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MASTER OF PUBLIC HEALTH

ASSESSMENT OF WILLINGNESS TO COMPLY WITH THE 'TAKE BACK UNWANTED MEDICINES' PROJECT AMONG CLIENTS AT SELECTED PHARMACIES IN ACCRA

BY

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DECLARATION

I, Amma Tutuwaa Akwaboah, declare that except for the other people's research work which all have been duly acknowledged, this work is the result of my original research and that this dissertation, either in whole or part has not been presented elsewhere for another degree.

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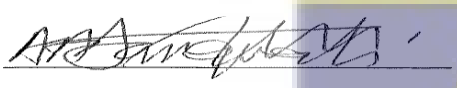
Date: 11th October, 2022

Dr. Augustina Koduah (Supervisor)



Date: 12th October, 2022

DEDICATION

This dissertation is dedicated to my daughter, Akua Anima Saah Darkwah, my husband George Darkwah, and my mother Grace Owusu who was of immense help during my time of studying for this Master of Public Health (MPH) degree while still nursing my baby.

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ABSTRACT

Background: Unwanted, unused, and expired drugs/medicines in homes pose a threat to vulnerable populations, mostly children and the elderly. The storage of drugs at homes may be as a result of incomplete large prescriptions, adverse drug reactions which leads to incomplete prescriptions, patronage of over-the-counter medications for self-medication, forgetfulness among other reasons. The disposal of these drugs inappropriately in the environment has been marked as the primary means by which drugs get into the environment, creating unnecessary exposure. In Ghana, the Public Health Act mandates the Food and Drugs Authority (FDA) to ensure that unwanted drugs are disposed of safely without damaging the environment and do not end up in the hands of consumers. The FDA has therefore established guidelines for the proper disposal of unwholesome products including drugs. The authority launched a pilot drug take-back project called "Take Back Unwanted Medicine (TBUM)" in October 2020, to collect unused, unwanted, and expired medications from consumers through community pharmacies in the Greater Accra Region and safely dispose them in a way that does not pose a public health risk. The objective of this study was to assess clients' willingness to comply to the TBUM project at the designated pharmacies in the Greater Accra Region.

Methods: The study employed a quantitative research approach using structured questionnaires and employed a cross-sectional design to collect data which was analysed with STATA 16. It aimed at understanding factors that influence willingness to comply with the TBUM Project. A purposive sampling technique was used to select the pharmacies for this study.

Results: Among the 301 clients visiting retail pharmacies in Accra, majority (53.5%) were between 21 to 30 years with tertiary education as the highest level of education obtained (65.8%). 31% of the client respondents were aware of the TBUM program, out of this number of which

81% were compliant to TBUM. Also 55% of the respondents confirmed they had unwanted drugs at home and over-the-counter drugs were the most predominant drugs stored in homes. 54% of the clients claimed to have disposed unwanted drugs in the last six months, among which the majority (65%) disposed them by throwing them in their home dustbins. Almost all of the pharmacists and other pharmacy staff surveyed agreed that it was their role to accept unwanted drugs from clients and it was their responsibility to counsel clients on the proper disposal of drugs.

Conclusion: Overall, the study discovered that there is a low level of awareness among clients about the TBUM project which negatively affected the overall willingness to comply with the project. Also, a higher proportion of clients surveyed had in their possession some unwanted or expired medications which were mostly disposed of through home dustbins or flushed down the toilet. Pharmacists at the designated pharmacies were aware of the implementation of the project and offer counseling on appropriate drug disposal methods. They also encourage clients to utilize TBUM to dispose their unwanted drugs, even though the study findings indicate majority of clients still do not return their unwanted medicines to these designated pharmacies.

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LIST OF ABBREVIATIONS

DUMP	Disposal of Unused Medicines Program
FDA	Food and Drugs Authority
TBUM	Take Back Unwanted Medicines
NATRUM	National Return Unused Medicines
ONDCP	Office of National Drug Control Policy
OTC	Over the Counter
RUM	Return Unused Medicines
SAMHSA	Substance Abuse and Mental Health Services Administration
WHO	World Health Organization

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

Drugs/medicines have been used for a variety of purposes since the dawn of time and have provided incredible benefits to both humans and animals. They however have the potential to be useful or harmful depending on how they are used by an individual. Drugs are designed to have a specific therapeutic effect as well as a certain level of safety. However, once expired, the assurance of efficacy and safety is no longer guaranteed and thus, if improperly disposed, can have toxic effects on the environment as well as on human health through pollution of soil, water, and land, posing a public health threat (E. Abahussain et al., 2012). Unwanted medications are medicines that are damaged, expired, or contaminated and are no more viable for human use (Santhosh Kumar & Rahman, 2017). They have been discovered throughout the environment and shown to have a harmful or detrimental effect. This usually occurs as a result of improper disposal of unwanted and expired pharmaceuticals among patients through environmentally unfriendly ways, such as waste bins, sinks, or water closets (Paut Kusturica et al., 2016)

The handling of unused and expired drugs, as well as the consequences on the ecosystem, has piqued global attention (Boxall et al., 2004). Improper disposal of unused and expired drugs has been identified as one of the main sources of chemical contaminants in the environment (Narvaez & Jimenez, 2012). Globally, the rational disposal of unwanted or unused medications particularly by consumers is of increasing concern among many countries. Many developed countries have programs targeted at disposal of unused medicines. In Australia and Canada, there is the National

Return and Disposal of Unwanted Medicines(NatRUM) Project which is fully backed by the government and the pharmaceutical industry. Drug take-back initiatives are also commonly practiced in the United Kingdom and Sweden and provinces in the United State periodically organize community drug-take-back events to allow residents within these communities to surrender their unwanted medications for safe disposal. There are also several initiatives and guidelines that advocate for proper drug disposal practices due to the undeniable negative consequences associated with improper drug disposal practices.

Every year, a vast number of medicines and other healthcare products are used to diagnose, manage, or relieve health issues of varying nature. However, not all drugs or medicinal products that reach the end user are consumed, several go unused or end up expiring. Improvements in the patient's health condition, huge medication packages, death of patients, and alteration of prescription due to side effects or lack of efficacy, poor adherence, and perceived adverse effects, all contribute to medicine waste in households and present reasons why one may want to discard their unused, unwanted or expired medications (Wheeler et al., 2017). Patients may also keep these unused medicines at home just in case they may need them in the future for self-medication or recommend to a friend or relative with similar symptoms.

Owing to a lack of knowledge about proper drug disposal practices, the accumulation of leftover, unused, or expired medicines at home may pose a threat to humans and if not properly disposed of, poses a threat to the environment (Ellis, 2018). Drugs that are poorly disposed mainly through home dustbins or flushed down the toilet have negative consequences on the ecosystem. This is because the chemicals in drugs can end up in water systems, causing harm to human health if drinking water is not adequately treated to remove such high concentration of toxic drug waste. This also affect and aquatic life, causing negative effects such as the feminizing effect of estrogen

and other chemicals on male fishes, altering the female-to-male ratio of fish species. Studies in the United States of America have reported some drug-related chemicals such as antibiotics, opiates, and some antihypertensive medications, have been discovered in waterways and even in drinking water (Ellis, 2018; Esseku & Esseku, 2014).

The Public Health Act of Ghana, Act 851 2012, Section 132 in Ghana mandates the Food and Drugs Authority (FDA) to ensure that unwanted drugs are disposed safely without damaging the environment and do not end up in the hands of unsuspecting consumers (Public Health Act, 2012). The FDA in pursuance of Section 132 of Act 851 has therefore established guidelines for the proper handling, treatment, and disposal of unwholesome products including expired, adulterated, and unwanted drugs to protect human health and the environment from potential hazards (Food and Drugs Authority, 2013). The basic requirement is that all drug disposal must be undertaken with FDA approval and supervision, and destruction of such must be performed in conjunction with an appropriate waste management agency, with the Environmental Protection Agency (EPA) acting as a witness if required for large quantities of controlled substances (Guidelines for Safe Disposal of Defective and Expired Drugs , Cosmetics , Household Chemical Substances and Medical Devices, 2013; Public Health Act, 2012). These guidelines however do not directly capture the disposal of unused drugs in the possession of individual consumers or private entities that are considered substandard or compromised (Esseku & Esseku, 2014). The FDA, therefore, launched a pilot drug take-back project called "Take Back Unwanted Medicine" (TBUM) in October 2020, intending to collect unused, unwanted, and expired medications of any form from tablets, syrups, capsules among others from consumers through community pharmacies in the Greater Accra Region and safely dispose of them in a way that does not pose a public health risk to humans and the environment and in accordance with the requirements of the Public Health Act, Act 851

mandate. With this project, consumers are required to locate a designated retail pharmacy within their community that has been provided with drug collection receptacles by the FDA to drop their unwanted or expired medications. These discarded drugs are then periodically collected by the FDA across the various designated pharmacies and safely disposed of in a manner that is safe while providing a safe and convenient mode of unwanted drug disposal for clients (http://fdaghana.gov.gh/consumer-safety-tips.php).

Client compliance to many healthcare programs has been problematic including compliance to prescription regimen(Stirner et al., 2022). This is because compliance is a highly individual phenomenon, and the decision to comply is a dynamic process. Therefore healthcare practitioners who wishes to respond to compliance problems must offer behavioral strategies that are tailored to individual clients and are continuously applied (Willis, 2000). In healthcare, compliance is widely used as a term to describe how well a client's behavior follows advice or recommendation from a healthcare professional (*Compliance | Definition of Compliance by Medical Dictionary*, n.d.).

Pharmacists in community retail pharmacies play an essential role in disseminating client medication usage and disposal information. According to research, pharmacists can promote drug efficient usage through patient education and decrease of over-prescription (Singleton et al., 2014), suggesting their ability to increase safe drug disposal through education and counseling on contact with their clients. According to studies, communication concerning medication disposal between pharmacists and clients varies(Ehrhart et al., 2020) and this therefore has varying outcomes on safe drug disposal practices by clients. Customer drug disposal could be improved with small educational efforts, especially directly from pharmacists and other healthcare staff.

1.2 Problem Statement

Expired, unused and unwanted drugs that are improperly disposed of such as through household dustbins could end up in the hands of scavengers and children if landfill sites are not properly guarded. The World Health Organization (WHO) postulates that globally more than half of all prescribed and recommended medications are unused by patients which causes unnecessary storage in homes and creates an environmental and human threat (Jindal & Goel, 2018). Improved patient health, large medication packages, patient death, and prescription changes due to side effects or lack of efficacy, poor adherence, and perceived adverse effects all contribute to medicine waste in households and present reasons why one may want to discard unused, unwanted, or expired medications. The presence of official national drug disposal guidelines impacts the disposal methods employed for discarding unwanted or expired medications(Michael et al., 2019) while its absence results in clients discarding medications improperly, such as throwing them in dustbins. Therefore, a lack of awareness of guidelines may impact disposal methods used or result in the employment of poor drug disposal methods. There is a paucity of data available in empirical studies concerning the awareness of drug disposal guidelines, especially among clients.

Improper drug disposal poses some public health risks because chemical constituents of medicines or drugs could enter water sources, some medicines could kill the bacteria required for sewage treatment, and the burning of such drugs could produce toxic air pollutants (Narvaez & Jimenez, 2012). When it comes to drug disposal, it is unfortunate that many people are unaware of how best to handle or get rid of their unused drugs but utilize methods that provide convenience to them. Many may even forget about existing medications in their homes, while others prefer to flush or throw away their unused medications indiscriminately (Ellis, 2018). As a result, drugs mainly tablets and capsules often end up in landfill sites, syrups in water supplies, or in the possession of

minors or potential abusers (Kumar S et al., 2019). In Ghana, a study by Aboagye et al in 2014 in the Greater Accra region uncovered that about 72.7% of people dispose of their unwanted medications in their home dustbins which ultimately end up in landfill sites while 71.6% keep their unused medications at home for future use or give it out to other relatives for whom the drug may not have been prescribed for but have similar symptoms. This poses a risk of unintended exposure and irrational use of medications which can result in aggravation of symptoms, indiscriminate prescribing and with antibiotics, may result in antibiotic resistance which currently is a global pharmaceutical burden.

Compliance with drug take back programs has not been extensively researched as there is limited data available from literature review, even though patient compliance to other regimen such as drug, diet, exercise and other regimen has been extensively studied. In a resource-constrained country like Ghana, there have been limited studies to investigate drug-take back programs, which prior to 2020 were mostly absent from the healthcare system for the general populace to assess. The Ghana FDA therefore piloted a project in Accra to initiate drug take back to community pharmacies, dubbed Take Back Unwanted Medicines(TBUM) project with the aim of collecting unwanted drugs from households through the return of such to designated community pharmacies. The research, sought to identify the various gaps and drawbacks to the effective implementation of the "Take Back Unwanted Medicines" project and suggest appropriate interventions to help improve clients' willingness to comply with the project, and ensure the overall aim of the project which is to reduce unwanted and expired medicines from homes is realized. It also assesses the role of pharmacists, who are the main healthcare partners with the regulator in this project, at the designated pharmacists in the implementation of the TBUM project.

