographical boundaries, therefore, all states generate pharmaceutical waste in their attempts to treat and manage diseases (Khan et al., 2019). Healthcare waste management is among the critical concerns, not only in low-middle income countries but is a global concern because of the detrimental effects of exposure which could possibly range from local and all the way to international effects due to water transfer basins and schemes (World Health Organization, 2016). The amount of pharmaceutical waste generated is rapidly rising and this could be attributed to an alarming growth in global population, along with the excess of medical facilities, and demand for pharmaceuticals to cater for the increasing diseases in the population (Caniato et al., 2015). Due to this situation, the WHO, concerned citizens, and other health organizations have developed and issued guidelines for handling and disposal of pharmaceutical waste, however, these guidelines are rarely followed, since every country uses methods that best suit their budget and objectives (Nialmul, 2017). This indicates that there is a critical need for stricter enforcement of these guidelines and the development of

more universally-applicable and sustainable waste management practices to effectively mitigate the adverse effects of pharmaceutical waste on a global scale.

2.6.1 Pharmaceutical waste management in high-income countries

North America, Europe and Asia are reported to be in the frontline when it comes to medical waste management and this is owed to their technological advances and adequate administrative provisions for waste management (Susmita et al., 2016). Most developed nations such as the United States (US), Canada, and United Kingdom have various options to handle their pharmaceutical waste and these are often tailored to each type of pharmaceutical waste with incineration being the most predominant method for disposal (Ariffin et al., 2019; Baresel et al., 2015)., High-income countries have implemented standards, policies, and laws to specifically deal with the management of pharmaceutical waste and these laws stretch from, the point of generation, handling, storage, and transportation (Praveena et al., 2018). Each country has by-laws to deal with pharmaceutical waste, although, high-income countries have made it a point that each institution or person generating pharmaceutical waste is held accountable for its management and ensuring its proper disposal (DEA, 2012). A review by Kalaji (2017), however, has revealed that high-income countries are the largest producers of pharmaceuticals and supply to the rest of the world, making them the largest generators of pharmaceutical waste, at rates higher than they can manage .This conclusion is supported by Megan (2019) who emphasized that certain parts of high-income countries are often overlooked and are on the receiving end of pharmaceutical waste which are detrimental to them. A report filed by the University of South Florida (2019) indicated that, although, developed continents, such as North America are deemed to be the most advanced to deal with medical waste, certain regions in the continent that are not as developed are often not studied with the intent to provide a more comprehensive overview, making it premature and inaccurate to conclude that the entire continent is advanced in managing medical waste.

2.6.2 Pharmaceutical waste management in low-middle income countries

Low-middle income countries are still beset with challenges, such as poverty, poor sanitary conditions, and limited resources, such as insufficient clean drinking water, food, electricity, and ineffective waste management systems (Nipa et al., 2017). These challenges are often tackled according to priorities of which waste management is the least prioritized, leading to the public relying on any method feasible for them to manage and dispose of their waste (Paudel et al., 2019). According to the World Bank Group (WBG 2019-2023), waste management in Africa is often the last and least prioritised matter.

Low-middle income countries are faced with a challenge regarding the management of medical waste in general and often do not segregate their medical waste at source (Olanyi et al., 2018); this leads to all types of medical waste such as pharmaceutical waste being managed in an umbrella approach (Selfoui, 2015). Most low-middle income countries have not yet advanced into the management of pharmaceuticals as a specialised type of waste, and this has resulted in difficulty in tracking pharmaceutical waste management status and the extent of their impacts (Thomas, 2017).

Lack of funding for healthcare systems, poor training, and lack of awareness of policies and legislations on handling pharmaceutical waste have led to increased improper handling of waste within hospitals, healthcare facilities as well as the transportation and storage of medical waste in most low-middle income countries (Olaniyi et al., 2018/2019). Some countries, including Ethiopia, Botswana, Nigeria, and Algeria, do not have national guidelines in place to adhere to the correct disposal of such waste (Gudeta, 2010).

Incineration is the most common and favored method for medical waste, including pharmaceutical waste, disposal in most countries, however most of the incinerators used in low-middle income countries are often poorly maintained with lower temperatures below the standard required for proper incineration (Jovanovic et al., 2016). Other methods of pharmaceutical waste disposal in low-middle income countries are landfilling where pharmaceutical waste is mixed with general waste and transported to the landfill for final disposal (Yong, 2015); in most cases, the landfills are often not properly lined and often lead to groundwater contamination (Winfeld et al., 2018). Landfilling, open burning, dumping, and using the drainage systems are the most common used unsafe methods for pharmaceutical waste disposal, in most low-middle income countries (Tabash et al., 2016). This was also confirmed by Selfoui (2015) who concluded that countries such as Bangladesh, Afghanistan, Congo, and Kenya are amongst the most low-income countries using unsafe methods to dispose of their pharmaceutical waste. A study by Seleshie (2018) revealed that the inconsistencies and non-uniformity in pharmaceutical waste management makes it difficult to estimate or study the extent of pharmaceutical waste impacts on both the environment and human health.

Comparative studies by Nipa (2017) and Yasir (2017) revealed that pharmaceutical waste traces were detected in water samples from both developed and low-middle income countries, however, high-income countries have advanced technologies to purify water, while low-middle income

countries cannot afford these technologies, exacerbating water contamination issues. According to Busfield et al. (2015) most developing and under-developing countries often receive enormous amounts of pharmaceuticals in donations from multiple organizations, such as UNICEF, United Nations (UN) and WHO to reduce mortalities and manage diseases or distresses that come with pandemics, however, according to a study conducted by Mike, (2012) these donations also contribute to the large amounts of pharmaceutical waste in these countries. One reason for this is these donations come in large amounts, which these countries do not have storage capacity to keep them; this leads to pharmaceutical wastage in large amounts, and they have minimum to no resources, funds, facilities, and technologies to properly dispose of the generated pharmaceutical waste.

2.6.3 Pharmaceutical waste management in South Africa

The Department of Environmental Affairs (DEA) of South Africa has drafted waste management guidelines for the country, outlining how different types of wastes should be handled, managed, and disposed. In South Africa, medical waste is defined and legislated through a variety of policies and legal documentation and is also assessed based on the risk it may cause to health (Hodes, 2019). The Department of Health has issued policies for management of medical waste which also breaks it down into different categories such as pharmaceutical waste; the Department also provides a step-by-step guide on the correct management of medical waste, including storage and contacting the contractors for removal. Studies conducted by Maseko (2014) and Olanyi (2019) however, have identified gaps in policy framework, nationally and institutionally, on medical waste management; both studies reported the lack of uniformity in medical waste management in medical facilities. These studies also reported that poor waste management practices were due to poor training, lack of commitment by stakeholders, inadequate infrastructure, and resources, as well as poor budget support. Addressing these systemic challenges, therefore, is crucial for improving medical waste management practices globally, ensuring adherence to standards, and minimizing environmental and health risks associated with improper disposal.

Health Professional Council of South Africa (HPCSA) has developed a comprehensive healthcare risk waste (HCRW) management guideline booklet, that provides a full definition of HCRW and classified the waste into various sub-categories. The booklet also discusses the risks associated with improper management of medical waste to human health and highlights the roles and responsibilities of each health-care category in ensuring proper management of HCRW. HPCSA, WHO, DEA and DOH have all stipulated that medical waste should be segregated at source of

generation to ensure that each category is managed and disposed in a suitable manner. The studies by Motlatla, (2015) and Olanyi et al. (2018) reported that majority of healthcare facilities in South Africa do not classify or segregate their medical waste at source, therefore, making it difficult to identify and deal with the risks associated with each category of waste being generated.

2.7 Pharmaceutical waste management in households

While pharmaceuticals play a crucial role in healthcare, improper disposal can lead to environmental contamination and pose risks to public health. Improper disposal practices are prevalent among households, with many individuals discarding unused or expired medications directly into household trash or flushing them down the toilet as indicated by studies by Daughton (2010) and Glassmeyer et al. (2009). Consumers' knowledge and perception of pharmaceutical waste management are pivotal factors influencing their disposal practices. Studies by Smith et al. (2017), Greenberg et al., (2019), Jansson et al. (2017) and Brown et al. (2021) have highlighted a gap in consumers' awareness regarding the environmental impacts of improper disposal and the potential for pharmaceutical residues to enter water systems.

Consumers' perception of pharmaceutical waste management is multifaceted, influenced by factors such as awareness campaigns, accessibility of disposal facilities, and the perceived environmental impact. A study by Johnson and Davis (2020) found that consumers are more likely to adopt proper disposal practices when provided with clear information and convenient disposal options. Challenges, however, persist, as demonstrated by the work of Anderson et al. (2018), which revealed a lack of education regarding pharmaceutical waste disposal among consumers.

Research by Fong and Newton (2017) suggests that targeted public awareness campaigns and educational programs can significantly influence household pharmaceutical waste management behaviors. These interventions address gaps in consumer knowledge, thus, fostering responsible disposal habits. Additionally, studies by Tong et al. (2011) and Hogenkamp (2012) focus on the necessity of clear communication strategies to inform the public about the environmental consequences of improper disposal and to promote responsible pharmaceutical waste management at the household level.

Legal and policy considerations play a crucial role in shaping household pharmaceutical waste management. The absence of clear regulations and guidelines can contribute to inconsistent practices among households, as noted by Ruhoy and Daughton (2008). Conversely, effective policy frameworks, such as take-back programs and extended producer responsibility initiatives,

have been shown to enhance proper disposal practices by providing convenient and responsible avenues for pharmaceutical waste disposal, according to Daughton and Ruhoy (2009) and McCullough et al. (2016).

2.8 The role of healthcare practitioners in pharmaceutical waste management

Healthcare practitioners also play a crucial role in the generation, handling, and disposal of pharmaceutical waste within the healthcare settings. The proper management of pharmaceutical waste is a paramount concern within the healthcare settings, requiring the active involvement and knowledge of healthcare professionals. This group includes professional nurses, pharmacists, and medical practitioners (Mohlaba, 2021). The disposal of medications in healthcare settings falls under their jurisdiction, emphasizing the need for these professionals to be well-informed about safe and appropriate pharmaceutical waste management practices. Healthcare professionals play a pivotal role in guiding and informing patients regarding pharmaceutical waste management, both when prescribing and during purchase. Research, however, indicates that healthcare professionals often do not view healthcare waste management as their responsibility, resulting in inadequate attention to proper waste management in healthcare facilities (Ngqwala & Muchesa, 2020). Addressing this challenge necessitates comprehensive training of healthcare professionals, given their role as primary handlers of healthcare waste and their responsibility for prescribing medications to patients (Akkait et al., 2020). These professional, despite various training efforts offered to them, contribute to some of the multiple factors contributing to inadequate healthcare waste management, such as non-provision of relevant information to consumers, a lack of essential resources such as waste containers, suitable infrastructure for waste storage, and financial constraints (Mugasi & Chasi,2018).

Studies by Williams et al. (2019) and Green et al. (2020) also highlight the responsibilities of healthcare practitioners, including proper segregation of waste, accurate identification of hazardous pharmaceuticals, and adherence to established disposal guidelines. The knowledge and compliance levels of practitioners significantly influence the overall effectiveness of pharmaceutical waste management within healthcare facilities., Healthcare practitioners encounter challenges in pharmaceutical waste management, despite their pivotal role. Research by Martinez et al. (2021) identifies issues such as inadequate training, lack of awareness, complexity of regulatory requirements and time constraints as barriers that hinder practitioners from consistently following optimal waste management practices (Doe et al., 2018).

Interventions aimed at improving the involvement of healthcare practitioners in pharmaceutical waste management have been explored in the literature. Educational programs, as suggested by Brown and Smith (2017) and Jones et al. (2022), have demonstrated positive outcomes in enhancing practitioners' knowledge and compliance with waste management protocols. The implementation of user-friendly disposal systems and clear communication channels within healthcare facilities has been proposed as a strategy to streamline practitioners' engagement in waste management practices (Miller et al., 2020; Patel and Clark, 2021).

Regulatory frameworks and policies also shape the role of healthcare practitioners in pharmaceutical waste management. Compliance with guidelines, such as the Resource Conservation and Recovery Act (RCRA) is crucial in ensuring appropriate disposal practices (EPA, 2017), however, studies by Anderson et al. (2019) and Yang et al. (2020) highlight the need for ongoing evaluation and refinement of these policies to address emerging challenges and promote sustainable pharmaceutical waste management practices.

CHAPTER THREE

RESEARCH METHODOLOGY

3.1 Introduction

This chapter outlines the chosen design and methodology for the study, delving also into the geographical characteristics of the study area. The study approach employs a mix of both qualitative and quantitative and the methods selected are tailored to the specific research objectives under consideration.

3.2 Study area

This study was conducted in the Vhembe District, situated in the northern part of South Africa's Limpopo Province; it shares borders with Capricorn, Mopani District municipalities in the eastern and western directions, respectively, as illustrated in Figure 3.1. The sharing of borders extends to Zimbabwe and Botswana in the Northwest and Mozambique in the southeast through the Kruger National Park respectively. The District comprises of four local municipalities: Thulamela, Makhado, Musina, and Collins Chabane. The Vhembe District predominantly consists of rural regions, with Thohoyandou in Thulamela and Louis Trichardt in Makhado serving as peri-urban areas, together they constitute 15% of the urbanized zone in Vhembe, while the remaining 85% of the District comprises of rural areas (IDP, 2019).

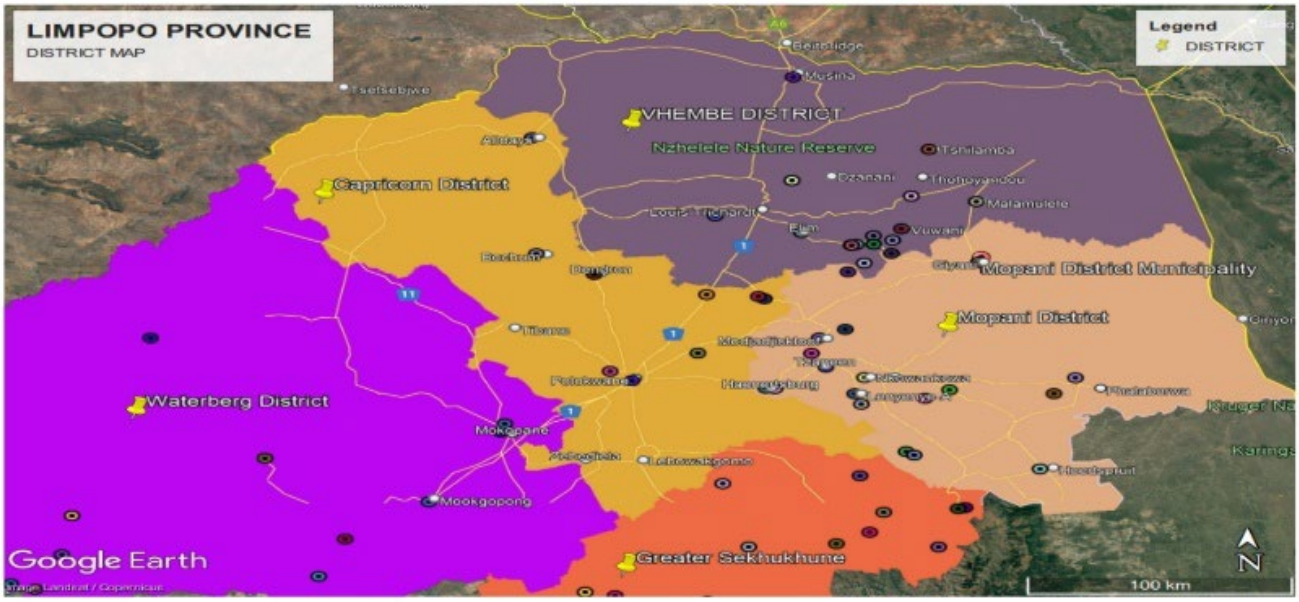

Figure 3.1: District Municipalities in Limpopo Source: (Researcher, 2024)

Statistics South Africa (2021) note Makhado and Thulamela local municipalities as the District's most populous local municipalities, followed by Collins Chabane, then Musina local Municipality, which is the least populated. According to the Limpopo Department of Health (2018/19), the Vhembe District hosts a total of 112 clinics, 7 public hospitals, 55 private practices, and 28 pharmaceutical outlets. The district is also home to three private medical centres situated in Thulamela, Makhado, and Musina. Figure 3.2 below illustrated the distribution of healthcare facilities in the district.

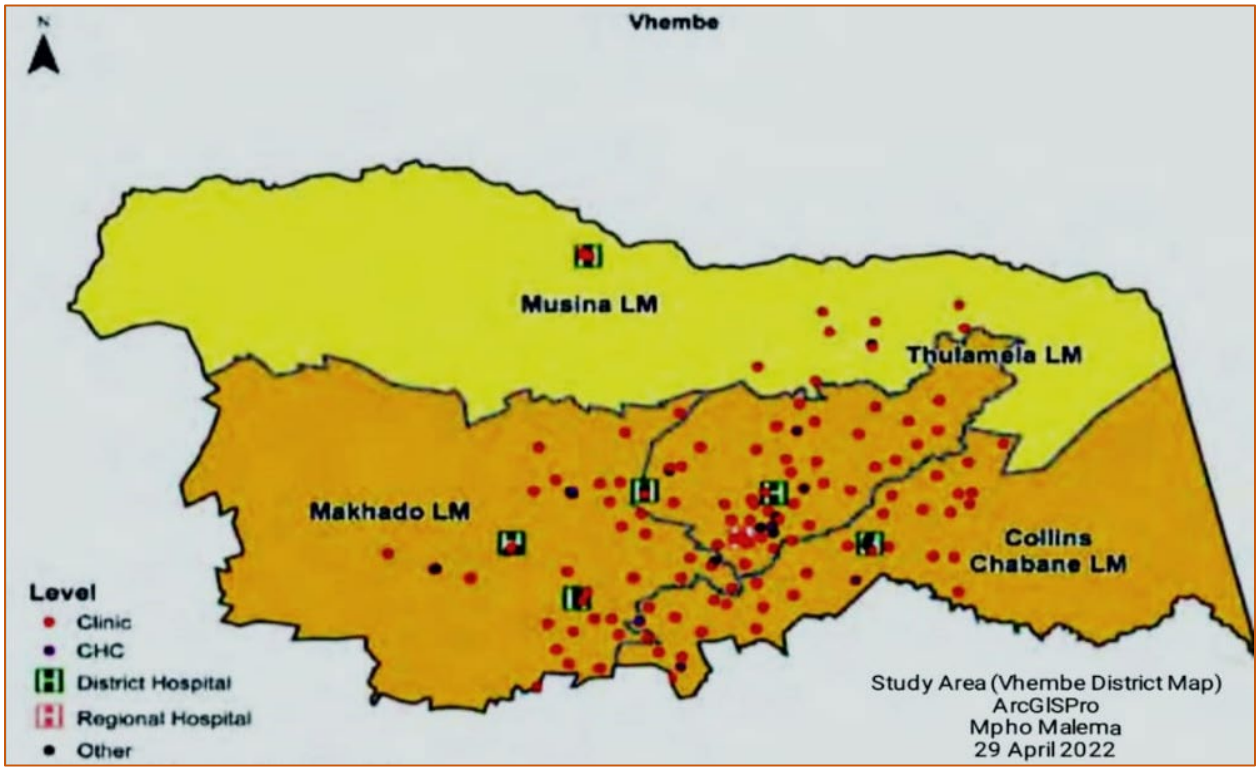

Figure 3.2: Distribution of healthcare facilities in the Vhembe District (Source: Researcher)

3.3 Site Selection and Sampling

According to Katz (2006), sampling is a method of picking groups of units from a population in a given area to collect data that may be used to make interpretations. There are two forms of sampling: probability and non-probability sampling; while non-probability sampling is subjective and purposeful, probability sampling involves selecting samples randomly, aiming for representation of the broader population (Katz, 2006).

3.3.1 Sampling for the study area

Purposive sampling, which involves selecting areas that provide optimal information, was the method used to choose the study areas. This approach simplified the sampling process, thereby saving considerable time and resources (Matthews & Ross, 2010). The study focused on three local municipalities: Thulamela Local Municipality, Makhado Local Municipality, and Collins Chabane Local Municipality. This selection was made to ensure a comprehensive representation of management practices in the District, considering the high population of Makhado and Thulamela, which also have peri-urban and rural zones. Collins Chabane was chosen to meet the criterion of representing over 50 percent of the municipalities, essential for drawing conclusions on pharmaceutical waste management in the District.

The scope of this study encompassed healthcare facilities in the Vhembe District that generate pharmaceutical waste, with a particular focus on both the public and private sectors. The objective was to investigate the similarities and differences in the generation and management practices of pharmaceutical waste in both public and private sector The study initially targeted 58 pharmaceutical outlets - 11 healthcare facilities in the public sector (hospitals and clinics) and 47 pharmaceutical outlets in the private sector. Private sector outlets were further categorized into 2 medical centers, 30 standalone private practices, and 15 pharmaceutical stores. The latter category was subdivided into pharmacies, drugstores, and supermarkets that sell medications.

During the data collection process, it became apparent, however, that some facilities lacked the capacity to provide the necessary data to fulfil the study's objectives. Many standalone private practices primarily offered consultation and diagnosis services, prescribing medications for patients to purchase from pharmacies, consequently, these practices did not generate pharmaceutical waste in their facilities. The researcher, however, later found that 20 standalone private practices did have pharmaceutical waste, leading to an adjustment in the number of facilities, so as to optimize the data collection process.

Table 3.1 illustrates the distribution and characteristics of the pharmaceutical outlets studied. Within this sample, the majority, or 77.6% of the facilities, were situated in the private sector, while the remaining 22.4% belonged to the public sector. Privately-regulated facilities included drugstores (5), medical centres (4), pharmacies (13), private practices (18), and supermarkets (5). On the other hand, facilities in the public sector comprised of public clinics (6) and public hospitals (7), which fall under public jurisdiction.

Table 3.1: Nature of facility

	Frequency	Percent
Drugstore	5	8.6
Medical Centre	4	6.9
Pharmacy	13	22.4
Private practice	18	31.0
Public Clinic	6	10.3
Public Hospital	7	12.1
Supermarket (OTC medication)	5	8.6
Total	58	100.0

3.3.2 Sampling for households and healthcare professionals

A cross-sectional survey was conducted to determine the required sample size for households using Equation 1.

$$\text{Sample size} = \frac{Z^2 \text{x } (P) \text{ x } (1 - P)}{C^2} \qquad (1)$$

where Z = Z value (e.g., 1.96 for 95% confidence level), P = percentage picking a choice, expressed as a decimal (0.5 used for sample size needed), C = margin of error, expressed as a decimal (e.g., 0.05 = ±5). A sample of 384 households was derived from the equation.

A total of 384 households were selected based on the formula. These households are in Thohoyandou within the Thulamela Municipality and Louis Trichardt in the Makhado Municipality. The rationale behind choosing these areas lies in their peri-urban nature, which provides residents with convenient access to healthcare facilities and proximity to pharmaceutical outlets. It is anticipated that such areas generate a higher volume of pharmaceutical waste compared to rural or village settings. To ensure equitable representation and prevent potential bias arising from overrepresentation, 192 households were surveyed in both Thohoyandou and Louis Trichardt. This balanced approach guaranteed fair and unbiased coverage of both areas in our study. Stratified sampling was used to select household representatives, whereby, only adults above 18 were considered for consent purpose and excluded households in which adults present do not

have the mental capacity to participate or any other disability that renders them incapable of participate in the study.

Equation 1 was also used to determine target sample size for administration of questionnaires to healthcare professionals and a target sample of 384 was derived. A walk-in survey in healthcare facilities was done to administer questionnaires to different healthcare professionals. Snowball sampling method was considered to reach the targeted sample. The snowball method, also known as chain-referral sampling, is a non-probability sampling approach for recruiting respondents for a research project in which existing individuals refer new participants (Parker et al., 2019). This meant that relevant individuals in healthcare facilities were approached to participate and these individuals then referred and/or recruited other relevant parties to get involved in the study. This method was chosen because participation was based on availability and willingness to participate in the study.

3.3 Research Design

A blended research design was used to address the problem statement and achieve the study's objectives. This approach incorporated both qualitative and quantitative research methods to gather information concerning pharmaceutical waste in the selected study areas. The data was collected from a desktop study, the administration of questionnaires, conducting of interviews, and site visits.

3.4 Types and sources of data

In this study, both primary and secondary data were employed to obtain information regarding pharmaceutical waste management practices (see Appendix 1).

3.4.1 Primary data

Primary data was collected through direct field observations, questionnaires, and interviews. These methods allowed for a firsthand acquisition of data from the study areas. Simultaneously, secondary data were gathered from existing research documented in peer-reviewed journals, books, the internet, newspaper articles, conference presentations, and reports from government and non-governmental organizations (NGOs). This combination of primary and secondary data sources contributed to a comprehensive data collection process for the study.

3.4.1.1 Field observations

Observation played a crucial role in addressing descriptive questions; this method proved instrumental in identifying and categorizing various types of pharmaceutical waste, encountered

in diverse pharmaceutical outlets and in assessing their respective management practices. During the observation process, a camera was employed to capture photographs, while a notebook was utilized for taking detailed notes. Additionally, a checklist was applied to ensure that all pertinent data was systematically collected throughout the observation process.

3.4.1.2 Interviews

Interviews were conducted during the research; this involved interactions between the researcher and pharmacists in pharmaceutical outlets, as well as individuals responsible for pharmaceutical waste management within various facilities. The interviews aimed to elicit in-depth responses, fostering detailed descriptions and explanations. An audio recorder was utilized during these interviews, after prior permission had been sought to its use. Audio recorders proved invaluable, enabling the researcher to revisit and review the recorded conversations when specific information was required.

