SCHOOL OF PUBLIC HEALTH

COLLEGE OF HEALTH SCIENCES

UNIVERSITY OF GHANA

COMPLIANCE WITH DISPOSAL OF EXPIRED AND UNUSED MEDICINES REGULATIONS AMONG RETAIL PHARMACIES AND OVER THE COUNTER MEDICINE SELLERS IN HO MUNICIPALITY

BY

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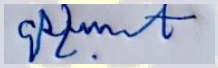
DECLARATION

I, Charles Adjei Mensah, hereby declare that except for the other people's investigations which have been duly acknowledged, this work is the result of my original research and that this dissertation, either in whole or in part has not been presented elsewhere for another degree

Charles Adjei Mensah (MPH Candidate) Signature: 24/05/2022 Date:



Prof Francis Anto (Academic Supervisor) Signature: 24/05/2022 Date:

DEDICATION

This work is dedicated to my dear wife Mary Abena Adoma and my lovely kids; Kwaku Agyei Mensah, Yankyerah Agyei Mensah and Yeboah Agyei Mensah for their love, support and prayers.

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God bless you all

ABSTRACT

Background: Globally, the consumption of pharmaceutical products is on the rise due to population increase and the use of medicines to maintain human health. These prescribed medicines are frequently left unused for variety of reasons and disposed of in an indiscriminate manner. This practice causes many environmental problems which leads to health hazards in adults and children.

Objective: The objective of the study was to assess the level of compliance with FDA and international guidelines for the disposal of expired and unused medicines and associated factors among retail pharmacies and OTCM sellers in the Ho Municipality.

Methods: An analytic cross sectional study design was used to survey all retail pharmacies and OTCM shops in the Ho Municipality. One hundred and sixteen (116) retail pharmacies and OTCM sellers were enrolled into the study after consenting. Semi-structured questionnaires were use to elicit information from respondents. These included demographic information, knowledge on disposal of expired medicines guidelines and the disposal practices. EpiData 6.0 software was used for data entry and exported to Stata version 16.0 for analysis. For categorical variables, simple frequencies and percentages were used, with statistical significance set at a P value of 0.05 at a confidence level of 95%.

Results: The overall high knowledge level on disposal of expired and unused medicines was 63.79%. Compliance to FDA and international guidelines for the disposal of expired and unused medicines was 57.76%. Significant factors associated with disposal practices among respondents were tertiary level of education [AOR= 2.95, p=0.017], pharmacies [AOR= 3.24, p= 0.0038] and good knowledge level on disposal of unsafe medicines

[AOR= 2.66, p=0.034]. Respondents who have ever disposed unsafe and unused medicines were 65% times less likely to have good disposal practice (p=0.025).

Conclusion: Despite having a high level of knowledge on how to dispose of expired and unused medicines, one out of every two respondents did not follow FDA and international guidelines for disposing of expired and unused medicines. There is the need for stakeholders to intensify education and promote cost-effective strategies in disposing expired and unused medicines.

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LIST OF ABBREVIATIONS

CEPS- Customs Excise and Preventive Services

FDA- Food and Drugs Authority

GDPA- General Directorate of Pharmaceutical Affairs

OTCM- Over the Counter Medicine

PVC- Polyvinyl Chloride

TFDA- Tanzania Food and Drugs Authority

WHO- World Health Organisation

DEFINITION OF KEY TERMS

Compliance: the act of following the set rules/guidelines

Disposal: the action of getting rid of something

CHAPTER ONE

INTRODUCTION

1.1 Background to the Study

The origin and significant history of medicine and drug has its old history in ancient times and even difficult to trace the first person who discovered the first medicine. However, the use of plant medicine stems right from ancient people to human civilization. Herbs played a significant role in the development of pharmacology and pharmacy as the world's ancient systems of medicine, for instance, Chinese Medicine, Ayurveda and Greek Medicine evolved (Wadud, Prasad, Rao, & Narayana, 2007). The existence of medicines in the world today plays an essential role and important component with regards to universal health care. It helps to improve health outcomes by improving patient recovery and overall quality of life by lowering morbidity and death (McLean, Kohler & Edwards, 2019).

The WHO's 13th General Programme which was introduced in 2019 sought to achieve universal health coverage through appropriate use of traditional and complementary medicine. As part of the programme, a well-developed policy and regulation is needed to guide the product, practices and practitioners on the use of traditional and complementary medicine across countries (WHO, 2019). Empirical evidences have shown that more than 50% of all medications used by the populace are not appropriately prescribed, sold or dispensed (Rodriguez-Gonzalez et al., 2011).

As the population increase their use of medicines, the disposal of unwanted medication from the households and pharmacies also becomes an issue of concern. There has been an identification of risk such as poisoning in children and medication diversion (Abruquah, Drewry & Ampratwum, 2014). Even after treatment and purification, it is now possible to

detect the presence of pharmaceutical substances in the environment, notably in ground water and potable water, thanks to the development of increasingly sensitive analytical tools (Sanderson, 2011). Some individuals and households undertake many disposal practices such as medication burying in ground holes, disposal via toilet and sink drains (Tong et al., 2011). For instance, a study carried out among residents of Konongo-Odumasi in the Ashanti Region revealed that 98% of residents indicated that they had unused medicines they wished to dispose and also had no knowledge on proper disposal of their medicines (Abruquah et al., 2014). In Kabul, evidence from a study also showed that antibiotics, anti-hypertensive and anti-diabetic medicines were mostly indiscriminately disposed through household trash (Bashaar, Thawani, Hassali & Saleem, 2017).

The pharmaceutical waste needs clear and systematic disposal approach to be destroyed and not exposed to the environment to cause any hazardous effects (Bashaar et al., 2017). In France, the WHO's European Centre for Environment and Health established and tasked an international group to develop guidelines that addresses problems facing health care waste management especially the getting rid of unwanted and unused medicine. In New Zealand and in Canada, the Disposal of Unwanted Medication Properly (DUMP) campaign was launched and initiated (Gagnon, 2009). In Afghanistan, the monitoring and evaluation of drugs and medicine supplies waste management is supervised by the General Directorate of Pharmaceutical Affairs (GDPA). As part of the responsibilities, GDPA ensures that one percent of the cost of all medicines to be provided in Afghanistan are contributed to the management of the disposal of expired medicines. Countries like Sweden, Nigeria and USA also have policies and guidelines on the disposal and management of unused and expired medicines (Persson et al., 2009; Michael et al., 2019; Glassmeyer et al., 2009). For

Ghana, the Food and Drugs Authority has developed a guideline under the Public Health Act, 2012, Act 851, for the disposal of unwholesome products of which expired and unused medicines are listed. There are limited empirical evidences on the compliance with FDA and international guidelines on the disposal of expired and unused medicines among retail pharmacies and Over the Counter Medicine (OTCM) sellers. Proper discarding of expired and unused medications protects the environment against hazardous effects. This study seeks to assess disposal practices of expired and unused medicines at retail pharmacies and over the counter medicines (OTMC) in Ho Municipality, Ghana.

1.2 Problem Statement

Globally, the consumption of pharmaceutical products is on the rise due to population increase and the use of medicines to maintain human health (Michael et al., 2019). According to the WHO, more emphasis is placed on medication coherence, ensuring that patients receive the appropriate doses of medication at the appropriate time and for the intended purpose (WHO, 2012). Prescription medication are mostly left unused and this may be due to change of treatment regimens, drug adverse effects and patient reluctance to continue medication due to improvement in heath condition which has a resultant effect of discontinuation of the course of treatment or expired medicines (Kheir et al., 2011).

In recent times, large quantities of pharmaceutical waste circulate in sewerages into water bodies and absorbed into the soil due to high improper disposal of medicines through general municipal waste bins, sinks, or flushed down through toilets, which are inconsistent practices to FDA and international regulations on pharmaceutical waste management. These unlawful routes put the environment at danger of future hazards and health risks (Peake et al., 2015; Raja et al, 2018.