1.3 Justification

Indiscriminate and irresponsible disposal of unused, unwanted, and expired medications is a major public health concern. The majority of drug users in Ghana dispose of their leftover and expired medications through home dustbins which eventually end up at various landfill sites resulting in contamination of the environment and water bodies (Aboagye & Kyei, 2014). Community retail pharmacies are widely distributed across all communities in Ghana and have trained staff who can effectively handle medications and give appropriate counseling relating to the rational use of medicines and their appropriate disposal where needed to visiting clients (Okai et al., 2019). These pharmacies are usually designated as drug collection points for unwanted, leftover, and expired drugs from households and individuals within the selected communities in countries where drug take-back programs are implemented (Fass, 2011a). Thus, the FDA in Ghana in 2020, launched a pilot project dubbed 'Take Back Unwanted Medicines'(TBUM) project in Accra with fifty selected community retail pharmacies, located across various communities within the region. The objective of TBUM is to help curb the menace of irresponsible and indiscriminate drug disposal within the Greater Accra region of Ghana (.http://fdaghana.gov.gh/consumer-safety-tips.php). This study, therefore, seeks to assess clients' willingness to comply at the fifty designated pharmacies to this novel initiative in Ghana to address the indiscriminate disposal of medicines within the communities in the pilot phase of the project. It also will investigate the major drawbacks that affect total adherence to this project by clients. It also seeks to underpin the roles and responsibilities of community pharmacists in educating and counseling of clients to encourage participation in the implementation of the project to promote appropriate discarding of unwanted and expired medications. The results of the study will also serve as feedback to the regulatory agency; FDA on the pilot phase of the implantation of TBUM project. This will aid in determining

the next level of scale up of the project and where feasible, increase awareness and education of the populace on safe drug disposal practices through media campaigns and educational programs to improve adherence to TBUM. Furthermore, the study's findings may be incorporated at the academic level into training modules to educate pharmacy students on their roles and the need for safe medication disposal techniques, or can also serve as a resource for the broader professional body.

1.4 Research Questions

1. What is the level of awareness of clients at designated pharmacies about the 'Take Back Unwanted Medicines' project?
2. What are the factors affecting clients' compliance with the "Take Back Unwanted Medicines" project?
3. What are the current disposal practices of clients for their unwanted and expired medications?
4. What is the role of pharmacy staff in the implementation of the "Take Back Unwanted Medicines" project at the piloted pharmacies?

1.5 General Objective

To assess clients' compliance at piloted pharmacies in Accra to the "Take Back unwanted medicine" project.

1.6 Specific Objectives

1. To ascertain the level of awareness of clients at selected pharmacies to the "Take Back Unwanted Medicines" project.

2. To assess the factors affecting client willingness to comply with the "Take Back Unwanted Medicines" project.

3. To identify practices for the disposal of unwanted and expired medications.

4. To identify the role of pharmacy staff in the implementation of the "Take Back Unwanted Medicines" project in the piloted pharmacies.

1.7 Significance of the Study

The research addresses the implementation phase of the policy cycle at the community level of the healthcare system. The pilot phase of the 'Take Back Unwanted Medicines' project being implemented by the regulator, Food and Drugs Authority, is being tested at the implementation phase across the fifty selected pharmacies, within the Greater Accra region before being scaled up to the national level for implementation at retail pharmacies across the country. The unit of analysis of the research is a project which forms a part of a bigger program of safe drug disposal.

1.8 Theoretical Underpinnings and Conceptual Framework for the Study

Several theories and models have been used to provide explanations to human behaviour and the health system. This study however adopted one of such theories; The Health Belief Model to design the conceptual framework.

The conceptual framework used for the study design, literature review, the research instruments, the review of literature, presentation of results and discussion of the findings from the study data analysis describes possible factors affecting the compliance of clients with Drug take-back programs similar to the "Take Back Unwanted Medicines" project being piloted by the FDA in Greater Accra across the fifty retail pharmacies. The framework was designed based on the Health belief model theory which is one of the most widely used frameworks to explain health behavior

that has been employed by healthcare practitioners as well as health educators (Rosenstock et al., 1988). The conceptual framework shows the interdependencies between the dependent variable (Compliance) and the independent variables such as client factors, and socio-demographic and economic factors of clients and how they interact to influence clients' compliance to the take-back unwanted medicines project.

The health belief model provides explanations to why clients and pharmacists may comply with the FDA project and adopt safe drug disposal practices. Based on the constructs of the HBM, clients are more likely to comply with the guidelines if they feel there is a threat (perceived susceptibility) which poses a level of risk to the environment and their individual health (perceived severity) when they engage in inappropriate disposal practices. Again, if they believe they can confidently handle measures and the recommendations proposed by the FDA drug disposal guidelines (self-efficacy) and there are benefits of complying with the said recommendation, such as a safer home and environment (perceived benefits), then they are more likely to engage in safer drug disposal methods. On the other hand, should they perceive that compliance with the project by returning their unwanted medicines outweighs the benefit they gain (perceived barrier), coupled with inadequate education, awareness creation and counselling by pharmacists and other pharmacy staff together with the implementing agency; FDA to stimulate action (lack of cues to action), it may inadvertently lead to non-compliance with the FDA drug disposal recommendations.

Socio-economic factors such as age may influence clients' attitude to comply to take back unwanted medicines programs as older people based on cultural practices are inclined to hold back on their unused medications and pass them on to others with similar symptoms who may need such medicines in the future. Again, educational level, income level, and occupation can also impact compliance. Less educated and people with low-income levels may not see the need to return

unused medications which they have purchased with their monies to pharmacies, just for them to be disposed, while they may need them in the future. Again, people who are employed in the health sector who have a good appreciation of the dangers and effects of drugs when inappropriately handled or disposed of are more likely to comply with drug take-back programs which ensure the safe disposal of unwanted or expired medications, rather than keep them at home where others including children may have undue access. Other factors such as the level of awareness of clients or otherwise to drug take-back projects are also a factor that directly affects compliance. Clients who are informed of such programs are more likely to comply than those who may not have a detailed understanding of education on the importance and the necessity of such a project (WHO, 1998).

Health system factors such as counseling by pharmacy staff and the accessibility and distance to retail pharmacies can also directly influence compliance with drug take-back programs and can also influence the awareness of clients (counseling). Trained pharmacy staff are required to counsel clients on the safe use of their medications which include appropriate disposal practices for unused and expired medications at every point during the dispensing of such medications to clients. Staff with a positive attitude and orientation on such good practices can have a direct influence on their clients to return their waste pharmaceuticals to them for safe disposal rather than storing them in their homes. Again, access to pharmacies is also key in determining clients' compliance. Pharmacies that may be cited close to the communities where people live or in an area with a cluster of businesses may have clients easily dropping their medications than those which are located further from their places of work or abode as transportation to these pharmacies may be a deterrent for some clients (WHO, 1998).

The availability of regulations or standards for dumping expired or undesired prescriptions impacts people's disposal of unwanted pharmaceuticals. Beyond the availability of these standards is the awareness of the populace of such mechanisms or procedure to follow to dispose their unwanted drugs. When there are policies and guidelines to ensure safe disposal and clients are made aware of such through appropriate media such as social and traditional media which is utilized by clients, they are more likely to comply with such guidelines and recommendations (Tong et al., 2011).

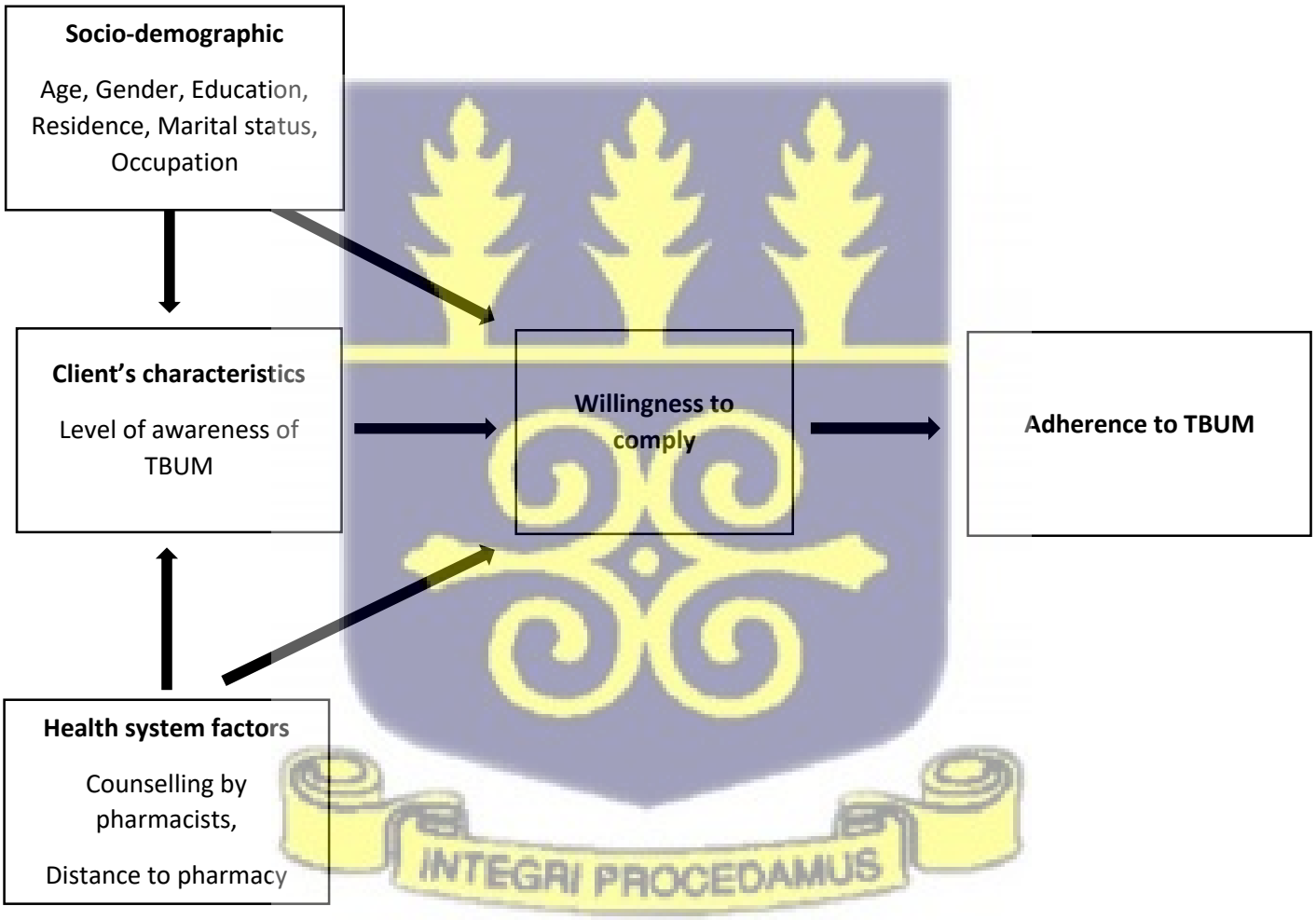

Figure 1: Conceptual framework for willingness to Comply with TBUM

Author's construct

[i]***Distance to pharmacy was not measured in this study***

CHAPTER TWO
2.0 LITERATURE REVIEW

2.1 Introduction

The chapter covers an empirical review to examine current literature relevant to the subject of compliance with drug take back programs across different countries. The review was guided by the objectives and the conceptual framework designed for this study. The literature review was conducted by searching for key words and phrases based on the concepts pertinent to the topic from search engines such as Science Direct, Google scholar, Research gate, PubMed among others. Words and phrases used include but not limited to drug disposal, drug take back programs, drug disposal guidelines, methods of drug disposal, etc. In –text citations obtained in articles were followed up to get the original sources of citations which was then used to obtain further information for a comprehensive literature review. The chapter therefore describes areas such as impact of pharmaceuticals on the environment,

2.2 Environmental Impact of Pharmaceuticals

Pharmaceuticals have been recognized as a rising environmental hazard by various researchers and regulatory bodies. This has resulted in an increase in awareness of the presence of pharmaceutical products in the environment within the last decade. (Kuster & Adler, 2014). The drugs chemicals commonly found to be improperly disposed and are present in water bodies and the soil have been linked to antibiotics, antidepressants, steroids, epilepsy medicines, painkillers, and some other medications, according to the University of Illinois (https://web.extension.illinois.edu/unusedmeds/whatarethey/unwantedmedicine.cfm). Not only do these substances have the ability to affect humans, but they also present a threat to marine ecosystems. Many organisms, especially frogs and fish, have shown changes in behavior,

reproduction patterns, and growth as a consequence of these prescription chemical by-products, according to studies.

Excretion from the human body (metabolites and parent compound) by urination/defecation, washing off directly from the skin while bathing (e.g. creams and ointments), or improper disposal in the toilet, sink, and/or household garbage are all ways for drugs to reach the environment. (Esseku & Esseku, 2014). Since sewerage systems are not designed to effectively remove medicines and their metabolites, they can be discharged into waterways and, as a result, into drinking water sources. Dumped medicines end up in landfills, where they can leach more slowly into water systems. Medicines and their metabolites can affect plants, aquatic, and animal life, as well as human life. The extent to which concentrations can be harmful to human health will be determined in future research works. (Yasir, 2017).

Many people are unaware that the fastest-growing opioid epidemic in the United States and the world is prescription drugs, not cocaine, heroin, or methamphetamines. Many teens wrongly believe prescription medications are safer or less harmful than other types of drugs, according to the Substance Abuse and Mental Health Services Administration (SAMHSA) in Rockville, Maryland (Jaramillo-Stametz et al., 2017; Narvaez & Jimenez, 2012).

Knowing the basics of pharmaceutical disposal will help people properly handle their medications and reduce the chances of them being abused. Prescription and over-the-counter drug use are rising globally, with over 4.5 trillion doses estimated to be consumed by 2020, up 24% from 2015. As a consequence of this change, more than half of the world's population will be taking more than one dose of medication every day by 2020, with increased use driven mainly by emerging markets such as India, China, Brazil, and Indonesia. As a result, reducing drug waste and establishing

proper recycling practices for discarded medicines (expired and in-date medicines that are no longer needed, including used or unused packs) is a global concern.

2.3 Drug Disposal Practices across the Globe

Consumers' proper disposal of unwanted, expired or unused drugs is a major concern worldwide. Unused medicine recycling schemes exist in many developing countries. For example, in Australia and Canada, the government and the pharmaceutical industry have fully embraced the National Return and Disposal of Unwanted Medicines Project. In the United Kingdom and Sweden, drug take-back schemes are also common.