3.4.1.3 Questionnaires

Questionnaires comprised of close-ended questions on pharmaceutical waste was designed and distributed to households. Closed-ended questions limit respondents to a list of answer choices from which they must choose (Dillman et al., 2009). Commonly, these types of questions are in the form of multiple choices, either with one answer or with a pick-all-that-apply option, but also responses can be in a scale format, where respondent should decide to rate the situation along a provided scale continuum (Dillman et al., 2009).

3.4.2 Secondary data

Secondary data played an integral role in the research, enriching the study with information from sources beyond the scope of the current research project. This supplementary data encompassed existing literature pertaining to pharmaceutical waste management, thereby contributing to a more comprehensive understanding of the subject matter. This secondary data was instrumental in the development of essential tools such as checklists for compliance assessment and questionnaires, ensuring that the research methodology was robust and well-informed.

3.5 Data Collection Process and Methods

Data were collected in the Northern region of South Africa within the Limpopo Province, specifically in the Vhembe District. The data collection process encompassed a diverse range of settings, including rural, peri-urban, and urban areas. Various types of medical facilities, including

public hospitals, clinics, private practices, and pharmaceutical outlets, were thoroughly examined to assess their pharmaceutical waste management practices. The selection of these medical facilities was conducted across three local municipalities located in the Vhembe District, namely, Thulamela Municipality, Makhado Municipality, and Collins Chabane Municipality. This approach ensured a comprehensive evaluation of management practices across the districts, facilitating a comparative analysis to identify differences and similarities to gain a comprehensive understanding of pharmaceutical waste management within the district.

The data collection occurred in two distinct stages:

Stage 1: A comprehensive desktop study was undertaken to gather background information and secondary data related to pharmaceutical waste management and disposal practices. This stage included an in-depth review of relevant literature, intended to supplement the data collection. The primary goal of this stage was to provide a theoretical context for the study and establish historical patterns concerning pharmaceutical waste management.

Stage 2: At this stage, the researcher incorporated both primary and secondary data. Primary data were collected using purposive sampling, a method in which specific individuals and areas are chosen for a particular purpose (Leedy, 2013). Additionally, secondary data, obtained from sources other than the current research project, were also included in the study. This two-stage approach ensured a comprehensive and well-rounded data collection process. This stage's data collection process revolved around structured visits to healthcare facilities, each visit serving a specific purpose and providing valuable insights into pharmaceutical waste management practices.

First Visit

The initial phase, conducted on the first day of each visit, was geared towards obtaining a comprehensive overview of pharmaceutical waste management within the facilities. This involved meticulous identification and categorization of the types of pharmaceutical waste generated. The primary aim was to comprehend the facility's methodologies for segregation, labelling, storage, and disposal of pharmaceutical waste. This initial interaction laid the groundwork, offering essential background information about the facility's approach to managing pharmaceutical waste.

Second Visit

The subsequent day of data collection was dedicated to conducting in-depth interviews with facility managers or designated personnel responsible for overseeing pharmaceutical waste management. These interviews were instrumental in obtaining first-hand insights into the current state of pharmaceutical waste management practices within the facilities. Facility managers or delegated personnel were well-positioned to provide intricate details about the strategies employed, challenges faced, and existing protocols concerning pharmaceutical waste management.

Third Visit

The third visit was scheduled strategically to coincide with either the disposal day for pharmaceutical waste or the collection day for facilities outsourcing waste management to third-party services. This visit allowed for direct observation and interaction with personnel responsible for waste disposal. It served as an opportune moment to ask specific questions that might not have been addressed during previous visits. The aim was to gain a holistic understanding of the actual disposal process and to gather any additional information pertinent to pharmaceutical waste management practices within the facility.

Identification of Pharmaceutical Waste: To accurately identify the types of pharmaceutical waste generated in each facility, the researcher collaborated with delegated personnel for guidance, through a facility tour. This tour was instrumental in understanding the nature of services offered by each facility, as the types of pharmaceuticals present are closely related to the services provided. The researcher categorized the pharmaceutical waste based on classes, characteristics, and potential risks associated with each type. While some facilities permitted the researcher to inspect the contents of their waste bins, others declined the request.

Quantification of Pharmaceutical Waste: A noteworthy observation from the study was that most facilities did not maintain records of the quantities of pharmaceutical waste they generate. In response to this omission, the researcher designed a questionnaire that was administered to facility managers and head pharmacists in retail pharmacies. This questionnaire aimed to solicit information from pharmacists regarding the regular generation of pharmaceutical waste, helping to establish a clearer understanding of types of pharmaceutical waste that was commonly generated throughout the facilities.

Observations: To supplement the data collection process, the researcher conducted on-site observations within each facility. These observations were instrumental in assessing the existing

pharmaceutical waste management practices, by directly observing how waste was segregated, labelled, stored, and eventually disposed of.

Questionnaires

Questionnaires consisting of close-ended questions related to pharmaceutical waste were designed and administered to both consumers and healthcare professionals who prescribe or administer pharmaceutical products to patients or consumers as detailed in Appendix 2 and 3. The questionnaires featured multiple sections designed to streamline completion and extract a comprehensive array of relevant information. For consumers, the questionnaire was segmented to cover various facets: Section A focused on general details, including the date of participation; Section B gathered demographic information; Section C delved into the specifics of pharmaceutical usage within households, focusing on the types of pharmaceutical products most frequently utilized. Section D aimed at assessing the consumer's knowledge concerning pharmaceutical waste. Section E explored in-depth the practices associated with pharmaceutical waste management, particularly, disposal methods utilized by consumers.

In the assessment of healthcare professionals' knowledge, perception and attitude towards pharmaceutical waste management, the questionnaire followed a three-part structure: Section A sought demographic profiles - age, gender, educational background, and specific roles within the healthcare sector. Section B undertook an evaluation of professionals' knowledge pertinent to pharmaceutical waste management, the questions required information on - their familiarity with practices, attitudes towards disposal methods, and awareness of the associated consequences. Section C delved into their attitudes and perceptions regarding the existing waste management practices within the healthcare settings, focusing on disposal methods and broader approaches to managing pharmaceutical waste.

3.6 Type of data collected

- **Data on types of pharmaceutical waste generated and management practices in facilities**

This data is pivotal as it provided crucial insights into the types of pharmaceutical waste generated and the management practices within facilities, forming the foundation for the implementation of targeted waste management strategies. The information was gathered through onsite visits, detailed observations, and interviews with facility managers. The data was presented incorporating photos, charts, and tables facilitating a comprehensive understanding of the intricacies involved in pharmaceutical waste management.

- **Consumer Attitude and Knowledge in Household Management of Pharmaceutical Waste**

This dataset holds significance since consumers in households, whether through prescribed medication or self-medication, are primary recipients of pharmaceutical products, suggesting that households may accumulate substantial amounts of pharmaceutical waste. The information was systematically collected through the distribution of questionnaires to selected households in the district. The analysis was done utilising the IBM SPSS Statistics version 26.0 and Excel sheets for quantitative analysis of survey responses. The findings were presented through charts and tables, effectively combining quantitative insights with qualitative details to provide a comprehensive view of pharmaceutical waste in households.

- **Healthcare Professionals' Knowledge, Attitude, and Perception**

This data was crucial as healthcare professionals play a key role in pharmaceutical waste management. The data was gathered through questionnaires, providing a comprehensive understanding of their perspectives. Employing a dual analytical approach, the dataset was first entered into Google Forms, then coded and imported into a Microsoft Excel spreadsheet. Subsequently, the data was imported into IBM SPSS Statistics version 26.0 (IBM SPSS Statistics Data Editor). This data was then presented using charts and tables.

- **Compliance with Regulatory Frameworks and Identification of Challenges**

This data was essential for assessing the compliance of facilities to the current pharmaceutical waste management framework. The data was gathered through a combination of on-site inspections, document reviews on guidelines, interviews, and a checklist drafted to evaluate compliance to the framework. The findings were presented through a comprehensive waste-management compliance-assessment report, providing a detailed understanding of current practices and their adherence to established standards.

- **Weaknesses and challenges of the existing Framework for Pharmaceutical Waste Management and development of a robust framework**

This dataset played a role in addressing challenges and shortcomings within the existing framework. It was systematically collected through stakeholder consultations and regulatory reviews, aimed at identifying gaps in the framework. The presentation of the data involved a comprehensive analysis, incorporating policy gap analysis, Strengths Weaknesses Opportunity Threats (SWOT) analysis, and Political, Economic, Social, Environmental and Legal (PESTEL)

analysis. These analytical tools contributed significantly to the development of an enhanced and evidence-based regulatory framework, designed to be responsive to the identified gaps and to strengthen the overall effectiveness of the framework.

3.7 Data analysis

This study employed a mixed approach for analysing data on pharmaceutical waste management practices. On-site observations, supported by photographs, and subjected to descriptive analysis provided real-time insights. The questionnaire data were collected through Google Forms, coded, and analysed using IBM SPSS Statistics 26.0, with results presented through tables and visual aids. Interview data from facility managers underwent thematic analysis to identify key patterns. The comprehensive integration of qualitative and quantitative methods facilitated a holistic understanding of pharmaceutical waste management in Vhembe District healthcare facilities, uncovering trends, challenges, and possible improvement strategies.

3.8 Ethical considerations

In conducting this research, stringent ethical considerations were adhered to at every stage of the process. The research began by obtaining ethical clearance, detailed in Appendix 6, setting the foundation for the ethical framework governing this study. Following this, formal permissions from the National Health Research Council were secured to allow for engagement in research activities within the healthcare facilities situated in the Vhembe District; clearance was granted and recorded in Appendix 7.

The requests for permissions extended to the targeted study areas indicated on Appendix 8, wherein formal requests, documented in Appendix 9, were either acknowledged through verbal agreement or responded to via email. Each step undertaken was guided by a sense of respect for the autonomy and privacy of the involved entities. An integral facet of the ethical approach adopted was the conscientious pairing of each questionnaire with a corresponding consent form (see Appendix 2 and 3). These consent forms served as comprehensive documents, explicitly outlining the study's objectives, emphasizing confidentiality measures, and affirming the voluntary nature of participation. Participants were duly informed that their involvement was entirely voluntary, and their decision to complete and sign the questionnaires stood as an informed consent to partake in the research endeavour. Throughout the research process, particular emphasis was placed on seeking permission from pharmaceutical outlets and medical practices before initiating data collection activities. The core principle of upholding confidentiality and

anonymity was maintained during data collection, analysis, and the subsequent reporting of research findings. Facilities were referred to in a generalized manner without disclosing specific names or locations. Additionally, confidential information of participants, such as names or personal identifiers, were not recorded in the results and findings. This approach ensured that the privacy of both facilities and participants was respected throughout the research process.

CHAPTER FOUR

RESULTS AND DISCUSSIONS

4.1 Introduction

Chapter Four provides a presentation of the research findings. The results are discussed for each objective set for the study on pharmaceutical waste management in the Vhembe District. The findings are presented using charts, graphs, themes, and photographs. At the end of the chapter, a summary of the research findings is provided.

4.2 Types of pharmaceutical waste generated and management strategies in facilities

Understanding how to manage pharmaceutical waste is essential for the protection of the environment, regulatory compliance, and the well-being of healthcare workers and the public. Amin et al. (2013) stress the need for careful planning in this area. Facilities can improve their waste disposal methods and minimise environmental impact by being aware of the types and amounts of pharmaceutical waste they generate (Sarkar et al., 2017). Compliance with regulations is critical, as underlined by the Environmental Protection Agency (EPA, 2016). Proper waste management not only ensures the following of rules and regulations, but also prevents accidental exposure to harmful substances, aligning with recommendations from the World Health Organization (WHO, 2019).

Strategic waste management in healthcare facilities does not only enhance safety but also aligns with sustainability goals and cost-effectiveness, according to Dormer et al. (2018). Gusca et al. (2015) provide a comprehensive view of waste management in healthcare facilities, covering - waste classification, generation, segregation, storage, transport, treatment, and disposal. For effective pharmaceutical waste management, facilities should proactively segregate waste and anticipate its volume. This approach helps with budget planning and aligns with the World Health Organization's recommendations (WHO, 2017). Figure 4.1 illustrates key steps that have been identified in the entire process of managing medical waste from the cradle to grave; nonetheless, challenges persist at each step, especially in the specific context of South Africa.

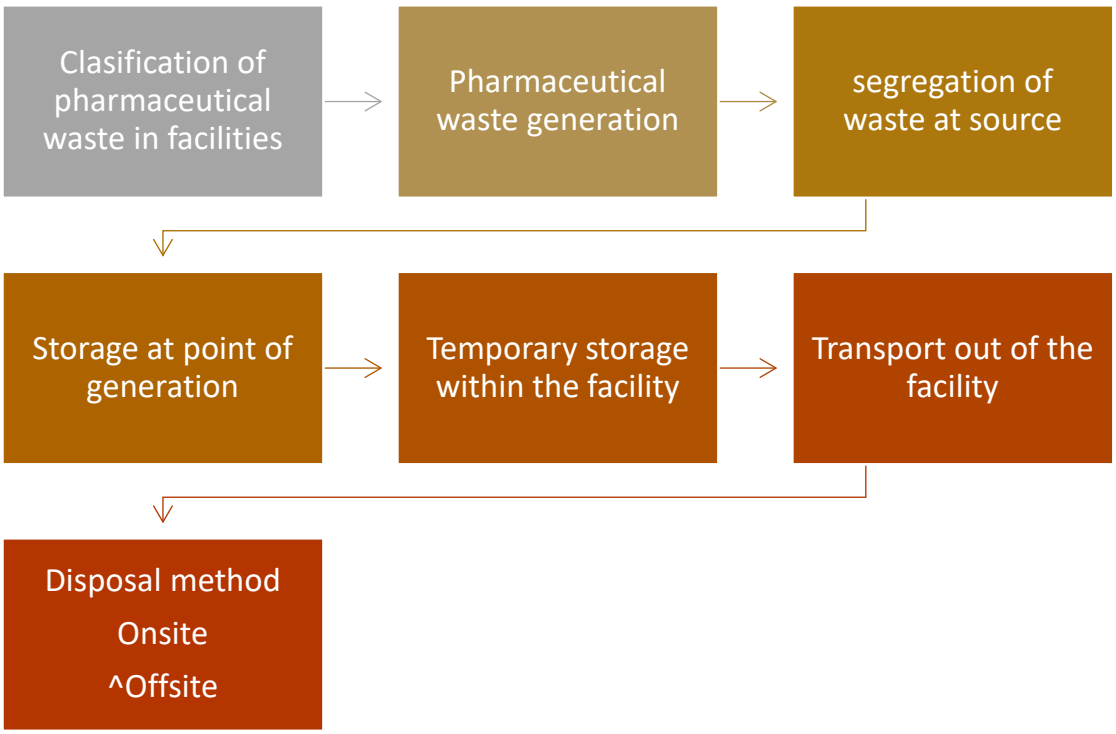

Figure 4.1: Pharmaceutical waste management process in facilities (Source, Researcher)

4.2.1 Classification of pharmaceutical waste in facilities

The initial phase in classifying pharmaceutical waste within facilities involves the identification of the diverse pharmaceutical products found in these facilities. The facilities under examination utilise a three-fold categorisation approach based on the guidelines provided by the South African Health Products Regulatory Authority (SAHPRA). According to SAHPRA, pharmaceutical products within facilities can be classified in several ways. This includes categorisation based on the type and function of medications, as well as classification according to schedules outlined in The Medicine and Related Substances Act of 1965 (Act 101 of 1965). The schedules in this Act regulate medications based on their associated risks and benefits, focusing also on aspects, such as usage, frequency, and authorisation for prescription, along with specifying the types of medications that facilities are authorised to provide. Medications are also categorised according to dosage type, denoting the specific form or product type, such as - pills, syrups, liquids, among others. Figure 4.2 below provides a visual representation of the diverse categorisations of pharmaceutical products observed in the studied facilities.

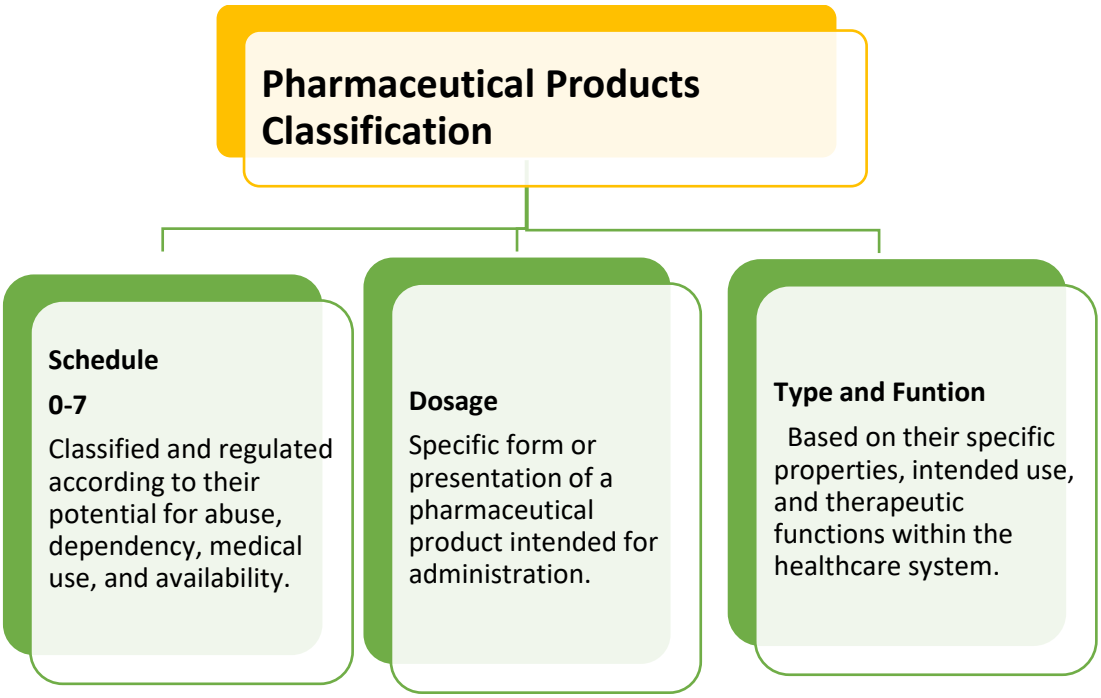

Figure 4.2: Pharmaceutical products categorization in facilities (Source: Researcher)

Figure 4.3 below show the medication schedules found across the selected facilities for this study. Majority of the facilities offer schedule 3-4, followed by schedule 5, while less than 30 of the facilities offer schedule 0, 2 and 7.. The difference in the schedule distribution in the facilities, is informed by the type of facility, service offered and authorisation to sell/offer or prescribe certain medications. In the current study, the distribution was influenced by the number and types of facilities selected.

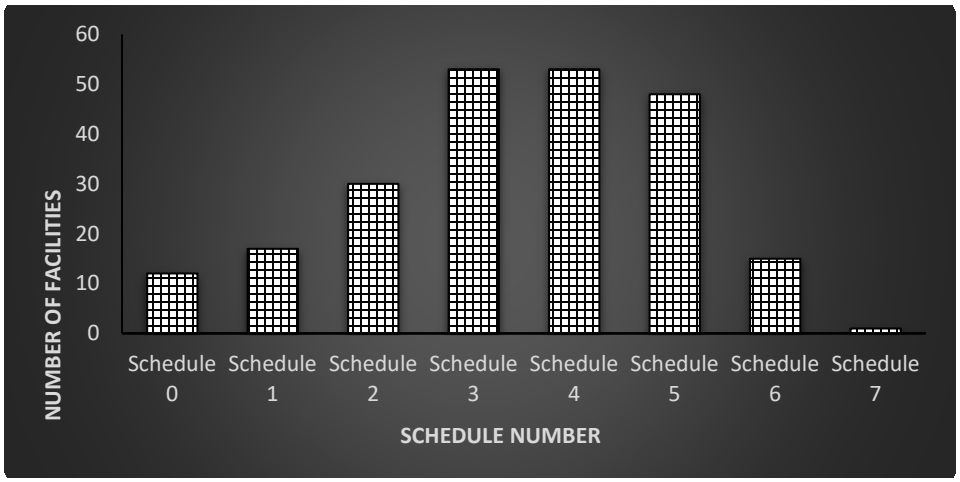

Figure 4.3: Pharmaceuticals in facilities by schedule numbers (Source; Researcher)

4.2.1.1 Classification by dosage form

Medications come in diverse dosage forms tailored for various administration routes and patient needs. The investigation aimed to analyse the spectrum of pharmaceutical waste according to their dosage forms, present within the healthcare facilities under study. In their study, Mohammed et al., (2021) revealed that pills and injectable constitute the predominant pharmaceutical dosage forms within healthcare facilities. This study consistently found that pills were the most prevalent dosage form across all 58 surveyed facilities, accounting for 100% of the facilities. In contrast, injectables were the least prevalent, found in only 25 facilities, representing approximately 43.10% of the surveyed sample. This variation in types can be attributed to the operational focus of the facilities. Facilities primarily engage in medication dispensation, where retail sales, showed a high prevalence of pill-based forms. Liquids were found in 75.86% of the facilities (44 out of 58), creams in 63.79% (37 out of 58), and ointments in 68.97% (40 out of 58) of the surveyed facilities. Injectables, less common in retail-oriented settings, were more frequently found in facilities actively involved in patient care, where injections or infusions are routine practices. This distinction underscores how operational focus influences the prevalence of dosage forms encountered in healthcare facilities, thereby impacting pharmaceutical waste management strategies accordingly. Figure 4.4 shows forms of pharmaceutical products dosages provided by the various healthcare facilities studied, including the prevalence of each form of dosage.

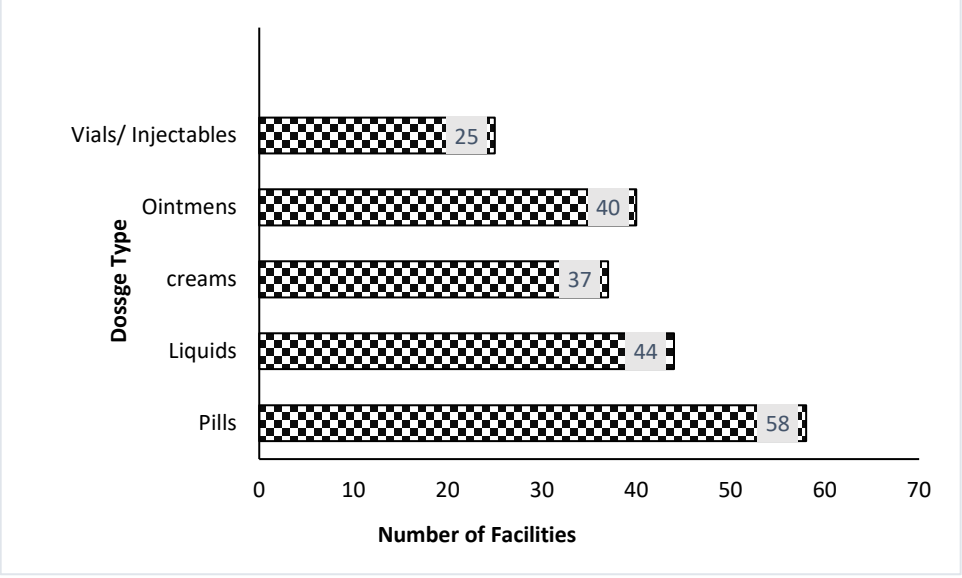

Figure 4.4: Pharmaceutical products in facilities by dosage forms (Source: Researcher)

4.2.2 Pharmaceutical waste generation

The initial phase in the waste management continuum holds paramount significance within the scope of this research. It serves as the foundational stage that dictates crucial aspects of pharmaceutical waste management, in relation to its volume, composition, origins, and inherent characteristics. Essentially, this pivotal stage establishes the groundwork for subsequent waste treatment and disposal activities. The generation of pharmaceutical waste is a multifaceted process, influenced by a myriad of factors that contribute to its diversity in terms of sources and causes. Among the prominent reasons for the generation of pharmaceutical waste are the expiration of medications, the presence of unused or unopened medication, the accumulation of surplus stock, and the discontinuation of specific pharmaceutical products, to name a few.

4.2.2.1 Factors contributing to pharmaceutical waste generation in facilities

Following the receipt and utilisation of pharmaceutical products within healthcare facilities and pharmaceutical outlets, various factors contribute to the subsequent generation of pharmaceutical waste. Through interviews with facility managers, distinct themes emerged, shedding light on the contributing factors, across different settings.

In retail pharmaceutical outlets, the prevalent theme of medication expiration was a major contributor to waste, and this aligns with existing literature. Research by Smith et al. (2018) stressed the need for effective inventory management and demand forecasting to minimize expiration-related waste in pharmaceutical retail settings. The second theme, the accumulation of unused medications, resonates with the challenges outlined by Anderson and Brown (2017), who stress the need for adhering to optimized stock levels to reduce wastage.

In facilities admitting patients, the theme of partial use of dosage forms referring to the specific physical forms in which pharmaceutical products, such as tablets, capsules, liquids, injections, or topical creams, are administered, aligns with studies emphasizing patient non-compliance and treatment plan adjustments (Johnson et al., 2019; Greenberg et al., 2020). The dynamic nature of patient care, as indicated by changes in treatment plans, mirrors the findings of research which notes the evolving nature of healthcare interventions (Doe et al., 2018). Effective inventory management practices, as recommended by Dormer (2019), remain crucial for mitigating pharmaceutical waste and promoting sustainability in healthcare operations.