In Ghana, empirical evidences on the disposal of unused or expired medicines revealed improper disposal of expired and unused medicines through channels such as trash bins or flushing down the toilets (Osei-Djarbeng et al., 2015; Sasu, Kummerer, & Kramer, 2012). Futhermore, evidence from a study that explored selected hospitals in Ghana also indicated that there was no separate collection and disposal of pharmaceutical waste at the various hospitals studied (Sasu et al., 2012).

Eventually, these unused and expired medicines are disposed-off indiscriminately and can result in the pollution of the environment, which leads to health hazards (Medhi, & Sewal, 2012). Adults and children have been poisoned as a result of improper disposal of expired medications (Michael et al., 2019).

As a result of expired medications in the sewage, there may be an increase in antibiotic resistance among the many strains of microorganisms found in sewage, which can evolve into lethal and resistant pathogens from otherwise harmless germs (Kadam, Patil, & Tumkur, 2016).

The presence of pharmacies and OTCM shops is essential for the receipt of unused and expired medicines from the general public. The FDA in 2020 tasked some community pharmacy shops in the Greater Accra region to collect unused and expired medicines from the public for proper disposal (FDA, 2020) as part of the *Take Back Of Unwanted Medicine (TBUM) Project* launch. In view of the fact that community pharmacies and OTCM shops play an important role in the public health preventive services with regards to disposal of unused and expired medicines, it is also imperative to assess their disposal practices in relation to the FDA guidelines, their knowledge on disposal of expired medicine and factors influencing their disposal practices. There is however, no empirical evidence to

assess disposal practices of expired and unused medicines at retail pharmacies and OTCM shops in Ho Municipality, Ghana, hence the aim of this study.

1.3 Justification of the study

The results of this study will contribute to academia and provide information to Pharmacy Council, FDA and other relevant stakeholders on the knowledge level for the discarding of expired medicines among retail pharmacies and OTCM sellers in the Ho Municipality. With information on their knowledge level, targeted and well-structured education program can be organized using media campaign by Pharmacy Council, FDA and other relevant stakeholders. It will also provide estimate on the level of compliance to FDA and international guidelines for the disposal of expired and unused medicines. The factors identified to be associated with the disposal of expired and unused medicines will inform FDA, the Pharmacy Council, the Environmental Protection Agencies, non-Governmental Organisations (NGOs) and other relevant stakeholders on developing cost-effective pharmaceutical waste management system to support retail pharmacies and OTCM sellers in the Ho Municipality. These findings will serve as a baseline study and reference for other future studies.

1.4 Research Questions

1. What is the level of knowledge of retail pharmacies and OTCM sellers of FDA and international guidelines for the disposal of expired and unused medicines?
2. What is the level of compliance of retail pharmacies and OTCM sellers in the Ho Municipality with FDA and international guidelines for the disposal of expired and unused medicines?

3. What are the factors associated with disposal practices of expired and unused medicines?

1.5 Study Objectives

1.5.1 General Objective

To assess the level of compliance with FDA and international guidelines for the disposal of expired and unused medicines and associated factors among retail pharmacies and OTCM sellers in the Ho Municipality.

1.5.2 Specific Objectives

1. To determine the level of knowledge of retail pharmacies and over the counter medicines (OTCM) sellers of FDA and international guidelines for the disposal of expired and unused medicines
2. To determine the level of compliance of retail pharmacies and OTCM sellers in the Ho Municipality with FDA and international guidelines for the disposal of expired and unused medicines
3. To determine factors associated with disposal practices of expired and unused medicines

1.6. Conceptual Framework

Demographic characteristics such as age, sex, religion, ethnicity etc. can influence discarding practices of expired and unused medicines. External factors such as location of facility, facility close to landfills, training on disposal practices and availability/unavailability of guidelines can also influence disposal practices of expired and unused medicines. Awareness on the discarding of unsafe/unused medicines can influence disposal practices of expired and unutilized medications as shown in figure 1.

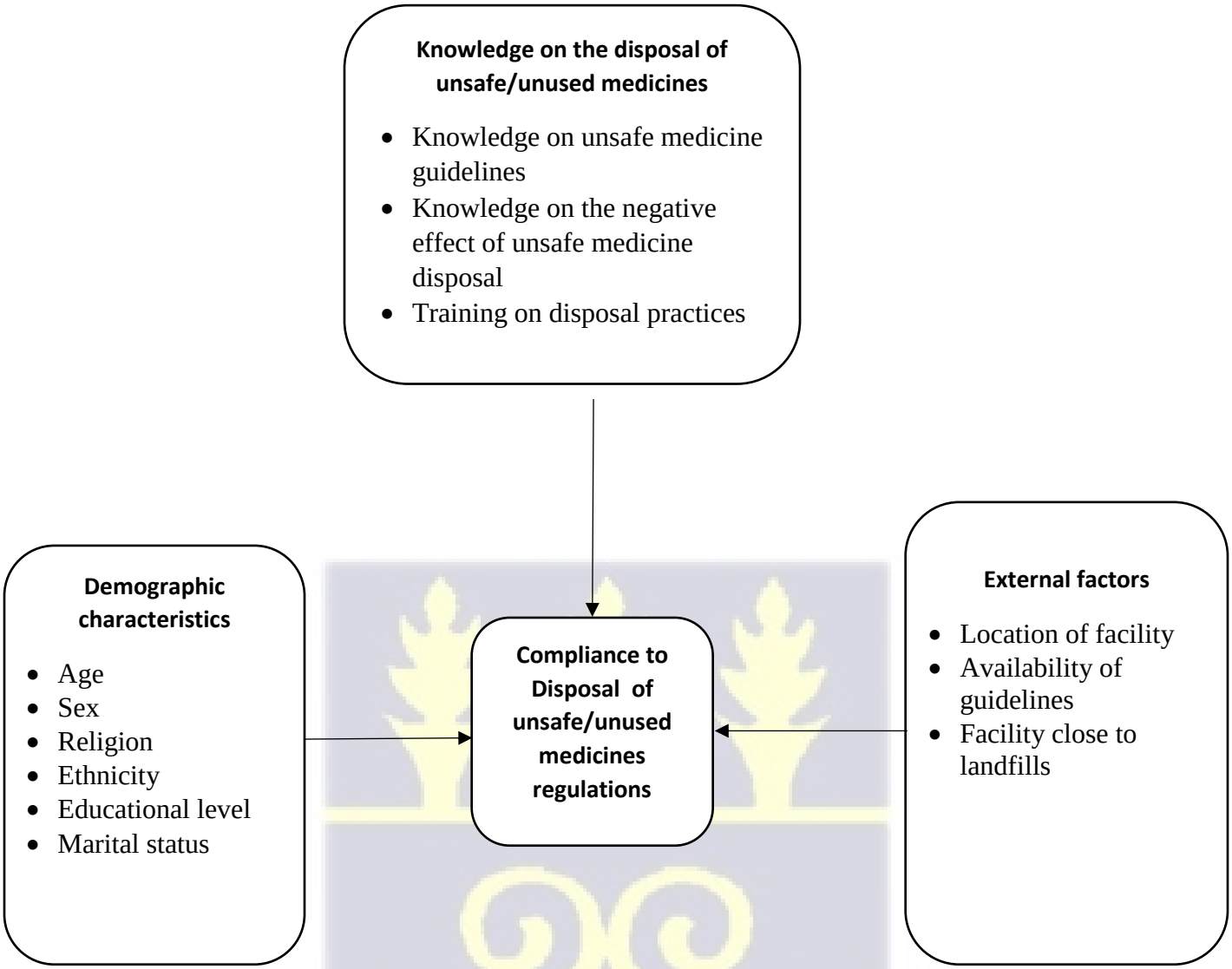

Figure 1: Conceptual framework on the disposal of unsafe/unused medicines

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 **Overview on the disposal of Expired and unused medicines**

Due to the potential toxicity and the inherent ability of accumulation in the environment, expired or unused medicines should be well managed to prevent proliferation of pharmaceuticals with potential toxicity in the environment (Braund et al., 2008). Changes in prescription regiments during the drug usage cycle can also lead to accumulation of unused medication. This approach causes pharmaceuticals to expire, which are then either kept or thrown away in sewage systems or as trash, or returned and stockpiled in community pharmacies (Braund et al., 2008; James, Helms & Braund, 2009). Research has substantiated the incomplete use of medications dispensed due to experiences related to adverse effects, drug alteration, and expiration of medication or patient feeling healthy (Ruhoy & Daughton, 2008). This section presents the disposal practices of expired and unused medicines among pharmacies and OTCM sellers. Literature on the availability of expired medicines disposal guidelines for countries, disposal practices, pharmacist disposal practices, knowledge on disposal practices, the Ghana Food and Drugs Authority guidelines on the disposal of unwholesome products and the negative effect of pharmaceutical exposure to the environment and health.