Studies conducted in various areas revealed that not only do people dispose leftover drugs in several ways, but they also are not always aware of the best practices. For example, a study conducted in Kenya and Nigeria revealed that throwing unused pharmaceuticals in garbage bins was the preferred method of disposal, followed by flushing in toilets. In another survey in Ethiopia, respondents kept the drugs in their homes because they didn't know what to do with them, whereas others offer them to friends and family. (Ayele & Mamu, 2018). These findings indicate that the majority of respondents are unaware of appropriate disposal procedures for unused drugs.

According to research on household disposal practices for unused medicines around the world, the most commonly used methods were pouring them down the toilet or sink or throwing them away. (Yasir, 2017). A systematic review of global disposal practices revealed that the preferred approach was determined by the formulation and/or type of medicine: liquids were disposed of in sinks or toilets, while solid and semi-solid types such as tablets/capsules and ointments/creams were disposed of in household garbage. Antibiotics, for example, were more often returned to a pharmacy, while over-the-counter (OTC) ‘everyday' items like cough medication were poured down the toilet or sink. Since streamlined guidance and procedures for effective disposal of unused

drugs, including access to a national disposal system, are missing in many countries, the aforementioned systematic review found that confusion still exists about the correct form of drug disposal (Santhosh Kumar & Rahman, 2017).

In Sweden, on the other hand, where a national disposal system that is based on pharmacies was developed in 1971, 73 percent of households surveyed said they would use this method to dispose unused medicines. Just 3% of those surveyed said they threw their discarded medicines in the trash, and none said they poured them down the drain. The majority of these consumers had previously used the National Return of Unused Medicines (NatRUM) program after learning about it from a pharmacist. The most common explanations for customers returning drugs were that they had expired (31%), that the person taking the drug (usually a relative) had passed (26%), or that the medicine (prescription) had changed (8.5%)(Wheeler et al., 2017).

2.4 Drug Disposal Practices in Ghana

In Ghana, according to the results of a study by Aboagye et al 2014, more than half of the respondents kept unused, leftover, or expired drugs at home. Per the report, more than two-thirds (71%) of respondents bought all (11.5%), most (16.4%), or some (70.5%) of their medications over the counter either from a pharmacy or licensed chemical shop. 40% of respondents did not finish their prescription, which was either discontinued or briefly stopped when their symptoms improved. The discarded drugs were then later reused, with little regard for the consequences of the product's condition (storage conditions, stability, degradation, expiry date). Patient non-compliance was often exacerbated by the onset of side effects or by medication changes. The lack of a facility for returning unwanted drugs, the country's low literacy rate, and patient non-compliance on the other hand, resulted in the prevalence of unused medications in homes. Just a

quarter of those surveyed was aware that pharmaceuticals have an environmental effect. The majority of respondents (44.6 percent) either ignored or were persuaded by this fact.

2.5 Guidelines on Drug Disposal

2.5.1 WHO Guidelines on Drug Disposal

The WHO provide guidance on the implementation of safe disposal of unused pharmaceutical products in emergencies and in countries in transition where official advice and assistance may not be available. These aim to assist where there is insufficient guidance or no guidelines at all to guide the safe disposal of unused drugs and not to replace local guidelines (WHO, 1999). It recommends that prior to disposal, drugs be sorted out into separate categories based of their formulations, as different methods for disposal may be required for different formulations.

Outline below are the recommended disposal methods by the WHO per the 1999 drug disposal guidelines.

2.5.1.1 Incineration

Purpose-built high-temperature incineration with adequate flue gas cleaning is the most environmentally friendly solution for pharmaceutical destruction. However, this isn't the only way to ensure proper disposal. Many countries do not have such a facility, but practical interim solutions to help with the safe disposal of unused medications could be used. The most effective way to do this is to sort the waste to reduce the need for costly or complicated disposal methods. Expired pharmaceuticals, chemical waste, used oil, tires, and other materials can all be disposed of in cement kilns. They have many characteristics that make them ideal for pharmaceutical disposal. Cement raw materials reach temperatures of 1450°C during combustion, while combustion gases reach temperatures of up to 2000°C. At these high temperatures, the gas residence time is several seconds. All organic waste components are essentially disintegrated in

these environments. Any potentially hazardous or harmful combustion materials are adsorbed into the cement clinker or removed in the heat exchanger. There would be much fewer effects on the local region if sufficient environmental impact management systems are in place. Pharmaceuticals should be added to the furnace as a limited percentage of the overall fuel supply. As a general rule of thumb, no more than 5% of the fuel fed into the furnace at any given time should be pharmaceutical content. Cement kilns normally produce 1,500 to 8,000 metric tons of cement per day, allowing for the disposal of significant amounts of pharmaceutical material in a short period. To prevent clogging and blockage of the fuel feed mechanisms, it may be important to cut packaging and/or grind the pharmaceuticals.

2.5.1.2 Landfills

The term "landfill" refers to the act of dumping waste into a landfill without first treating or treating it. Landfilling is the oldest and most commonly used form of solid waste disposal. There are two types of landfills: uncontrolled open non-engineered dumps and planned/engineered landfills. In developing countries, the most common method of land disposal is a non-engineered dump. Untreated waste dumped into an unregulated, non-engineered open dump is not environmentally friendly and should not be used. Untreated waste pharmaceuticals can only be disposed of in such a location as a last resort. If immobilization of waste pharmaceuticals is not practicable, the untreated wastes must be quickly filled with large amounts of urban waste to avoid scavenging. Disposing of in-free, unregulated dumps with inadequate isolation from other watercourses should be avoided.

Engineered landfills are usually landfills that have been built. Any features of such a landfill are designed to prevent chemical leakage into the aquifer. Discharging immobilized pharmaceutical waste into such a landfill is preferred over direct dumping pharmaceuticals. Municipal solid

wastes, including waste pharmaceuticals, can be safely disposed of at properly built and maintained landfill sites. The aquifer must be protected first and foremost. An adequate landfill consists of an evacuated pit above the water table and is isolated from watercourses. To preserve sanitary conditions, each day's solid waste is compacted and covered with soil. The term “safe sanitary landfill” refers to such a site that is adequately situated, constructed, and managed. The upgrade of an unregulated waste disposal site to a suitable standard should be considered, and WHO does offer guidelines.

2.5.1.3 Waste immobilization: encapsulation

Encapsulation is one method of waste immobilization. The pharmaceuticals are immobilized in a solid block inside a plastic or steel drum during encapsulation. Drums should be thoroughly washed before use and should not have previously held explosive or dangerous materials. They are filled to 75 percent capacity with solid and semi-solid pharmaceuticals, with the remaining space filled with cement, cement/lime mixture, plastic foam, or bituminous sand. The drum lids should be cut open and bent back for ease and speed of filling. Care should be taken to avoid cuts to hands when placing pharmaceuticals in the drums. After the drums have been filled to 75 percent capacity, a 15:15:5 (by weight) mixture of lime, cement, and water is added, and the drum is filled to capacity. To achieve a sufficient liquid consistency, a greater amount of water can be required at times. Steel drum lids should then be bent back and sealed with seam or spot welding, if possible. The sealed drums should be buried in fresh urban solid waste at the bottom of a landfill. The drums can be mounted on pallets, which can then be loaded onto a pallet transporter for easy transportation.

2.5.1.4 Inertization:

This is a form of encapsulation that involves removing the packaging materials from the pharmaceuticals, such as paper, cardboard, and plastic. The blister packs of pills must be separated. After that, the pharmaceuticals are ground and mixed with water, cement, and lime to make a homogeneous paste. Since there is a risk of dust, workers must wear protective clothing and masks. The paste is then transported to a landfill in a liquid condition by a concrete mixer truck and decanted into regular municipal waste. The paste then solidifies into a solid mass that is spread throughout the municipal solid waste. The procedure is relatively inexpensive and can be completed in a short amount of time.

Sewer: Most liquid pharmaceuticals, such as syrups and intravenous fluids, may be diluted with water and flushed into sewers in limited amounts over time without causing damage to public health or the environment. Tiny amounts of well-diluted liquid pharmaceuticals or antiseptics may also be flushed by fast-flowing watercourses. In cases where sewers are in poor condition or have been damaged, the assistance of a hydrogeologist or sanitary engineer may be required.

2.5.1.5 Chemical decomposition:

If an appropriate incinerator is not available, chemical decomposition, followed by landfill, may be used in accordance with the manufacturer's recommendations. If you don't have access to chemical knowledge, this approach is not recommended. Chemical inactivation is laborious and time-consuming, and chemical stocks for treatment must be kept on hand at all times.

The Food and Drug Administration in Ghana is legally responsible for disposing of expired medications and other substances in a safe manner. Before drugs or chemicals may be disposed of, they must first be approved by the FDB.

2.5.2 Drug Disposal Guidelines in other Countries

According to a study by Abahussain and Ball (2007), there is a need for each country to develop guidelines on drug disposal and distribute these guidelines to the populace. This should be accompanied by public awareness campaigns in the media on the dangers of expired medicines and poor drug disposal practices (E. A. Abahussain & Ball, 2007). The presence of policies or official guidelines for discarding expired or unwanted medications influences the disposal of unused pharmaceuticals by people(Tong et al., 2011). Many countries throughout the world have regulations or standards in place to ensure the proper disposal of unwanted medications. Despite the availability of these standards in lots of countries, there are no documented procedures for disposing unwanted medication in New Zealand, Saudi Arabia, Nepal, Saudi Arabia, and Libya. Nonetheless, residents are encouraged to return unwanted medications to community pharmacies (Atia, 2021; Tong et al., 2011).

2.5.3 Guidelines On Drug Disposal in Ghana

The National Medicines Policy and the Public Health Act, Act 851 in Ghana both require the Food and Drugs Authority (FDA) to ensure that drugs are disposed of responsibly and do not end up in the hands of customers. (National Medicines Policy, 2017). The Ghanaian Food and Drug Administration (FDA) has developed guidelines for the safe disposal of unfit products. (Food and Drug Administration, 2019). The fundamental requirement is that all drug disposals must be undertaken with FDA approval and supervision. All destruction must be conducted in collaboration with an appropriate waste management agency, with the Environmental Protection Agency functioning as a witness where necessary. The following requirements are instituted by the policy (FDA, 2019):

- It states that under no circumstances should an individual dispose of medicine without authorization and supervision from the Authority.
- Individuals must seek approval from the FDA and pay a prescribed fee for the safe destruction of unwanted medications.
- Applicants are responsible for conveying unwanted medications to the destruction site and liaising with a waste management company to help with the disposal.
- The following agencies, where feasible, shall be present and serve as witnesses: The Audit Service, the EPA, the Ghana Police Service, and the Customs Excise and Preventive Service.
- The unwanted medications to be destroyed should be appropriately managed
- The FDA will decide with the applicant and set a date for the destruction of the unwanted medications.
- After destruction, the FDA will issue a certificate to the applicant.

According to the policy document, anyone who contravenes these recommendations in the guidelines commits an offence and if convicted, will be liable to pay a fine.

2.5.4 Compliance with Safe Drug Disposal Guidelines

Despite the availability of established guidelines from several regulatory bodies like the EPA, FDA, and WHO regarding the disposal of unwanted medicines, there is a large body of literature indicating environmentally unfriendly drug disposal methods such as rinsing down a sink, flushing down the toilet, or throwing them in the garbage that still go on (Alhomoud et al., 2021).

In terms of compliance with drug disposal guidelines, the result of a study shows that 23.4% of the respondents (community pharmacies) were completely compliant with the National Agency for Food and Drug Administration and Control (NAFDAC) guidelines in Nigeria. Whereas 54.5% and 22.1% were non-compliant and partially compliant, respectively. This indicates that the majority of respondents were not completely compliant with the drug disposal guidelines (Michael et al., 2019). Similarly, to the findings of Michael et al. (2019), another study conducted in Libya among community pharmacists revealed that most respondents (69.8%) were not compliant with the drug disposal guidelines for unused medications established by the WHO (Atia, 2021). According to the study, about 28.1% and 2.1% of the respondents were partially compliant and completely compliant, respectively (Atia, 2021). Another study in Anambra State, Nigeria, reported a low degree of compliance with practice regulations among community pharmacies (Anyachebelu & Aluh, 2018).

In this regard, to improve pharmacies' compliance, governmental bodies must review existing laws regulating disposal of medication waste, especially those relating to financial responsibility for delivering the service, to increase the level of compliance among pharmacies (Jonjic´ & Vitale, 2014). It is also necessary for agencies such as the MOH to provide guidelines to enable community pharmacies to accept returned unwanted medication from clients and to educate pharmacists on proper disposal methods (Atia, 2021).

2.6. Return-of-Drugs Initiatives

The drug return program is a generally recognized program that ensures that pharmaceuticals are disposed of safely. This service allows patients to return any unused or expired medications to the place where they were purchased, such as a hospital, pharmacy, or chemical store. Prescription drug take-back programs offer a mechanism for consumers to safely and legally return unused

drugs to the proper authorities with a singular objective to reduce the supply of prescription drugs available for diversion, misuse, or abuse.

Although there are many different types of take-back programs, the four most common are pharmacy-based permanent collections, law-enforcement-based permanent collections, community event-style programs, and mail-back programs. Drug take-back programs accept a wide range of medications, including over-the-counter and prescription drugs, as well as uncontrolled and controlled substances. Authorized collectors may set up collection receptacles and/or run mail-back programs at a registered place. Collection receptacles at long-term care facilities may be managed by retail pharmacies, hospitals, and clinics with onsite pharmacies. Approved collection bodies must follow a certain collection, handling, storage, transportation, and disposal regulations set by federal, state, and local entities, which differ by country, state, and sometimes locality. Legal and regulatory compliance (federal, state, and local), consumer convenience, sustainability (including but not limited to funding), outreach and education, and collaborations with law enforcement are all factors that lead to the effectiveness of a prescription drug take-back program (https://www.productstewardship.us/page/GoToGuide).