4.2.2.2 Types of pharmaceutical waste generated

The nature, quantity, and rate at which pharmaceutical waste is generated within pharmaceutical waste outlets situated in the Vhembe District are contingent upon several key determinants. First and foremost, the type of pharmaceutical outlet facility in question plays a pivotal role. Variations in waste generation patterns are often tied to the specific services rendered by these facilities and their corresponding product offerings. Furthermore, the South African Health Products Regulatory Authority (SAHPRA) have identified a critical influence in this context. SAHPRA holds jurisdiction over the licensing and oversight of pharmaceutical product sales and provision within South Africa. As such, the types of pharmaceutical products permitted or licensed for sale and provision within a facility are instrumental in shaping the characteristics of the pharmaceutical waste generated.

The data, as illustrated in Figure 4.5, indicate a clear hierarchy in the frequency of occurrence of various pharmaceutical waste categories across the 58 facilities. Antibiotics emerged as the predominant contributors, mentioned in 53 facilities (91.4%). This finding sheds light on the prevalent types of pharmaceutical waste generated within the pharmaceutical outlets under investigation. Following antibiotics, analgesics were the second most prevalent pharmaceutical waste, mentioned in 47 facilities (81%). Hormonal medications and controlled substances were also found to be major contributors, mentioned in 45 facilities (77.6%) and 43 facilities (74.1%), respectively. Antivirals, although slightly less prevalent, were still mentioned in 32 facilities (55.2%). Considering the growing importance of antivirals in healthcare, the proper disposal of these medications becomes crucial to prevent any unintended consequences. The study also revealed the presence of antipyretics, supplements, and vitamins in the pharmaceutical waste stream, mentioned in 26 facilities (44.8%), 10 facilities (17.2%), and 9 facilities (15.5%), respectively.

These findings are consistent with previous studies, revealing the uniformity in pharmaceutical waste generation patterns across diverse settings. For example, both Yamini (2016) in a study in2016 and Madikizela et al. (2020) in a study in 2020 identified antivirals (ARVs), antibiotics, hormone medication, and analgesics as the primary types of pharmaceutical waste in various African countries.

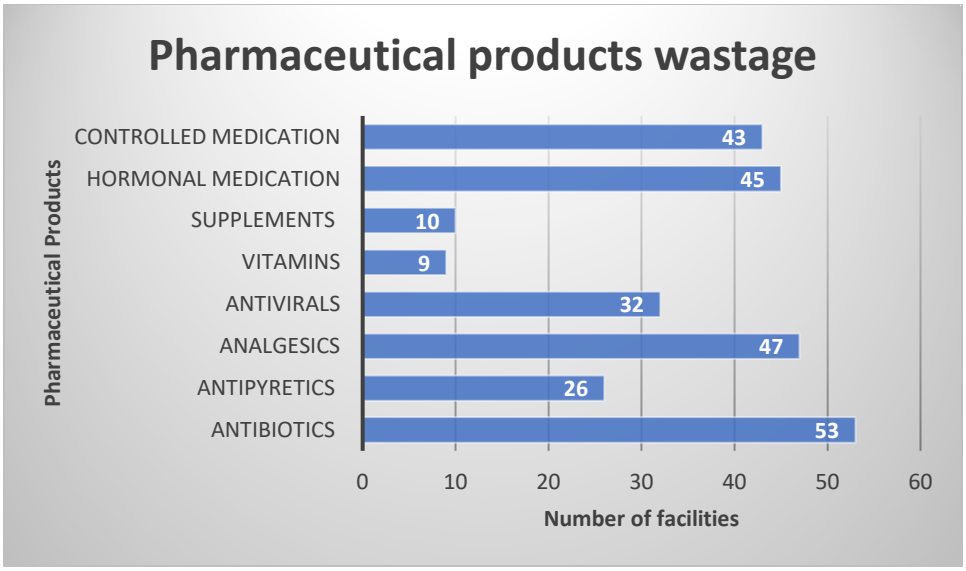

Figure 4.5: Types of pharmaceutical waste generated in healthcare facilities (Source: Researcher).

4.2.2.3 Pharmaceutical waste quantities

The regulatory framework in South Africa, as established by bodies such as the South African Department of Health, the South African National Standards, and Provincial Departments of Health, clearly mandates healthcare facilities to maintain accurate records of medical waste quantities. A significant number of discrepancies, however, was observed during the study, revealing that most of the investigated healthcare facilities do not have records of their pharmaceutical waste quantities. This critical issue can be attributed to several interconnected factors. First and foremost, one of the primary reasons for the lack of records is the absence of proper waste management practices at the point of generation within these healthcare facilities. In many cases, waste segregation at the source is not diligently implemented. This failure to segregate pharmaceutical waste from other types of waste at the point of generation, hinders the facilities' ability to accurately measure and record the quantities of pharmaceutical waste produced.

Additionally, some healthcare facilities have outsourced their waste management to external service providers and while it is expected that these service providers would maintain records, they often do not provide the facilities with the necessary recorded documentation. This breakdown in communication and accountability between service providers and healthcare facilities results in a lack of record-keeping on the facility's part. Furthermore, some healthcare facilities do not prioritize or recognize the importance of maintaining records of pharmaceutical waste quantities. This oversight may be due to a lack of awareness regarding the environmental

and regulatory significance of accurate record-keeping. In some instances, facilities simply generate waste, store it temporarily, and then dispose of it either through municipal collection or onsite methods without conducting a thorough characterization of the waste or quantifying its volumes.

4.2.3 Segregation of waste at source

The proper segregation of pharmaceutical waste at its source is a critical component of responsible waste management within healthcare facilities, with far-reaching implications for public health, environmental sustainability, and regulatory compliance. Multiple reputable organizations, including the World Health Organization (WHO), the South African Health Products Regulatory Authority (SAHPRA), and the Health Professions Council of South Africa (HPCSA), have issued guidelines and recommendations emphasizing the necessity of pharmaceutical waste segregation. Such guidelines aim to foster a healthcare ecosystem that is safe, more sustainable, and environmentally responsible. Effective pharmaceutical waste segregation serves as a cornerstone in mitigating the adverse effects of improper waste disposal. Failure to segregate pharmaceutical waste can result in contamination, environmental pollution, and public health risks. The consequences of such lapses are not merely theoretical; they have been substantiated by various studies conducted in healthcare facilities globally.

In the current study, the findings reveal a concerning lack of pharmaceutical waste segregation practices. Only 18 of the investigated facilities were found to segregate pharmaceutical waste from other forms of medical waste; 10 facilities were observed to categorize their pharmaceutical waste into distinct groups. An even more disconcerting revelation was made when evaluating bins' content within patient-admitting facilities and pharmacies, as pharmaceutical waste was often co-mingled with other medical waste types (Figure 4.6). These findings underscore the common practice for healthcare waste management, signifying a substantial gap between recommended practices and their actual implementation within healthcare settings. The consequences of this deficiency are manifold, including heightened risks of environmental contamination, exposure to hazardous substances, and non-compliance to regulatory frameworks.

Figure 4.6: Non-segregated pharmaceutical waste (Source: Researcher).

This study confirmed the mixing of general and medical waste as previously confirmed by the study conducted by Olaniyi (2020) in the District. This previous study noted that pharmaceutical waste is often mixed with other subcategories of medical waste and that pharmaceutical waste is not categorized according to its type, dosage and schedule thus making its management difficult. Once pharmaceutical waste has been mixed at source it makes it difficult to identify the types and quantity of pharmaceutical waste generated in the facility; additionally, mixed waste poses risk of exposure to injuries from sharp objects, infections and contact with hazardous chemicals. Mixing general waste with pharmaceutical waste has been identified as a reason for the high cost of treating healthcare risk waste because once mixed, the entire waste stream must be treated as hazardous (Department of Health, 2016).

4.2.4 Storage at point of generation

Figure 4.7 visually illustrates the observed variations in the types of containers used for the temporary storage of pharmaceutical waste during facility inspections. The temporal storage of medical waste at the point of generation represents a critical juncture in the healthcare waste management process. Such storage locations, including admission rooms, patient wards, theatres, and dispensaries, function as pivotal buffers, safeguarding the public from the inherent hazards posed by medical waste. Proper temporal storage is essential for effective waste categorization within healthcare facilities, ensuring that healthcare risk waste (HCRW) is appropriately segregated right from its source. To facilitate this segregation process, healthcare facilities typically employ specialized equipment, such as color-coded bins, each designated for

specific waste categories; for instance, yellow bins with red liners are for infectious waste, yellow bins are designated for sharp and vial waste, and green bins are reserved for pharmaceutical waste. These color-coded bins assist healthcare staff in segregating medical waste, enabling them to deposit general waste and various sub-categories of HCRW into separate containers at the point of generation.

The current study, however, has unearthed a concerning issue within healthcare facilities under investigation: a significant proportion of the temporal storage bins used for pharmaceutical waste did not meet the prescribed standards. Specifically, in 74.1% of the facilities surveyed, pharmaceutical waste was found to be stored in containers that did not adhere to the established specifications and labeling requirements.

Figure 4.7: Pharmaceutical waste stored in unlabelled containers (Source: Researcher).

This disparity between prescribed standards and observed practices points to a critical gap in adherence to waste management guidelines within healthcare settings. Inadequate temporal storage facilities not only hinder the proper segregation of pharmaceutical waste but also potentially exposes healthcare workers, patients, and the environment to avoidable risks.

Figure 4.8 showcases an example of good pharmacy practice observed in four facilities where pharmaceutical waste was appropriately stored in suitable containers. This illustration aligns with the recommendations of WHO, highlighting the significance of correct waste segregation and containment. Compliance with such practices not only minimizes risks but also contributes to a safer and more efficient healthcare waste management system. Ensuring that pharmaceutical waste is separated into its subcategories is particularly essential to prevent hazardous substances with the potential to react, from being mixed with inert substances. Such mixing can lead to chemical reactions, the release of harmful gases, or other dangerous consequences, further emphasizing the need for meticulous waste categorization.

Figure 4.8: Appropriate temporal storage for pharmaceutical waste in facilities (Source: Researcher)

The interviews conducted with facility managers provided valuable insights into the challenges and perceptions surrounding the temporal storage of pharmaceutical waste within healthcare facilities. These responses shed light on the factors contributing to the lack of proper temporal storage and reveal contrasting priorities and resource constraints faced by healthcare managers. One common issue mentioned by facility managers is the delay in receiving proper bins for medical waste, which can lead to the utilization of whatever resources are available at the time of waste generation. This issue highlights the logistical challenges faced by healthcare facilities in obtaining the necessary equipment in a timely manner.

The emphasis placed on patient safety is another recurrent theme in their responses. Facility managers are acutely aware of their responsibility to protect patients from exposure to medical waste in general. This focus on patient safety, however, may sometimes lead to suboptimal waste management practices, such as placing waste containers in less accessible areas to minimize patient exposure; the cost factor is also significant in shaping the priorities of facility managers. Many view service providers for medical waste as expensive, and they prioritize bins for infectious waste due to the potential legal repercussions of improper disposal. This perspective reflects the complex decision-making process that facility managers must navigate when allocating limited budgets among competing needs. The lack of adequate budget allocation for waste management emerged as a critical challenge. Facility managers often face difficult choices between investing in waste management infrastructure, including bins and service providers, and allocating resources to meet immediate patient healthcare needs, such as medication procurement. This underscores the tension between maintaining quality healthcare service delivery and implementing robust waste management practices.

Interestingly, the interviews revealed that temporary storage for pharmaceutical waste is often found in domestic waste bins, plastics, or boxes, and even when specific bins for pharmaceutical waste are present, issues like non-segregation and improper closure of bins are observed. This observation highlights the need for greater awareness and education on the hazards associated with pharmaceutical waste and the need for proper waste management.

4.2.5 Temporary storage within the facility

Table 4.1, below, offers a valuable snapshot of the state of storage rooms observed in the field. This Table provides a visual representation of the conditions and compliance levels of medical waste storage rooms, within the healthcare facilities under investigation. The findings presented in this Table shed light on the extent to which healthcare facilities adhere to regulatory guidelines and standards in terms of storage room design and maintenance. When bins in hospital wards, operating theatres, clinics, and admission areas reach capacity, they should be transported to a specifically-designated storage area within the healthcare facility. Here, they will be temporarily stored until they can be managed appropriately. This process applies to facilities that handle onsite disposal of waste as well as those awaiting collection by a contracted third-party waste management company for offsite disposal. Properly designed and maintained medical waste storage rooms are essential for ensuring the safety of healthcare workers, patients, and the environment.

The Healthcare Risk Waste (HCRW) Act in South Africa, officially known as the National Health Act, 2003 (Act No. 61 of 2003), plays a central role in regulating the storage of risk waste within healthcare facilities. This legislation outlines specific requirements for the design and construction of medical waste storage rooms. According to the Act, these storage rooms should be designed in a manner that prevents unauthorized access, which is crucial to minimize the public's risk of exposure to potentially hazardous waste materials. Additionally, the rooms should be easy to clean and disinfected, which is essential for maintaining a hygienic and safe environment. Adequate ventilation and proper lighting are also stipulated in the Act, promoting the well-being of healthcare personnel tasked with managing medical waste.

Table 4.1 below shows the state of storage rooms as observed in the field.

Variables	Frequency	Percent
Designated storage area with limited access		
No	35	60.3
Yes	23	39.7
Storage clearly marked with Biohazards signs		
No	46	79.3
Yes	12	20.7
Storage well organized and ventilated		
No	42	72.4
Yes	16	26.6

These observations made during the fieldwork regarding the storage of medical waste in healthcare facilities underscore significant challenges and shortcomings in waste management practices. One notable issue is the lack of properly constructed or designated storage rooms for medical waste in many healthcare facilities. Only two medical centres adhered to regulations with dedicated storage areas for medical waste, however, even facilities with storage buildings designated for storage purposes, inadequacies were observed. These storage spaces were found to be clustered, not well organized, and lacked proper ventilation. This situation raises concerns about the safety of healthcare workers and the effectiveness of waste management practices in these facilities.

Another challenge is the repurposing of rooms within healthcare facilities for storage purposes, thereby combining medical waste storage with other items, like cleaning equipment or old patient files. This practice not only hinders proper waste segregation and containment but also creates a potentially unhygienic and unsafe environment. The coexistence of medical waste with other materials poses risks to both healthcare staff and patients. Pharmacies were also found to lack designated storage areas for pharmaceutical waste, resorting to using any available space, such as kitchen cupboards, or alongside kitchen sinks; similarly, private doctors' in their practices stack waste buckets in corners or dispensary rooms. These ad hoc storage practices can lead to poor waste segregation and complicate disposal procedures. Figure 4.9 illustrates the observed state of storage areas within healthcare facilities, highlighting the need for improvements and adherence to regulatory standards.

Figure 4.9: State of medical waste storage areas in facilities (Source: Researcher)

In some healthcare facilities, access to the storage room was denied to the researcher, with explanations provided as "safety purposes" and "privacy concerns." Additionally, it was observed that the majority of the storage rooms lacked proper security measures or signs indicating access restrictions for unauthorized individuals. These storage rooms, which were situated within the facilities, were often poorly ventilated and had insufficient space for storage purposes; some facilities did not have dedicated storage rooms at all and resorted to placing their waste bins in the backyard. This study's findings align with a prior investigation conducted by Raphela (2014), which reported similar challenges in healthcare waste management practices. The same study identified that over 53% of clinics in the Polokwane Municipality did not possess dedicated storage rooms for medical waste, instead, these clinics repurposed consulting rooms for the temporal storage of medical waste, highlighting the prevalence of inadequate waste storage infrastructure. Inadequate ventilation and limited storage space in storage rooms pose significant challenges As poor ventilation can result in the buildup of noxious odors and potentially harmful gases, creating an unhealthy environment for healthcare workers and patients. Limited storage space can lead to overcrowded storage rooms, hindering proper waste segregation and containment.

4.2.6 Transportation offsite

This aspect is pertinent for healthcare facilities that choose to dispose of their pharmaceutical waste using external services, typically third-party waste management providers. In such scenarios, healthcare facilities establish contractual arrangements with waste management firms to collect and transport their medical waste, including pharmaceutical waste, for appropriate treatment and disposal. The contractual agreements between healthcare facilities and waste

management firms frequently include provisions related to the frequency of waste collection, which is customized to align with the size of the facility and the volume of waste generated. This tailored approach ensures efficient waste management practices that are also cost-effective (Gautam et al., 2019).

Within the realm of the public healthcare facilities studied, the frequencies of waste collection were thoughtfully structured to meet the specific requirements of hospitals and clinics. Hospitals, characterized by their larger size and higher waste generation rates, generally undergo more frequent waste collections, often occurring two to three times per week. In contrast, clinics, which are smaller in scale and generate less waste, might experience less frequent waste pickups, with intervals ranging from weekly to fortnightly or, in some cases, monthly. This variance in collection frequencies aligns with the varying rates of waste generation observed in these different healthcare settings as well as in study by Alagöz & Kocasoy (2008).

The differences in collection schedules between hospitals and clinics can be attributed to several factors. Hospitals naturally produce a higher volume of waste due to their larger patient populations, the performance of complex medical procedures, and the provision of a broader array of medical services. Consequently, hospitals require more frequent waste pickups to prevent overflow and maintain sanitary conditions. On the other hand, clinics generally serve fewer patients and generate less medical waste overall, which allows for less frequent waste collection schedules to be feasible. Additionally, the scheduling of waste collection in hospitals is often more structured, with specific days of the week designated for pickups, given the consistent and substantial waste production. In contrast, clinics may have less predictable scheduling due to their lower waste volumes, and the collection days may vary based on demand.

In addition, clinics are often dispersed over wider geographical areas, particularly in rural regions. Waste generation in individual clinics may not be sufficient to warrant frequent waste collection trips, and it might be logistically impractical to collect waste from each clinic separately. To address this challenge efficiently, the waste management company opts for a pragmatic approach - when one clinic requests waste collection, the company seizes the opportunity to service multiple clinics in the vicinity. This strategy optimizes the use of resources and ensures that waste from multiple clinics is collected in a single trip.

Figure 4.10: Medical waste removal from facilities by 3rd party (Source: Researcher)

In healthcare settings where third-party waste management services are not utilized, medical waste, including pharmaceutical waste, is typically managed onsite using diverse disposal approaches. For those facilities that do not opt for onsite disposal, pharmaceutical waste is typically transported from its point of generation to designated storage areas, later removed from the premises on scheduled municipal refuse collection days, along with general waste. Another approach adopted by some facilities involves using their own vehicles to transport both general waste and pharmaceutical waste generated within the facility to a landfill, where a standard waste disposal fee is applied.

It is essential to note that the National Health Act of 2003 (Act No. 61 of 2003) outlines specific regulations concerning the transportation of healthcare risk waste. These regulations mandate that entities responsible for the transportation of such waste must be registered with the relevant environmental authority in South Africa. In the case of Limpopo Province, this authority is the Limpopo Economic Development Environment and Tourism (LEDET). To acquire a license for the transportation of hazardous waste, transport vehicles must meet predefined standards pertaining to vehicle cleanliness, waste handling procedures, and safety protocols.

Facilities that choose to commingle their pharmaceutical waste with general waste and subsequently dispose of it at landfills without the necessary licensing are found to be in violation of these regulations. Such practices can have detrimental consequences, including environmental contamination and potential health risks for waste handlers and communities surrounding the landfill.

4.2.7 Disposal methods

Figure 4.11 in the study illustrates the diverse methods commonly used across the studied facilities. Out of the 58 facilities surveyed, the methods used are - drainage systems, utilized by 51.7% (30 facilities); municipal waste services, employed by 72.4% (42 facilities); burning,

practised by 25.9% (15 facilities); and returning waste to the pharmacy, chosen by 46.6% (27 facilities). This variability underscores the complex decision-making process involved in pharmaceutical waste management within healthcare settings, demonstrating the need for standardized guidelines and improved infrastructure to ensure environmentally and socially responsible practices.

The World Health Organization (WHO) advises healthcare facilities to adhere to local regulations and best practices when it comes to the treatment and disposal of pharmaceutical waste. These disposal methods should consider both environmental and health factors (WHO, 2021). The Health Professions Council of South Africa (HPCSA) expects healthcare professionals, including pharmacists and doctors, to uphold ethical and professional standards, which requires the appropriate disposal of pharmaceutical waste. Inappropriate disposal practices, such as flushing medications down toilets, discarding them in the trash, or pouring them into drains, can result in the contamination of water bodies and soil, potentially harming the aquatic ecosystems and human health.

Many pharmaceutical products contain active ingredients that can persist in the environment, raising concerns about potential long-term effects on human health and the development of antibiotic-resistant bacteria (Chen et al., 2019); such residues have been detected in drinking water sources. Improper disposal of pharmaceutical waste can also contribute to substance abuse and addiction issues when unused medications are easily accessible in household trash or public disposal locations (Substance Abuse and Mental Health Services Administration [SAMHSA], 2019). Additionally, it can lead to accidental poisonings, particularly in children or pets who may ingest discarded medications (Centers for Disease Control and Prevention [CDC], 2020).

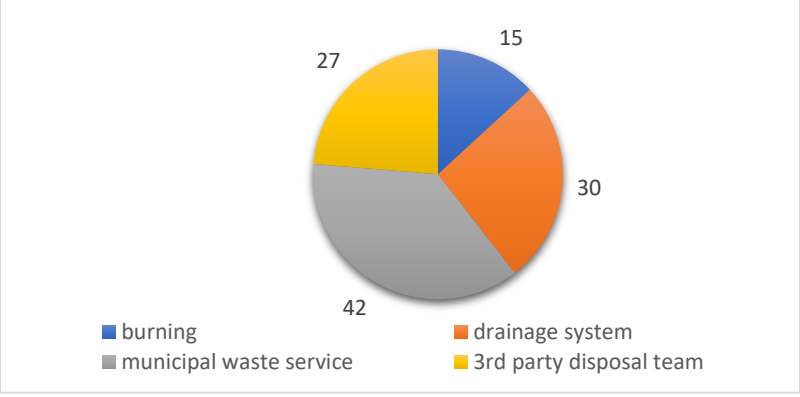

Figure 4.11: Common disposal methods utilized in facilities (Source; Researcher)

The most employed methods for pharmaceutical waste disposal in the healthcare facilities under investigation in the Vhembe region were municipal waste services and drainage systems, followed by the utilization of third-party waste management companies and incineration. Figure 4.12 in the study visually illustrates a municipal waste collection point situated outside a healthcare center. While this practice may seem to provide a convenient solution, it introduces a complex set of challenges that carry significant negative implications for public health, environmental conservation, and adherence to regulatory standards.

Figure 4.12: Waste from private facility awaiting collection by municipality waste management services (Source: Researcher).

Pharmaceutical waste generated by healthcare facilities is made up of a diverse range of substances, including expired medications, unused drugs, contaminated materials, and sharps (U.S. EPA, 2017). One of the most critical issues associated with the utilization of municipal waste services for pharmaceutical waste disposal, is the potential for environmental contamination. Pharmaceutical compounds could persist in the environment and have been identified in water bodies, soil, and even drinking water supplies (Kolpin et al., 2002). Following collection, municipal waste trucks transport the accumulated waste to landfills, primarily designed to handle general household waste, rather than specialized hazardous materials like pharmaceutical waste. When pharmaceuticals are discarded in regular trash receptacles, they typically become part of municipal solid waste streams, eventually reaching landfills (Daughton, 2010). This study includes excerpts from participants' interviews in which they have explained their choice or preference for

municipal waste services for pharmaceutical waste disposal. These excerpts shed light on the diverse reasons behind this preference:

Excerpt 1: "It is not really a preferred method, but rather a method we use when the storage gets full as we wait for collection from the service provider." - Public Clinic respondent

Excerpt 2: "Our pharmaceutical waste is not listed as part of the pharmaceutical waste that needs special treatment." - OTC store manager

Excerpt 3: "Pharmaceutical waste is not as high risk as infectious waste and it can be disposed at the landfill unlike infectious, anatomical or sharps waste which can even put the facility into disrepute if it was found in the open or in the landfill." - Private Practice participant

Excerpt 4: "I honestly was not aware that pharmaceutical waste cannot be mixed with general waste because even in our houses there is no special method for it clearly; we must have awareness campaigns." - OTC store manager

Although participants provided varying responses regarding their choice or preference for municipal waste services over other disposal methods, common factors emerged. These included resource limitations, cost constraints (as municipal services are often free or less expensive), regulatory confusion, convenience, limited storage capacity, lack of awareness, and inadequate education and training.

The second most employed method for pharmaceutical waste disposal, selected by over 50% of the facilities, is the sewer system. This method is typically utilized for pharmaceutical waste in soluble dosage forms, including pills and liquid such as unused liquid medications, intravenous solutions, and liquid chemical reagents. Studies have indicated that numerous pharmaceutical compounds exhibit resilience to traditional wastewater treatment methods, potentially leading to their persistence in treated effluents and posing risks to aquatic ecosystems (Spongberg and Witter, 2008). During this study, it was observed that facilities incorporating the sewer system method alongside other disposal methods were often less concerned or unaware of the potential implications of this method on the environment and human health. Some responses explaining their choice to use the sewer system for pharmaceutical waste disposal include:

Excerpt 1: "To me, this method is better than using bins because this way we can tell that indeed medication was dissolved and disposed of, rather than leaving it in bins which may take longer to be serviced, and in the meantime, people may be exposed to the dangers of these pills."

Excerpt 2: "This method means that people are not exposed to the hazardous chemicals in the tablets, and it goes to the sewage system where all the other unwanted waste goes."

Excerpt 3: "To me, this method makes sense because it is quicker and safer for the general public.