2.2 Guidelines on the Disposal of Expired and Unused Medicines for Countries

Proper disposal of pharmaceutical residues is very important due to its adverse effect on health and environment. In Sweden, there is a well-developed guideline on the disposal of

expired and unused medicines in the country. The Swedish Pharmaceutical Society oversees their disposal system, which is operated by the government in collaboration with a national pharmaceutical wholesaler. The Sweden guideline states that unused or waste medication should be returned to pharmacies. The pharmacies will then destroy the expired products by using high-temperature incineration to destroy the active ingredients effectively (Persson, Sabelström, & Gunnarsson, 2009). In the United States (US), not all pharmacies accept the returned drugs as done in Sweden (Glassmeyer et al., 2009). In Nigeria, the National Agency for Food and Drug Administration and Control (NAFDAC) guideline on disposal of expired drugs is available for pharmacist to follow in disposing expired and unused medicines (Michael, Ogbonna, Sunday, Anetoh & Matthew, 2019). The Tanzania Food and Drugs Authority has also designed a detailed document on the disposal of expired drugs (TFDA, 2009). For Afghanistan, policy states all pharmaceutical waste management activities, should be contributed by 1% of medication cost provided in Afghanistan. The General Directorate of Pharmaceutical Affairs (GDPA) has the responsibility of ensuring orderly monitoring and evaluation of drugs and medical supplies waste management throughout the country (MOPH, 2014). In Ghana, the Food and Drugs Authority has developed a guideline under the Public Health Act, 2012, Act 851, for the disposal of unwholesome products of which expired and unused medicines are apart. A desk review carried out on the governance on the use of medicines in Ghana revealed that out of the 45 indicators on the governance of prescription medicines and its promotion, 21 of them were met in Ghana. Some of the indicators met were the existence of a national medicine policy, medicines regulatory authority and a national guide for the promotion of prescription pharmaceuticals and the national medicines list among others (McLean et al.,

2019). In New Zealand, there is no specific guideline for the disposal of expired or unused medications as found in countries like Sweden, Afghanistan, Nigeria and Ghana (Tong et al., 2011).

2.3 Disposal Practices of Expired Medicines

For all expired or unused medicines, there are appropriate disposal practices. When there are constraints with regards to funding for pharmaceutical waste disposal, it is necessary to use cost minimizing management and methods. For this reason, it is best for sorting to be done to remove the barrier of expensive or complicated disposal methods (Gray, Hogerzeil, Prüss & Rushbrook, 1999). The return of expired medicine to donor, pharmacy or manufacturer, use of dumping grounds, waste confinement, sewer, burning in open container, novel elevated temperature burning and chemical decomposition are all ways by which expired and unused medicines can be disposed (Ferronato & Torretta, 2019).

2.3.1 Return to Donor, Pharmacy or Manufacturer

Returning of expired medicine or unused medicine to donor or to the pharmacy is one of the numerous options and practically less expensive. This mostly applies to drugs that present pertinent disposal problems such as antineoplastics, and requires to be returned to the donor. In some cases, there are unwanted or unrequested donations that may arrive past or close to the expiry date, and such products needs to be returned to the donors (WHO, 2006). For the return of drugs to the pharmacies, it is mostly encouraged among individuals and households to return unused medicines and expired ones back to the pharmacist for appropriate disposal (Gray et al., 1999).

2.3.2 Landfill

Mostly this practice is used for solid waste and identified as one of the oldest systems in place for the disposal of expired medicines (WHO, 2006). Landfill is used to dispose litter directly on the designated landfill sites without preceding treatment or preparation. The three types of landfills include; uncontrolled non-engineer dump, engineered landfill and highly engineered sanitary landfill (Gray et al., 1999).

The most common disposal landfill used in developing countries is the uncontrolled non-engineer dump. This form of waste disposal system needs to be avoided as it does not protect the environment (Baía, 2015). Unless as a last resort, direct discarding of untreated pharmaceutical waste is not recommended (Ferronato & Torretta, 2019). In cases where this system is practiced, large quantities of municipal waste should be used to cover them to discourage scavenging which will end up polluting the environment (Gray et al., 1999; Olinic & Olinic, 2018).

Engineered landfill is more protective than the uncontrolled non-engineer dump as some features protects from loss of chemicals into the aquifer (Tischler, Buzby, Finan & Cunningham, 2013). It becomes best when direct deposal of pharmaceutical waste is immobilized and disposed into the landfill (Gray et al., 1999).

Highly engineered sanitary landfill is the best practice and properly built and operated landfill site that promotes a safe route for the disposal route for both pharmaceutical waste and municipal waste (Ejeromedoghene, Nwosisi, Tesi, Noragbon, & Akinyeye, 2021). This protects the aquifer which is top priority. The system is such that, it is properly sited, constructed and the management is done to protect human lives and the environment (Gray et al., 1999).

2.3.3 Waste Immobilization encapsulation

The waste immobilization encapsulation method requires that the pharmaceutical waste is solidified within a plastic or steel drum. The container which can be either plastic or steel should be cleaned before used and free from any hazardous or explosive material previously (Ferronato & Torretta, 2019). The substance is then filled to about three quarter (75%) capacity with the solid or semi-solid pharmaceutical waste as the remaining space is filled with a cement medium/lime mixture, plastic foam or bituminous sand. A steel drum lid should be used to seal the vessel, ideally by seam or spot welding. The sealed drums should be buried at the base of the land disposal site and covered with fresh municipal waste (Gray et al., 1999).

2.3.4 Sewer

The sewer approach can be used to dispose off liquid pharmaceutical waste such as syrups and intravenous (IV) fluids (Michael et al., 2019). The waste can be combined with water and flushed into sewers in small amounts over a period of time with no negative consequences for human health or the environment (Michael et al., 2019).This practice is mostly practiced at the household level.

2.3.5 Burning in Open Containers

The practice of burning waste in open containers especially at low temperature is hazardous, toxic and can easily pollute the air. The Paper and cardboard packaging for instance can be burned or recycled. Polyvinyl chloride (PVC) substances needs not to be burned as they can pollute the environment (Zhang, Buekens, Jiang & Li, 2015). In cases

where waste has to be burnt, they have to be only in very small quantities of waste pharmaceutical and mostly not encouraged (Hirschler, 2017)

2.3.6 Novel High Temperature Incineration

Many countries are not economically sound for this type of technology since it is expensive and sophisticated (Bean et al., 2016). High temperature technology such as cement kilns, coal-fired thermal power stations, or foundries, which has an operation temperature exceeding 850°C, with long combustion retention times and exhaust dispersion using chimneys to high heights, is an environmentally friendly method for protecting the environment from chemical pollutants (Kassahun & Tesfaye, 2020).