In the United States of America, the Office of National Drug Control Policy (ONDCP) and the Food and Drug Administration (FDA) developed a federal guideline that includes a list of 27 drugs that should be flushed, and drugs not included on this list be thrown away in the garbage, such as coffee grounds, cat litter, etc. Drug take-back systems are also recommended by the FDA and the ONDCP for prescription disposal. The Controlled Substances Act makes no provisions for how controlled substances can be disposed of by individuals. As a result, the Drug Enforcement Administration (DEA) was created which birthed The Secure and Responsible Drug Disposal Act of 2010, which amends the Controlled Substances Act to include drug take-back services for the

disposal of controlled substances as decided by an attorney, in 2010. Permanent Drug collection sites are authorized retail, hospital, or clinic pharmacies, and sometimes some law enforcement facilities offer onsite medication drop-off bins or mail-back programs to assist in the safe disposal of unused or expired medications. There is also periodic drug take-back events, dubbed "National Prescription Drug Take-Back days" during which temporary drug collection stations with collection bins are mounted in communities across the country for clients to drop off their unused and expired medications at no cost for safe disposal. Specific states also have multi-state medication take-back initiatives which also run concurrently with the national programs all in the stead to encourage safer and more appropriate drug disposal practices, especially for prescription and controlled medications which are known sources of poisoning in homes (Fass, 2011b). Patients are encouraged to remove all personal information from prescription medications before returning them for collection and all drugs collected are destroyed.

In Australia, the Return Unused Drugs (RUM) project is a nationwide initiative that collects out-of-date and unwanted medications. This program encourages Australians to dispose of their medications responsibly. The returned drugs are then properly disposed of and not reused or recycled in any way (Wheeler et al., 2017). Disposal of the returned medicines is conducted in accordance with regulatory and EPA requirements. All pharmacies in Australia will accept your out-of-date and unwanted medications as they have the required equipment to accept any medication for free and in a convenient way from consumers. Prescription and over-the-counter medications, herbal or complementary supplements, gels, liquids, creams, and pet medications can all be returned to your community pharmacy for free and secure disposal. Most medications may be discarded in the Return Unwanted Medicines (RUM) Project's disposal bin, but certain medicines (such as strong pain relievers and other controlled drugs) will need to be stored or

handled differently by the pharmacist, so patients are encouraged to specify the type of medication they are returning to the pharmacist. The Return Unwanted Medicines (RUM) Project is funded by the Australian Commonwealth Department of Health & Aging. Over 704 tons of unused drugs were obtained in 2016 by the Project. The most frequently returned drugs, according to an analysis, were unexpired opened packets of medicines for the treatment of acute conditions.

Although there is no national program for disposing of household pharmaceutical waste in Canada, most provinces have developed or are developing provincial-level programs. A variety of pharmaceutical disposal services are also available in a number of municipalities and communities. Consumers may return unwanted and expired pharmaceuticals to community pharmacies or recycling depots. Programs are implemented by provincial governments, the pharmaceutical industry, and/or pharmaceutical organizations with the goals of increasing safe pharmaceutical disposal and reducing pharmaceutical waste. Only publicly returned pharmaceuticals are approved, and participation is entirely voluntary. The Post-Consumer Pharmaceutical Stewardship Association (PCPSA), is a non-profit organization that supports provinces/territories with stewardship programs. The only regulatory scheme that requires funding from the pharmaceutical industry is in British Columbia, although similar laws are being established in Ontario and Manitoba. The pharmaceutical industry and/or governments provide funding elsewhere voluntarily; In most cases, pharmaceutical waste is incinerated or buried in licensed landfill sites. Brochures, posters, and websites are used to create awareness of programs to the general public. (Gagnon, 2009)

Many European countries have localized prescription return services where people can return any unused or expired drugs. Pharmaceutical waste should be returned to community pharmacies in Norway, which are required to collect unwanted drugs from individuals. All remaining

medications must be sent to pharmacies in Sweden, France, and Poland as well. They are then transported to licensed facilities for drug incineration. Medicines should never be discarded in the trash or flushed down the toilet. Empty pharmaceutical packaging, such as blisters, cartons, and containers, must be sorted and disposed of as other packaging according to local regulations. If there are noticeable medication traces on the package or if it is difficult to ascertain, it should be returned to pharmacies with the remaining drugs. In Germany, the various disposal routes for drugs and medicines are ecologically friendly and safe. Since most household waste in Germany is incinerated (>80%), disposing of unused or expired medication by general waste is the safest and most recommended method in most places. In no case does this waste end up in a landfill untreated. Hazardous Waste disposal routes or returning to a pharmacy can only be used in such locations or exceptional situations.

In some African countries such as south Africa, pharmacies are mandated by law to accept expired or unused medicines from clients to assist with the safe disposal of medicines (Carmen, 2020). The country's National drug policies recommend prompt and safe disposal of unwanted medications and emphasizes that the government through legislation will make sure the disposal is conducted in a way that is not detrimental to communities and the environment. (National Drug Policy South Africa, 1994).

In Ghana, to assist with the safe disposal of unwanted and expired medications, the FDA in 2020 launched the "Take Back Unwanted Medicine" project in the Greater Accra Region that seeks to collect such medicines from the public (Safe Drug Disposal Pilot Launched - Graphic Online, n.d.). Prior to this intervention by the FDA, the only take-back program that was implemented in Ghana was introduced by the Cocoa Clinic in 2009. This was called the "Disposal of Unused Medicine Project" (DUMP) which was initiated to meet an identified need of unnecessary drug

storage by clients during the dispensing of drugs to clients who visited the clinic (Abruquah et al., 2013).

2.7 Role of Pharmacists in Drug-Take Back Programs

Pharmacists can have a significant effect on the community by engaging in drug take-back programs and offering patient education on how to properly dispose prescription and other non-prescription drugs. To improve data quality, their duties also include documenting the names of returned medicines and distinguishing between prescription and non-prescription medicines. They also aid in the identification of loose tablets in unlabeled bottles, as well as patient education and medication information and counseling to the general public(Kristina et al., 2018).

Pharmacists are the healthcare professionals most qualified to provide information about medicines, right from dispensing to disposal as they are the experts on medicines. They can also be stewards of the environment by encouraging safe disposal methods for unwanted drugs (Gray-winnet et al., 2010) (WHO, 1998).

In the United Kingdom, there is a contractual agreement between the National Health Service and representatives of community pharmacies which stipulate services to be carried out by community pharmacists (NHS England, 2018), among which include the disposal of unwanted medicines which is considered an essential service(PNSC,2018). The contract requires community pharmacists to take back unwanted medicines from clients and sort them out, after which the NHS arrange for these to be collected and disposed at regular intervals (PSNC,2015)

2.8 Theoretical Framework

The health belief model (HBM) was established in the 1950s and is one of the most extensively utilized frameworks of health behavior used by healthcare practitioners and public health

professionals (Rosenstock et al., 1988). The first model was based on four key constructs, but researchers eventually expanded it to six key constructs. The constructs are perceived susceptibility (a person's assessment of the threat of illness), perceived severity (a person's assessment of how serious the illness is), perceived barriers (a person's assessment of factors that negatively influence the adoption of an action or behavior), perceived benefits (a person's assessment of what they would gain from adopting the behavior or action), cues to action (exposure to factors that stimulate action), and self-efficacy (confidence in one's own ability to do something) (*Green EC, Murphy E: Health Belief Model. In The Wiley Blackwell Encyclopedia of Health, Illness, Behavior, and Society. John Wiley & Sons, Ltd; 2014: 766-769.*, n.d.; Rosenstock et al., 1988)

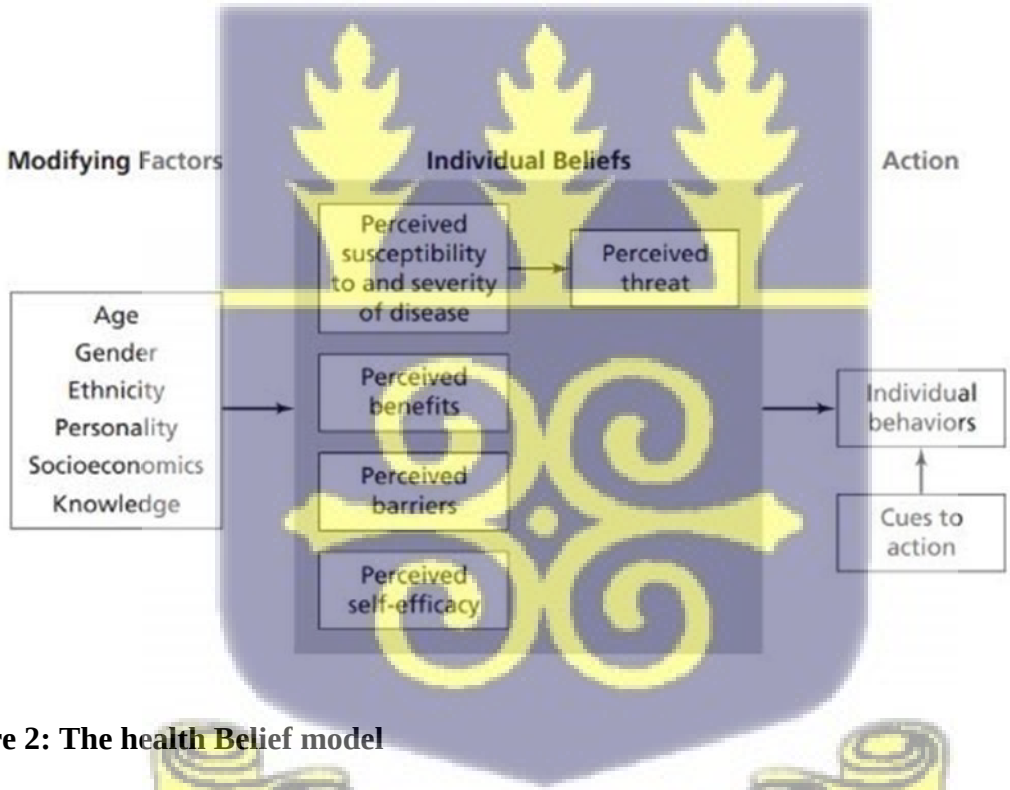

Figure 2: The health Belief model

Source: Champion & Skinner (2008)

CHAPTER THREE

3.0 METHODS

3.1 Introduction

This chapter discusses the methods employed in the study. It includes information on the research design, study area, sample size, sampling technique, ethical issues, methods of data collecting, and data analysis.

3.2 Study Design

The study used a quantitative cross-sectional research approach and employed a fixed design research strategy because of its pre-specified independent variables that included client factors, health system factors, and socio-demographic factors of clients that were set before data collection, and how these variables interacted to influence the outcome variable of compliance, which was measured in the study. Also, the data on the variables that were collected were mainly quantitative data, which makes a fixed design the most appropriate strategy for the study. A cross-sectional design was the best fit for this study because it provided a "snapshot" of the outcome of the study at a specific point in time(Levin, 2006). According to Goertzen (2017), quantitative research methods are focused on the gathering of data and the analysis of structured data that may be presented numerically(Goertzen, 2017). A quantitative research method was selected as it allowed for the systematic investigation of the topic of enquiry using numerical and statistical data on the background that the phenomena being investigated were measurable.

3.3 Knowledge Paradigm Used

The knowledge paradigm that this research was hinged on is positivism. The research aimed to understand factors that influence the outcome variable of clients by observing the independent variables which can be measured and seeking to detect cause and effect through observation, measurement, and analysis of these variables.

3.4 Study Area

The study was conducted in the Greater Accra Region of Ghana across the various municipalities and districts within the region, in fifty community retail pharmacies located in various communities distributed across the region. These pharmacies are designated by the FDA for the initial pilot phase of the implementation of the TBUM project. The Greater Accra region is the national capital of Ghana with a mixed population of upper class, middle and low-class residents but the locations of these designated pharmacies were randomly selected based on the population of the district or municipality.

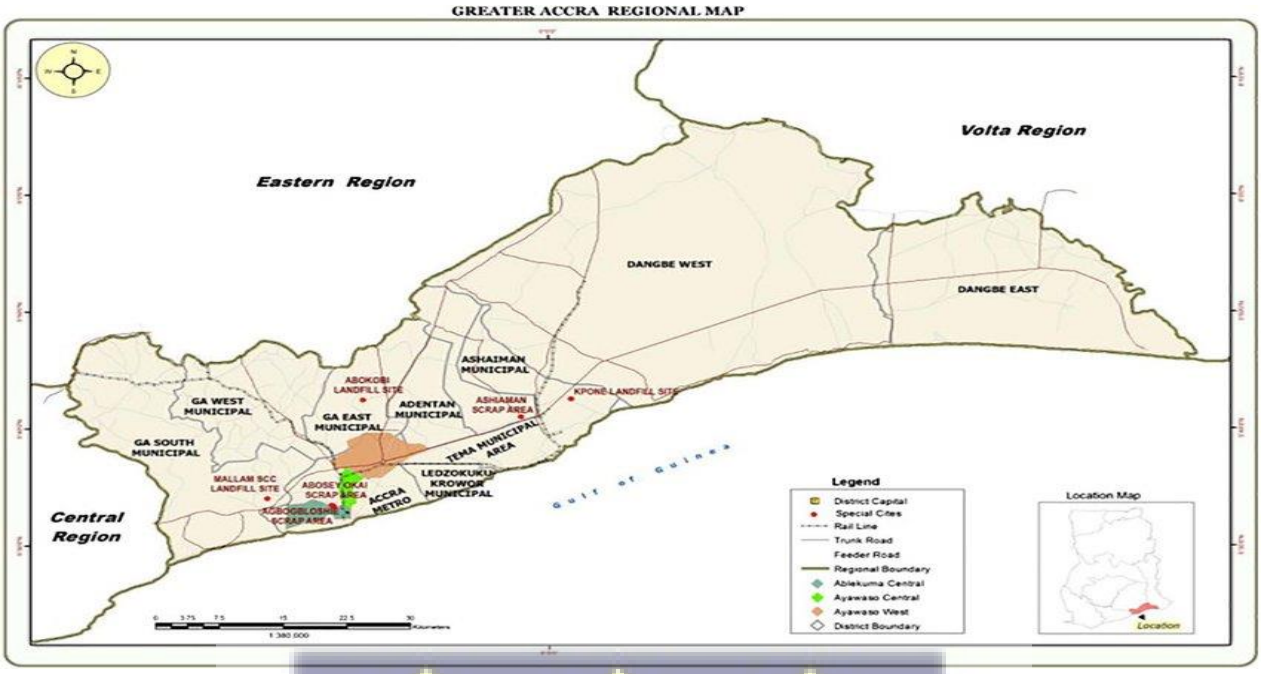

Figure 3: Map of the Greater Accra Region of Ghana.