One of the primary reasons cited for using the sewer system for pharmaceutical waste disposal is its efficiency and convenience. Facilities' managers argue that this method ensures quick and thorough disposal of medications, especially those in soluble forms like pills and liquid medications. Unlike traditional waste bins, which may require longer time for servicing and can expose individuals to the hazards of pharmaceutical waste, the sewer system appears to offer a more efficient and timely solution. The study reveals a concerning trend that many facilities using the sewer system method seem to be unconcerned or unaware of the potential environmental implications of this disposal approach. The accumulation of pharmaceuticals in the environment can contribute to antibiotic resistance, disrupt aquatic ecosystems, and potentially harm human health through exposure via drinking water or seafood consumption (Spongberg and Witter, 2008).

The third most used method for pharmaceutical waste disposal, chosen by healthcare facilities, is the engagement of third-party waste management companies. Proper utilization of third-party pharmaceutical waste management services ensures safe, compliant, and environmentally responsible disposal of pharmaceutical waste. This service offer specialized expertise and resources to healthcare facilities, pharmacies, and pharmaceutical manufacturers, aiding them in effectively navigating the complexities of pharmaceutical waste management.

In public healthcare facilities, the Department of Health contracts a waste management company for the transportation of medical waste, including pharmaceutical waste, from every public healthcare facility for treatment and disposal. The Department assumes responsibility for the payment of equipment supplied by the waste management company, treatment costs of healthcare-risk waste, as well as the supply of temporary storage bins. In private sector facilities, their owners are accountable for selecting their own third-party waste management company and

are liable for payment according to the service level agreement. The waste management company also maintains records of the quantity and type of medical waste, including pharmaceutical waste, collected in a facility. Measurement of the quantity of medical waste generated is typically conducted by the waste management company's representative in the presence of a representative from the healthcare facility.

The findings of the study underscore the diversity of methods employed for pharmaceutical waste disposal in healthcare facilities. While the sewer system and third-party waste management companies are common choices, the reasons behind these choices vary and are influenced by factors, such as convenience, safety, environmental concerns, and regulatory compliance.

Figure 4.13: Medical waste count on collection day (Source; Researcher)

A copy of the record of the quantity of the HCRW collected may be left in the facility or sent back to the facility with the certificate of destruction. A certificate of destruction is a document that provides proof that pharmaceutical waste has been safely disposed of. It is an important record that must be filled out and submitted when shipping hazardous waste and it allows facilities to track their pharmaceutical waste, ensures the waste has been disposed of appropriately and provides information on where the pharmaceutical waste was taken; however, some managers were not aware of the existence of such a certificate, and they do not have copies in their files. The responses from various managers regarding the issuance of certificates of destruction and their awareness of such certificates can be grouped under the following themes:

Theme 1: Lack of Awareness and Certificates:

- This theme encapsulates responses from managers who express a lack of awareness regarding the existence and provision of certificates of destruction. They maintained that they had not received any certificates, indicating that they may not have a clear understanding of what is expected from waste management providers.

Theme 2: Reliance on Service Level Agreements (SLAs):

- Some managers indicated that they rely primarily on service level agreements (SLAs) with waste management providers as evidence of their engagement in medical waste management. These managers mentioned that they do not possess certificates of destruction but have SLAs and invoices as proof of their compliance with waste disposal regulations.

Theme 3: Uncertainty about Documentation:

- This theme highlights responses from managers who express uncertainty regarding the specific documentation they should receive after utilizing waste management services. They responded that they have paid for the services but do not have clarity on what documentation should be provided to them.

Theme 4: Invoice and Payment Records:

- A subset of managers confirmed that they receive invoices and maintain records of payments made to waste management providers, hence, while they may not have certificates of destruction, they argue that these payment records and SLAs can serve as proof of compliance.

These themes collectively underscore the variability in awareness and documentation practices among healthcare facility managers, regarding pharmaceutical waste disposal. While some managers are well-informed and possess certificates of destruction, others rely on alternative documentation or are uncertain about the specific requirements.

The last method used for disposal of pharmaceutical waste was open burning, 15 of the 58 facilities used open burning for their pharmaceutical waste disposal. This method of disposal involves the burning of pharmaceutical products in an open, uncontrolled setting, often in open pits or barrels. This method was widely used in standalone private practices, especially those

that are situated in semi-rural areas. Burning pharmaceuticals openly and at low temperatures results in the release of toxic pollutants into the air (Windfeld, 2015).

Figure 4.14: Burning of non-segregated pharmaceutical waste (Source: Researcher)

Among the safety concerns associated with this method is the potential release of hazardous substances, carcinogens, and pollutants into the atmosphere as a byproduct of the combustion process. Such emissions pose a dual threat: endangering the well-being of healthcare workers and neighboring communities while simultaneously contributing to atmospheric pollution and environmental degradation. This hazardous nature of open burning aligns with the World Health Organization's (WHO) warnings regarding the deleterious health consequences associated with exposure to emissions from open-burning practices; some of the consequences are - respiratory complications, cardiovascular ailments, and the heightened risk of cancer (WHO, 2015). Some facility managers admitted that the method is not in line with the existing environmental regulations but they still practised it; reasons for this practice were centered around lack of resources and funds as they complained that most service providers are expensive, hence, they cannot afford them.

4.3. Consumer knowledge, perception, and management of pharmaceutical waste in households

Evaluating and assessing the knowledge, perspective, and management practices of pharmaceutical waste in households were crucial for several reasons. First and foremost, improper disposal of pharmaceutical waste can lead to environmental contamination, posing risks to ecosystems and potentially harming human health. Ascertaining the knowledge levels and perspectives of households regarding pharmaceutical waste helps to identify any gaps in

awareness, facilitating targeted educational interventions. Effective waste management practices are essential to mitigate the environmental impact of discarded medications. Additionally, assessing current management practices aids in the development of evidence-based guidelines and policies for the safe disposal of pharmaceutical waste at the household level.

4.3.1 Socio-demographic information

Table 4.2 presents the socio-demographic characteristics of the respondents. The research sample consisted of a total of 384 participants, equally distributed between Makhado Municipality and Thulamela Municipality regions. The majority of the participants, constituting 80.1%, identified as African, while a smaller segment, 6.9%, were classified as white. Gender-wise, the majority of the respondents were female; additionally, 56.2% of the respondents had educational qualifications below matric.

Table 4.2: Socio-demographic characteristics of the respondents

Variables	Frequency (n=384)	Percentage (%)
Municipal Region		
Makhado Municipality	192	50.0
Thulamela Municipality	192	50.0
Age category		
18-25	33	8.4
26-35	92	23.9
36-40	60	15.8
41-50	139	36.1
50+	60	15.8
Gender		
Female	275	71.8
Male	109	28.2
Ethnicity		
African	311	80.9
White	47	12.2
Indian	26	6.9
Level of Education		
Below Matric	216	56.2
Post Matric Qualification	132	34.4

Variables	Frequency (n=384)	Percentage (%)
Postgraduate Qualification	36	9.4

4.3.2 Knowledge of pharmaceutical waste

The research utilized various variables to gauge the public's knowledge and understanding of pharmaceutical waste (PW) within households, as detailed in Table 4.3. It was noteworthy that 71.2% of respondents claimed awareness of what PW encompasses, although only 20.1% were acquainted with the associated risks. Building on Angi'enda and Bukachi's (2016) recommendation to include risk warnings and disposal instructions in product packaging, this study explored consumers' habits regarding medication packaging. Surprisingly, 63.6% admitted to not reading their medication packaging, while 24.4% reported regular reading, and 12% mentioned occasional perusal. These findings point at the possibility that warning signs or disposal instructions, if present, may be overlooked, thereby, advocating for verbal and interactive awareness initiatives to ensure informed decision-making regarding PW management. The revelation that 84% of respondents were unaware of any PW-related policies suggests a potential gap in consumers fulfilling their responsibilities around the possession of medications and this raises questions about their ability to report non-compliance by local pharmacies if such issues arise.

Table 4.3: General public knowledge of pharmaceutical waste

Variables	Frequency (N)	Percentages (%)
Disposal of Left-over Medication		
Yes	273	71.2
No	111	28.8
Knowledge regarding risks associated with pharmaceutical waste.		
No	307	79.9
Yes	77	20.1
Reading Medication Packaging		
No	244	63.6
Yes	94	24.4
Sometimes	46	12.0
Awareness of Disposal Policies		
No	323	84.0
Yes	61	16.0

4.3.3 Household Pharmaceutical Waste Generation

The study focused on several key aspects, shedding light on patterns and factors that contribute to the generation of pharmaceutical waste at the household level. One crucial aspect of these findings pertains to the sources from which consumers procure their medication. Pharmacies and over the counter (OTC) stores emerged as the primary outlets for medication acquisition, with hospitals and clinics also playing a significant role in this regard. This observation provides a valuable standpoint on consumer preferences and the availability of medication sources, aligning well with the existing literature on the topic (González et al. 2021). The researcher delved into the prevalence of excessive medication acquisition, which is a pressing concern in pharmaceutical waste management. A substantial number of respondents admitted to frequently purchasing or being prescribed more medication than necessary, corroborating previous studies (Banwat, 2016; Lowet, 2022). This finding highlights the need for interventions to curtail the over-prescription of medication, which contributes to the accumulation of unused drugs in households. Medication adherence is another vital aspect of the study. The results reveal that a significant proportion of individuals do not complete their prescribed medication regimens, indicating a lack of adherence to treatment plans (Rogowska et al., 2019). Majority of respondents attributed this issue to the presence of leftover medications from previous purchases or prescriptions. Additionally, discontinuation of treatment when individuals feel better, changing prescriptions, experiencing severe side effects, and concerns about medication expiration were reported as contributing factors (Rogowska et al., 2019; Banwat, 2016; Lowet, 2022).

Table 4.4: Medication Utilization Patterns within Households

Variables	Frequency (N)	Percentage (%)
Belief about Over-Prescription or Over-Purchasing		
Yes	308	80.2
No	76	19.8
Sources of Medication		
Clinics		
Hospital	46	12.0
Over-counter	87	22.6
Pharmacy	98	25.4
	153	39.9
Number of leftover/unused medication in your home based on type.		

Variables	Frequency (N)	Percentage (%)
1 -5		
11 - 16	172	44.8
6 – 10	69	18.0
	143	37.2
Frequency of Finishing Medication		
Never	185	48.2
Sometimes but not often	165	43.0
Very often	34	8.8
Reason for leftover medication		
Change of prescription		
Left over from previous purchase.	41	10.6
Passed expiry date.	217	56.2
Self-discontinued (Voluntarily stopped)	17	4.3
Severe side effects	83	21.6
	27	7.1

4.3.4 Frequently used and disposed medication in households

Investigating the variety of medicines stored and used within households is relevant as it provides insights into their role in generating household pharmaceutical wastes (HPWs). Figure 6.1 below presents a visual depiction of the types of medications commonly consumed and discarded within households.

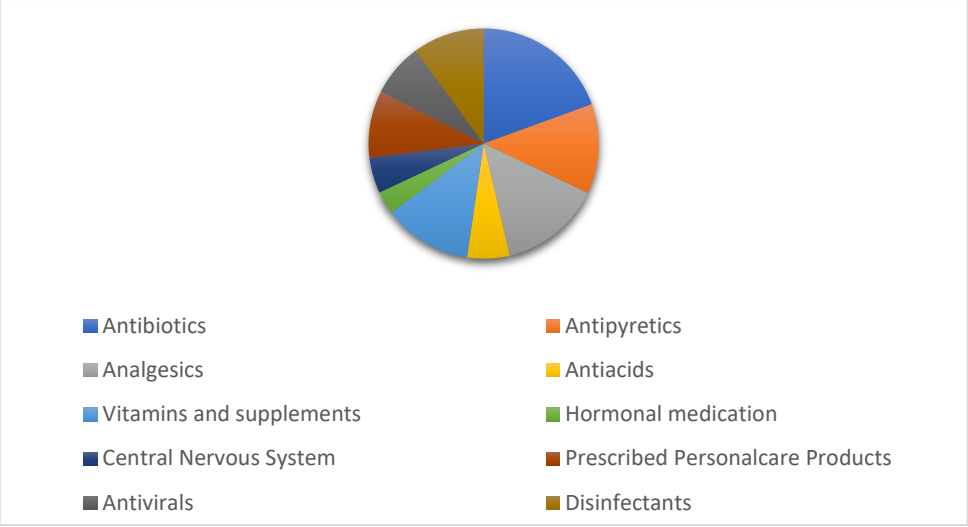

Figure 4.15: Frequently used and disposed medications in households (Source: Researcher).

The data presented in Figure 4.15 above reveals that antibiotics are the most discarded medications in households, closely followed by analgesics. This observation aligns with the findings of Sekhon (2021), which identified antibiotics as one of the most frequently used and consequently discarded medication categories. Antibiotic consumption has surged significantly, with a 65% increase over a 15-year period from 2000 to 2015, as reported by the World Health Organization (WHO, 2018). A study conducted by Madikizela and Chimuka (2017) noted analgesics, or painkillers, as one of the most frequently purchased medication categories. This high usage is attributed to their easy accessibility in pharmaceutical outlets without the need for a prescription, contributing significantly to the substantial volume of pharmaceutical waste generated in households.

The current study also identified other prominently consumed and disposed-of medications within households, as - antipyretics, vitamins and supplements, and disinfectants. Research conducted by Kim et al. (2021) indicates a noteworthy increase in the consumption rates of these pharmaceutical groups during the years 2020-2022, particularly during the Covid-19 pandemic. This upsurge in usage may be indicative that during that period, individuals sought to safeguard themselves against the virus. Conversely, medications with medium to low consumption and disposal rates in households were identified as - prescribed skincare products, antivirals, antacids, central nervous system (CNS) drugs, and hormonal medications, in that order. Figure 4.16 below depicts some of the pharmaceuticals commonly used in households.

Figure 4.16: Commonly-used medications in households (Source: Fieldwork)

4.3.5 Management of pharmaceutical waste in households

In the exploration of management practices pertaining to unused pharmaceuticals, it was imperative to gain insights into how respondents managed their household pharmaceutical waste. The results illustrated that a substantial majority opted for the disposal of their unused medications. It was, however, disconcerting that a portion of respondents either dispensed their medications to individuals in need or retained them for future utilization, which is consistent with the concerns raised by Brown and Johnson (2017) regarding the potential health hazards associated with self-diagnosis and the utilization of incorrect or expired medications. HPCSA and WHO advocate for the return of unused medications to pharmacies, take-back centers, or healthcare facilities to ensure their safe disposal. Sadly, only a minority of the respondents in this study reported the return of their unused medications to pharmacies, as also observed by Ayele and Atul (2018).

In view of the fact that the predominant mode of managing pharmaceutical waste within households involves self-disposal, it was imperative to scrutinize whether healthcare professionals furnish patients or consumers with guidance regarding appropriate disposal practices at the time of medication procurement or prescription (Green et al., 2016). Regrettably, only a fraction of the respondents confirmed their receipt of such information, while a substantive number negated any such provision. This discovery underscores an evident void in communication between healthcare practitioners and patients regarding the proper and secure management of pharmaceutical waste. Matlala (2020) drew attention to the predominant practice of amalgamating hazardous waste with general waste in households, even though pharmaceutical waste carries a potentially perilous nature. This practice aligns with numerous antecedent studies highlighting the quandary of waste separation at the household level, which poses a substantial hurdle to the efficacious management of waste (White and Brown, 2015).

It is salient to note that a significant portion of the respondents in the present study asseverated their non-adherence to the segregation of pharmaceutical waste from other waste streams generated within their households. This further corroborates the recurrent impediments associated with the separation of waste materials at the household level, as also highlighted by White and Brown (2015). A small proportion of the respondents affirmed their active participation in the separation of pharmaceutical waste, a testament to the prevailing issue and in line with antecedent scholarly investigations and reports (Johnson and Smith, 2020).

Table 4.5: Pharmaceutical waste management practices in households

Variables	Frequency	Percentage
Management of left-over medication		
Dispose	312	81.2
Give it to someone else or save it for later.	49	12.7
Return to pharmacy/facility	23	6.1
Informed of proper disposal upon prescription or purchase		
No		
Yes	265	69.0
	119	31.0
Segregation of pharmaceutical waste from household waste		
No	330	86.0
Yes	54	14.0
Responsibility for proper management of pharmaceutical waste		
All of the above	146	37.9
Consumers (A)	55	14.2
Medical Practitioners(C)	40	10.4
Municipality (D)	113	29.3
pharmacists (B)	31	8.1

Collectively, these revelations underscore the exigency of enhanced awareness, educational initiatives, and endeavours aimed at fostering safe pharmaceutical waste disposal practices. They also underscore the significance of fortifying communication channels between healthcare professionals and patients, particularly regarding this facet of healthcare and waste management (Johnson and Smith, 2020).

4.3.6 Disposal Practices

Respondents were asked to indicate how they disposed of their pharmaceutical wastes from households, and findings revealed a notable pattern of non-uniformity in pharmaceutical waste disposal practices, which are influenced by numerous factors. Figure 4.17 illustrates the results of the various common disposal methods used in households in the Vhembe District. Among the 384 households surveyed, the majority, 59.64%, used municipal waste disposal services, however, this method, like the others, carries risks of environmental contamination. Additionally, 17.71% of households reported flushing or draining their pharmaceutical waste, while 9.11% threw them in pit latrines, and 5.21% opted for burning the waste - each however, contributing to

environmental pollution and potential health hazards. Only 10.94% of households returned their pharmaceutical waste to pharmacies, which is the recommended and safe method.

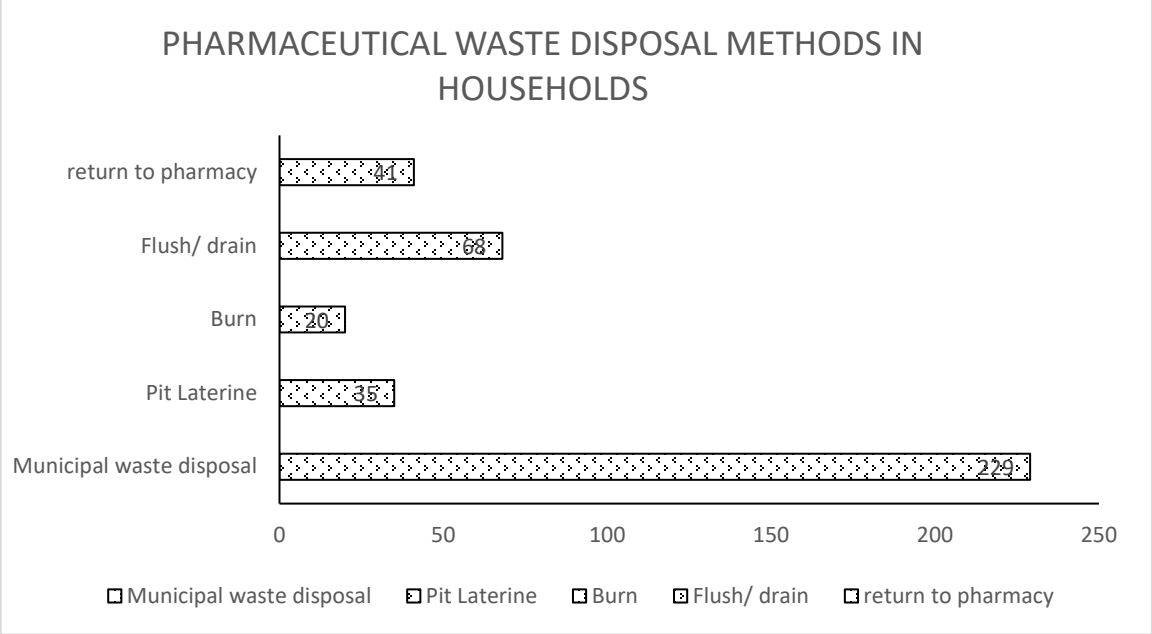

Figure 4.17: Pharmaceutical waste disposal methods in households (Source: Researcher)

A prominent contributor to this non-uniformity is insufficient education, knowledge, and awareness concerning waste management. It is evident that a majority of consumers, as demonstrated in Table 4.4, are unaware of any regulations related to the proper disposal of pharmaceuticals in household settings. Consequently, households tend to manage their PW in ways that are most convenient for them, resulting in a diverse range of PW disposal methods without consideration for safety. The use of municipal service disposal is the most commonly-adopted approach for pharmaceutical waste (PW) disposal, supporting findings by Smith et al. (2019) and Anderson (2018) who conducted research in different regions and found that municipal service disposal was the most prevalent method for HPW management. Other disposal methods were also noted in the current study, such as flushing of medications and burning, however, it is important to note that each of these methods has its own drawbacks and may have detrimental impacts on the environment and public health.

4.3.7 Drawbacks of Household Pharmaceutical Waste Disposal Methods

The practice of mixing pharmaceutical waste with general household waste can have detrimental impacts on the environment. In the current survey, it was revealed that a significant 86% of

consumers do not segregate their pharmaceutical waste in households, a pattern consistent with previous studies conducted by Smith et al. (2018) and Johnson and Brown (2017) who reported that a significant percentage of consumers do not separate pharmaceutical waste from general household waste. In the current study, the prevailing practice is that pharmaceutical waste is indiscriminately disposed of in common trash bins, which are later placed outside for pick-up by municipal refuse removal, as depicted in Figure 4.18. This practice of interim storage of waste in outdoor rubbish bins or refuse bags, before municipal collection, introduces potential risks that warrant attention. these concerns are echoed by Garcia and Patel (2019) and Martinez et al. (2018) who concluded that this approach introduces potential risks related to other individuals' unauthorized access to discarded medications and the inadvertent reuse of pharmaceuticals, highlighting the potential dangers to both human health and the environment.

Figure 4.18: Household waste awaiting municipal collection at the pickup point outside (Source: Researcher).

After waste has been removed from households by municipal refuse collection, it heads to landfills, signifying that substantial quantities of pharmaceutical waste generated in households eventually find their way to landfills. This observation echoes findings from previous studies conducted by Lubick (2010) and Anderson (2018) who have reported the occurrence of pharmaceutical waste, in landfills. In the current study, municipal waste personnel, in both local municipalities were specifically queried about instances whereby pharmaceutical waste was found in landfills and their responses indicated that such instances do occur. This aligns with the concerns raised by prior studies (Garcia and Patel, 2017; Martinez et al., 2016); further

underscoring the presence of pharmaceutical waste in landfills and the associated environmental implications.

Figure 4.19: Pharmaceutical waste in landfills (Source: Researcher)

Municipal landfills are primarily designed for the disposal of solid waste and are not adequately equipped to manage pharmaceutical waste, which is categorized as hazardous (WHO, 2018). Numerous studies conducted on landfill leachate have consistently reported the occurrence of pharmaceutical waste in landfill leachate, drawing attention toenvironmental concerns associated with this practice (USGS, 2014; Zhang et al., 2023; Kummerer et al., 2020).

Findings indicate that roughly 17% of respondents use the flush/drain method which can have significant environmental consequences. Flushing pharmaceuticals down the drain can lead to the contamination of water sources, as active pharmaceutical ingredients may persist and enter the aquatic ecosystems. These findings align with prior research by Jones et al. (2017) which emphasized the need for increased public awareness and improved disposal methods to reduce the environmental impact. The 9% of respondents who dispose of their pharmaceutical waste (HPW) in pit latrines and the 5% who resort to burning it represent less common but concerning practices. Disposing of HPW in pit latrines can potentially lead to the leaching of harmful substances into groundwater, posing risks to both the environment and public health. Additionally, burning pharmaceutical waste can release toxic chemicals and contribute to air pollution, as noted in studies by Brown et al. (2018) and White et al. (2019). These findings underscore the need for not only discouraging these practices but also providing alternative, safer methods for disposing of HPW.

The consistency of these findings with prior research, illustrates the persistent nature of the problem. It suggests that existing interventions and educational efforts may not be sufficient in

changing disposal habits. Returning unused and leftover medication to the pharmacy is widely recognized as a best practice for the safe disposal of pharmaceutical waste (Hai et al., 2020). This method not only ensures proper disposal but also helps prevent the environmental and public health risks associated with inappropriate disposal practices, however, it is concerning to note that only 11% of consumers investigated in the Vhembe region opt for this responsible approach. This discrepancy between the recommended best practice and the actual behaviour of consumers underscores the need for more targeted campaigns to raise awareness about the proper disposal of pharmaceutical waste and the potential long-term environmental and health consequences associated with improper practices.

4.3.8 Factors affecting Consumer behaviour and Interventions

Consumer behaviour towards pharmaceutical waste is shaped by a multitude of factors, spanning from individual, social, and environmental dimensions. Awareness and knowledge levels of consumers play a pivotal role in their behaviour, as studies have found that a lack of awareness regarding the proper disposal of pharmaceuticals can lead to improper practices (Tong et al., 2011). Additionally, the perceived risk associated with improper disposal practices can influence consumers' behaviour, with research indicating that a comprehensive understanding of the health and environmental risks encourages proper disposal (Giacomini et al., 2015). Accessibility to convenient collection and disposal facilities is another vital factor affecting consumer behaviour.

Research has underlined the significance of easy access to disposal options, such as drop-off locations and take-back programs, in shaping consumer behaviour (Kusturica et al., 2012), moreover, the influence of social norms and peer behaviour cannot be overlooked. When individuals observe their peers engaging in responsible pharmaceutical waste disposal, they are more likely to follow suit, aligning their behaviour with social norms (Ajzen, 1991). The Capability Opportunity Motivation Behaviour (COM-B) model served as the foundation for identifying the factors influencing consumer behaviour towards pharmaceutical waste within the Vhembe region. By employing this behaviour change framework, the study systematically dissected the elements impacting behaviour, categorizing them into Capability, Opportunity, Motivation, and Behaviour. This structured approach allowed for a comprehensive understanding of the several factors influencing the disposal of pharmaceutical waste among consumers in the specific context of Vhembe. Through this model, the study revealed how individual and environmental factors, such as consumer knowledge, accessibility to disposal facilities, and environmental concern, interplay to influence behaviour. Figure 4.20 below depicts the overall factors affecting consumer behaviour

towards pharmaceutical waste management in the Vhembe Region and possible intervention strategies.