2.3.7 Chemical Decomposition

In situations where there is the unavailability of appropriate incineration tools, landfill methods can be used, preceded by chemical decomposition in lieu with manufacturers recommendations This method should be done by chemical experts since it is time consuming and tedious. This method is also quite expensive as chemicals needs to be always available and in stock (Gray et al., 1999).

2.4 Effect of Environmental Exposure to Pharmaceutical Residue

According to research, renal failure has been observed in vultures following feeding on carrion of cattle treated with diclofenac, a commonly used non-steroidal anti-inflammatory drug (NSAID). Estrogenic compounds used in combined oral contraceptives such as 17-α-ethinylestradiol makes fishes feminine even in low concentrations, which results in reproductive complications (Tong, Peake, & Braund, 2011). Pharmaceuticals and their

metabolites have been found in trace concentrations in various drinking water supplies (Kadam et al., 2016).

2.5 Knowledge on the Disposal of Expired and Unused Medicines among Retail Pharmacies and OTCM Sellers

In New Zealand, findings from a study carried out among community pharmacist revealed that over 60% of participates responded they think the contractors burnt the collected unused medication retrieved from them (Tong et al., 2011). In assessing the knowledge of Nigerian pharmacist on the disposal of expired medicines by the third party, some (22.1%) responded that NAFDAC uses incineration or other forms of heat to dispose of expired drugs while 24.7% reported they do not have any knowledge on how NAFDAC disposes of their expired drugs (Michael et al., 2019). Pharmacists in Iraq showed a lack of understanding of drug disposal procedures. About 65.9% mentioned that returning drug as a disposal method was appropriate. Also, a good number of them supported disposing of drugs in the trash. However, education was cited by 63.6 percent as the greatest impediment to the establishment of a medicine–take–back program in Iraq. (Albaroodi, 2019).

2.6 Disposal practices among Retail Pharmacies and OTCM Sellers on the Expired and Unused Medicines

A cross sectional study carried out among New Zealand community pharmacists with regards to discarding practices for unutilized or expired medicines showed that solid and semi-solid pharmaceuticals were disposed-off by contractors in 80.4 percent and 61.1 percent of cases, respectively. They again added that for liquid and Class B controlled drugs, they were mostly discarded using the pharmacy sink drainage (Tong et al., 2011).

Findings from a study conducted by Michael and colleagues in Nigeria revealed that, solid expired and unused medicines were disposed by various ways such as through NAFDAC (31.8%), drug distributors (23.9%) and rubbish bins (9.1%). Also, 7.1% indicated that their liquid dosage expired medicines are disposed using the sink drainage system and 29.6% noted they do not stock Class B controlled drugs (Michael et al., 2019).

2.7 Compliance level on the Disposal of Expired Medicines Retail Pharmacies and OTCM sellers

Indiscriminate disposal of expired and unused medicines endangers the environment as pharmaceutical waste and chemicals flow through sewerages into water bodies and absorbed into the soil (Peake et al., 2015). These waste contains hazardous substances that can endanger the environment and therefore needs to be discarded appropriately. Compliance to safe disposal guidelines is essential to protect the environment from pharmaceutical waste which poses many health threats in the future. A study conducted in Nigeria among pharmacist showed that more than half (54.5%) of pharmacist did not comply with the national guidelines on disposal of expired drugs, less than a quarter (23.4%) complied fully while 22.1% complied partly to the guidelines on the disposal of expired medicines (Michael et al., 2019).

2.8 Factors associated with disposal practices and compliance to guidelines

In a study carried out by Zajacova and Lawrence (2018), they reported the influence of education on health practices, indicating that individuals with higher levels of education tend to be more cautious of their health decisions. Thus, knowledge of harmful effects of poor disposal of pharmaceutical waste positions individuals with a higher level of

education to be more compliant. Further, higher educational levels can be argued to influence appreciation and understanding of guidelines and rules, which consequently influences compliance. When medicines are disposed by means of throwing into wastebasket, they will end up with reaching landfills with other solid waste, which will result in serious environmental and health hazards. According to Radhakrishna and Nagarajan (2015) pharmaceutical waste that is disposed using the landfill comes from homes and other sources where availability of waste bins is scarce and all waste is discarded in a single bin without segregation or sorting. According to Seehusen and Edwards (2006), low knowledge on safe disposal among patients who are given prescription medication results in patients mostly failing to complete the full dosage given to them once there is an improvement in their medical condition, experience side effect of the medications, or when a prescriber changes their medications; and these lead to unused or expired medicines in the homes. Such medicines are normally disposed of by throwing them away in the trash or rubbish, flushing them down the toilet, sink or gutter; and others keep them for future use.

Various factors also contribute to non-usage and disposal of medicines. It is evident from published literature that medication users normally receive instructions on how to use and store medications but it is rare to obtain proper information on safe and appropriate methods to dispose of such medications unless information is obtained from healthcare providers. There are specific guidelines formulated by the Food and Drugs Authority, which specifies the disposal of unused medicines (Swaroop et. al., 2015).

A study by Lagishetty et al. (2013) showed that only 3.63% of medicine users from the study were having information regarding safe disposal of medications and majority of the

consumers throw or dispose of left-over medicines into the garbage. This is consistent with a study by (Gupta et. al., 2013). Few studies have reported on the factors influencing the compliance to FDA or appropriate regulations on the disposal of expired or unused medicines among retail pharmacies and OTCM sellers. Findings from this study will contribute to the body of knowledge.

2.9 Ghana Food and Drugs Authority Regulations on the disposal of Unwholesome Products

The Food and Drugs Authority was founded under the Public Health Act of 2012, Act 851, to ensure public health and safety. As part of the authorities' responsibility under section 132 of the Public Health Act, 2012, which includes overseeing the safe disposal of unwholesome regulated products, such as substandard/falsified products. Guidelines for the safe disposal of regulated products that are inappropriate for human and animal consumption have been created using powers granted to the Authority by Part Seven, Section 148 of the Public Health Act, 2012 (Act 851).. All parties involved in management of drugs, medical devices, cosmetics, and household chemical substances must adhere to the guidelines created to ensure the safe disposal of unwholesome items and to ensure that these products do not cause harm. This is because unwholesome products need to be handled properly, treated properly to ensure protection of human and environmental health from hazards.

It also lays out a detailed procedure for bringing the activities of unwholesome product manufacturers, processors, producers, wholesalers, retailers, importers, and exporters into

compliance with Part Seven, Section 132 subsections 2 and 3 of the Public Health Act of 2012, (Act 851).

General Requirements

Without the consent and supervision of the Food and Drugs Authority (FDA), no one may dispose of any unwholesome product.

The FDA must approve the application and ensure that any unwholesome product is properly disposed of.

According to the fee schedule, the applicant must pay a set fee for destruction.

The applicant must arrange with the appropriate Waste Management Agency to assist in the destruction and be responsible for transporting the unfit products to the destruction location.

The Environmental Protection Agency (EPA), Customs Excise and Preventive Services (CEPS), Audit Service, and Ghana Police Service (GPS) representatives will be present as witnesses if needed.

Management of unwholesome product shall include:

a) Maintaining an unwholesome product registry

b) Separating unwholesome items, particularly those that fall under the regulation of controlled substances, and any other dangerous products.

c) Sorting unwholesome goods into distinct dosage categories (e.g. solids, liquids etc.)

d) To avoid unintentional use, unwholesome products should be clearly labeled.

Specific Requirements

All applications for destruction of unwholesome products shall be made to the FDA office through a letter addressed to

THE CHIEF EXECUTIVE

FOOD AND DRUGS AUTHORITY

P.O.BOX CT 2783

CANTONMENTS – ACCRA

The letter shall be accompanied by a completed application form as well as a list of items in both hard copy and soft copy (excel format) that includes the following information:

a) Product description

b) Quantities

c) Unit cost

d) Total commercial values and

e) Reason (s) for which the products are declared unwholesome.

f) Batch (applicable to recalled SF products)

In addition, the applicant shall pay a non-refundable fee (find information on Approved Fee on the FDA website)

The Authority shall appoint a regulatory officer to evaluate and validate the information presented in respect to the consignment to be disposed of upon receipt of the request for disposal. If the supplied list is altered after verification to include additional products, the applicant will be required to pay an additional cost.