Adapted from: **Tahiru, 2020**

3.5 Study Population

The population for the study consisted of clients visiting the fifty designated retail pharmacies in Accra, as well as pharmacists and other pharmacy staff where appropriate at these designated pharmacies.

3.5 Variables of The Study

3.5.1 Dependent Variable

The outcome variable that was studied was willingness to comply with the TBUM project. An outcome variable is the variable that responds to the effect of the independent variables and by manipulating the independent variables purposefully, a researcher hopes to cause a response in the dependent variable to establish the relationship and the strength of that relationship(Leatham, 2012). Willingness to comply was measured using a three-set of questions assessing how easy it

will be for clients to return unwanted or expired medicines to the designated pharmacies and their willingness to continue to practice TBUM. The sum of the scores was determined and a score of 2 or more out of a total of 3 meant compliance whiles a score less than 2 meant non-compliant to TBUM.

3.5.2 Independent variables

The independent variables studies in the research were socio-demographic characteristics, clients' characteristics and health system factors. An independent variable is defined as those variables that a study investigator manipulates to measure the effect of the manipulation on another variable(Leatham, 2012).

Gender, age, occupation, highest educational level, marital status, and the location of residence were all included in the study as sociodemographic characteristics significant to understanding willingness to comply with drug take-back programs. The client characteristics measured in the study was the level of awareness to TBUM and current disposal practices. The awareness level of clients was determined by summing the scores of each of the respondents who responded positive to knowing about TBUM, out of a five-set of questions that was asked to determine awareness. These included questions oh having heard of TBUM, how they got to know about it, what TBUM means and its overall implication on drug disposal. Respondents that scored 4 or more out of 5 were classified as having high awareness and a total score below 4 was classified as low awareness.

Table 1: Study variables

Variable	Operational definition	Level of measurement	Categories
Dependent Variable			
Willingness to comply with TBUM	Willingness to adhere to FDA recommendation to return drug to designated pharmacies.	Categorical, Binary	Compliant(yes), Non-compliant (No)
Independent Variables			
Age	Completed age computed from birth	Continuous	Absolute age in years
Gender	Biological feature of being male or female	Categorical	Male, Female
Marital status	Being formally married or not	categorical	Married, single, divorced ,co-habiting
Education	Highest level of education attained	ordinal	Primary, secondary, tertiary, none

Occupation	A person's principal work	categorical	Self-employed, unemployed, government employed
Area of residence	A person's primary place of residence	categorical	
Level of awareness of TBUM	Denotes the state of having a high or low awareness of disposal guideline	categorical	Low awareness, High awareness
Disposal Practices	Means of getting rid of unwanted medicines	Categorical	Dustbin, buried, burnt, flushed, other

3.6 Inclusion Criteria

The study included random clients of both sexes, males and females above 18years who visited the fifty retail pharmacies and were willing to participate in the study after they completed the participant consent form given to them. Pharmacists and other pharmacy staff who work in the designated pharmacies who were more than 18years and willingly consented to the participation in the study were also included in the data collection process for the study upon completion of the participant consent form.

3.7 Exclusion Criteria

The study population excluded pharmacists and clients visiting designated pharmacies who are 18 years and older but did not consent to participate in the study. Clients and pharmacists who were unwilling to observe COVID-19 protocols were also not engaged in the data collection process as the study was conducted in a manner to minimize risk of transmission and infection of COVID-19. Hence all COVID-19 protocols were strictly adhered to as approved by the Ethic review committee.

3.8 Sample Size Determination

The fifty pharmacies used in the study were purposively sampled as they are the pharmacies designated by the Food and Drugs Authority for the initial pilot phase of the Take Back Unwanted Medicines project in Accra.

The sample size for this study was calculated using the Cochran's (1977) formula for large populations:

$$\text{Sample size, } n = \frac{Z^2 Pq}{d^2} \quad \text{where;}$$

z being the confidence limits which in this study will be 95% level of confidence and 1.96 as critical value, **p** as 50%, **q** as the acceptable deviation from the assumed proportion (1-0.50 = 0.50), **d** as the margin of error around p estimated as 0.05 in this study.

$$\text{Therefore, } n = \frac{(1.96)^2 \times (0.50) \times (0.50)}{(0.05)^2} = \mathbf{384}$$

All the pharmacists at the fifty designated pharmacies for the pilot of TBUM were surveyed for their role in the implementation of the project. Clients were then randomly selected at each pharmacy as they visited, to complete the client's questionnaire.

Three hundred and fifty-three total responses from clients and pharmacists /pharmacy staff, representing a response rate of 91.93%, were collected and analyzed.

3.9 Study Sampling

A non-probability sampling method; purposive sampling technique was used to sample community pharmacies. This sampling strategy was used because these pharmacies were the designated pharmacies chosen by the Food and Drugs Authority for the pilot phase of the TBUM project. However, a random sampling technique was used to collect data from 301 visiting clients to these designated pharmacies, which was a representative sample of clients who visit these pharmacies daily.

A convenient sampling strategy was also used to select 52 pharmacists and the pharmacy staff who worked at the 50 designated community retail pharmacies.

3.10 Data Collection

Two different semi-structured questionnaires, one to collect responses from clients and the other to collect responses from pharmacists and other pharmacy staff were used to collect data from the study participants. These questionnaires were issued individually and directly to clients who are literate to complete, on their exit from the pharmacies after completing the purposes for which they visited the pharmacies. Pharmacists and other pharmacy staff were also issued a different structured questionnaire to collect data on their awareness and roles in the implementation of the TBUM project. The two different questionnaires for both clients and pharmacists and pharmacy staff were pretested in ten selected pharmacies for validity. These pharmacies were however not part of the designated pharmacies for the TBUM project. The questionnaires were therefore tested

in these pharmacies before developing the final questionnaires that was used for the data collection process.

3.11 Data Cleaning and Analysis

Data from the field was cleaned, edited, and checked for completeness by the principal investigator before handing it over for analysis. Data were analyzed using STATA version 16 software. Descriptive statistics were performed to obtain the frequencies and percentages of responses recorded. These responses were displayed in tables and graphs for easy visualization. In finding the factors influencing clients' compliance to TBUM, a multivariate logistic regression and backwards stepwise regression models were used to determine the association between the independent variables (socio-demographic characteristics, health system factors, and clients' factors) and the dependent or outcome variable; compliance. Statistical significance was determined at a confidence level of 95% and a p-value of 0.05.

3.12 Ethical Issues

Ethical approval to conduct the study was obtained from the Ghana Health Service Ethics Review Committee with approval number GHS-ERC 038/07/21 and permission to the study sites was granted by the pharmacy council of Ghana regional office in Accra. An informed consent form with a clear explanation of the purpose and the procedure for the study was read to the participant before each interview. Before issuing the questionnaires, all respondents were presented with the option of declining to answer any of the questions. Furthermore, respondents were made aware of the fact that they may withdraw from the study at any point in time if they no longer wish to continue participating. Respondents' safety was ensured as well as the confidentiality of responses was ensured. All respondents either clients visiting these pharmacies or pharmacists and pharmacy staff interviewed were required to observe all COVID- 19 protocols which included washing

hands, sanitizing of hands, wearing of face mask, and adequate social distancing during the administration of the questionnaires.

CHAPTER FOUR

4.0 RESULTS

4.1 Introduction

This chapter provides data on the socio-demographic characteristics of clients and pharmacists who were the study respondents. The results are presented along the study objectives and the conceptual framework that was designed for the study. The chapter is sectioned based on the results from the clients and pharmacists and other pharmacy staff surveys.

4.2 Results from Clients' Survey

4.2.1 Demographic Characteristics of Clients

A total of 301 clients out of the 334 expected client respondents (response rate = 90%) completed the survey. The sample was 49% female and 51% male. The majority of the respondents were aged from 21 to 30 years and the mean age is 30.1 years and a variance of 100.5. The most occurring level of education was tertiary constituting about 66% of the respondents. A large fraction (64%) of the respondents were single whereas being employed or schooling constituted a greater portion (70%) of clients' occupational status. The majority of the respondents were from Madina, Ashongman, East Legon and Oyarifa combined constituting about 32%. This is shown in **table 5.**

Table 2: Demographic characteristics of clients

Characteristics	Frequency (n)	Percentages (%)
Age		
≤20	31	10.3
21-30	161	53.5
31-40	66	21.9
41-50	30	10.0
51-60	7	2.3
≥61	6	2.0
Gender		

Female	148	49.2
Male	153	50.8
Level of education		
None	6	2.0
Primary	15	5.0
Junior Secondary	20	6.6
Secondary	62	20.6
Tertiary	198	65.8
Marital status		
Co-habiting	15	5.0
Divorced	7	2.3
Married	85	28.2
Single	194	64.5
Occupation		
Unemployed/Retired	91	30.2
Employed/Schooling	210	69.8
Area of residence		
Ablekuma/Lapaz	30	10.0
Chorkor/Dansoman/Korlebu	48	16.0
Haatso/Kwabenya	23	7.6
Kasoa	23	7.6
Laterbiokorshie/Kaneshie	3	1.0
Madina/Ashongman/East Legon/Oyarifa	96	31.9
North Kaneshie/Darkuman	6	2.0
Osu/Teshie/Labadi	28	9.3
Tema/Ashaiman	25	8.3
Weija/Gbawe/Mallam	19	6.3

4.2.2 Clients' Awareness of TBUM.

Table 6 shows clients' awareness of the ongoing TBUM project. Among the 301 clients surveyed, about 93 (31%) of the respondents reported having heard of TBUM project. Out of the 93, about 52% of them reported that they heard about TBUM from either a pharmacist or another health personnel, followed by 24% who heard from social media, 17% from TV/radio and 8% from friends and family.

Table 3: Clients' awareness of TBUM.

Questions	Frequency (n)	Percentages (%)
Awareness of TBUM?		
No	208	69.1
Yes	93	30.9
Source of Information about TBUM		
Pharmacist/Health personnel	48	51.6
Social media	22	23.7
TV/radio	16	17.2
Other (friends/family)	7	7.5

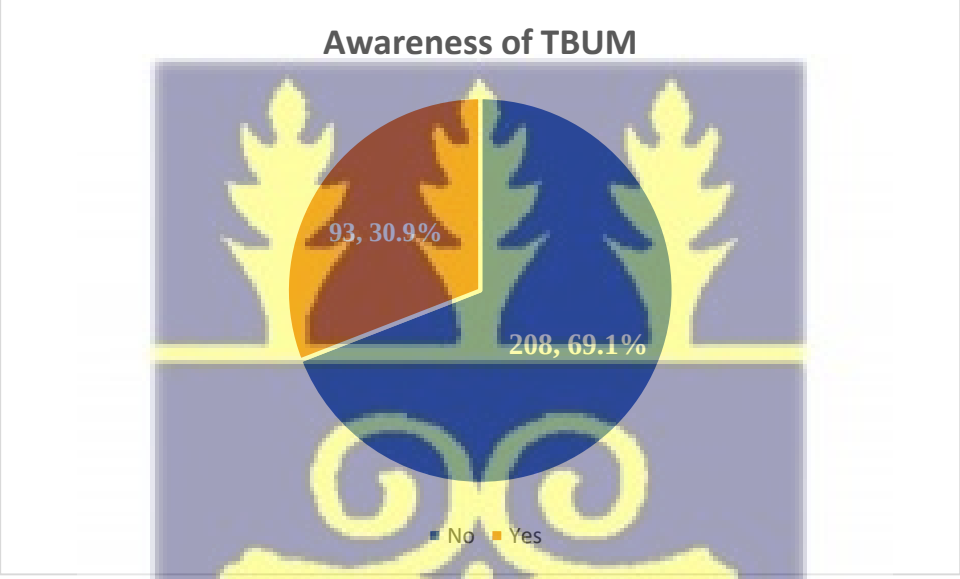

Figure 4: Client's awareness of TBUM

4.2.3 Disposal Practices of Unwanted Drugs Among Clients

Table 7 shows the disposal practices of unwanted and expired drugs among clients. About 55% of the respondents said they had unwanted drugs at home and over-the-counter drugs were the most mentioned type of drug stored in their homes (mentioned by 50% of those who had unwanted drugs at home). About 67 (40%) of the respondents mentioned that they obtained these drugs

through prescriptions and about 163 (54%) of the clients claimed to have disposed of unwanted drugs in the last 6 months, among which the majority, 106 clients representing 65% of clients who had in their possession unwanted drugs disposed them by throwing it in their home dustbins as represented in figure 5.

Table 4: Disposal Practices of Clients.