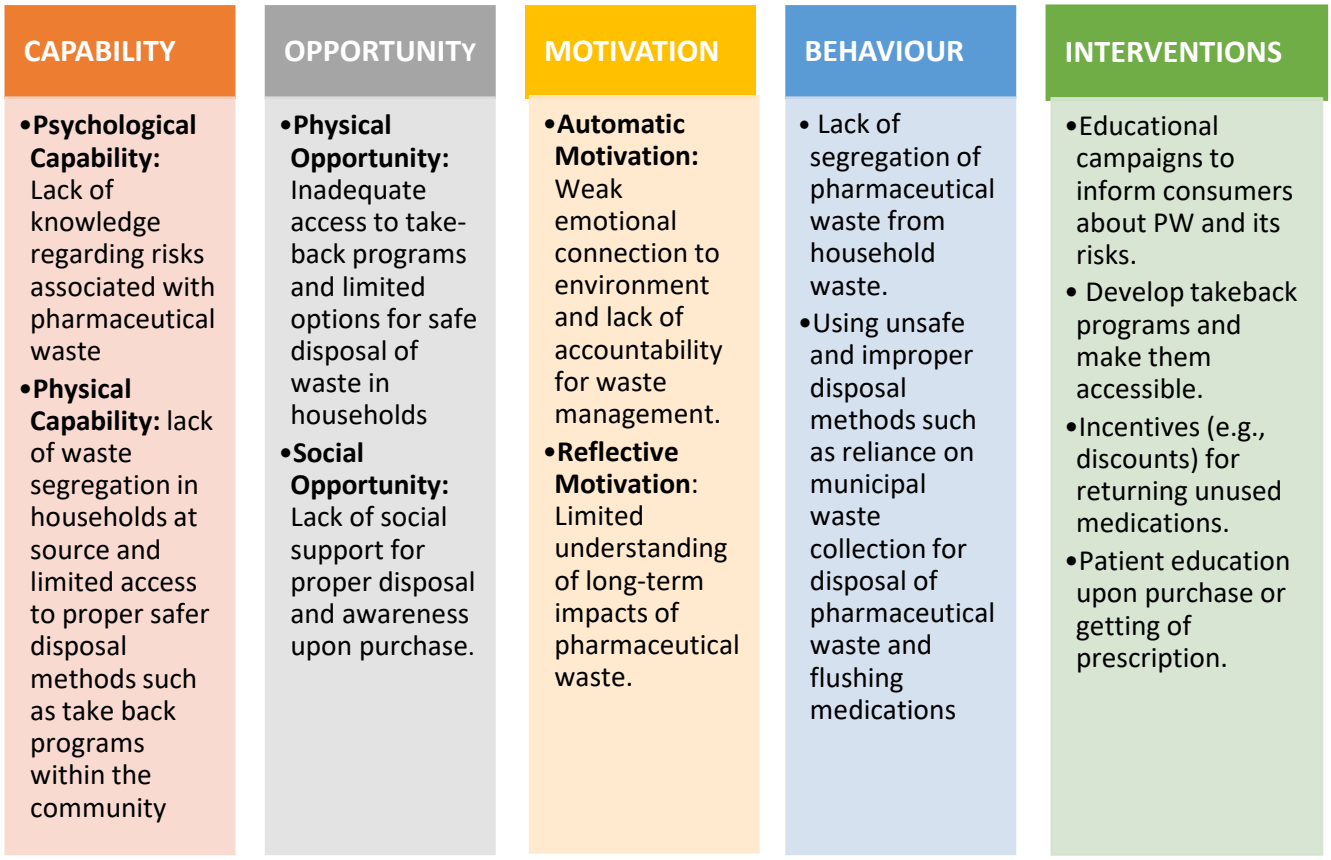

Figure 4.20: Factors affecting consumer behaviour and intervention (Source: Authors work)

4.4 Healthcare professionals' perception, knowledge, and attitude towards pharmaceutical waste management

To predict an individual's likelihood of engaging in a specific behavior at a particular time and place, the Theory of Planned Behavior (TPB), as formulated by Ajzen (1998), offers a valuable framework. This theory postulates that an individual's attitude, perceptions, and the information they possess significantly influence their behavior in each context (The HIV/AIDS Network, 2014). Consequently, evaluating respondents' perceptions, knowledge, and attitudes regarding pharmaceutical waste management becomes essential to comprehensively understand their participation in effective waste management practices. By applying the TPB framework, we can gain insights into the factors that shape individuals' intentions and behaviors related to

pharmaceutical waste management, ultimately contributing to the development of more effective waste management strategies.

4.4.1 Socio-demographic information

Table 4.6 provides an overview of the socio-demographic attributes of the survey participants. These attributes are - the healthcare professionals' workplace sector, occupation, age group, gender, ethnicity, and educational qualifications. The study included a total of 384 healthcare professionals with 210 employed in the private sector and 174 in the public sector. The predominant proportion of respondents identified as African (n=294; 76.4%) and females (n=232; 60.3%).

Table 4.6: Demographic information of healthcare professionals

Variables	Frequency (n = 384)	Percentages (%)
Medical facility		
Public Healthcare	174	45.5
Private Healthcare	210	54.5
Gender		
Female	232	60.3
Male	153	39.7
Age Group		
18-24	80	20.8
25-35	177	46.0
36-40	92	23.9
40-50	31	8.1
50+	5	1.3
Ethnicity		
African	294	76.4
Asian	2	.5
Indian	54	14.0
White	35	9.1
Occupation		
Nurse	140	36.3
Medical Doctor	134	35
Pharmacists	87	22.5
Others	24	6.2
Level of Qualification		
Honors	172	44.7
Masters	18	4.7
Phd	2	0.5
Undergraduate Degree	193	50.1

Variables	Frequency (n = 384)	Percentages (%)
Years of Experience		
1-5 years	122	31.7
5-10 years	94	24.4
10-15 years	40	10.4
15-20 years	5	1.3
25+ years	124	32.2

4.4.2 Knowledge of Pharmaceutical Waste Management

The study's revelation that over half of the healthcare professionals surveyed had not encountered pharmaceutical waste management content in their academic programs (53.8%) is a matter of concern. This finding underscores a potential gap in the education of healthcare professionals, considering the relevance of this knowledge in healthcare settings. As highlighted by Godia et al. (2013), the absence of this content in academic curricula could impact the expertise and knowledge of healthcare professionals. The study indicates that a significant portion of healthcare professionals (52.2%) did not receive pharmaceutical waste management training before entering professional practice. This underscores the need for a more uniform and consistent approach to pre-practice training to ensure that a higher percentage of healthcare professionals are well-prepared to manage pharmaceutical waste. For those who received training, its effectiveness varied according to the participants - 43.5% considered it quite effective, 32.6% found it non-effective, and 23.9% perceived it as highly effective. These results suggest room for improvement in the content and delivery of pharmaceutical waste management training, so although the training is only minimally effective, there is potential for enhancing its impact further. The survey revealed that healthcare professionals in the Northern region of South Africa have varying levels of knowledge and awareness regarding pharmaceutical waste and its impact. A substantial percentage claimed to be only partially informed about pharmaceutical waste (38.7%) and its environmental impact (32.7%). A smaller fraction, however, saw themselves as well-informed (29.4%) regarding pharmaceutical waste and 29.4% about its environmental impact). Conversely, a large majority (77.9%) reported being aware of the effects of pharmaceutical waste on human health.

These findings imply that there is a need for more comprehensive and standardized education on pharmaceutical waste management in academic curricula and in pre-practice training. Additionally, efforts to enhance the effectiveness of pharmaceutical waste management training and to bridge knowledge gaps about pharmaceutical waste and its impact, especially the

environmental aspects, could significantly contribute to improved healthcare waste management practices. The study findings underscore the importance of continuous education and training in ensuring healthcare professionals are well-equipped to manage pharmaceutical waste effectively, which in turn can lead to better healthcare waste management practices and reduced environmental and health risks.

Table 4.7: Knowledge and training of healthcare professionals

Variables	Frequency (N=384)	Percentages (%)
Coverage of Pharmaceutical Waste Management in School Curriculum		
Yes	174	46.2
No	210	54.8
Training on Pharmaceutical Waste Handling prior to practice		
Yes	183	47.8
No	201	52.2
Effectiveness of training		
Highly effective	40	23.9
Not effective	60	32.6
Quite effective but there is room for improvement	80	43.5
Knowledge of Environmental Impacts of pharmaceutical waste		
Not informed at all	118	30.6
Partially informed	126	32.7
Well-informed	86	22.3
Very well-informed	53	14.3
Awareness of Human Health Impacts of pharmaceutical waste		
No	84	22.1
Yes	300	77.9

4.4.3 Knowledge on regulations

Proper medical waste disposal hinges on healthcare professionals (HCPs) having a comprehensive understanding of various disposal methods (Matlala, 2017), however, the findings presented in Table 5.3 reveal a concerning gap. They indicated that the curriculum of most medical schools lacks content related to Pharmaceutical Waste Management (PWM), therefore, , some HCPs may not receive training on the appropriate management of Pharmaceutical Waste (PW) before commencing their professional practice. The study indicates that healthcare professionals do recognize the need to separate Healthcare-Related Waste (HCRW) from other types of waste, with over 70% of respondents affirming its significance. When questioned about their knowledge of further segregating PW within the broader category of HCRW based on its type and dosage, only 37% claimed to have such knowledge, while the majority (63%) confessed to being unaware of the need for this additional segregation. These findings corroborate observations made by Ngqwala and Muchesa (2020), indicating that while there is significance is paid to separating HCRW from general waste and distinguishing anatomical waste from other HCRW, less attention is paid to the segregation of pharmaceutical waste. Kim et al. (2021) also supported these findings by highlighting that pharmaceutical waste often receives less priority due to its delayed impact compared to anatomical waste, which poses immediate risks such as foul odors and non-compliance exposure. The data also shows that less than 50% of HCPs are well-informed about the legislations governing PWM.

Table 4.8: Knowledge regarding regulations on pharmaceutical waste

Variables	Frequency (N=384)	Percentages (%)
Knowledge of National Pharmaceutical Waste Management Legislations		
Not informed at all	92	23.9
Partially informed	135	35.1
Very well-informed	55	14.3
Well-informed	102	26.8
Importance of Segregation of Pharmaceutical Waste		
Yes	291	75.8
No	93	24.2
All pharmaceutical waste must be placed in a single bin if labelled **as pharmaceutical** waste.		
False	145	37.7
True	239	62.3

This knowledge gap is concerning, as it indicates a lack of awareness about the regulations and policies in place for the proper management of pharmaceutical waste. These results, therefore, raise questions about the preparedness of HCPs in understanding the regulations and policies governing PW management and their practical implementation. These findings presented also underscore the need for addressing gaps in the curricula of medical schools, enhancing training programs, and raising awareness among HCPs about the regulations and policies governing pharmaceutical waste management. It is essential for HCPs to be well-informed and equipped to implement appropriate disposal practices to ensure the safety of patients, healthcare workers, and the environment.

While limited literature specifically addresses HCPs' perspectives on pharmaceutical waste, existing studies on overall healthcare waste management indicate the necessity of educating and training HCPs. Studies done by Smith et al. (2018) and Johnson et al. (2020) suggest that inadequate knowledge and training can lead to non-compliance with waste management regulations therefore stressing the necessity for HCPs to understand the regulations, their implementation, and the need to provide training is underscored to ensure safe and compliant waste management.

In the current study, HCPs were asked about their level of understanding of the regulations and guidelines for pharmaceutical waste management. Approximately 25.7% of HCPs found these regulations clear and relatively easy to implement. A larger group, constituting 41% of the respondents, perceived the regulations as clear but challenging to put into practice. On the other hand, 19.7% of HCPs considered the regulations to be complicated, while 13.2% went further, asserting that the regulations were both complex and impossible to implement. Similar findings have been reported in other studies examining healthcare professionals' perceptions of regulations and guidelines in various contexts. For instance, a study by Smith et al. (2018) found that a substantial percentage of healthcare professionals acknowledged the clarity of waste management regulations but faced challenges in their practical implementation. Additionally, a survey conducted by Parle (2019) identified a comparable pattern, with a significant portion of respondents considering the regulations intricate and posing difficulties in implementation.

Table 4.9: Comprehension of the pharmaceutical waste management framework

Opinion on Legislations, Standards, and Guidelines for Pharmaceutical Waste Management		
	Frequency (N)	Percent (%)
Clear and easy to implement	99	25.7
Clear but difficult to implement	158	41.3
Complicated	76	19.7
Impractical (impossible to implement)	51	13.2
Total	384	100.0

4.4.4 Perception and Attitude Towards Consumer Education

The improper disposal of pharmaceuticals in households can have far-reaching consequences for both human health and the environment. A study by Zock et al. (2018) investigated households' pharmaceutical waste disposal practices and found that most respondents disposed of unused medications in the household trash, or flush them down the toilet which can lead to the contamination of water sources. Numerous research studies have underscored the necessity of consumer education for healthcare professionals regarding the proper disposal methods of pharmaceutical waste. This education would play a pivotal role in ensuring that patients and consumers are informed about the safe and responsible management of unused or expired medications. Additionally, a study conducted by Persson et al., (2018) examined the role of pharmacists in educating patients about pharmaceutical waste disposal. The research indicated that it is paramount that pharmacists routinely provide information and guidance on safe medication disposal to patients. The study also revealed that patients who received this information from healthcare professionals were more likely to dispose of their medications in an environmentally-friendly manner. The current study probed healthcare professionals on whether they routinely inform consumers and patients on how to handle any remaining medication after purchase or prescription. The data revealed that most healthcare professionals, approximately 66%, did not provide such information. Table 4.10 provides crucial insights into the need for patient education among healthcare professionals. Among the surveyed healthcare workers, the data reveals that 43.5% (approximately 169 individuals) perceive that their duty ends with medication prescription, while 32.6% (around 124 professionals) believe that the significance of consumer education varies based on the type of medication prescribed or purchased, while 23.9% of the respondents (92 professionals) considered patient education to be essential across all circumstances.

Table 4.10: Attitude towards consumer education

Opinions on Informing Patients/Consumers about Pharmaceutical Waste Disposal upon prescribing or purchase		
	Frequency (N)	Percent (%)
It depends on the type of medication prescribed or bought	124	32.6
No, my duty ends at prescription	168	43.5
Yes, all the time	91	23.9
Total	384	100

A study by Ngqwala and Muchesa in 2020 suggested that 70-80% of pharmaceutical waste originates from households, emphasizing the need for consumer education, on the associated risks of pharmaceutical waste is crucial, however, findings of the current study indicate a contrasting perspective within healthcare facilities in the Vhembe District. This discrepancy underscores the regional variations in practice and the importance of addressing these differences in healthcare education and practice.

4.4.5 Pharmaceutical waste management responsibility in facilities

In the realm of medical waste management, several factors come into play that can significantly influence its success. These factors encompass factors like, a lack of - essential infrastructure, financial resources, and knowledge - among others (Olaniyi, 2018). One particularly noteworthy aspect that affects the effectiveness of healthcare waste and resource management (HCRWM) in healthcare facilities, however, is the attitude of healthcare professionals (HCPs) towards waste management, as highlighted by Winfield (2015).

When inquired about who is primarily responsible for pharmaceutical waste management (PWM) in the facilities where they work, the majority of healthcare professionals (HCPs) indicated that

the responsibility lies with the cleaners (41.4%). In a quest for further insights, in discussions during the face-to-face distribution of questionnaires, HCPs explained that they assign this task to cleaners primarily because their schedules are fully occupied with patient care. The demands of patient care leave them with minimal time to be involved in waste management activities. Pharmacists were indicated as responsible by 15.9% of respondents, while doctors were indicated by 1.6%, and nurses by 7.0%. Additionally, 34.4% of respondents indicated that everyone who handles pharmaceutical waste is responsible for its management.

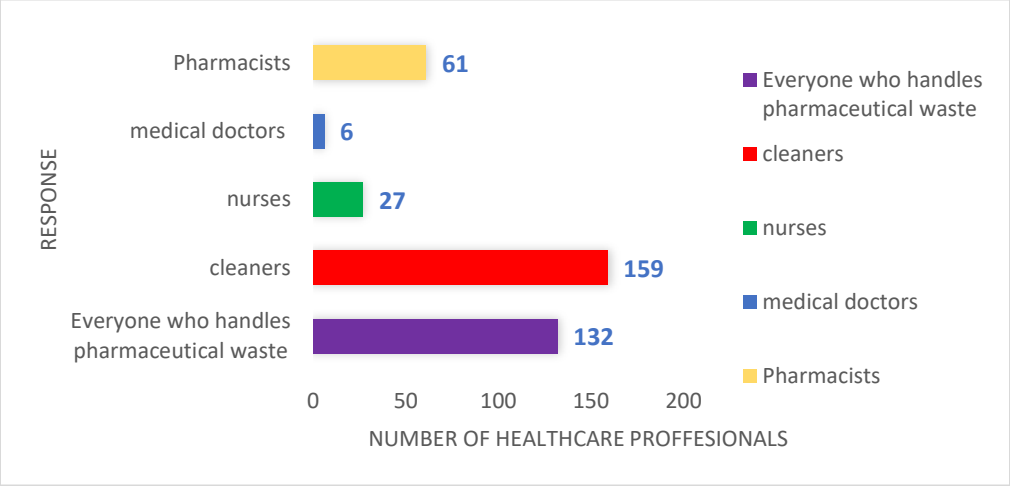

Figure 4.21: Responses of healthcare professionals on who is responsible for pharmaceutical waste management in the facilities (Source; Researcher).

It is important to note that the researcher recognizes the shortage of healthcare workers in the Vhembe region, which was consistently brought out by multiple HCPs. They pointed out that they frequently find themselves understaffed, which, in turn, presents them with a dilemma as they must often choose between attending to the next patient's medical needs and ensuring the proper management of medical waste.

4.5 Compliance Status to Existing Regulatory Framework

Compliance with regulatory frameworks in pharmaceutical waste management is essential to safeguard public health and safety. A compliance report assessing the district's pharmaceutical waste management, utilized findings from sections 4.2 and 4.4 to gauge the overall adherence to regulations. The detailed compliance report provided a breakdown of the criteria, specific findings, and their impacts. The outcomes reveal a prevalent lack of compliance among facilities, indicating a significant deviation from the prescribed standards for comprehensive medical waste management, including the handling of pharmaceutical waste. Table 4.11 below indicates the

overall compliance status report of the healthcare facilities and pharmaceutical outlets in Vhembe District. To underscore the significance of understanding the potential consequences, a risk rating was incorporated, as illustrated in Table 4.12.

Table 4.11: Compliance status of pharmaceutical waste management in 58 facilities in Vhembe District

Criteria	Finding/Status	Potential Impact	Risk rating
Segregation of waste at source	• 30 facilities do not segregate waste at source. • 8 facilities segregate their medical waste at source. • 10 facilities segregate pharmaceutical into different categories.	Leads to mixed waste streams, complicating the disposal process and increasing the likelihood of environmental pollution and health hazards.	
Storage package and labelling at point of generation	• 43 facilities do not have properly labelled bins at points of generation.	Poses a significant challenge, potentially leading to issues in waste segregation, disposal, and overall management efficiency.	
Temporary storage in the facility	• 35 of 58 facilities do not have designated storage area.	Poses potential risk of exposure for both workers and the public, including unsafe handling practices, increased chances of accidents, potential exposure to hazardous materials, and environmental contamination.	
Disposal Methods	• 42 of the evaluated facilities use municipal waste services for their pharmaceutical.	Poses potential risks of environmental contamination, public health concerns, regulatory non-compliance, limited traceability, increased operational costs, efficiency challenges.	
Record-keeping	• 20 facilities claimed proper record-keeping but only 2 were able to provide the records	Creates a gap in documentation practices, potentially posing risks related to regulatory compliance, accountability, and accurate tracking of waste management activities within the evaluated facilities.	
Staff training	• 22 facilities indicated that their staff gets trained for waste management, prior to practice.	May result in non-compliance pertaining to proper waste segregation and affect overall efficiency of the regulatory framework.	

Table 4.12: Risk rating guideline (Source; Researcher)

Risk Rating	Definition
Critical	Severe control weakness leading to significant environmental damage, serious health risks, or regulatory non-compliance with immediate action required, including notification to authorities.
High	Major adverse effects such as significant environmental impact or potential legal consequences, requiring prompt management action.
Moderate	Significant adverse effect including moderate environmental impact or short-term operational disruptions, necessitating short-term management action.
Low	Minor control weakness with minimal impact on waste management, requiring routine management action and attention.

4.5.1 Waste Segregation at Source

The segregation of waste at the source is a fundamental practice outlined in South African National Standards (SANS) 10248 and the National Environmental Management: Waste Act, however, our findings reveal that 51.7% (30 out of 58) facilities do not adhere to this crucial practice. This non-compliance leads to mixed waste streams, complicating the disposal process and elevating the risk of environmental pollution and health hazards. The observed non-compliance with waste segregation practices aligns with findings from studies in various regions. A study by Akormedi et al. (2017) conducted in Ghana's healthcare facilities identified similar challenges in waste segregation, drawing attention to the need for targeted interventions and training. This consistency in findings underscores the global nature of the issue and indicates the urgency for standardized solutions. Further supporting evidence comes from a study by Wilson et al. (2018), which found that healthcare facilities in Sub-Saharan Africa face common challenges in hazardous waste management, including inadequate segregation practices.

4.5.2 Storage Package and Labelling: Proper storage and labelling at the point of generation are imperative for effective waste management. In this assessment, 74.1% (43 out of 58) facilities were without properly-labelled bins at the point of generation. Such non-compliance not only poses challenges in waste segregation and disposal but also raises concerns about overall management efficiency. Similar challenges in proper labelling and storage have been

documented in studies beyond the Vhembe District. Lin et al. (2019), in their investigation of medical waste management during the 2019-2020 novel coronavirus pandemic, noted instances of inadequate labelling leading to confusion in waste segregation. A study by Sefah et al. (2016) conducted in Ghana's hospitals also highlighted deficiencies in labelling practices and the subsequent negative impact on waste management efficiency. These collective findings reinforce the need for addressing labelling issues on a broader scale, to ensure global best practices.

4.5.3 Temporary Storage in the Facility: The absence of designated storage areas in 60.3% (35 out of 58) facilities is a significant concern. This non-compliance with the Occupational Health and Safety Act and SANS 10248 poses potential risks, including exposure to hazardous materials, accidents, and environmental contamination. Adequate storage is paramount to ensuring the safety of both workers and the public. The lack of designated storage areas with its associated risks aligns with research in various healthcare settings. Pourzahedi et al. (2020), in a study conducted in Iran, found that inadequate temporary storage facilities contributed to safety hazards and inefficient waste management. This concurs with the concerns highlighted in this study, reiterating the need for global standards in temporal storage infrastructure. Akormedi et al. (2017), in their study in Ghana, also identified challenges in designated storage areas, showing the urgency of incorporating safety measures to protect healthcare workers.

4.5.4 Disposal Methods: Findings indicate that 72.4% (42 out of 58) facilities use municipal waste services for pharmaceutical waste disposal. This practice poses potential risks of environmental contamination, public health concerns, regulatory non-compliance, and increased operational costs. Compliance with SANS 10248 and the Waste Act necessitates the use of specialized, licensed disposal services for pharmaceutical waste. The reliance on municipal waste services for pharmaceutical waste disposal, as identified in the study is echoed in studies from various regions. Khademvatani et al. (2019), in their study in Iran, found a similar pattern where healthcare facilities often utilized general waste disposal services for pharmaceutical waste. This practice, as indicated in both studies, poses environmental and public health risks. Tadesse et al. (2018) conducted a study which focused on the urgency of regulatory guidance in shaping effective pharmaceutical waste management practices.

4.5.5 Record Keeping: Effective record-keeping is essential for regulatory compliance, accountability, and traceability, however, our assessment found that only 3.4% (2 out of 58) facilities claiming proper record-keeping were able to provide records. This gap in documentation practices raises concerns about the accurate tracking of waste management activities within the evaluated facilities. The challenge of maintaining accurate records is a common theme identified in various studies. Singh et al. (2019) found that healthcare facilities often struggle with

comprehensive record-keeping, hindering effective waste management practices. Bokhoree et al. (2018), in their research on digital record-keeping in waste management, found that the transition to digital systems enhances transparency and accountability. This aligns with the recommendation for implementing digital record-keeping systems, due to its potential benefits in improving waste management efficiency. The convergence of findings supports the global applicability of enhanced record-keeping practices.

4.5.6 Staff Training: While 37.9% (22 out of 58) facilities indicated that their staff undergo training for waste management, although the adequacy of such training remains uncertain. Incomplete or insufficient training may result in non-compliance regarding proper waste segregation, affecting the overall efficiency in the performance of the regulatory requirement. The uncertainty regarding the adequacy of staff training is a common concern across various studies. Usharani et al. (2020) note the need for continuous training programs to keep healthcare staff informed about evolving waste management guidelines and best practices. This confirms the ongoing challenge of ensuring effective training measures. Aung et al. (2018) recommends tailored and ongoing training to address specific challenges in healthcare waste management and to improve overall compliance.