The applicant must schedule and agree with the FDA on a time when the destruction can be completed.

After the disposal procedure is completed, the Authority will provide a certificate of product destruction.

PENALTIES

Anyone who violates or fails to comply with any provision of these Regulations, or who directly or indirectly assists another person in violating these Regulations, commits an offense under the Act.

Any individual found guilty of an offence under these regulations faces a fine under Part Seven, Section 129 of the Public Health Act, 2012. (Act 851).

CHAPTER THREE

3.0 METHODS

3.1 Study Design

A cross sectional analytic study involving registered retail pharmacies and OTCM shops in the Ho municipality was undertaken during the month of March 2022. Attempt was made to include all registered retail pharmacies and OTCM shops in the Ho municipality. Data on demographic characteristics, knowledge regarding FDA and international guidelines for the disposal of expired and unused medicines, disposal practices on expired and unused medicines, availability of guidelines and location of shop were collected from the main pharmacists and OTCM seller using a semi-structured questionnaire.

3.2 Study location

Ho Municipality is found within the central part of Volta Region and is designated as the capital city of the region. It has an area of 2.660 square kilometers and is located between latitudes 6°36' 3.02" N and longitude 0°28' 16.68" E. The Municipality shares boundaries with the Adaklu-Anyigbe District to the South, Hohoe Municipality to the North, South-Dayi District to the West and the Republic of Togo to the East. It is situated to the west of the Republic of Togo and east of Lake Volta. The Region, which is divided into 25 administrative districts, is multi-ethnic and multilingual, with ethnic groupings such as the Ewes, Guans, and Akans. The Lolobi, Likpe, Akpafu, Buem, and Nkonya are among the Guan people. As Ho Municipality is the capital, it makes it an urban center with numerous government and private-owned basic schools as well as well-established offices and shops. Ho Municipality has a population of 177,281, accounting for 8.4% of the total population of the region, according to the 2010 Population and Housing Census. The municipality has

hospitals, health centers and Community based health and Planning Services (CHPS) compounds that render health services. The Ho Municipal health insurance scheme is located in the capital of the Municipality (Ghana Statistical Service, 2014). There is a Pharmacy council situated in Ho Municipality, which regulates the operations of all pharmacies and OTCM shops. According to the pharmacy council, there were 105 OTCM shops and 20 retail pharmacies as of 2020.

Figure 3.2: Map of Ho Municipality (Ghana Statistical Service, 2014)

3.3 Study Variables

The main dependent variable was level of compliance to disposal of unsafe/unused medicines guidelines. The independent variables include demographic characteristics such as age, sex, marital status, educational level, religion, ethnicity and religious affiliation. It also includes variables related to the facility such as facility location, availability of disposal of unsafe/unused medicine guidelines in the facility, facility close to landfills, and

training on disposal practices of unsafe/unused medicines and knowledge on the disposal practices of unsafe/unused medicines.

Definition of study variables

Table 3.1: Definition and Operationalization of Study Variables

Variables	Operational definitions	Types of Variables	Scale of measurement
Level of compliance to disposal of unsafe/unused medicines	Compliance level to the disposal of unsafe/unused medicines in accordance to FDA and international guidelines	Dependent	Categorical
Age of respondent	The age in completed years of respondent	Independent	Continuous
Sex of the respondent	The sex of the respondent	Independent	Categorical
Marital status	The marital status of the respondent	Independent	Categorical
Ethnicity	The tribe the respondent belongs to	Independent	Categorical
Highest Educational level	The highest educational level attained by the respondent	Independent	Ordinal categorical
Religious affiliation	The religion the respondent belongs to	Independent	Categorical
Knowledge on the disposal of unsafe/unused medicines	The knowledge level of respondents on the disposal of unsafe/unused medicines	Independent	Continuous
Location of facility	Where the facility is situated	Independent	Categorical
Availability of disposal of unsafe/unused medicine guidelines	The availability of disposal of unsafe/unused medicine guidelines	Independent	Categorical
Facility close to landfills	The facility closeness to landfill	Independent	Categorical

Training on disposal practices of unsafe/unused medicines	The respondent received training on disposal practices of unsafe/unused medicines	Independent	Categorical
Knowledge on disposal practices of unsafe/unused medicines	Knowledge on the procedure for disposal Who is responsible for disposal	Independent	Categorical
Disposal of expired and unused solid medicines	Disposal practice of respondents on expired and unused solid medicines	Independent	Categorical
Disposal of expired and unused semi-solid medicines	Disposal practice of respondents on expired and unused semi-solid medicines	Independent	Categorical
Disposal of expired and unused liquid medicines	Disposal practice of respondents on expired and unused liquid medicines	Independent	Categorical

3.4 Study Population

For this research, the study population were the head pharmacist in charge of retail pharmacists and OTCM sellers whose shops and have registered their pharmacies and OTCM shops with the Pharmacy Council in Ho Municipality. According to the Pharmacy Council, there were 125 retail pharmacies and OTCM shops registered as of the year 2020.

3.5 Inclusion and Exclusion Criteria

Inclusion criteria

1. Retail pharmacies and OTCM shops registered with the Pharmacy Council in Ho Municipality

2. All retail pharmacists and OTCM sellers aged 18 years and above, with at least 6 months working experience and resident in Ho Municipality

Exclusion criteria

1. Eligible retail pharmacists and over the counter medicines (OTCM) sellers who were sick at the time of visit were excluded from the study.

3.6 Sample Size Determination

All registered retail pharmacies and OTCM shops in the Ho Municipality by the Pharmacy Council (Volta Region) as of the year 2020 were involved in this study. From each retail pharmacy and OTCM shop, the pharmacist and OTCM seller in charge of the facilities were invited to participate in the survey. All the registered retail pharmacies and OTCM shops were surveyed because the population size is manageable, and therefore sampling was not required (Nworgu, 2006).

3.7 Sampling Method

A census technique was used in this study. A list containing detailed information of all registered retail pharmacies and OTMC shops was obtained from the Volta Regional Pharmacy Council. The main pharmacist and OTCM seller who were eligible per the criteria in this study responded to the research questions after consenting to participate in the study. All the registered retail pharmacies and OTCM shops were surveyed because the population size is manageable, and therefore sampling was not required (Nworgu, 2006). A minimum number of 10 participants interviewed in a day, with an average 12 days for the whole data collection.

3.8 Data Collection procedure

Prior to visiting the retail pharmacies and OTCM shops for the data collection, appointments was scheduled beforehand with the main pharmacists and OTCM sellers. Face-to-face interviews with pre-tested semi-structured questionnaires was used to conduct the survey. On the day of the interview, the research assistants visited the retail pharmacies and OTCM shops to meet up with the person in-charge. The interviewers explained all the research information including the risk, benefits, compensation and criteria for participation to the participants. Two copies of the approved consent form by the ethics committee were given the participants to be signed. They kept a copy and the other copy kept by the research assistant. The interview was carried out in a quiet and airy space. All COVID-19 protocols such as observing social distancing, wearing mask were observed by both the interviewer and the respondents.

3.9 Data Collection Instrument

The information from the respondents in this study was gathered using a semi-structured questionnaire. The questions consisted of four sections. The section one focused on respondents' demographic information, such as age, gender, religion, ethnicity, and highest educational level.

The section two comprised of questions to assess the knowledge of respondents regarding FDA and international guidelines on the disposal of expired and unused medicines. Thirteen questions were asked to assess the level of knowledge among the respondents. Some of the questions that were asked were who is responsible for the disposal of expired and unused medicines, why is appropriate disposal practice important.