Questions	**Frequency (n)**	**Percentages (%)**
Possession of unwanted drugs (N=301)		
No	135	44.6
Yes	166	55.2
Type of unwanted medication? (n=166)		
Herbal	25	15.1
OTC	83	50.0
Prescription drug	54	32.5
Other (Local remedy)	4	2.4
Acquisition of these medications? (n=166)		
Bought from the pharmacy	62	37.4
Prescription	67	40.4
Relatives/friends	31	18.7
Other	6	3.6
Disposed of unwanted drugs in the last 6 months (N=301)		
No	138	45.9
Yes	163	54.2
Disposal method (n=163)		
Buried	5	3.1
Burnt	15	9.2
Dustbin	106	65.0
Flushed down the toilet	12	7.4
Gave it to someone	22	13.5
Other (can't find them)	3	1.8

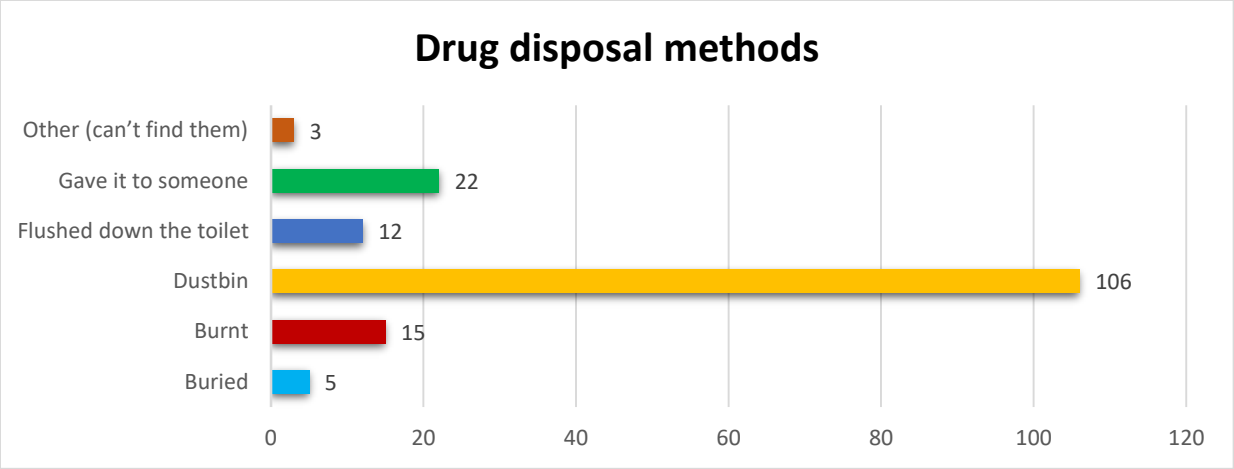

Figure 5. Disposal practices among clients

4.2.4. Clients' Willingness to Comply with TBUM

Table 8 shows the results of clients' willingness to comply with the TBUM project. About 75% of the respondents agreed that it will be easy to return unwanted drugs to designated pharmacies. On the other hand, among the 25% respondents who did not agree that it will be easy to return unwanted drugs, the majority of them indicated that the drugs if returned will not be accepted. About 79% of the respondents agreed that they will return unwanted drugs to pharmacies and 82% said they will encourage family and friends to return unwanted drugs. Overall, about 81% of the clients were willing to comply and 19% were not willing to comply. This is shown in figure 3.

Table 4: Clients' willingness to comply with TBUM

Statements	Frequency (n)	Percentages (%)
It will be easy to return unwanted drugs to a pharmacy		
No	76	25.3
Yes	255	74.8
Reason for it not being easy. (n=64)		
Distance	5	7.8
I will need them in future	3	4.7
It will not be accepted	27	42.2
Not possible/Not right to do	10	15.6
The pharmacist will sell it to someone	3	4.7

The unfriendly attitude of the pharmacist	3	4.7
Waste of time	10	15.6
I will dispose of it myself	3	4.7
I will return unwanted drugs to pharmacies		
No	63	20.9
Yes	238	79.1
I will encourage family and friends to return unwanted drugs		
No	55	18.3
Yes	246	81.7
Willing to Comply		
No	58	19.3
Yes	243	80.7

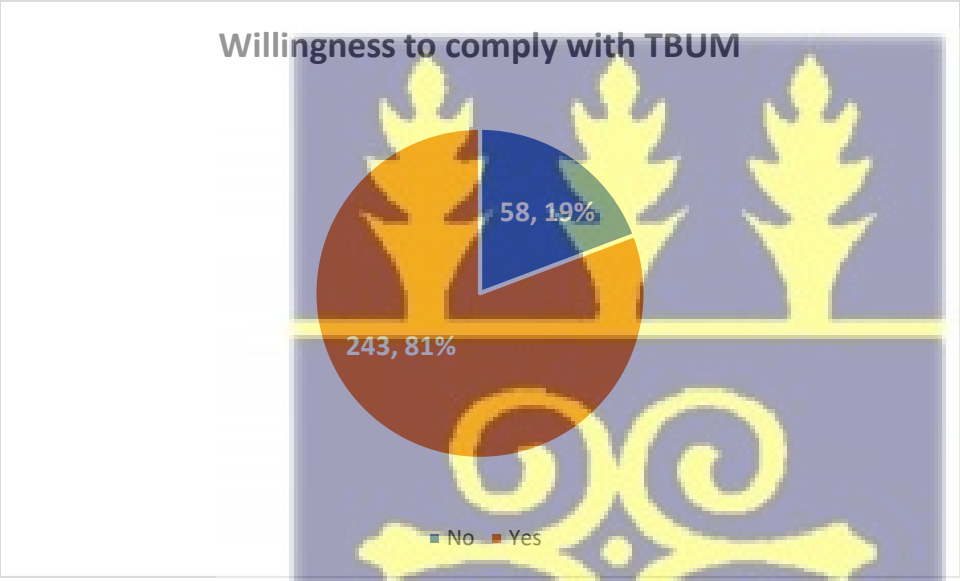

Figure 6: Clients' willingness to comply with TBUM

4.2.5 Relationships Between Willingness to Comply and Associated Factors

In bivariate analysis conducted to determine the association between compliance and socio-demographic characteristics of clients, the relationship between clients' willingness to comply and its associated factors was determined. The following two factors were significantly associated with clients' willingness to comply with TBUM: level of education of respondents (p = 0.003; Cramér's V = 0.2306), and awareness of TBUM

(p = 0.002; Cramér's V = 0.1808). All other factors were not significantly associated with willingness to comply with TBUM, thus (p > 0.05). This is shown in Table 9.

Table 6: Chi square test of association

	Willingness to comply			
Characteristic	**No**	**Yes**	**Pearson x^2**	**P-value**
Age			9.036	0.108
≤20	9 (29.0)	22 (71.0)		
21-30	34 (21.1)	127 (78.9)		
31-40	8 (12.1)	57 (83.8)		
41-50	4 (13.3)	26 (86.7)		
51-60	3 (42.9)	4 (57.1)		
≥61	0 (0.0)	6 (100)		
Gender			0.023	0.880
Female	28 (18.9)	120 (81.1)		
Male	30 (19.6)	123 (80.4)		
Education			16.005	**0.003**
None	4 (66.7)	2 (33.3)		
Primary	1 (6.7)	14 (93.3)		
Junior Secondary	7 (35.0)	13 (65.0)		
Secondary	15 (24.2)	47 (75.8)		
Tertiary	31 (15.7)	167 (84.3)		
Marital status			2.026	0.567
Co-habiting	2 (13.3)	13 (86.7)		
Divorced	2 (28.6)	5 (71.4)		
Married	13 (15.3)	72 (84.7)		
Single	41 (21.1)	153 (78.9)		
Occupation			3.024	0.082
Unemployed/Retired	23 (25.3)	68 (74.7)		
Employed/Schooling	35 (16.7)	175 (83.3)		
Area of residence			12.233	0.200
Ablekuma/Lapaz	2 (6.7)	28 (93.3)		
Chorkor/Dansoman/Korlebu	7 (14.6)	41 (85.4)		
Haatso/Kwabenya	7 (30.4)	16 (69.6)		
Kasoa	8 (34.8)	15 (65.2)		
Laterbiokorshie/Kaneshie	0 (0.00)	3 (100)		
Madina/Ashongman/East Legon/Oyarifa	22 (22.9)	74 (77.1)		
North Kaneshie/Darkuman	1 (16.7)	5 (83.3)		

Osu/Teshie/Labadi	3 (10.7)	25 (89.3)		
Tema/Ashaiman	4 (16.0)	21 (84.0)		
Weija/Gbawe/Mallam	4 (21.0)	15 (79.0)		
Awareness of TBUM			9.844	**0.002**
No	50 (24.0)	158 (76.0)		
Yes	8 (8.6)	85 (91.4)		

4.2.6 Factors Influencing Clients' Willingness to Comply with TBUM

Table 10 display results of the full and reduced models of the regression analysis. The reduced model contains only factors identified as significant using the backwards stepwise regression. Several factors were identified to be associated with willingness to comply with TBUM: having attained a primary school education (OR = 12.62, 95% CI: 1.65, 96.48), Secondary school education (OR = 2.33, 95% CI: 1.27, 4.30) or tertiary school education (OR = 3.95, 95% CI: 2.61, 5.96) against JHS education; and being aware of TBUM program (OR = 3.39, 95% CI: 1.52, 7.58). The study found that clients with a primary school education were

Table 1 Multivariate Logistic regression model for clients' willingness to comply with TBUM programs

	Full model				Reduced model			
Characteristic	**OR**	**p-value**	**[95% Conf. Int]**		**OR**	**p-value**	**[95% Conf. Int]**	
Awareness of TBUM								
No	Ref				Ref			
Yes	4.00	**0.003**	1.61	9.96	3.39	**0.003**	1.52	7.58
Education								
Junior High	Ref				Ref			
None	1.36	0.778	.16	11.70	.40	0.303	.07	2.30
Primary	23.95	**0.010**	2.15	266.57	12.62	**0.015**	1.65	96.48
Secondary	3.08	**0.045**	1.03	9.21	2.34	**0.006**	1.27	4.30
Tertiary	4.35	**0.005**	1.56	12.18	3.94	**0.000**	2.61	5.97
Age								
21-30	Ref							
≤20	.88	0.804	.33	2.39				
31-40	2.05	0.172	.73	5.70				
41-50	3.00	0.124	.74	12.18				
51-60	.25	0.232	.02	2.44				
≥61	Omitted							
Gender								
Female	Ref							
Male	1.10	0.785	.56	2.13				
Marital status								
Co-habiting	Ref							
Divorced	.22	0.222	.02	2.49				
Married	1.09	0.900	.28	4.20				
Single	1.59	0.443	.48	5.23				
Occupation								
Employed/Schooling	Ref							
Unemployed/Retired	.74	0.411	.36	1.51				
Area of residency								
Ablekuma/Lapaz	Ref							
Chorkor/Dansoman/Korlebu	.99	0.990	.25	3.92				

Haatso/Kwabenya	.36	0.174	.08	1.58
Kasoa	.19	**0.024**	.05	.81
Laterbiokorshi/Kaneshie	Omitted			
Madina/Ashongman/East Legon/Oyarifa	.40	0.119	.12	1.27
North Kaneshie/Darkuman	.52	0.604	.04	6.09
Osu/Teshie/Labadi	1.56	0.582	.32	7.57
Tema/Ashaiman	.59	0.508	.12	2.85
Weija/Gbawe/Mallam	.43	0.298	.09	2.11

4.3 Results from Pharmacists' Survey

4.3.1 Demographic Characteristics of Pharmacists

Table 1 shows the Demographic characteristics of pharmacists who were engaged in the research data collection. A total of 52 pharmacists took part in the research. There were 34 (65%) male pharmacists and 18 (35%) female pharmacists among them. The majority of pharmacists, 52%, were between the ages of 21 and 30, according to the survey. The majority of pharmacists had 0-5 years of experience, with those with 6-10 years of experience following closely behind. As a result, the percentages are 46 percent and 44 percent, respectively.

Table 8: Demographic characteristics of pharmacists.

Characteristics	Frequency (n)	Percentages (%)
Age (Mean: 32.19, Sd: 8.83)		
21-30	27	51.9
31-40	18	34.6
41+	7	13.5
Gender		
Female	18	34.6
Male	34	65.4
Years of Practice		
0-5 years	24	46.2
6-10 years	23	44.2
Over 10 years	5	9.6

4.3.2 Awareness and Attitudes of Pharmacists towards TBUM

Table 2 below shows the Awareness and Attitudes of pharmacists towards TBUM. About 88% of the agreed that they were aware of the "Take Back Unwanted Medication" program compared to 12% that agreed that they were not aware of the program. Among those that agreed to be aware of the program, about 89% of them indicated that they encourage their clients to practice TBUM compared to 11% that do not encourage their clients to practice TBUM. Less than half of the respondents (31%) revealed that clients return unwanted or expired medication to their pharmacy.

Table 9: Awareness and Attitudes of pharmacists towards TBUM.

Characteristics	Frequency (n)	Percentages (%)
Awareness of TBUM		
No	6	11.5
Yes	46	88.5
Encouraging clients to practice TBUM (n=46)		
No	5	10.9
Yes	41	89.1
Clients return their unwanted medication		
No	36	69.2
Yes	16	30.8

4.3.3 Roles and Responsibilities of Pharmacists in Implementation of TBUM

Concerning the roles and responsibilities, about 48% of the respondents indicated that pharmacists were responsible for handling returned drugs from clients followed by pharmacy assistants (37%). About 87% of the respondents agreed that it was their role to accept unwanted drugs from clients. Furthermore, 94% also agreed that it was their responsibility to counsel clients on the proper disposal of drugs. This is shown in **Table 3**.

Table 10: Roles/responsibilities of pharmacists in TBUM.

Characteristics	Frequency (n)	Percentages (%)
Handling of returned medicines from clients		
Pharmacist	25	48.1
Pharmacy assistant	19	36.5
Technician	1	1.9
Other staff	7	13.5
Receive unwanted drugs from clients		
No	7	13.5
Yes	45	86.5
Counsel clients on the proper disposal of drugs		
No	3	5.8
Yes	49	94.2

4.3.4 Timeliness for the Collection of Returned Drugs

The most mentioned timeliness for the collection of returned drugs in the designated pharmacies was yearly bases. This was revealed by 75% of the pharmacists and 87% of them revealed that the FDA was responsible for the collection of unwanted drugs from their pharmacy. This is shown in Table 4.