4.6 Challenges and weaknesses of the current regulatory framework for pharmaceutical waste management in different facilities

It is relevant to evaluate weaknesses, gaps, and challenges within the current regulatory framework for pharmaceutical waste for several reasons. Firstly, such an evaluation will provide a comprehensive understanding of the shortcomings and areas of non-compliance, allowing for targeted improvements to be proposed. This in-depth analysis is essential to uncover systemic issues that may contribute to weaknesses of the framework. Secondly, identifying these weaknesses helps to address the root causes of non-compliance, whether it is due inadequate waste segregation or sub-optimal storage practices. By doing so, the regulatory framework can be strengthened to align more effectively with the accurate contexts of the facilities, ensuring better environmental sustainability and public safety. Additionally, this evaluation acts as a foundation for fortifying the existing framework, emphasizing the need for continuous improvement to address emerging challenges and maintain the framework's relevance in evolving healthcare contexts. A multifaceted analysis was conducted to gain a comprehensive understanding of regulatory framework for pharmaceutical waste management in South Africa. This analysis consisted of three key components: a policy gap analysis, a SWOT analysis, and a PESTEL analysis.

4.6.1 Policy Gap Analysis

Policy gap analysis is a systematic approach that plays a crucial role in evaluating the effectiveness of waste management policies and regulations (Belhadef et al., 2018). This method involves identifying and assessing disparities between existing policies and the intended outcomes or objectives in the realm of waste management. Such analysis is particularly significant in the context of environmental sustainability, public health, and economic efficiency. By pinpointing the areas where current policies fall short of achieving their intended goals, policy gap analysis offers valuable insights that can inform relevant policy development, reforms, and improvements. Policy gap analysis holds significance in waste management, serving as a diagnostic tool to identify deficiencies in existing policies. It helps pinpoint where policies fall short in addressing emerging environmental concerns, changing waste patterns, and technological advancements. This process guides policymakers in refining their strategies to better manage waste, hence, optimizing resource allocation by directing efforts to areas with the most critical policy gaps, thereby, improving environmental and public health outcomes.

Additionally, policy gap analysis promotes compliance and enforcement by aligning policies with goals and ensuring effective communication with stakeholders. This alignment facilitates better waste management practices and reduces the environmental impact of improper waste disposal. It enables policymakers to measure policy effectiveness over time, track progress, and make necessary adjustments to achieve waste management objectives more efficiently.

Numerous studies have adopted policy gap analysis to evaluate and enhance waste management policies; for example, in a European context, Belhadef et al. (2018) conducted a policy gap analysis to assess the effectiveness of waste management policies and regulations. Their research uncovered discrepancies between existing policies and the region's targets for recycling and reducing landfilling, articulating the need for policy adjustments to achieve these objectives. In the United States, Sliz-Szkliniarz et al. (2014) applied policy gap analysis to assess regulations and policies governing hazardous waste management. Their findings revealed the need for refining policies to minimize potential environmental and public health risks associated with hazardous waste. These studies, among others, showcase the practical application and significance of policy gap analysis in evaluating waste management policies, leading to more

effective and environmentally responsible waste management practices. The process for the policy gap analysis in the current study is depicted in Figure 4.21 below.

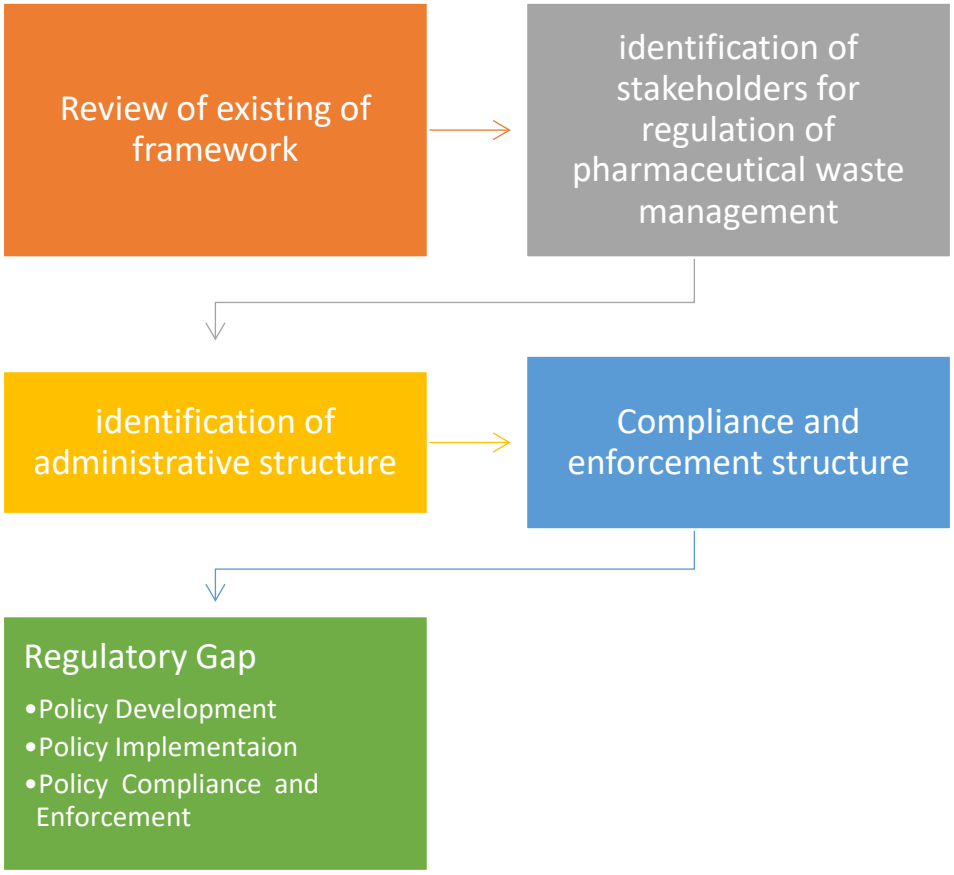

Figure 4.21: Policy gap analysis structure (Source: Author's work)

Step 1: Review of existing regulation frameworks

International Regulatory Framework

At the international level, the World Health Organization (WHO) has played a significant role in advocating for proper pharmaceutical waste management practices. Their guidelines detail the necessity of minimizing - the generation of pharmaceutical waste, proper storage and labelling of pharmaceuticals, as well as the establishment of collection and disposal systems that ensure safety and environmental protection (WHO, 2019). These guidelines serve as a foundation for many countries, including South Africa, in developing their pharmaceutical waste management policies.

In addition to the WHO, the United Nations Environment Program (UNEP) has also prioritized the responsible management of pharmaceutical waste as part of its broader focus on hazardous waste. UNEP advocates for the environmentally sound management of hazardous waste, which

includes pharmaceuticals. Its efforts encompass guidelines and conventions such as, the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal. The Basel Convention, administered by UNEP, is a global treaty designed to minimize the generation of hazardous waste and ensure its safe disposal. Many countries, including South Africa, are parties to this convention, obliging them to adhere to its principles.

In Europe, the European Medicines Agency (EMA) has issued guidelines for the environmentally-friendly disposal of pharmaceuticals. These guidelines are part of the European Union's approach to pharmaceutical waste management, which ensures that pharmaceuticals are disposed of in a manner that minimizes environmental impact. While not directly applicable to South Africa, however, these guidelines exemplify international efforts to address pharmaceutical waste on a regional level.

Beyond the efforts of the international organizations, is the International Pharmaceutical Manufacturers and Associations (IFPMA), representing the research-based pharmaceutical industry worldwide, which has taken steps to promote responsible manufacturing practices. This includes advocating for the reducing of waste generation and improving the management of pharmaceutical waste throughout a product's life cycle. These industry efforts have influenced pharmaceutical practices and contributed to the global framework for safe waste management (IFPMA).

Similarly, the United States Pharmacopeia (USP) has established global standards for the quality and safety, in handling medicines. These standards, including guidelines for pharmaceutical waste disposal, have been adopted and implemented by pharmaceutical companies and healthcare providers worldwide (USP, n.d.). They serve as a reference point for best practices, ensuring that pharmaceutical waste management is aligned with quality and safety standards internationally.

South African Regulatory Framework

In South Africa, the management of pharmaceutical waste is subsumed under the broader category of "healthcare risk waste management". These may not be specific regulations exclusively dedicated to pharmaceutical waste, although, they are comprehensively governed within the framework of healthcare risk waste management. Pharmaceutical waste is considered a subset of healthcare risk waste, and it is subject to the regulations and guidelines established under the National Environmental Management: Waste Act (NEM: WA) and the National Health Care Waste Management Regulations. These regulations set forth the requirements for the

appropriate segregation, collection, storage, transportation, and disposal of pharmaceutical waste in healthcare facilities. Table 4.13 details some of the regulations that govern the management of healthcare waste, which include pharmaceutical waste.

Table 4.13: Regulations governing healthcare waste in South Africa

Regulation/Policy	Description
National Environmental Management: Waste Act (Act No. 59 of 2008)	Provides the legal framework for waste management in South Africa, including pharmaceutical waste. Defines responsibilities for waste generators, transporters, and disposal facilities. Classifies waste into categories (hazardous and non-hazardous) to guide appropriate handling, storage, and disposal methods.
National Environmental Management Act (NEMA) (Act No. 107 of 1998)	Encompasses the overall framework for environmental protection in South Africa. Provides guidelines for managing hazardous waste, including pharmaceutical waste, ensuring safe handling, transportation, and disposal to uphold environmental standards.
National Health Act (Act No. 61 of 2003)	Focuses on healthcare regulations, including provisions for the disposal of healthcare waste, including pharmaceutical waste. Specifies responsibilities and requirements for healthcare facilities to manage pharmaceutical waste to protect public health and the environment.
National Health Care Waste Management Policy and Strategy	Sets out a strategic framework for healthcare waste management in South Africa, including pharmaceutical waste. Emphasizes waste minimization, segregation, proper storage, and safe disposal practices in healthcare settings.
Medicines and Related Substances Act (Act No. 101 of 1965)	Governs aspects of pharmaceuticals, including registration, sale, and disposal. Addresses safe and environmentally responsible disposal of pharmaceutical products to promote responsible practices in the pharmaceutical industry.
South African Pharmacy Council Guidelines	Provides specific guidelines for pharmacies and pharmaceutical institutions on the proper disposal of pharmaceutical waste. Includes instructions on segregation, labeling, and disposal practices to ensure compliance with legal requirements.
South African National Standards (SANS)	SANS 10248 outlines standards for healthcare waste management, including pharmaceutical waste. Provides guidelines for safe collection and disposal to protect safety, environmental health, and public health.
Provincial and Local Government Regulations	Provinces and local governments may have additional regulations and by-laws complementing national policies. These regulations provide regional guidelines and enforcement mechanisms for effective healthcare waste management within their jurisdictions.

Step 2: Identifying stakeholders

A multitude of stakeholders play vital roles in ensuring the safe and environmentally responsible disposal of pharmaceutical waste.

Government agencies, such as the Department of Forestry, Fisheries and the Environment (DFFE) and the Department of Health, serve as key drivers of the regulatory framework for waste management (Department of Environmental Affairs, 2009). Their policies and guidelines, including the National Environmental Management: Waste Act, provide the legal foundation for pharmaceutical waste management, outlining the responsibilities of waste generators and disposal facilities (Department of Environmental Affairs, 2009). These regulations are pivotal in shaping the overall approach to pharmaceutical waste management in the country, emphasizing environmental protection and public health. Lastly, local government authorities also enact by-laws and regulations to regulate and monitor waste management practices, aligning them with national policies (Department of Environmental Affairs, 2009).

Healthcare facilities, including hospitals, clinics, and pharmacies, are significant generators of pharmaceutical waste and are responsible for proper segregation and on-site storage (Ejiogu et al., 2020). These facilities are crucial in implementing policies and procedures for the safe disposal of pharmaceutical waste, which is essential for public safety and environmental sustainability. Their compliance with waste management regulations is crucial to preventing environmental contamination and health risks associated with improper pharmaceutical waste disposal.

The pharmaceutical industry contributes to responsible pharmaceutical waste management by designing products with environmentally friendly features, such as biodegradable packaging (Mabiza et al., 2017). This design approach aligns with global sustainability goals and demonstrates a commitment to reducing the environmental footprint of pharmaceutical products. Additionally, regulatory bodies like the South African Pharmacy Council oversee standards and regulations in the pharmaceutical sector, ensuring that pharmaceutical manufacturers adhere to safety and environmental standards in their product design and labelling (South African Pharmacy Council, 2018).

Healthcare professionals, including doctors, nurses, and pharmacists, play vital roles in ensuring pharmaceutical waste is correctly segregated and labelled before disposal (Nzimakwe et al., 2020). Their knowledge and compliance with pharmaceutical waste management guidelines, therefore are essential for the proper handling of pharmaceutical waste within healthcare facilities. Pharmacists are actively engaged in the collection and safe disposal of unused or expired medications (Mashanje et al., 2019). Their efforts contribute to minimizing the environmental impact of pharmaceutical waste and protecting public health by preventing unauthorized access to expired or unused medications. Waste management companies are

pivotal in collecting, transporting, and disposing of pharmaceutical waste while adhering to safety and environmental standards (Nsiah-Asare et al., 2018). Their role is to bridge the gap between waste generators, including healthcare facilities and pharmacies, and disposal facilities. The compliance of these waste management companies with regulations ensures that pharmaceutical waste is safely transported and disposed of, preventing contamination of land and water resources.

Environmental organizations and advocacy groups also have a role in raising awareness and advocating for environmentally responsible pharmaceutical waste management practices (Mbongwa et al., 2018). Their efforts contribute to public awareness and education about the essential need for pharmaceutical waste management, fostering responsible disposal practices among healthcare facilities, pharmacies, and the public. They serve as advocates for the environment and public health in the context of pharmaceutical waste.

Academic and research institutions contribute through research and studies that inform policy development and best practices in pharmaceutical waste management (Udofia et al., 2020). Their studies help identify emerging challenges and opportunities in pharmaceutical waste management, providing valuable insights for policymakers and stakeholders. Furthermore, their research often informs the development of more effective and environmentally-friendly pharmaceutical waste management strategies.

Local communities and patients are crucial stakeholders in pharmaceutical waste management, as they must ensure proper disposal of their medications and avoid contributing to improper waste disposal (Olowolagba et al., 2019). Patients, as end-users of pharmaceuticals, also play a vital role in the responsible use and disposal of medications. Local communities can also influence pharmaceutical waste management practices through local initiatives and awareness campaigns. Their roles include, enforcement of regulations and monitoring of compliance within their jurisdictions. By collaborating with national government agencies and stakeholders, local authorities can ensure that pharmaceutical waste management practices are consistent and effective on a regional level.

Step 4: Administration structures

Healthcare Institutions: Pharmaceutical waste is generated primarily within healthcare institutions, such as hospitals, clinics, and pharmacies. These institutions, must therefore, play a crucial role in the collection, segregation, and initial storage of pharmaceutical waste. The National Health Act (2003) prescribes the requirements and procedures that healthcare facilities must follow for the safe management of pharmaceutical waste (Nzimakwe et al., 2020). It is within these institutions that healthcare professionals, including doctors, nurses, and pharmacists, actively

participate in pharmaceutical waste management by adhering to established procedures for segregation and labeling (Nzimakwe et al., 2020). They play a crucial role in ensuring the proper management of pharmaceutical waste generated during patient care.

Regulatory Bodies: South Africa has several regulatory bodies responsible for specific aspects of pharmaceutical waste management. The South African Pharmacy Council, for instance, plays a pivotal role in regulating the pharmacy profession in the country and has issued guidelines for the safe disposal of pharmaceutical waste by pharmacies in South Africa (South African Pharmacy Council, 2018). These guidelines provide comprehensive instructions for pharmacies, detailing the need for proper segregation and disposal practices. The Medicines Control Council is responsible for overseeing the registration and sale of pharmaceutical products, including their safe and environmentally-responsible disposal (South African Pharmacy Council, 2018). These regulatory bodies serve as guardians of pharmaceutical waste management practices, ensuring that healthcare institutions and pharmacies adhere to established guidelines.

Waste Management Companies: Waste management companies form a crucial part of the administrative structure by facilitating the collection, transportation, and proper disposal of pharmaceutical waste. The National Environmental Management: Waste Act, 2008, outlines the role of waste transporters and disposal facilities, which includes those handling pharmaceutical waste (Department of Environmental Affairs, 2009). These companies are responsible for ensuring that pharmaceutical waste is safely and responsibly transported and disposed of, by meeting stringent safety and environmentally-sound standards (Nsiah-Asare et al., 2018).
Environmental Organizations and Advocacy Groups: Environmental organizations and advocacy groups play a significant role in the administrative structure by advocating for responsible pharmaceutical waste management and raising awareness among healthcare professionals and the public. These groups are crucial in promoting environmentally-responsible practices and ensuring that healthcare institutions and pharmaceutical companies comply with regulations and best practices (Mbongwa et al., 2018).

Step 4: Compliance and Enforcement

A key determinant of the efficacy of PWM compliance and enforcement, is the availability of adequate resources. A well-structured framework ensures that all parties involved, from healthcare facilities to regulatory bodies, have a clear understanding of their roles, responsibilities, and the potential consequences of non-compliance. It serves as the backbone of the system,

providing the necessary structure and guidelines for effective enforcement. Ongoing reviews of this framework are crucial in evaluating its clarity and robustness, as stated by Sefouhi et al. (2013). This assessment sets the foundation for a successful pharmaceutical waste management (PWM) enforcement system.

Adequate funding, personnel, and infrastructure are essential to carry out monitoring, inspections, and enforcement actions effectively. Without these resources, the regulatory authorities may struggle to enforce compliance, leading to potential violations. A comprehensive review, as highlighted by Belhadef et al. (2018), should also focus on whether South Africa has allocated sufficient resources to support these activities. Addressing resource limitations is essential to ensure the enforcement of the system's functions optimally.

Monitoring and inspections are fundamental aspects of ensuring compliance with PWM regulations. Any review must scrutinize the frequency and comprehensiveness of these inspections to gauge their effectiveness. As suggested by Ngqwala et al. (2020), regular and thorough inspections of healthcare facilities, pharmaceutical manufacturers, and waste management facilities are essential to verify adherence to waste management regulations. An effective review should assess the monitoring and inspection programs to determine if they adequately guarantee compliance and identify areas for improvement.

Compliance reporting is an integral component of any enforcement system. The regulatory framework should establish a clear process for reporting and documenting compliance or non-compliance, promoting transparency and accountability. Ensuring that compliance reports are readily accessible to relevant authorities and stakeholders is another vital aspect, as recommended by Sliz-Szkliniarz et al. (2014). An efficient compliance reporting mechanism is essential for monitoring compliance and initiating corrective actions when necessary, ensuring that violations do not go unchecked.

Penalties and enforcement actions play a critical role in deterring non-compliance and promoting responsible pharmaceutical waste management. The regulatory framework must outline robust and corrective measures, such as fines, warnings, and legal actions, to address violations appropriately, aligning with the severity of the infraction. Sefouhi et al. (2013) advocate the need of assessing whether these penalties and enforcement actions are effective in achieving their intended objectives. Striking the right balance between punitive measures and encouraging responsible behavior is essential in maintaining a compliant PWM system.

Education and training are imperative in ensuring that all stakeholders are informed and compliant with PWM regulations. The presence and effectiveness of training programs for healthcare staff,

waste management personnel, and other relevant parties should be assessed. These initiatives, as underlined by the World Health Organization (2018), promote awareness and responsible waste disposal practices, contributing to overall compliance with PWM regulations.

Comprehensive data and record-keeping systems are fundamental for tracking waste management practices and assessing compliance. The regulatory authorities should maintain organized records of inspections, compliance reports, and enforcement actions. These records should be accessible and transparent, enabling evidence-based decision-making within the enforcement process. Carlos et al. (2013) dwell on the significance of proper data and record-keeping in facilitating transparency, accountability, and system improvements. It is, however, essential to note that the current study has indicated shortcomings in data and record-keeping for PWM, noting areas that require immediate attention and enhancement to strengthen the enforcement system.

Step 5: Regulatory gaps

Policy Development

Pharmaceutical waste under the umbrella term of - healthcare waste in South Africa - can present significant challenges. One primary concern is that this classification approach might inadvertently lead healthcare facilities to assume they have the flexibility to prioritize different types of medical waste over others, potentially leading to instances where pharmaceutical waste is treated as general waste. This can result in a lack of clear guidance and enforcement, with facilities potentially neglecting proper pharmaceutical waste management practices. While various frameworks and regulations exist to govern the management of healthcare waste management, there can be a lack of clarity regarding the specific responsibilities of different stakeholders in ensuring their implementation and enforcement. The ambiguity around accountability and enforcement may undermine the overall objectives of safe and responsible pharmaceutical waste management, potentially exposing public health and the environment to unnecessary risks. To address this issue, it is crucial to clarify roles, enhance oversight, and detail the need for stringent compliance to healthcare waste regulations to ensure the proper management of pharmaceutical waste and all healthcare-related waste streams.

Policy Implementation

One major regulatory gap relates to the inconsistent implementation of healthcare waste management policies. While South Africa has established policies and regulations governing the appropriate disposal of healthcare waste, there is a lack of uniformity in their application across different healthcare facilities and regions. This inconsistency can be attributed to the decentralized

nature of healthcare waste management, with various provinces and municipalities having their own guidelines and levels of compliance. As a result, some facilities may adhere to the regulations more stringently than others, leading to disparities in the management of healthcare waste and pharmaceutical waste.

Furthermore, the disposal of pharmaceutical waste in South Africa presents a specific challenge due to the lack of clear guidelines and regulations. Pharmaceutical waste, which includes expired or unused medications, can pose significant environmental and public health risks if not managed appropriately. The absence of comprehensive regulations for the collection and disposal of pharmaceutical waste leaves healthcare facilities uncertain about the best practices. This regulatory gap allows for the inappropriate disposal of pharmaceutical waste, potentially leading to the contamination of water sources and the emergence of drug-resistant pathogens.

Stakeholder disconnection exacerbates these regulatory gaps. Effective healthcare waste management necessitates collaboration among various stakeholders, including government bodies, healthcare facilities, waste management companies, and local communities, however, there is often a lack of coordination and communication among these stakeholders. This disconnection can result in the inadequate training of healthcare workers in waste segregation, limited access to appropriate waste disposal infrastructure, and insufficient public awareness campaigns regarding the significance of proper waste management. As a result, healthcare facilities may lack the knowledge, resources, and motivation to adhere to healthcare waste management regulations, leading to potential health and environmental risks.

Policy Enforcement and Monitoring

One of the fundamental problems contributing to the regulatory gap is the absence of effective monitoring mechanisms. While South Africa has established policies and regulations to govern healthcare and pharmaceutical waste management, however, there is often limited monitoring of compliance with these policies. Healthcare facilities, both public and private, frequently operate without consistent audits or inspections to ensure adherence to these regulations. This lack of enforcement results in sub-optimal waste segregation, storage, and disposal practices, posing significant risks of environmental contamination and threats to public health.

Within this context, the monitoring of pharmaceutical waste, including expired and unused medications, remains inadequate. The dearth of stringent and clear guidelines for pharmaceutical waste disposal leads to improper practices within healthcare facilities. The risk of unused medications being inappropriately discarded contributes to water source contamination and potential harm to ecosystems. The absence of regular inspections and oversight further amplifies inadequate monitoring in pharmaceutical waste management.

Additionally, the absence of standardized reporting and data collection systems presents a substantial challenge. Comprehensive data on healthcare waste generation, collection, and disposal are essential for gauging policy compliance and identifying areas requiring improvement. Inconsistent or absence of reporting mechanisms hinder regulatory authorities' ability to assess the effectiveness of policy implementation, complicating efforts to address specific compliance issues.

These concerns extend to the fact that pharmaceutical outlets and healthcare facilities often lack awareness of any compliance and monitoring mechanisms, creating a substantial barrier to policy adherence. It has been observed that some healthcare facilities operate without ever being visited by compliance stakeholders, indicating a significant lack of oversight and accountability in the healthcare waste management process. Improper and unsafe methods employed for the disposal of pharmaceutical waste in numerous healthcare facilities, contribute to public health and environmental concerns. In many instances, the storage infrastructure within these facilities does not align with the requirements outlined in healthcare waste management policies, leading to unsafe storage practices and potentially far-reaching consequences.

Some municipalities face challenges in providing accurate count of healthcare facilities within their jurisdiction, complicating compliance monitoring efforts. In the private sector, it has been observed that some healthcare practitioners view waste management as optional, assuming that obtaining a practice number is the primary requirement for operating a healthcare facility. This perception can lead to a lax approach to healthcare waste management, further contributing to the ill-effects of regulatory gap. An concerning discovery was the fact that some of the provincial governments lack records concerning healthcare facilities. Consequently, the responsibility for drafting guidelines and compliance evaluation falls upon different government departments. While the Department of Health possesses the necessary data on healthcare facilities and drafts guidelines, the compliance monitoring aspect is delegated to the Department of Environmental Affairs. This fragmented approach can hinder the overall effectiveness of healthcare waste regulation.

4.6.2 SWOT analysis

SWOT analysis, is a strategic planning tool employed for assessing organizations or projects by examining their internal strengths and weaknesses, as well as external opportunities and threats (Humphrey, 2005). A SWOT analysis is a versatile strategic planning tool that plays a vital role in various sectors, including waste management. It provides a structured framework for assessing internal strengths and weaknesses, as well as external opportunities and threats, making it applicable to a wide range of industries and contexts. In waste management, SWOT analysis is particularly valuable for evaluating current practices, identifying areas for improvement, and

developing strategic plans to optimize waste management processes and outcomes. Olaniyi et al. (2020), for instance, applied SWOT analysis to evaluate medical waste facilities, shedding light on their operational strengths, such as efficient waste disposal methods. Their analysis revealed weaknesses, including potential issues with waste segregation and disposal and opportunities for improvement were identified, such as implementing advanced waste treatment technologies. In a related study, Owojori et al. (2020) utilized SWOT analysis to assess waste management practices in a university setting. The analysis uncovered strengths like effective recycling programs while also identifying weaknesses in public awareness and participation. Opportunities, they established included, adopting sustainability policies, whereas potential threats encompassed evolving environmental regulations and limited funding. The current study employed SWOT analysis to identify the existing regulatory framework for pharmaceutical waste management on a broader scale. Table 4.13 below highlights the summary of the strength, weaknesses, opportunities, and threats of the current pharmaceutical waste management in the Vhembe region.