The section three asked questions on the compliance to the FDA regulations and other international guidelines on the disposal practices of expired and unused medicines by pharmacies and OTCM shops. Three questions were asked to measure the level of compliance among respondents. The questions were in line with the FDA and international guidelines on the disposal of expired and unused medicines.

The section four focused on questions such as availability of guidelines at pharmacies/OTCM shops, location of pharmacies/OTCM shops, closeness of the pharmacies/OTCM shops to a landfills etc.

3.10 Data Processing

Data collected from the field was checked for content completeness and accuracy by ensuring that all questions on the questionnaire are filled in appropriately. It was ensured that codes are correctly written on the questionnaire. After each day's work, the questionnaires were counted to ensure that the expected number had been obtained. Data was cleaned and checked after entry to ensure quality before analysis.

3.11 Data Analysis

Data collected from the field were entered into EpiData 6.0 software. The cleaned database was then exported to Stata version 16.0 for analysis. The instrument's internal consistency was checked using a reliability test analysis (Cronbach's alpha analysis). For categorical variables, simple frequencies and percentages were used while for continuous variables, means, median, and standard deviation were used.

The knowledge level of respondents was determined by using responses to 13 knowledge questions. These included availability of FDA guidelines for safe disposal, expired medicines can be disposed off without permission and supervision, FDA approval for

disposal of expired medicine, pay fee for disposal, work with a waste management agency for safe disposal, stakeholders to witness disposal, maintain register, keep separately controlled drugs and any hazardous products, keep expired products in different categories of dosage forms, clearly label products and how the different dosage forms of unwholesome products are disposed off by a waste management agency. The knowledge level variable was a dichotomous variable having two possible answers, given 1 point for correct response and zero point for wrong or uncertain response. Good knowledge was defined as having a score of at least 6 and above for the 13 knowledge items, and poor knowledge was defined otherwise.

To determine compliance level to disposal of expired and unused medicines regulations, responses to 3 compliance questions were used (how will you dispose off expired and unsafe medicines in the three different dosage forms) to grade participants' responses dichotomized as "0" for wrong or uncertain response and "1" for correct response. Compliance was also defined as having a score of three of the total three responses i.e. 100% for the 3 compliance items, and non-compliance for scores below 3.

Binary logistic regression (C.I of 95% and p value <0.05) was used to determine the association between level of compliance, which was the dependent variable and the independent variables. Logistic regression (odds ratio) was used to assess the strength of the association and statistical significance was considered at a P value <0.05 at a confidence level of 95%. Results from this study were displayed in tables and graphs.

3.12 Quality Control

Two (2) research assistants with prior experience with data collection in the health sciences were instructed on how to utilize the data collection tool a week before to the data

collection. The principal investigator supervised the training, as more attention was on how questioning was done and filled. After data collection each day, the team met to validate the data collected by ensuring that all questions were responded to.

3.13 Pre-Testing

The semi-questionnaire was pretested among 10 pharmacies and OTCM shops outside the Ho Municipality. After pre-testing, necessary adjustments were made in the questionnaire. The pretesting was done to identify potential problems with the questionnaire.

3.14 Ethical Consideration

The Ghana Health Service Ethical Review Committee **(Protocol ID: GHS-ERC: 019/02/22)** gave its written clearance before the study began. Approval was sought because the study involved human subjects directly.

3.15 Study Area Approval

The approval certificate that was obtained from the institutional review board was presented to the Volta Regional Pharmacy Council for permission to carry out the study in the Municipality. Permission letter was also obtained from the Volta Regional Pharmacy Council.

3.16 Potential Risk/Benefits of the study

This study involved a face to face interaction and there was a likelihood that you may be exposed to COVID-19 in this era. However, the research assistants/interviewers strictly complied with all the COVID-19 prevention protocols instituted by the Government of Ghana as well as the Ghana Health Service guidelines instructions such as social distancing, the use of face mask etc. Also, it was ensured that the interview was carried out

in a safe environment to protect the study participant and interviewer. There was no direct benefit from participating in this study. However, the findings will inform stakeholders and other researchers and direct decision-making in other to strengthen the compliance to disposal of expired and unused medicines.

3.17 Consenting Process

Verbal and written consent were sought from the participants before they were involved in the study. The participant was informed on the duration and purpose of the study. They were also told that they could resign from the study at any moment and that this would have no negative consequences.

3.18 Privacy/Confidentiality

Special codes were assigned to you, as your name(s) will not be captured in any form. The entered database, which was encrypted with a secret password, was only accessible by the Principal Investigator (PI).

3.19 Data Security and storage

Data was secured and properly managed by the use of special password and encrypted. All information obtained from participants was kept confidential and was not revealed to anyone except where required by law and regulations.

3.20 Voluntary Withdrawal

Respondents were advised that participating in the study was entirely voluntary. They were also assured that if they choose not to participate in the study, they would not be physically or verbally harassed.

3.21 Compensation/payment

Participants would not be paid to take part in the research. Because this effort was exclusively for academic purposes, they would not be paid for their involvement.

3.22 Conflict of Interest

There was no potential for a conflict of interest.

CHAPTER FOUR

4.0 Results

4.1 Demographic Characteristics

Table 4.1 presents demographic characteristics of retail pharmacists and over the counter medicines (OTCM) sellers involved in this study. A total 116 pharmacists and over the counter medicines (OTCM) sellers participated in the study giving a response rate of 92.8%. The majority of the respondents, 40 (34.48%) were within the age range of 30-39 years. Majority, 60 (51.72%) of the respondents were females. The Ewe ethnic group constituted majority 99 (85.34%) of respondents in the study. In terms of education, 56 (48.28%) of the respondents had attained secondary level of education, followed by tertiary education 47 (40.52%), JHS level education 12 (10.34%) and 1 (0.86) respondent had no education. Christians constituted (97.41%) of the respondents in the study. Majority, 67 (57.76%) of the respondents were married, 47 (40.52%) being single. Also, majority 94 (81.03%) were OTCM respondents and 22 (18.97%) were from Pharmacies. More than half 57 (52.3%) had five or less years of working experience.

Table 4.1: Socio-demographic characteristics of respondents

Variable	Frequency (N=116)	Percentage (%)
Age group (years)		
18-20	8	6.90
20-29	35	30.17
30-39	40	34.48
40-49	15	12.93
50-59	12	10.34
60+	6	5.17
Sex		
Male	56	48.28
Female	60	51.72
Ethnicity		
Akan	16	13.79
Ewe	99	85.34
Ga	1	0.86
Educational level		
None	1	0.86
JHS	12	10.34
Secondary	56	48.28
Tertiary	47	40.52
Religion		
Christian	113	97.41
Islam	3	2.59
Marital status		
Single	47	40.52
Married	67	57.76
Divorced	1	0.86
Separated	1	0.86
Type of shop		
Over the counter medicines	94	81.03
Pharmacy	22	18.97
Years of experience		
≤5	59	50.86
>5	57	49.14

4.2.1 Knowledge on the disposal of unwholesome products among retail pharmacies and OTCM sellers

Table 4.2a presents the knowledge of respondents on disposal of expired and unused medicines. Majority 71 (61.21%) of the respondents knew that, the FDA has guidelines for the disposal of unwholesome products. Majority 75 (64.66%) of the respondents agreed that expired and unused medicines should be disposed with permission and supervision from FDA. Majority 71 (61.21%) of the respondents agreed that, approval for disposing expired and unused medicines should be sought from FDA. A significant number 52 (45.22%) did not have knowledge about the need to pay fees for the destruction of expired and unused medicines by FDA whilst only 37 (32.17%) were knowledgeable.