Table 11: Timeliness for the collection of returned drugs from pharmacies

Characteristics	Frequency (n)	Percentages (%)
Timeliness for the collection of returned drugs (n=20)		
Monthly	4	20
Quarterly	1	5
Yearly	15	75
Person/Agency responsible for the collection of returned drugs from your pharmacy (n=38)		
FDA	33	86.8
Pharmacist	3	7.9
Staff from parent/another branch	2	5.3

CHAPTER FIVE

5.0 DISCUSSION

5.1 Introduction

Drug waste management and disposal have captured a lot of attention globally in recent years since the discovery of incorrect drug disposal as the cause of damage to the environment, disruption of the food chain and even harm to living beings was made. This study used quantitative methods to assess client's compliance to the Take Back Unwanted Medicines project. The Health Belief Model was used to guide the study and to construct the conceptual framework for the study. This chapter discusses the findings from this study conducted in fifty selected retail pharmacies within the Greater Accra Region of Ghana to assess the compliance of clients to the Take Back Unwanted Medicines pilot project, currently being implemented by the Food and Drugs Administration of Ghana to aid in rational and responsible drug disposal by households in Ghana. This section discusses the findings of the study addressing each of the four specific objectives.

5.2 Level of Awareness of Clients of The TBUM Project

The first objective of the study was to ascertain the level of the clients' awareness of the ongoing implementation of the TBUM project by the FDA at the fifty designated pharmacies. Concerning this objective and to answer the corresponding research question, the study discovered that only 31% of clients who were surveyed were aware of the ongoing TBUM project. On the other hand, the remaining 69% were not aware of the project and this may imply that these clients are still likely to be engaging in improper drug disposal practices for their unwanted medications in their homes. Even though 31% of the respondents agreed that they were aware of the TBUM project,

about 28% of those who were aware of the project had a high level of awareness whereas the remaining 72% had a no or low level of awareness based on the set of five questions that were used to assess the level of awareness. This further highlights an increased implication for indiscriminate drug disposal using inappropriate means among these clients, which alludes to the urgent need for more extensive campaigns and engagements of the populace, particularly within the various communities through health promotion activities, to raise awareness of the ongoing TBUM project to help improve awareness, as the project seeks to encourage the use of appropriate mediums and methods for proper drug disposal. These findings are however in sharp contrast to several other study findings from developed countries such as the United States and Australia, where the general population is mostly very aware of ongoing drug take-back programs both at designated collection points or periodic community events and they do utilize such programs for the safe disposal of their unwanted drugs(Fass, 2011b; Gray & Hagemeier, 2012a; Jaramillo-Stametz et al., 2017; Kumar S et al., 2019; Yang et al., 2015).

It is interesting to note that among the 31% that responded positively to being aware of the TBUM project, about 95% of these clients agreed that "TBUM means returning unwanted drugs to designated pharmacies" which was the main purpose and objective of the TBUM project as implemented by the FDA, 91% agreed that TBUM is the right way to dispose of unwanted drugs in our homes, 96% agreed that TBUM helps to get rid of expired drugs which may be a potential hazard to both young and old in various homes, 91% responded that these designated pharmacies are obliged to accept unwanted or expired medication and 86% agreed that anybody can practice TBUM. It can therefore be deduced from these findings that the more people are educated and become aware of safer disposal practices for their unwanted medications, the more likely they are to patronize these safer alternatives in disposing of their unwanted and expired medications, which

will eventually result in safer environments with reduced or minimized pollution from chemicals from these unwanted drugs.

The low level of awareness of the ongoing implementation of the TBUM by the majority of client respondents was discovered in this study. This is in consonance with study findings by Kustarica et al in 2016, where many clients were aware of the environmental effects of improper drug disposal, but this awareness however did not translate to the practice of safer disposal practices or methods by study respondents(Paut Kusturica et al., 2016). The low level of awareness can also be attributed to the channels used for the education on the implementation of TBUM by the FDA. The campaign was run mainly on social media and the newspapers, with printed pull up banners and posters on the project at the designated pharmacies, in English, which may not be the dominant or the most widely used language for communication among Ghanaians. There is also limited health literacy among Ghanaians, even among the educated population, as reported by Ansu-Yeboah et al, hence the ability to access, understand and use health information to enhance health by Ghanaians is generally inadequate (Evans et al., 2019). This was confirmed in this study in that despite the education and campaigns on the TBUM project, there is a low level of awareness among clients, which affected their willingness to comply with the project.

Another important finding from the study was that, overall, there was a high level of awareness (88.5%) among the pharmacists and other pharmacy staff about the ongoing implementation of the TBUM project, which is similar to findings by Abahussain et al in 2012 where 82% of pharmacists surveyed in Kuwait were aware of the negative implications of improper drug disposal on the environment and hence agreed to the use of their pharmacies both in hospitals and polyclinics as unwanted drug collection points (E. Abahussain et al., 2012). This finding of a high level of awareness among pharmacists in the study could also be attributed to the fact that these pharmacies

for the pilot phase of the TBUM project had been pre-selected by the FDA as designated pharmacies for the TBUM project. Therefore, there is a high possibility that the staff, mainly pharmacists, may have been trained or sensitized on the project before the final roll out of the pilot phase of the project. This information was however not collected or measured in this study.

5.3 Factors Influencing Clients' willingness to comply with TBUM

Overall, 19% of the respondents in this study who indicated they were aware of TBUM were seen to be non-compliant with the TBUM project whereas 81% were compliant based on the assessment with the three sets of questions to measure compliance. The results of the bivariate analysis revealed a significant association between socio-demographic characteristics such as the level of education and other clients' characteristics such as their initial of awareness of TBUM played a critical role in their willingness to comply to the Take Back Unwanted Medication project or otherwise. The study further revealed that clients with primary school as their highest level of education were about 13times more likely to be compliant with the TBUM project compared to those with Junior high school as their highest level of education. The varied magnitude of confidence interval for this association however suggests that the willingness of clients with Junior high school to comply with TBUM varies widely. Hence further studies with larger sample size may be needed to confirm this association. Similarly, clients with secondary school education were twice more likely to comply while those with tertiary education as their highest level of education were three times more likely to willingly comply with TBUM, compared to clients with Junior secondary school as their highest level of education. These findings however contradict the regular notion that academically advanced and inclined persons are expected to be more likely to adhere or willingly comply with such interventions based on their level of understanding of the importance of keeping the environment safe from chemical exposure. Studies have also shown that

self-medication rates increases as people become more educated and therefore assume well informed positions on their health, and are therefore more likely to hold on to their medicines they may no longer require for future use or recommend to others (Machado-Alba et al., 2014; WHO, 1998)

Again, with association between previous awareness of TBUM and the willingness to comply to the project, the reduced model showed that clients who were aware were about three times more likely to willingly comply with the project by returning their unwanted medicines to pharmacies for appropriate disposal compared to those who had never heard about the project. This association was also statistically significant as revealed by both the full and reduced regression models. This emphasizes the need for education and awareness creation on projects to the grass root before project implementation and its effect on project adoption and buy in by the populace. The increased willingness to comply by clients who were aware of TBUM may also be attributed to the effective role of the pharmacists in educating clients on rational disposal of drugs. 89% of pharmacists surveyed confirmed giving adequate information and encouraging the clients who visited their pharmacies to practice TBUM to get rid of their unwanted medications. However, it is of high importance for further research to be conducted in these areas to establish a definite association.

5.4 Client Practices for Disposal of Unused and Expired Medications

Clients' disposal practices for their unused, unwanted, and expired medications vary among those visiting retail pharmacies designated as drug collection points by the Food and Drugs Authority for the pilot phase of the Take Back Unwanted Medicines project.

Over 55% of clients in the sampled population surveyed had in their possession some unwanted or expired medications at home which were mainly over-the-counter medications, which pose

potential safety concerns. The majority of these medications were noted to have been obtained from the pharmacy either through a valid prescription from a medical practitioner or recommended by a health care practitioner, but ended up unused or the duration of the prescription was not completed. This is consistent with other findings from previous work by Kumar et al in 2019, where the majority of the clients surveyed had in their possession some form of unwanted drugs such as Non-steroidal anti-inflammatory drugs, antibiotics, and antihypertensive, the majority of which were obtained with a valid prescription from a pharmacy or a health facility(Kumar S et al., 2019). Many other studies from various countries have also reported common trends where the majority of drugs collected from community drug take-back events were mainly composed of controlled and other prescription drugs which can only be acquired by a client through a valid prescription from a doctor or pharmacists(Fass, 2011a, 2011b; Gray & Hagemeier, 2012b; Jaramillo-Stametz et al., 2017).This increased number of drugs on clients may also be attributed to increased accessibility to drugs, especially over the counter. Consumers prefer the convenience of readily available drugs from pharmacies, compared to having to wait in long queues in hospitals to be seen by health care professionals, as reported by WHO(WHO, 1998). It is however worth noting that this current study did not go further to gather data on the class of drugs that were in clients' possession from the clients interviewed, apart from how these drugs were acquired.

Another interesting finding on client disposal practices for unwanted medications from the current study was that the majority of the clients surveyed in the study disposed of their unused and expired medications through household dustbins (65%) or passed them on to either a relative or someone else (14%) who had similar symptoms. These rates corroborate the findings of a number of previous research studies that investigated the disposal of leftover drugs in Ghana by Aboagye et al, 2015, which reported that 73% of respondents in that study threw their leftover medicines into

their home dustbins. Other research studies published by Osei-Djarbeng et al, also reported a majority of drugs in different dosage forms such as solids, liquids, and semi-solids were all disposed of through home trash bins, which is consistent with the observations of this current study. Again, studies done in other African countries in Kenya and Nigeria by Ayele et al in 2018, depicted similar trends, where the main methods of drug disposal by individuals surveyed were mostly through household dustbins, followed by flushing in the toilet(Ayele & Mamu, 2018). The findings from this study, confirm further that a lot people still utilize unapproved and improper disposal practices as mentioned above to get rid of drugs they no longer need, without considering the effects these active pharmaceutical ingredients from these drugs will have on the environment in the future. Also, household bins are the dominant means of discarding unwanted drugs as these drugs are treated just like all other trash produced from these households which end up in landfill sites untreated. This can be attributed to a lack of knowledge on appropriate and safer methods of disposal, rather than what they see as convenient, which from this study and other published data is mostly disposal through home dustbins or flushing down the drain, which further highlights the need to expand the knowledge, awareness creation and education on the TBUM project in Ghana to help rid homes of unwanted medications, to minimize the health and environmental impact of these drugs when improperly disposed of. These studies however were published before the launch and pilot implementation of the "Take Back Unwanted medicines" project in the Greater Accra Region in Ghana at selected retail pharmacies, hence it's difficult to compare them directly to low compliance to the TBUM project and thus comparison of the findings of this study to previous work must be done with caution.

However, even though the results from this study on awareness of TBUM were not so encouraging, as just about 10.11% of total clients surveyed in this study were aware of TBUM,

76% of the 10.11% among those who are aware confirmed it will be easy to subsequently return their unwanted medicines to a designated pharmacy for safe disposal whiles 82% of clients are willing and would go on to encourage their friends and other relatives to also practice TBUM for safe drug disposal. These results further add to the evidence that proper education and instruction on appropriate medication disposal, which still remains an area of improvement, is a key factor to improving proper drug disposal practices which include to a large extent drug take-back programs, as reported by Kinrys et al in their commentary on summary on existing data from various research works looking at the presence of pharmaceutical substances in the environment(Kinrys et al., 2018).

The most interesting findings of the research were that, among the 25% of clients who acknowledged it will not be easy to practice TBUM, the reasons they attributed for this include distance to the pharmacy (8%), keeping for future use (5%), not right thing to do (16%), concerns of reselling of their drugs to someone else by pharmacy staff (5%), the unfriendly attitude of pharmacists and other pharmacy staff (5%), waste of time (16%), with a majority of them believing the drugs will not be accepted (42%) as this is not a common practice in Ghana. These results are also consistent with the report by Okai et al, which investigated the perception and trends in the use of community pharmacies in Ghana, and reported that reasons for not using community pharmacies included distance to pharmacies, absence of pharmacies in the various communities and lack of trust in pharmacists and other pharmacy staff as well as religious beliefs of clients(Okai et al., 2019). In as much as these findings are disappointing, it further explains the mindset of the general Ghanaian population towards the TBUM project and further confirms the reason for the low awareness, compliance, and patronage of the project. This however highlights the need for continuous engagements by policymakers and implementers with the grass-root at which certain

projects are targeted, to help break misconceptions and myths around these projects in order to get the full buy-in of projects that are implemented especially at the community level. It is also paramount to get key opinion leaders and role models who can champion such projects with education within their local communities to help get the buy-in of the larger population as postulated by Albert Bandura in the Social Cognitive theory of health promotion(Martin & Guerrero, 2020).