Table 4.14: SWOT analysis of the PWM in the Vhembe Region

	POSITIVE	NEGATIVE
	STRENGTHS	WEAKNESS
INTERNAL	• There are existing frameworks for healthcare waste which cover pharmaceutical waste. • There are guidelines, documents, and posters. Ability of staff to read and understand. • Most facilities are aware of existing healthcare policies	• The lack of an existing framework specifically detailing the proper management of pharmaceutical waste. • Lack of compliance with the existing framework makes it difficult to monitor its effectiveness. • Lack of waste segregation at point of generation was leading to lost records of type, quantities and volumes of pharmaceutical waste generated in the facility. • Lack of commitment, poor perception, and attitude of healthcare practitioners towards pharmaceutical waste management. • Insufficient budgetary allocation to waste management activities.

		• Inadequate knowledge and training of medical practitioners for proper management of pharmaceutical waste • Lack of skilled personnel for overall waste management in the facilities.
EXTERNAL	OPPORTUNITIES	THREATS
	Sustainable Practices • Increasing global focus on sustainable and eco-friendly waste management • Adoption of eco-friendly technologies and methods. Technological Advancements • Access to advanced waste disposal and treatment technologies • Collaborate with international organizations and businesses to access and implement advanced waste management technologies locally. International Collaboration • Learning from countries with successful pharmaceutical waste management systems. • Actively engage with international organizations and countries with expertise in pharmaceutical waste management to share knowledge, best practices, and collaborate on solutions. Health and Environmental Benefits • Effective pharmaceutical waste management can lead to improved public health and environmental conservation. • Promote the health and environmental benefits of responsible waste management to garner local support for sustainable practices.	Environmental Impact • Poor pharmaceutical waste management can harm the environment. • Inadequate waste management practices. • Risk of environmental damage. Health Risks • Inadequate management of pharmaceutical waste can pose health risks. • Mishandling and contamination risks. Economic Impact • Mishandling pharmaceutical waste can result in economic losses. • Economic losses due to mismanagement. Political and Regulatory Changes • Changes in government policies or regulations related to pharmaceutical waste management. • Difficulty in adapting to changing regulations

4.6.3 PESTEL Analysis

PESTEL analysis is a strategic planning tool that has proven its relevance in a wide range of sectors and scenarios, providing a structured framework for assessing external macro-environmental factors. Its applicability extends to various domains due to its ability to comprehensively evaluate the external influences that organizations, projects, or sectors may encounter. This versatility makes it a valuable tool in decision-making processes Vlados et al. (2019)

PESTEL analysis encompasses an examination of political, economic, social, technological, environmental, and legal influences (Shapiro, 2014). In research related to the waste management sector, a PESTEL analysis can play a pivotal role in understanding the broader context in which waste management operations operate. The process, for instance can reveal how political factors, such as government regulations and policies, influence waste management practices. Economic factors, such as funding availability and the cost of services, highlight the financial aspects that shape waste management. Social factors, such as public attitudes and behaviors, underscore the need for effective public engagement, while technological influences emphasize the role of advanced waste management solutions. Environmental considerations reflect the significance of sustainable waste disposal practices, and legal factors focus on regulations and compliance requirements. A PESTEL analysis, hence, aids researchers in comprehensively assessing external opportunities and threats, enabling informed decision-making in waste management research.

Political:

- An absence of a Dedicated Framework: The research findings reveal a critical political challenge in the absence of a dedicated framework for managing pharmaceutical waste. The absence of a specific and tailored framework has left healthcare facilities and regulatory bodies without clear guidelines and regulations for handling pharmaceutical waste. This gap presents a significant risk, as it can lead to confusion and inconsistencies in waste management practices. To address this issue, there is a compelling need for political commitment and legislative action. Creating and enforcing a comprehensive pharmaceutical waste management framework should be a priority. This framework should detail clear guidelines, responsibilities, and regulations, providing a roadmap for healthcare facilities and regulatory authorities to follow. By establishing a dedicated framework, the political landscape can pave the way for more effective pharmaceutical waste management practices.

Fragmented Stakeholder Engagement: The research revealed a challenge related to fragmented stakeholder engagement in pharmaceutical waste management. The lack of a cohesive approach among stakeholders in the administration and execution of waste management policies significantly hampers effectiveness. This fragmentation can result in a lack of alignment and coordination between governmental bodies, healthcare facilities, and waste management service providers. Without a unified approach, it becomes difficult to ensure that all stakeholders are working towards the same goals and fulfilling their respective responsibilities.

Economic:

- **Inadequate Financial Resources for Professional Service Providers**: A notable economic challenge identified in this research is the inadequate financial resources to engage professional service providers for pharmaceutical waste management. This limitation hampers the ability of healthcare facilities to access specialized services that are essential for the safe and efficient disposal of pharmaceutical waste. Engaging professional service providers ensures that waste is handled in compliance with regulations and best practices, reducing environmental and health risks. To address this challenge, securing more funding for professional waste management services is crucial. Adequate financial resources will enable healthcare facilities to benefit from the expertise of these providers, resulting in more effective pharmaceutical waste disposal.

- **Limited Availability of Service Providers for Hazardous Healthcare Waste (HCRW)**: The research findings also revealed the challenge of limited availability of service providers for hazardous healthcare waste (HCRW). This scarcity of service providers specializing in the management of hazardous healthcare waste escalates the cost of disposal, as it reduces competitive pressures that could help lower service fees. Collaborating with service providers to improve waste management and increasing the number of HCRW service providers can alleviate this economic challenge. Expanding the pool of providers will not only create competition but also has the potential to reduce disposal costs, while maintaining service quality. A broader choice of service providers allows healthcare facilities to select cost-effective and reliable options for pharmaceutical waste disposal.

- **Absence of Dedicated Hazardous Waste Disposal Facilities**: The absence of dedicated hazardous waste disposal facilities within the province is a significant economic challenge that exacerbates the waste management issue. Without these specialized facilities, healthcare facilities must rely on external providers, incurring additional costs and logistical challenges.

Investing in dedicated provincial hazardous waste disposal facilities is a critical step in addressing this challenge. These dedicated facilities would be able to offer a safe, regulated, and cost-effective means of disposing of pharmaceutical waste. By reducing the reliance on external providers and creating a more convenient and sustainable disposal option, dedicated hazardous waste disposal facilities can help mitigate the economic burdens associated with pharmaceutical waste management.

Social:

- **Secondary Medication Use**: The practice of secondary medication use, where individuals access and use medications not prescribed to them, poses a considerable health risk. This behaviour can lead to adverse reactions, improper dosages, and potential drug interactions, putting individuals' health in jeopardy.
- **Antibiotic Resistance**: The contamination of water sources by pharmaceutical waste can contribute to antibiotic resistance. This is a global health concern, as antibiotic-resistant infections are more difficult to treat and can lead to severe health consequences.

Technological:

An absence of Tech-Driven Record Keeping: The absence of technology-driven record-keeping hinders efficient pharmaceutical waste management. Implementing technology-driven record-keeping systems can streamline data collection, improve transparency, and enhance regulatory compliance. It is necessary to pioneer advanced technology for pharmaceutical waste disposal, such as digital tracking and inventory management, to ensure accurate record-keeping.

- **Absence of Tech-Driven Record Keeping**: The research identified a crucial technological challenge in the absence of technology-driven record-keeping systems for pharmaceutical waste management. Traditional, paper-based record-keeping can be inefficient, error-prone, and time-consuming. Without digital tools to streamline data collection, healthcare facilities may struggle to maintain accurate records of pharmaceutical waste generation, disposal, and compliance with regulatory standards.

  Implementing technology-driven record-keeping systems holds the potential to address these challenges comprehensively. Digital solutions can provide a platform for healthcare facilities to record and track pharmaceutical waste data in real-time, enhancing accuracy and transparency. These systems can offer features like barcode scanning, electronic manifests,

and cloud-based storage, facilitating efficient data collection and storage. Moreover, advanced technology can enable regulatory authorities to access and monitor data remotely, ensuring compliance with waste management regulations.

Environmental:

- **Environmental Pollution**: The research findings identified a significant environmental challenge stemming from pharmaceutical waste management, namely, environmental pollution. Improper disposal of pharmaceutical waste, including its disposal in landfills, poses a substantial risk to the environment. The presence of pharmaceutical residues in landfills can lead to soil and groundwater contamination, potentially affecting local ecosystems and water sources. To address this issue, it is imperative to enhance eco-friendly pharmaceutical waste disposal methods, through implementing practices such as recycling or advanced treatment techniques which can significantly reduce environmental pollution. Rigorous measures should be put in place to minimize the use of landfills for pharmaceutical waste disposal. Promoting sustainable waste management practices, such as reducing waste at the source and encouraging proper disposal methods, are essential to mitigate environmental pollution and protect local ecosystems.

- **Risk of Water Contamination**: Another pressing environmental concern is the risk of water contamination due to pharmaceutical waste disposal. Improperly disposed pharmaceutical waste can leach into water sources, posing a serious threat to water quality and aquatic life. The contamination of water sources with pharmaceutical residues can have long-lasting and detrimental effects on the environment. To address this challenge, stringent measures should be implemented to reduce the risk of water contamination. This should include, appropriate waste segregation to prevent pharmaceutical waste from entering water systems and the implementation of water-treatment technologies to remove pharmaceutical residues from wastewater. Collaboration with environmental agencies and stakeholders is also essential to monitor and mitigate the risks of water contamination, ensuring the safeguarding of water sources and the preservation of local ecosystems.

Legal:

- **Weak monitoring and enforcement:** The research findings reveal a legal challenge in the non-compliance existing in the pharmaceutical waste management frameworks and the presence of weak enforcement mechanisms. It is concerning to note that most facilities in the

Vhembe region use unsafe and improper disposal methods for their pharmaceutical waste, and their compliance with regulations is lacking. To address this issue, strengthening compliance with existing regulations and enhancing enforcement actions are necessary. Regulatory authorities should be equipped with the necessary tools and resources to enforce pharmaceutical waste management standards effectively. This could be in the form of conducting regular inspections to ensure compliance, issuing fines for violations, and, when necessary, taking legal action against facilities that persistently fail to adhere to waste management regulations. Robust enforcement is vital to compel healthcare facilities to adopt responsible pharmaceutical waste management practices, mitigate environmental and health risks, and ensure overall compliance with legal standards.

Table 4.15: PESTEL Analysis of Pharmaceutical Waste in South Africa

Factors	Threats	Opportunities
Political	• The absence of a dedicated framework for managing pharmaceutical waste. • Fragmented engagement among stakeholders regarding policy administration and execution. • Limited collaboration between different departments in ensuring regulatory compliance and enforcement. • Insufficient financial resources and inefficient resource allocation for the adequate and secure management of pharmaceutical waste	• Establish a dedicated waste management framework. • Improve stakeholder coordination for policy implementation. • Foster inter-departmental collaboration in regulation enforcement. • Increase financial support for effective waste management.
Economic	• Inadequate financial resources hinder the ability to engage professional service providers for PWM. • Scarcity of service providers for HCRW escalates the cost of disposal. • The absence of dedicated hazardous waste disposal facilities within the Province exacerbates the waste management challenge.	• Secure more funding for professional waste management services. • Collaborate with service providers to improve waste management. • Increase the number of HCRW service providers to reduce disposal costs. • Promote local businesses to provide waste management services. • Invest in dedicated provincial hazardous waste disposal facilities to enhance waste management.
Social	Human health impacts due to. • Secondary medication use • Antibiotic resistance from contaminated water. • Addiction risk from bin-sourced medications Lack of education to consumers and patients about proper disposal of PW	• Increase public awareness about safe pharmaceutical disposal. • Promote responsible medication use through education. • Prevent antibiotic resistance by educating about water contamination. • Mitigate addiction risk through proper disposal.
Technological	• Absence of tech-driven record keeping. • Inadequate technology for pharmaceutical waste disposal.	• Implement technology-driven record keeping. • Pioneer advanced technology for pharmaceutical waste disposal.

Factors	Threats	Opportunities
Environmental	• Environmental pollution from improper PW disposal, including landfills. • Risk of water contamination.	• Enhance eco-friendly pharmaceutical waste disposal methods. • Implement rigorous measures to reduce the risk of water contamination.
Legal	• Non-compliance with existing frameworks and weak enforcement	• Strengthen compliance with existing regulations and enhance enforcement.

4.7 Designing a sustainable pharmaceutical waste management system framework

A systematic approach was employed to investigate external factors influencing pharmaceutical waste management practices, integrating insights from PESTEL analysis, policy gap analysis, and SWOT analysis. The PESTEL framework facilitated a comprehensive evaluation of political, economic, social, technological, environmental, and legal dimensions impacting waste management. Key findings, such as - regulatory gaps, financial constraints, health-related risks, and environmental impacts - were identified. These findings formed the basis for targeted strategies aimed at establishing a sustainable pharmaceutical waste management system. These strategies, derived from the PESTEL analysis, policy gap analysis, and SWOT analysis, provided a coherent roadmap. The integrated approach considered multifaceted challenges and proposed actionable strategies, contributing to the establishment of a sustainable system that benefits society, protects the environment, and bolsters the economy. This ensured that the study was rooted in a robust analytical framework, poised to yield practical and sustainable solutions in pharmaceutical waste management. Table 4.15 below illustrates the Sustainable Framework Design proposed.

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Table 4.16: Sustainable Framework Design

	ACTIVITY AREA					
	Political	**Economic**	**Social**	**Technological**	**Environmental**	**Legal**
STRATEGIES	Create a dedicated framework for pharmaceutical waste management with clear guidelines and regulations. Facilitate collaboration among government, healthcare facilities, and waste management entities for effective policy execution. Promote inter-departmental cooperation to enforce regulations and enhance the regulatory environment. Advocate for increased funding through government initiatives and private sector partnerships to support secure waste management.	Seek additional funding through grants and subsidies for healthcare facilities to access professional waste management services. Foster partnerships with waste management service providers to enhance waste collection, transportation, and disposal processes. Increase the number of hazardous waste service providers to lower costs through competition then encourage local businesses to provide PWM services and reduce outsourcing expenses. Invest in dedicated hazardous waste disposal facilities to fill the infrastructure gap in the province.	Launch public awareness campaigns. Develop educational materials and programs. Provide training for healthcare professionals. Improve labeling and packaging with disposal instructions. Engage communities in clean-up events. Create online resources for easy access to information. Collaborate with environmental organizations and make use of take-back programs. Maintain regular communication through various channels.	Implement Tech-Driven Record Keeping and Adopt modern technology for record keeping, including electronic record systems, to streamline and improve data management for pharmaceutical waste. Advanced Waste Disposal Technology by Investing in and deploying advanced technology for pharmaceutical waste disposal, including efficient and environmentally-friendly disposal methods and equipment.	Enforce Stringent Laws for Regulation of Municipal Landfills. Establish Dedicated Collection Centers. Organize Medication Take-Back Programs. Improve Labeling and Packaging with Clear Disposal Instructions. Educate the Public About Environmental Consequences. Partner with Pharmacies for Collection and Education.	Strengthen Compliance: Strengthen compliance with existing regulations by conducting regular audits, inspections, and implementing penalties for non-compliance. Enhance Enforcement: Invest in the enforcement infrastructure, including more personnel and technology, to ensure that regulations are followed, and penalties are enforced consistently.

CHAPTER FIVE

CONCLUSION AND RECOMMENDATIONS

5.1 Introduction

This chapter serves as a comprehensive summary and conclusion for the study on pharmaceutical waste management within the Vhembe District of Limpopo Province. Additionally, this Chapter 5 provides pertinent recommendations for improving the management of pharmaceutical waste while acknowledging the study's limitations and raising areas for future research.

5.2 Summary of findings

5.2.1 Summary on Pharmaceutical Waste Management practices of facilities in the region

The research reveals a notable deficiency in pharmaceutical waste management within the region. The studied facilities displayed inadequate waste management practices, marked by an absence of source segregation and the use of sub-optimal temporary storage containers chosen for convenience rather than efficiency. Additionally, the infrastructure for waste storage within these facilities proved to be sub-standard. Most facilities relied on a combination of methods, with a primary dependence on municipal waste collection services and sewer drainage systems, both of which raise environmental concerns and potential health risks.

5.2.2 Summary on Attitude and Perception of Healthcare Professionals towards Pharmaceutical waste

The study noted a significant gap in education and training regarding pharmaceutical waste management (PWM) for healthcare professionals, hence, an urgent need for a shift in healthcare education, practice, and regulation to ensure responsible PWM. The research found that healthcare professionals often perceived their responsibility as ending at the issuing of a prescription, leading to a lack of preparedness to manage pharmaceutical waste in line with legal requirements. Additionally, the study identified challenges related to understanding waste categories and regulations, emphasizing the necessity to simplify and clarify these regulations for healthcare professionals. Overall, the findings underscored the crucial call to prioritize education and training in pharmaceutical waste management, within the healthcare sector.

5.2.3 Summary on knowledge, perceptions, and management practices of consumers in households

More than 70% of the respondents indicated that they understood what pharmaceutical waste is, while only 20% were aware of the associated risks. The study revealed that a significant 80.2% of consumers often purchase or acquire more medication than they need, leading to leftover medication being the most common reason for pharmaceutical waste in households. Furthermore, most consumers, unfortunately, do not segregate their pharmaceutical waste from other types of household waste, which is then collected and sent to landfills via municipal refuse removal.

This finding indicates that a substantial amount of pharmaceutical waste generated in households ends up in landfills, even though municipal landfills are not suitable for the disposal of such waste. Consumers consistently expressed that they are often not informed about the proper management of pharmaceutical waste in households. This underscores the urgency of patient education during the prescription or purchase process, as the percentages show the need for better awareness and practices in pharmaceutical waste management.

5.2.4 Summary of findings regarding compliance to the existing regulatory framework

The research findings demonstrate significant challenges in how pharmaceutical waste is managed within Vhembe District facilities. Over half (51.7%) of the facilities face issues in properly sorting waste, posing risks to the environment and safety; a considerable number (74.1%) struggle with correct storage and labeling of medicines and the non-availability of designated storage spaces was noted by (60.3%) which raised concerns about worker safety and environmental impact. Majority (72.4%) rely on regular garbage services, thereby neglecting proper disposal methods. Record-keeping was noted as a substantial challenge, with only a small percentage (3.4%) maintaining proper records in the facilities, although some staff (37.9%) undergo training, there is still room for improvement. These findings underscore the need for comprehensive improvements in pharmaceutical waste management practices within the Vhembe District facilities.

5.2.4 Summary of weaknesses of the regulatory framework for pharmaceutical waste Management

The findings show a notable absence of dedicated regulatory measures addressing pharmaceutical waste, specifically. Instead, this category often falls under the broader umbrella of healthcare waste management, however, the existing framework is marred by a substantial disconnect in the processes of policy development, implementation, and enforcement. This disconnect can be attributed to the fact that regulations are frequently formulated by different

administrative stakeholders who do not effectively collaborate or coordinate their efforts. As a result, there is a discernible lack of clarity, making it challenging for stakeholders to comprehend their respective roles and responsibilities in the context of ensuring the effective implementation and compliance with regulations related to pharmaceutical waste. This disconnect and ambiguity in roles and responsibilities are key issues that need to be addressed to enhance the management of pharmaceutical waste within the broader healthcare waste management framework.

5.3 Conclusion

This study's insights shed light on pervasive challenges in pharmaceutical waste management within the Vhembe District, stressing the need for transformative interventions. Across healthcare facilities, the lax handling of pharmaceutical waste, often considered general waste, underscores a critical awareness gap among facility managers. This deficiency in understanding the distinct nature and risks of pharmaceutical waste calls for a comprehensive approach, necessitating enhanced regulatory oversight, clear guidelines, mandatory training, and regular audits of healthcare facilities.

The household pharmaceutical waste (HPW) management practices identified in this research uncovered significant issues related to consumer behaviors. The accumulation of surplus medications due to consumer tendencies, coupled with a lack of awareness regarding environmental and health risks, constitute a daunting challenge. Widespread adoption of inappropriate disposal methods, such as municipal waste services and flushing down the drains, amplifies the need for targeted public education which can lead to responsible HPW management practices. The study accentuates the pivotal role of patient education during medication prescription in promoting safer disposal practices and mitigating the environmental and health risks associated with HPW.

Additionally, the study underscores a compelling demand for substantial improvements in education and training related to pharmaceutical waste management (PWM) for healthcare professionals. Identified knowledge gaps and awareness deficiencies necessitate a paradigm shift in healthcare education, which would integrate practical skills alongside theoretical knowledge. Bridging these gaps, is paramount for ensuring compliance with legal requirements, including appropriate segregation, labelling, and disposal of pharmaceutical waste. The study advocates for the incorporation of PWM content into medical schools' curricula and pre-practice

training to produce environmentally-conscious healthcare professionals capable of championing responsible waste management practices throughout their careers.

Furthermore, the research reveals a void in dedicated regulatory measures addressing pharmaceutical waste, showing a disconnect in policy development, implementation, and enforcement. The existing framework, which encompasses pharmaceutical waste within the broader healthcare waste management, lacks clarity and effective collaboration among administrative stakeholders. Addressing this disconnect and clarifying roles and responsibilities are imperative for advancing the overall management of pharmaceutical waste within the broader healthcare waste management framework.

In conclusion, this research has highlighted multifaceted challenges in pharmaceutical waste management and advocates for transformative strategies. Coordinated efforts, regulatory enhancements, public education, and improved training for healthcare professionals are essential elements of a comprehensive approach to mitigate environmental and public health risks associated with poor management of pharmaceutical waste.

5.4 Recommendations

Based on the findings from this study, the following recommendations are made to various stakeholders:

Policy Makers:

- Develop dedicated regulations: Create specific and comprehensive regulations for pharmaceutical waste management to address the existing gap and provide clear guidance.
- Promote collaboration: Facilitate cooperation among various administrative stakeholders to ensure a coordinated approach to policy development and implementation.
- Monitor and enforce: Establish mechanisms to monitor compliance and enforce regulations rigorously to deter improper disposal practices.
- Educational initiatives: Invest in public awareness campaigns to inform the public and healthcare facilities about the importance of proper pharmaceutical waste disposal.
- Research and innovation: Support research into environmentally-friendly disposal methods and encourage the adoption of innovative technologies.

- Incentives for compliance: Consider offering incentives or rewards for healthcare facilities that excel in pharmaceutical waste management.
- Regular audits: Conduct regular audits and assessments of healthcare facilities' waste management practices to identify areas for improvement.
- Waste reduction strategies: Promote pharmaceutical waste reduction strategies, such as controlling medication prescribing and dispensing.
- Reporting systems: Implement reporting systems for adverse environmental impacts due to improper pharmaceutical waste disposal.
- Regulatory clarity: Ensure that regulations are written in a clear and understandable manner to avoid miscomprehension.

Healthcare Facilities:

- Compliance with regulations: Adhere to all pharmaceutical waste management regulations and ensure proper training for staff.
- Designate responsible Staff: Appoint dedicated personnel to oversee and manage pharmaceutical waste disposal within the facility.
- Segregation of waste: Implement a well-defined system for segregating different types of pharmaceutical waste at the source.
- Safe storage: Establish secure storage areas for pharmaceutical waste to prevent unauthorized access.
- Training and education: Provide regular training to healthcare staff on pharmaceutical waste management and disposal practices.
- Waste tracking: Implement systems for tracking and documenting the disposal of pharmaceutical waste.
- Regular audits: Conduct internal audits to assess the effectiveness of pharmaceutical waste management within the facility.
- Sustainability initiatives: Explore sustainable disposal options, such as recycling or energy recovery, where feasible.

- Community engagement: Engage with the local community to raise awareness and offer guidance on proper disposal practices.
- Continuous improvement: Continuously evaluate and improve pharmaceutical waste management practices based on best practices and changing regulations.

Healthcare Professionals:

- Compliance: Ensure strict adherence to pharmaceutical waste disposal guidelines and regulations.
- Proper labeling: Clearly label pharmaceutical waste containers to distinguish them from other waste streams.
- Segregation: Segregate pharmaceutical waste according to its type and potential hazards.
- Training: Regularly attend training programs on pharmaceutical waste management to stay updated on best practices.
- Reporting: Report any issues or concerns related to pharmaceutical waste management within the healthcare facility.
- Reduce medication waste: Minimize medication wastage by controlling prescription practices and dispensing.
- Safe handling: Handle pharmaceutical waste with care to prevent accidents and contamination.
- Educate patients: Educate patients on proper disposal methods for their unused or expired medications.
- Environmental awareness: Stay informed about the environmental impact of pharmaceutical waste and advocate for responsible disposal practices.

Consumers:

- Medication usage: Use medications as prescribed, minimizing unnecessary waste.
- Return programs: Participate in pharmaceutical take-back programs provided by pharmacies or local authorities.
- Read labels: Follow disposal instructions on medication labels, and never flush medications down the toilet.

- Education: Educate yourself and your family on the urgency of proper pharmaceutical waste disposal.
- Avoid stockpiling: Avoid accumulating excessive medications, which may lead to unnecessary waste.
- Consult pharmacists: Ask pharmacists for guidance on disposing of unused or expired medications.
- Community awareness: Promote awareness of responsible pharmaceutical waste disposal within your communities.
- Proper containers: Use designated containers for pharmaceutical waste, if available.