While majority 58 (50.00%) of the respondents agreed that an applicant does not need to work with waste management agency for safe destruction of expired and unused medicines, 45(38.79%) said an applicant needs to work with waste management agency for safe destruction of expired and unused medicines. Most 72 (62.07%) of the respondents did not know that representatives from the Environmental Protection Agency, Customs Excise and Preventive Services (CEPS), Audit Service and the Ghana Police Service shall be present as witnesses where necessary for the destruction of expired and unused medicines.

For this study, majority 62 (53.45%) of the respondents said that FDA regulations expect maintaining a register for expired and unused medicines. Most 92(79.31%) of respondents agreed that expired and unused medicines especially those that fall under controlled drugs and any other hazardous products should be kept separately and 57 (49.14%) responded that FDA regulations expect keeping expired and unused medicines into different

categories by dosage forms. Additionally, 105 (90.52%) said FDA regulations expect unwholesome products be clearly labeled to avoid its unintended use.

Table 4.2a: Knowledge of respondents on disposal of expired and unused medicines

Variable	Frequency (N=116)	Percentage (%)
FDA has safe disposal guidelines		
Do have	71	61.21
Do not have	9	7.76
Don't know	36	31.03
Permission from FDA of to dispose Expired/Unused drug		
Disposed without permission	27	23.28
Disposed with permission	75	64.66
Don't know	14	12.07
Seeking FDA approval for safe disposal		
Do not seek approval	30	25.86
Seek approval	71	61.21
Don't know	15	12.93
Payment of fees for safe disposal		
Do pay	37	32.17
Do not pay	26	22.61
Don't know	52	45.22
Do not need to work with waste management agency for safe disposal		
Do not need	58	50.00
Do need	45	38.79
Don't know	13	11.21
Stakeholders to witness safe disposal		
Do require	29	25.00
Do not require	15	12.93
Don't know	72	62.07
Expecting register Maintenance for safe disposal		
Expect	62	53.45
Do not expect	34	29.31
Don't know	20	17.24
Separate expired and unused medicines for safe disposal		
Separate	92	79.31
Do not separate	3	2.59
Don't know	21	18.10
Categorise different dosage forms for safe disposal		
Categorise	57	49.14
Do not categorise	37	31.90
Don't know	22	18.97
Clearly label expired medicines for safe disposal		
Label	105	90.52
Do not label	3	2.59
Don't know	8	6.90

The study showed that 66 (56.90%) of the respondents did not know how waste management agencies dispose expired and unused solid medicines. All the respondents (100.0%) did not know how waste management agencies dispose expired and unused liquid medicines and a large proportion of respondents 67 (57.76%) knew how waste management agency dispose expired and unused semi-solid medicines as shown in **Table 4.2b**

Table 4.2b: Knowledge of respondents on disposal of expired and unused medicines

Variable	Frequency (N=116)	Percentage (%)
Knowledge on solid disposal by waste management agency		
Do know	50	43.10
Do not know	66	56.90
Knowledge on Liquid disposal by waste management agency		
Do know	0	0.0
Do not know	116	100.0
Knowledge on Semi-solid disposal by waste management agency		
Do know	67	57.76
Do not know	49	42.24
Overall Knowledge Level		
High	74	63.79
Low	42	36.21

4.2.2 Knowledge level on disposal of expired and unused medicines

Figure 4.1 shows level of knowledge on disposal of expired and unused medicines by retail pharmacies and over the counter medicines sellers. Majority (63.79%) of the respondents had high level of knowledge on the disposal of expired and unused medicines.

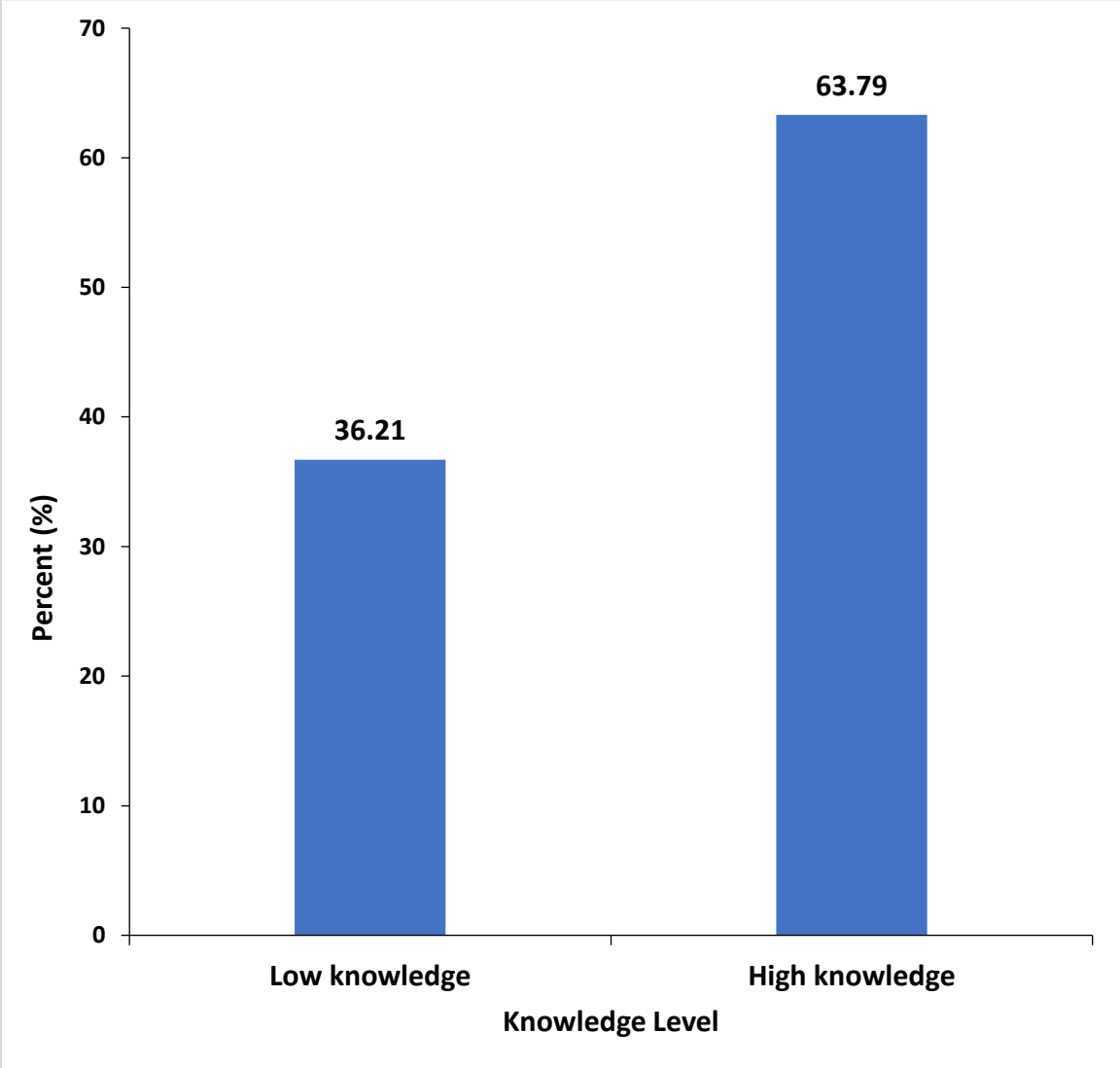

Figure 4.1: Knowledge level on disposal of expired and unused medicines by retail pharmacies and OTCM sellers

4.3.1 Compliance of Disposal Practice by Retail Pharmacies and OTCM Sellers

This study revealed that all 116 (100.0%) the pharmacies or OTCM sellers involved in the study were registered with the pharmacy council. Majority 81 (69.83%) of the respondents had disposed expired and unused medicines. Regarding steps taken to dispose expired and unused medicines, only 8 (6.90%) said they would contact FDA, a significant number 37 (31.90%) said they would burn or bury them while 24 (20.69%) said they would dump at a site. Specifically on the disposal of solid, liquid and semi-solid expired and unused medicines, 53 (45.69%), 53 (45.69%) and 54 (46.55%) respectively indicated they would contact the FDA for necessary disposal. Similarly, on the disposal of solid, liquid and semi-solid expired and unused medicines 33 (28.45%), 25 (21.55%) and 36 (31.03%) said they would use dumping site or dustbin.