5.5 The Roles and Responsibilities of Pharmacists and other Pharmacy Staff in the Implementation of the TBUM Project

Pharmacists are a vital source of information to clients to help improve proper drug disposal practices, especially with the pilot of the TBUM project, which is proposed to be rolled out across Ghana in the near future. The findings from the study revealed that pharmacists at the designated pharmacies were very much aware of the TBUM project and do offer counseling and encourage clients visiting these pharmacies on proper drug disposal practices (89%), even though a majority of clients still do not return their unwanted medications to these pharmacies. This finding is similar to that reported by Abrons et al, who looked at the role that education of the public on proper disposal played after an intervention (education) of pharmacy students pre and post the intervention, where a statistically significant change was observed in a large proportion of participants surveyed where they indicated a change of intention to adopt appropriate means of disposing of their unwanted drugs(Abrons et al., 2010). Further to that, 52% of clients surveyed in this study acknowledged getting to know about the TBUM project through a pharmacist or some healthcare personnel at the pharmacy which adds to the evidence of the awareness and the active role of pharmacists in these designated pharmacies in the implementation of the TBUM project currently in its pilot phase in Ghana. This goes to further suggest that drug disposal practices can

be improved with increased education and counseling from pharmacists and possibly other healthcare professionals to clients who visit different retail pharmacies and other health access points across the country, as these pharmacies and healthcare facilities are usually the first port of call for clients when they want to access healthcare. This accords with earlier observations by Abrons et al that reported an improvement from baseline measures through a post pharmacy education survey of 80% of respondents willing to change their current drug disposal methods and practices after education by pharmacy students in the United States and further highlights that pharmacists can be a good resource for education and information on safe drug disposal(Abrons et al., 2010).

Even though a majority of clients surveyed in this study do not return their unwanted medicines to the pharmacies in this study in Ghana, which was contrary to the expectations of this study, most pharmacists at these designated pharmacies are irrespective very supportive of the TBUM program and are aware and do offer counseling to clients to use TBUM for safe drug disposal (88.46%) and few of these pharmacists do receive the returned drugs from clients themselves (48.08%) or they have designated that duty to other staff at the pharmacies to perform such role with their supervision within the pharmacy, which serves as a good motivation to encourage clients to continue to practice TBUM. Ehrhart et al also reported similar findings where pharmacists at drop box locations consistently educated clients on proper disposal methods and consistently supported drug take-back initiatives in Portland, Vancouver (Ehrhart et al., 2020). Fass 2012 also reported the role of pharmacists in the community take-back events across the United States, where pharmacists were involved in identifying returned drugs, documenting these drugs, and keeping an up-to-date stock of drugs collected in these events (Fass, 2011a). These roles however were performed outside the community pharmacy during community drug take-back events and hence

cannot be compared directly to the role pharmacists have to play when unwanted drugs are returned to them directly in community retail pharmacies as was assessed in this study. Singleton et al, however, suggested the critical role pharmacists can play in safe drug disposal as they play a role in encouraging environmentally responsible handling of drug waste as they have a professional commitment to the quality use of drugs and their participation in the medicine management pathway and the education of other health professionals and the general public on responsible disposal of unwanted drugs(A. Singleton et al., 2014).

One method for enhancing safe disposal rates among clients is to install drug take-back boxes, often known as drop boxes, within pharmacies as was done by the FDA in the implementation of TBUM in Ghana. Also, the presence of these disposal boxes at the pharmacies are important educational tools as clients visiting these pharmacies will take note of them and ask questions about them which will offer the pharmacists an opportunity to offer education on safe drug disposal practices and this will further encourage and greatly improve adherence to the TBUM project as clients become aware of it and begin to use these bins for their drug disposal (Ehrhart et al., 2020). As was observed in this study from the pharmacist survey, drug collection bins served as a strong prompter for visiting clients to ask more questions which allowed the pharmacists to offer more education which further improved awareness. Pharmacies where these drug collection boxes were not visibly displayed rather had clients from these pharmacies reporting unawareness and low compliance to the TBUM project.

5.6 Limitations of the study

Although the study has identified the socio-demographic, client and health system factors that affect willingness of clients to comply to the TBUM project, it is important to situate the conclusion in the context of the limitation of the study. The study was conducted using a purposive

sampling approach to select the study sites and a convenient sampling strategy to select the pharmacists' participants. Therefore, there may be a limit to the extent to which the findings can be generalized to other pharmacists and visiting clients in other pharmacies which were not included in the study. However, to circumvent the effects of this limitation, clients visiting the designated pharmacies were randomly selected

CHAPTER SIX

6.0 SUMMARY, CONCLUSION AND RECOMMENDATION

6.1 Introduction

This chapter provides a summary of the major findings of the study in line with study objectives, and relevant conclusions for each objective. It also provides the findings in study as contributions of the study to the body of knowledge. It concludes by providing the implication of the study for policy reshaping and recommendations of the study and suggestions for further research.

6.2 Summary of Findings

The study employed a quantitative approach to assess the willingness of clients to comply with the Take Back Unwanted Medicines project. A survey was conducted with 301 clients and 52 pharmacists who were 18 years and above at designated pharmacies for the implementation of TBUM. Purposive sampling was used to select the 50 pharmacies for the study and a random sampling was used to select clients visiting these pharmacies, while the pharmacists working in these pharmacies were conveniently sampled. The main findings of the study include:

1. The study reported there is a low level of awareness among clients of the ongoing implementation of TBUM at the 50 designated pharmacies.
2. The study found that for clients who were aware of the project, there is a low level of compliance to the TBUM project as majority of clients still do not utilize TBUM to dispose their unwanted, unused or expired medicines,
3. The study also reported that disposal of drugs through home dustbins was the main route used by clients for disposal of drugs.

4. The study found that initial awareness of TBUM and level of education of clients affected their willingness to comply to the TBUM project.
5. The study reported that pharmacists at the designated pharmacies were aware of the project and encouraged clients to patronize the project to dispose their unwanted drugs, even though majority of the clients still do not dispose their drugs through this safe and effective method.

6.3 Conclusions

Overall, the study discovered that there is a low level of awareness among clients visiting the piloted pharmacies of the ongoing implementation of the TBUM project at these pharmacies even though the project had run for over one year since its launch in Accra before data for this study was collected for analysis. This low level of awareness negatively affected the overall compliance to the project and this indicates an increased risk of improper and indiscriminate disposal of drugs and improper drug disposal practices among clients as was seen in the study. Also, a higher proportion of clients surveyed had in their possession some unwanted or expired medications in their various homes which were mainly obtained either over the counter from a pharmacy or through a valid prescription by a doctor or other healthcare practitioners. These unwanted drugs were however mostly disposed of through home dustbins or flushed down the toilet or passed on to other relatives or friends, which are not recommended routes for drug disposal, hence an increased chance of drug accumulation in the environment mainly in the soil through landfill sites where most garbage from homes is disposed or in water bodies when these chemicals from drugs seep through the land into the water table underground.

Again, pharmacists at the designated pharmacies were very aware of the implementation of the TBUM project and they do offer counseling on appropriate drug disposal methods and encourage

clients to utilize the TBUM to dispose of their unwanted drugs, even though the findings from the study indicated a majority of clients still do not return their unwanted medicines, with the most outstanding reasons being health system factors such as distance of pharmacies from their homes and also attitudes of pharmacists and pharmacy staff, while general lack of knowledge or awareness to the project was also a predominant factor. However, among the clients who acknowledged being aware of the TBUM project implementation, their compliance level with the TBUM project was appreciable in terms of their awareness and also their ability to comply and encourage others to also utilize the TBUM project for the safe disposal of unused drugs to help rid the environment of the toxins from these chemicals in drugs.

6.4 Recommendations

This section looks at recommendations of the study. It makes recommendations to improve awareness and overall compliance to the TBUM project and also general recommendations to inform policy on drug disposal practices.

6.4.1 Recommendations based on study findings

Some recommendations based on the findings from this study include:

1. The Food and Drugs Authority which is the implementing agency of the TBUM project should improve upon the current education and publicity around the implementation of this innovative project among the general public to help improve the awareness of the masses to the project and increase patronage and utilization of the TBUM for proper and safe disposal of unwanted drugs among clients.
2. The pharmacy council of Ghana which is the regulator of the practice of the pharmacy profession in Ghana should institute educational intervention to increase pharmacists'

knowledge of proper drug disposal methods, both during pharmacy education in tertiary institutions and during the on boarding of newly qualified pharmacists. This can help change the current status quo of indiscriminate and irrational drug disposal among the general population of Ghanaians and help reduce the environmental impact of improper drug disposal as pharmacists cascade this education down to the populace.

6.4.2 General recommendation to policy makers

1. FDA which is the implementer can look at the possibility of extending the TBUM project to other healthcare facilities apart from retail pharmacies such as clinics and hospitals where many clients access healthcare. This is because alterations in clients' prescriptions usually happen at such facilities and it will be easier to collect the drugs clients no longer require and safely dispose of them by health care personnel rather than entrusting clients to ensure these unwanted drugs are safely disposed.

2. The pharmaceutical society of Ghana, which is the only professional body for practicing pharmacists in Ghana should implement and support specific continuous professional development programs targeted at pharmacists. This can help to continue build capacity of pharmacists to improve their knowledge of proper drug disposal practices and empower them to further cascade such information down to the general populace.

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APPENDICES

CLIENT'S QUESTIONNAIRE

ASSESSMENT OF CLIENTS' COMPLIANCE TO THE 'TAKE BACK UNWANTE MEDICINES' PROJECT

Section A: Demographic Characteristics

1. Age: ☐
2. Gender: □ Male □ Female
3. What is your level of education?

   □ None □ Primary □Junior secondary □Secondary □Tertiary
4. What is your marital status?

   □ Married □ Single □Divorced □ Co-habiting
5. What is your occupation?

   □ Government employed □ Self-employed □ Unemployed
6. Where do you live? .....

Section B: Awareness of TBUM

7. Have you heard of 'Take Back Unwanted Medication'?

   □Yes □No (***if no, skip to 15***)
8. If yes, how did you get to know about the project?

   □ TV/Radio □ Pharmacist/Health personnel □ Social media □ Other……
9. Take Back Unwanted Medication means returning unwanted drugs back to a nearby pharmacy.

   □Yes □No
10. Take Back Unwanted Medication is the right way to dispose unwanted drugs in our homes.

    □Yes □No
11. Take Back Unwanted Medication helps to get rid of expired drugs which are a potential hazard to young and old.

□Yes □No

12. Pharmacies are obliged to accept back unwanted medicines from clients.

□Yes □No

13. Anybody can practice 'Take Back Unwanted Medication'.

□Yes □No

Section C: Disposal Practices

14. Do you currently have any unwanted or expired medication at home?

□Yes □No

15. What type of medication is it?

□ OTC □ Prescription drug □ Herbal □ Other…….

16. How did you get these medication?

□ Prescription □ OTC □ Relatives/friends □ Other

17. Have you disposed of any unwanted or expired medication in the last 6 months?

□Yes □No

18. How did you dispose these medications?

□ Dustbin □ Flushed down toilet □ Buried □ Burnt □ Gave it to someone

Other …….

Section D: Compliance to TBUM

19. Will it be easy for you to return an unwanted drug to a nearby pharmacy?

□Yes □No

20. If no, why?.....

21. Would you continue to return or ever return unwanted or expired medication to a nearby pharmacy?

□Yes □No

22. Would you encourage your family and friends to practice TBUM?

□Yes □No

QUESTIONNAIRE FOR PHARMACISTS

ASSESSMENT OF CLIENTS' COMPLIANCE TO THE 'TAKE BACK UNWANTED MEDICINES' PROJECT

Section A. Demographics

1. Location of pharmacy…….
2. Age of pharmacist…….
3. Gender Male female
4. How long have you been practicing as a pharmacist?

   □0-5years □6-10years □Over 10years

Section B. Awareness of TBUM

5. Are you aware of the 'Take Back Unwanted Medicines' project?

   □ Yes □ No

6. If yes, do you encourage clients visiting your pharmacy to use it for disposing unwanted medicines?

   □ Yes □ No

Section C. Roles of pharmacy in TBUM

7. Do clients return their unwanted medicines to your pharmacy?

   □ Yes □ No

8. Who handles the returned medicines from clients?

   □ Pharmacist □ Technician □ Pharmacy assistants □ Other untrained staff

9. It is my role to offer counselling to clients on proper drug disposal practices.

   □Yes □No

10. It is my role to provide valuable education on proper medical disposal.

    □Yes □No

11. It is my role to accept any unwanted drug from clients

    □Yes □No

Section D. Collection of returned drugs

12. How often are returned medicines collected?

    □Monthly □ Quarterly □ Half yearly □ Yearly

13. Who is responsible for the collection of unwanted drugs from your pharmacy? …….

ETHIC REVIEW COMMITTEE APPROVAL LETTER

GHANA HEALTH SERVICE ETHICS REVIEW COMMITTEE

In case of reply the number and date of this Letter should be quoted.

Research & Development Division
Ghana Health Service
P. O. Box MB 190
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Email: ethics.research@ghsmail.org

My Ref. GHS/RDD/ERC/Admin/App 21|347
Your Ref. No.

23rd August, 2021

Amma Tutuwaa Akwaboah
University of Ghana, School of Public Health, Legon
P. O. Box, OS 2226, Accra

The Ghana Health Service Ethics Review Committee has reviewed and given approval for the implementation of your Study Protocol.

GHS-ERC Number	**GHS-ERC 038/07/21**
Project Title	Assessment of Clients' Compliance To The "Take Back Unwanted Medicines" Project.
Approval Date	23rd August, 2021
Expiry Date	22nd August, 2022
GHS-ERC Decision	**Approved**

This approval requires the following from the Principal Investigator

- Submission of yearly progress report of the study to the Ethics Review Committee (ERC)
- Renewal of ethical approval if the study lasts for more than 12 months,
- Reporting of all serious adverse events related to this study to the ERC within three days verbally and seven days in writing.
- Submission of a final report after completion of the study
- Informing ERC if study cannot be implemented or is discontinued and reasons why
- Informing the ERC and your sponsor (where applicable) before any publication of the research findings.
- Please note that any modification of the study without ERC approval of the amendment is invalid.

The ERC may observe or cause to be observed procedures and records of the study during and after implementation.

Kindly quote the protocol identification number in all future correspondence in relation to this approved protocol

SIGNED.....
Dr. James Akazili
(Head, Ethics & Research Management Department)

Cc: The Director, Research & Development Division, Ghana Health Service, Accra

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