Pharmaceutical Companies

- Clear disposal instructions: Ensure product labeling includes clear disposal instructions, emphasizing responsible disposal methods.
- Support take-back programs: Collaborate with stakeholders to establish and support pharmaceutical take-back programs for unused or expired medications.
- Consumer education: Educate consumers about the environmental and health risks of improper pharmaceutical disposal through public awareness campaigns and informative resources.
- Supply chain efficiency: Implement efficient supply chain management to reduce overproduction and minimize waste in pharmaceutical manufacturing and distribution.
- Collaboration with facilities: Collaborate with healthcare facilities to optimize medication dispensing and reduce pharmaceutical waste.
- Stakeholder engagement: Collaborate with waste management companies, regulatory agencies, and environmental organizations to develop and implement effective waste management initiatives.
- Legislative advocacy: Advocate for regulations and legislation that support responsible pharmaceutical waste management and ensure compliance.
- Regular reporting and resource Sharing: Maintain transparency, share best practices, and regularly communicate with stakeholders to continually improve pharmaceutical waste management practices.

5.6 Limitations of the study

Necessary efforts were made to ensure that this study is valid and credible, that trustworthiness of the findings is achieved using triangulation during data collection, and careful consideration of the recommendations to ensure their practicality and ease of implementation. Nevertheless, several limitations are acknowledged in the study:

Geographical Limitation:

- The study was conducted only in one District Municipality (DM) out of five in Limpopo Province.
- Strategies developed are based solely on data from VDM, which may not represent other DMs.

Lack of Previous Studies:

- No prior studies have been conducted on the subject matter within the Province.
- Existing studies primarily focused on a broader perspective of medical waste management, lacking exclusivity for pharmaceutical waste management.

Healthcare Facility Response:

- Healthcare facilities tend to assume data requests are associated with the media or external stakeholders.
- This assumption often led to cautious and restricted responses, potentially influencing data transparency and depth.
- Some facilities declined to be part of the study due to the assumption that inquiries were related to the media, further affecting the study's comprehensiveness and representativeness.

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APPENDIX 1: RESEARCH PLAN OVERVIEW

Assessment of Pharmaceutical waste management in the Northern Region of South Africa

The data collection process involved a comprehensive approach utilizing observations, questionnaires, and interviews. The researcher visited several selected pharmaceutical outlets and medical facilities situated in the Northern Region of South Africa, particularly within the Vhembe District of Limpopo Province. Equipped with essential tools such as a pen, notebook, cell phone, camera, checklist, and prepared interview questions, the researcher embarked on this data-gathering mission.

Interviews were a key aspect of the process, offering detailed insights into pharmaceutical management practices within each facility (refer to Appendix 3). The interview sessions aimed to delve into the challenges encountered by these establishments in managing pharmaceutical waste. The interview methodology included the following steps:

1. The researcher introduced herself and provided a concise explanation of the study's purpose and potential benefits.
2. Interviews were conducted with both pharmacists and individuals responsible for pharmaceutical waste management at the facilities.
3. Occasionally, an audio recorder was employed to assist in data analysis, always with prior permission sought before recording any conversations.
4. To ensure confidentiality and anonymity, respondents' identities remained undisclosed in the research report.

Observations also played a crucial role in data collection:

1. The researcher introduced herself and outlined the study's objectives and benefits before commencing observations.
2. Photographs were taken whenever necessary to support and authenticate the observations made.
3. During the observation phase, the researcher utilized a checklist and sought clarification through pertinent questions on specific matters.

4. Adhering strictly to safety and health precautions, the researcher ensured personal safety and the well-being of participants throughout the process.

Upon completing the observations, the researcher expressed gratitude to the respondents and the Municipality for granting permission to conduct the study.

Additionally, two types of questionnaires were distributed:

1. The first questionnaire targeted consumers of pharmaceuticals, aiming to evaluate their knowledge and practices regarding the disposal of pharmaceutical waste.
2. The second questionnaire was distributed to pharmacists and medical practitioners responsible for prescribing pharmaceuticals to assess their understanding, attitude, and management practices concerning pharmaceutical waste generated within their facilities.

APPENDIX 2: CONSUMER CONSENT FORM AND QUESTIONNAIRE

Assessment of Pharmaceutical waste management in the Northern Region South Africa

Consumer knowledge and disposal practices of pharmaceutical waste

SECTION A: PARTICIPATION CONSENT

I, the undersigned ……... (Surname and initials) volunteer to participate in the study conducted by ……. (Name of researcher) on ……... (Date of participation) at……. (Area) regarding pharmaceutical waste management. I agree that I have read and have had a verbal explanation of the study, purpose, and relevance of the study.

I acknowledge that my participation is entirely on voluntary basis and there will be no renumeration warded for my participation.

I furthermore, confirm that all my responses and information provided are accurate and correct and hereby……...(signature of participant) consent that my responses may be used for this study as part of findings.

SECTION A: DEMOGRAPHIC INFORMATION

MUNICIPALITY

THULAMELA	**MAKHADO**

GENDER

FEMALE	**MALE**

ETHNICITY

AFRICAN	**WHITE**	**INDIAN**	**OTHER**

AGE GROUP

18-24	**25-35**	**36-40**	**40-50**

SECTTION B: PHARMACEUTICALS USED AND WASTE GENERATED

QUESTIONS	RESPONSES					
How often do you use medicines	Daily	Once a week	Several time a week	Once a month	Once in two months	
Where do you often get your medicines	Hospital	Pharmacy	Over-counter	Clinics	Other (specify)	
Classes of medication used (may tick more than one if applicable)	Anti-biotics	Anti-pyrectics	Analgesics	Anti-acids	Vitamins/ syrups	Hormonal drugs
Common type of your medication	tablets	Capsules	Syrups	Repulses	Lozenges	Creams/ lotions
Do you often finish your medication doses?	Yes	Never	Sometimes but not often	Very often		
Number of leftover/unused medication in	0	1-5	6-10	11-16	16-20	>20

QUESTIONS	RESPONSES					
your home based on type						
Reason for leftover medication	Self-discontinued (Voluntarily stopped)	Change of prescription	Passed expiry date	Left over from previous purchase	Severe side effects	

SECTION C: KNOWLEDGE OF PHARMACEUTICAL WASTE

QUESTIONS	RESPONSES			
Do you know what pharmaceutical waste is?	Yes	No		
Are you informed about proper management of each type of medication you receive?	Yes	No		
Do you read your medication packaging?	Yes	No	Sometimes	
Do you believe pharmaceutical waste needs to be separated from other waste?	Yes	No		
Are you aware of human health impacts of pharmaceutical waste?	Yes	No		

SECTION D: PHARMACEUTICAL WASTE DISPOSAL PRACTICES

QUESTIONS	RESPONSES				
Do you believe you are often prescribed or buy more medication than needed?	Yes	No			
How often do you receive or buy medication?	Every month	3 months	6 months		
What do you do with your left-over medication?	Dispose	Return to pharmacy/facility	Give it to someone else or save it for later	Other (specify)	
Do you separate your pharmaceutical waste from your household waste?	Yes	No			
Are you told about disposal methods of your pharmaceutical waste, where you buy or get them from?	Yes	No			
Where do you dispose of your unused medication?	Toilet	Sink	General garbage bin	Burn or bury	Other (please specify)
Which method of disposal is best for pharmaceutical waste?	Flushing down the toilet	Rinsing down the sink	Municipal collection service	Return to pharmacy	
Who is responsible for ensuring that pharmaceutical waste is managed properly?	consumers	Pharmacists	Medical practitioner	all of the above	
Are you aware of environmental impacts associated with improper disposal of pharmaceutical waste?	Yes	No	A bit		
Do you believe pharmaceutical waste should be disposed	Yes	No			

QUESTIONS	RESPONSES				
differently from other waste?					
Are you aware of any policies for pharmaceutical waste disposal?	Yes	No			
In your personal opinion, do you think more awareness need to be made regarding pharmaceutical waste and its impacts on the environment and human health?	Yes	No			

APPENDIX 3: HEALTHCARE PRACTITIONERS CONSENT AND QUESTIONNAIRE

Assessment of Pharmaceutical waste management in the Northern Region South Africa

Medical practitioner's pharmaceutical waste knowledge, attitude, and disposal practices

SECTION A: PARTICIPATION CONSENT

I, the undersigned ……... (Surname and initials) volunteer to participate in the study conducted by ……. (Name of researcher) on ……... (Date of participation) at……. (Medical facility/pharmacy) regarding pharmaceutical waste management. I agree that I have read and have had a verbal explanation of the study, purpose, and relevance of the study.

I acknowledge that my participation is entirely on voluntary basis and there will be no renumeration warded for my participation.

I, furthermore, confirm that all my responses and information provided are accurate and correct and hereby…….... (signature of participant) consent that my responses may be used for this study as part of findings.

SECTION B: DEMOGRAPHIC INFORMATION

MEDICAL FACILITY

PHARMACY	PUBLIC HOSPITAL	PUBLIC CLINIC	PRIVATE MEDICAL PRACTICE/CENTER

OCCUPATION

PHARMACIST	MEDICAL DOCTOR	NURSE	OTHER (Specify)

GENDER

FEMALE	MALE	OTHER

ETHNICITY

AFRICAN	WHITE	INDIAN	OTHER

AGE GROUP

18-24	25-35	36-40	40-50

LEVEL OF QUALIFICATION

UNDERGRADUATE	HONORS	MASTERS	PHD

SECTION B: KNOWLEDGE, ATTITUDE AND MANAGEMENT PRACTICES

QUESTIONS	RESPONSES				
Does your school curriculum cover pharmaceutical waste management?	Yes	No			
Which type of pharmaceutical waste do you dispose the most in your facility (may select more than 1 answer)	pills	Vials	vitamins	Creams/ointments	Disinfectants
Which types of pills do you dispose the most?	Analgesics	Antibiotics	Anti-viral	Hormonal drugs	other
Do you think it is important for healthcare professionals to know about pharmaceutical waste?	Yes	No			
How well informed are you about pharmaceutical waste?	Very well-informed	Well-informed	Partially informed	Not informed at all	
Do you believe segregation of pharmaceutical waste at source is important?	Yes	No			
How informed are you about environmental impacts of pharmaceutical waste?	Very well-informed	Well-informed	Partially informed	Not informed at all	
Do you receive training on how to manage pharmaceutical waste prior to practice?	Yes	No			
If yes, how effective is the training in your opinion?	Very effective	Quite effective but there is room for improvement	Not effective and there is a lot that needs to be done		
Do you inform consumers/patients on how to manage any remnant from the medicines they buy from you?	Yes	No			
Do you think it is important to inform patients about proper disposal of	No, my duty ends at	Yes, all the time	It depends on the kind of medicatio		

QUESTIONS	RESPONSES				
pharmaceutical waste upon prescription?	prescription		n prescribed		
Which disposal method do you often recommend to consumers/ patients?	Return to facility	Dispose in general waste bins	Drain in toilet or sink	Bury or burn	Other (please specify)
Who is responsible for safe pharmaceutical waste management in the facility?	Cleaners	Medical practitioners	Pharmacists	Everyone who handles pharmaceutical waste	
What do you do with unused and expired medication?	Return to supplier	Give to 3rd party for disposal	Dispose in the facility	Picked up by municipal waste collection	Other (specify)
All healthcare workers and stuff who comes in contact with pharmaceutical waste in the facility should be provided with training and guidelines on how it should be managed	Strongly agree	Agree	Disagree	Strongly disagree	
Occupational safety of all parties handling pharmaceutical waste is a must.	Strongly agree	Agree	Disagree	Strongly disagree	It depends
How well-informed are you about National pharmaceutical waste management legislations?	Very well-informed	Well-informed	Partially informed	Not informed	
Please complete the following sentence by selecting applicable answers. In your opinion these legislations are------	Clear and easy to implement	Clear but not easy to implement	Complicated	Impractical	
Does the facility you work in have policies, standards and guidelines on pharmaceutical waste?	Yes	No			
On a scale of 1-5 how would you rate the effectiveness of these standards and guidelines? With 1	1	2	3	4	5

QUESTIONS	RESPONSES				
being the worst and 5 being the best					
Do you use different bins with different coding for pharmaceutical waste?	Yes	No, all pharmaceutical waste goes into the same bin			
According to National standards, pharmaceutical waste should be stored in a facility awaiting disposal no longer than?	1 day	A week	A month	90 days	
All pharmaceutical waste should be thrown into the same bin as long as it is labelled that it is for pharmaceutical waste	True	False			
Colour coding for disposal of solid dosage form medication bin is	Yellow	Green	Red	Black	Other (specify)
Bin coding for creams, ointments, and powders	Green	Yellow	Red	Black	Other (specify)
Cytotoxic pharmaceutical waste should be placed in a different bin and labelled	True	False			
How often are pharmaceutical bins changed?	Daily	Weekly	Monthly	When they are full.	
How often is your facility audited for pharmaceutical waste?	Monthly	Quarterly	Seasonally	Yearly	
Who takes accountability when there is non-compliance recorded?	Facility manager	Ward managers	Medical practitioner	Cleaners	Other (Please specify)
Do you believe your pharmaceuticals supply meets the demand?	Yes, they are balanced	No, we tend to have more supply than demand	No, we have shortage		
What is the reason for most of your pharmaceutical waste?	We tend to receive more medication than we use	Most of the medication arrive near its expiration date	Other (Please specify)		

QUESTIONS	RESPONSES				
In your opinion, how would you rate the overall pharmaceutical waste management system in your facility?	Excellent (Everyone plays their part to ensure it works)	Good (Majority works hard to ensure better management)	Average (There is a lot of room for improvement)	Poor (There is a need for intervention)	
Add comments on what you believe can be done to ensure best pharmaceutical waste management in your facility.					

APPENDIX 4: COMPLIANCE CHECKLIST

Assessment of Pharmaceutical waste management in the Northern Region of South Africa

Regulatory Frameworks Compliance Checklist

Researcher's name: ……..

Pharmacy /Medical facility: ……

Observation date: ……

List	Yes	No	Comments
Pharmaceutical waste storage			
Does segregation occur at point of generation?			
Is pharmaceutical waste sorted according to categories?			
Are waste containers labelled and properly marked?			
Are containers not more than 3 quarters full?			
Is waste kept out of public sight?			
Is waste stored in a designated storage with limited access?			
Does everyone dealing and handling pharmaceutical waste have appropriate PPE?			
Is waste storage area clearly marked with warning signs (Biohazards)?			
Is waste storage well ventilated?			
Is the storage room organized, well packed, and not overfilled?			

APPENDIX 5: PERSONAL INTERVIEWS WITH MANAGERS.

Assessment of Pharmaceutical waste management in the Northern Region South Africa

Personal interviews with medical practitioners in facilities and pharmacists

1. What constitutes pharmaceutical waste?
2. Which types of pharmaceutical waste do you have in your facility?
3. What is the quantity of pharmaceutical waste being generated in your facility? Daily, weekly, monthly and yearly?
4. How do you manage your pharmaceutical waste in the facility - from point of generation to disposal?
5. Which category of pharmaceutical waste do you dispose of often?
6. Where do you dispose your pharmaceutical waste?
7. If you are using 3rd party for disposal, do they provide you with certificate of treatment or disposal?
8. What are the potential environmental and human health risks of pharmaceutical waste?
9. What is the importance of pharmaceutical waste segregation from other waste?
10. Does your curriculum in school cover pharmaceutical waste management?
11. Who is responsible for pharmacist waste management?
12. What are the challenges you face regarding pharmaceutical waste management?
13. What are the mitigation measures taken to manage potential risks associated with pharmaceutical waste?
14. What do you think can be done to ensure that pharmaceutical waste is managed safely and effectively?
15. Which regulations govern pharmaceutical management?
16. Do you think pharmaceutical waste regulations are effective?
17. Are there compliance assessments done on pharmaceutical waste management in your facility?
18. Who takes accountability when there is non-compliance to regulations?
19. What are the penalties for non-compliance?
20. Do you believe that the current pharmaceutical waste disposal methods are safe and sustainable?
21. How much do you spend on pharmaceutical waste management?
22. Do you believe that you are financially equipped to ensure pharmaceutical waste is managed properly?
23. How do you ensure that pharmaceutical waste does not end up in public areas?
24. Do you inform patients about proper disposal methods of pharmaceutical waste in their homes?
25. Are consumers informed about risks and impacts of pharmaceutical waste?
26. Is everyone responsible for handling and managing pharmaceutical waste, trained?

APPENDIX 6: ETHICAL CLEARANCE

ETHICS APPROVAL CERTIFICATE

ETHICS APPROVAL CERTIFICATE

FACULTY OF SCIENCE, ENGINEERING AND AGRICULTURE
RESEARCH ETHICS COMMITTEE

NAME OF RESEARCHER/INVESTIGATOR: Malema Mpho Bridget

STAFF/STUDENT NO: 16002614

PROJECT TITLE: Assessment of Pharmaceutical Waste Management in Vhembe district, Limpopo, South Africa

ETHICAL CLEARENCE NO: FSEA/22/GES/21/1707

SUPERVISORS/ CO-RESEARCHERS/ CO-INVESTIGATORS

NAME	INSTITUTION & DEPARTMENT	ROLE
Prof f JN Edokpayi	University of Venda, Department of Geography and Environmental Sciences	Supervisor
Dr V Masindi	Magalies Water	Co-supervisor

Type: **Student research**

Risk: **Minimal risk to humans, animals, or environment (Category 1)**

Approval Period: **March 2023-January 2025**

The Faculty Research Ethics Committee (FREC) of the Faculty of Science, Engineering and Agriculture hereby approves your project as indicated above.

University of Venda

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"A quality driven financially sustainable, Comprehensive University"

APPENDIX 7: FACILITY ACCESS PERMIT

LIMPOPO
PROVINCIAL GOVERNMENT
REPUBLIC OF SOUTH AFRICA

DEPARTMENT OF
HEALTH

Ref : LP_2023-04-009
Enquires : Dr Ramalivhana NJ
Tel : 015-293 6028
Email : Phoebe.Mahlokwane@dhsd.limpopo.gov.za

MPHO BRIDGET MALEMA

PERMISSION TO CONDUCT RESEARCH IN DEPARTMENTAL FACILITIES

Your Study Topic as indicated below;

ASSESSMENT OF PHARMACEUTICAL WASTE MANAGEMENT IN VHEMBE DISTRICT IN LIMPOPO PROVINCE, SOUTH AFRICA

1. Permission to conduct research study as per your research proposal is hereby Granted.
2. Kindly note the following:
   a. Present this letter of permission to the Office of District Executive Manager a week before the study is conducted.
   b. This permission is **ONLY for Vhembe District facilities.**
   c. In the course of your study, there should be no action that disrupts the routine services or incur any cost on the Department.
   d. After completion of study, it is mandatory that the findings should be submitted to the Department to serve as a resource.
   e. The researcher should be prepared to assist in the interpretation and implementation of the study recommendation where possible.
   f. The approval is only valid for a 1-year period.
   g. If the proposal has been amended, a new approval should be sought from the Department of Health
   h. Kindly note that, the Department can withdraw the approval at any time.

   Your cooperation will be highly appreciated.

18/04/2023

Head of Department **Date**

pp

Private Bag X9302, Polokwane
Fidel Castro Ruz House, 18 College Street, Polokwane 0700. Tel: 015-293 6000/12. Fax: 015 293 6211.
Website: http/www.limpopo.gov.za

The heartland of Southern Africa – Development is about people!

APPENDIX 8: PERMISION REQUEST LETTER TO PRIVATE FACILITIES

Faculty of Science, Engineering and Agriculture
Department of Earth Sciences

8th April 2022

To whom it may concern

This is a letter to request that you allow Mpho Bridget Malema who is a student at the University of Venda doing her Master's in Environmental Sciences under my supervision (Dr. Joshua Edokpayi) and Dr. Vhahangwele Masindi. We kindly request that you grant Miss Malema permission to collect data necessary for her to be able to conduct and complete her master's studies. The researcher is required to collect data in healthcare facilities and pharmaceutical outlets in the Northern region of South Africa in Limpopo province.

Note: The study is specifically for academic research purpose, pharmaceutical outlets and healthcare facilities names will not be shared but only identified as facility number and type.

Details of the Student Researcher

1.1	Title: Miss
1.2	Student Number: 16002614
1.3	Name of Applicant (Project Leader): Mpho Bridget Malema
1.4	Academic Qualifications: Environmental Sciences Honors(BEHERM)
1.5	Department: Ecology and Resource Management
1.6	School: Environmental Sciences
1.7	Position: Student
1.8	Current Registered Qualification: Masters Environmental Science
1.9	Email: b.mphomalema@gmail.com Telephone: 071 786 6591
1.10	ID NUMBER: 9607200615089

University of Venda

PRIVATE BAG X5050 THOHOYANDOU 0950 SOUTH AFRICA
TEL: +27 (0)15 962 8065
E-mail: Joshua.Edokpayi@univen.ac.za

Faculty of Science, Engineering and Agriculture
Department of Earth Sciences

Title of the Research

Assessment of pharmaceutical waste management in the Northern region of South Africa in Limpopo Province. Limpopo Province.

Principal Investigator/ Researcher : Mpho Bridget Malema

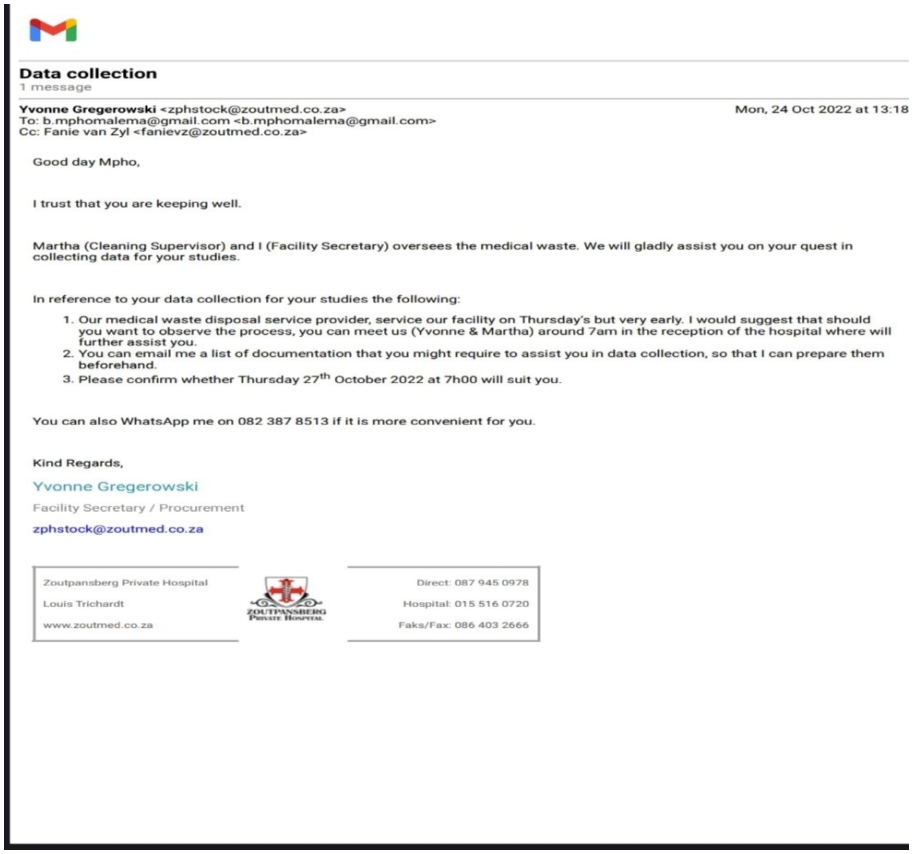
Supervisor : Dr. Joshua Edokpayi

Co-Supervisor : Dr Vhahangwele Masindi

Brief Introduction and Purpose of the Study: The study is about assessing the sustainability pharmaceutical waste management practices in healthcare facilities and pharmaceutical outlets.

Outline of the Procedures: The researcher will use observations, questionnaires, interviews, and a checklist will be used to collect data. Observations will be used to obtain visual data of pharmaceutical waste management practices in the facility; a camera will be used to take photographs where necessary to get visual data on storage, collection, and disposal methods of pharmaceutical waste in the facility. Questionnaire will be distributed to healthcare practitioners for assessment of pharmaceutical waste knowledge, Interviews will be conducted with medical practitioners and waste management personnel in

APPENDIX 9: PERMISION FROM PRIVATE HOSPITALS



Data collection
1 message

Yvonne Gregerowski <zphstock@zoutmed.co.za> Mon, 24 Oct 2022 at 13:18
To: b.mphomalema@gmail.com <b.mphomalema@gmail.com>
Cc: Fanie van Zyl <fanievz@zoutmed.co.za>

Good day Mpho,

I trust that you are keeping well.

Martha (Cleaning Supervisor) and I (Facility Secretary) oversees the medical waste. We will gladly assist you on your quest in collecting data for your studies.

In reference to your data collection for your studies the following:

1. Our medical waste disposal service provider, service our facility on Thursday's but very early. I would suggest that should you want to observe the process, you can meet us (Yvonne & Martha) around 7am in the reception of the hospital where will further assist you.
2. You can email me a list of documentation that you might require to assist you in data collection, so that I can prepare them beforehand.
3. Please confirm whether Thursday 27th October 2022 at 7h00 will suit you.

You can also WhatsApp me on 082 387 8513 if it is more convenient for you.

Kind Regards,

Yvonne Gregerowski
Facility Secretary / Procurement
zphstock@zoutmed.co.za

Zoutpansberg Private Hospital
Louis Trichardt
www.zoutmed.co.za

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Hospital: 015 516 0720
Faks/Fax: 086 403 2666