Table 4.3: Disposal Practice of Expired and Unused Medicines among Respondents

Variable	Frequency	Percentage (%)
Shop Registered with Pharmacy Council		
Registered	116	100.0
Not registered	0	0.0
Ever Disposed Expired and Unused Medicines		
Ever disposed	81	69.83
Never disposed	35	30.17
Steps Taken to Dispose Expired and Unused Medicines		
Burning/Burying	37	31.90
Contacting FDA	8	6.90
Contacting Supplier	15	12.93
Damping/Dustbin	24	20.69
Waste Management Agency	14	12.07
Have not Disposed Products	13	11.21
Other (Inform owner, don't know etc.)	5	4.31
Disposal of Expired and Unused Solid Medicines		
Burning/Burying	16	13.79
Contacting FDA	53	45.69
Damping/Dustbin	33	28.45
Others (Toilet/sink, contacting supplier etc.)	14	12.07
Disposal of Expired and Unused Liquid Medicines		
Burning/Burying	9	7.76
Contacting FDA	53	45.69
Discard and burn container	11	9.48
Damping/Dustbin	25	21.55
Toilet/sink	12	10.34
Other (Inform owner, don't know etc.)	6	5.17
Disposal of Expired and Unused Medicines Semi-solid		
Burning/Burying	13	11.21
Contacting FDA	54	46.55
Damping/Dustbin	36	31.03
Toilet/sink	7	6.03
Other (Inform owner, don't know etc.)	6	5.17
Overall Compliance level		
Compliant	49	42.24
Non-complaint	67	57.76

Disposal Practice of Expired and Unused Medicines among Retail Pharmacies and OTCM Sellers

Figure 4.2 shows that, 57.76% and 42.24% respectively had poor and good disposal practices of expired and unused medicines by retail pharmacies and OTCM sellers.

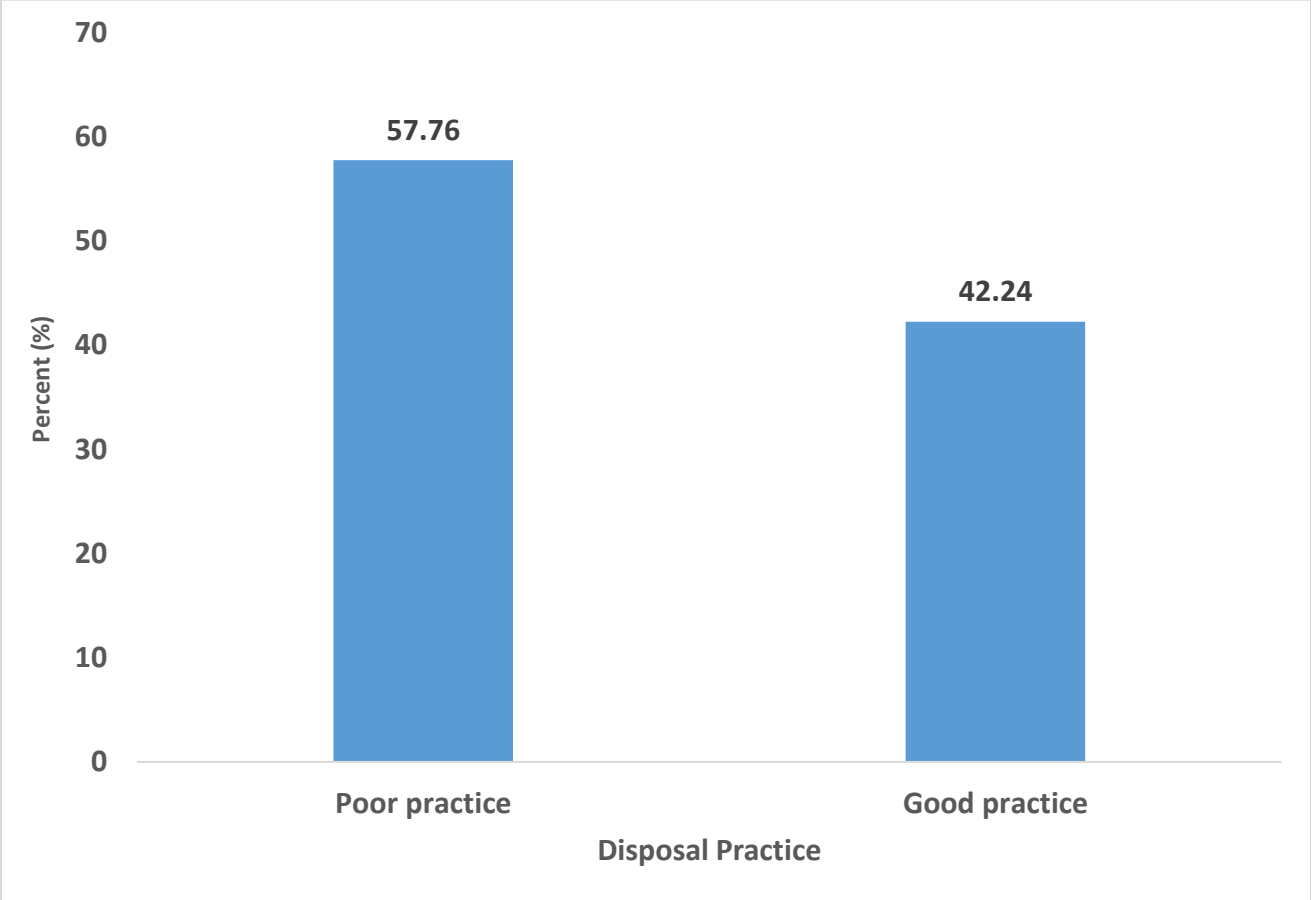

Figure 4.2: Disposal practice of expired and unused medicines by retail pharmacies and OTCM sellers

4.4 Factors associated with disposal practices of expired and unused medicines

Table 4.4 below presents the Chi square associations between compliance to disposal practice of unsafe and unused medicines and background characteristics of respondents. Variables age, sex and ethnicity of respondents were not statistically significantly associated with compliance to disposal practice with chi-squares and p-values ($\chi2$ =5.38, p=0.371), ($\chi2$ =1.00, p=0.318) and ($\chi2$ =1.83, p=0.400) respectively. However, educational level and type of shop were significantly associated with compliance to disposal practice as the chi-squares with p-values ($\chi2$ =10.15, p=0.017) and ($\chi2$ =10.34, p=0.001) respectively

In addition, no statistically significant associations were found between religion, years of experience and marital status and disposal practice as the chi-squares and p-values were ($\chi2$ =0.10, p=0.752), ($\chi2$ =1.21, p=0.272) and ($\chi2$ =2.21, p=0.530) respectively. Knowledge level and ever disposing products were statistically significantly associated with compliance to disposal practice ($\chi2$ =5.04, p=0.025) and ($\chi2$ =4.56, p=0.033) respectively.

Table 4.4: Association between compliance to disposal practice of unsafe and unused medicines and background characteristics of respondents

Variable	Non-compliant n (%)	Compliant n (%)	Total N (%)	χ^2 (p-value)
Age group (years)				
<20	5 (7.46)	3 (6.12)	8 (6.90)	5.38 (0.3712)
20-29	22 (32.84)	13 (26.53)	35 (30.17)	
30-39	23 (34.33)	17 (34.69)	40 (34.48)	
40-49	10 (14.93)	5 (10.20)	15 (12.93)	
50-59	6 (8.96)	6 (12.24)	12 (10.34)	
60+	1 (1.49)	5 (10.20)	6 (5.17)	
Sex				
Male	35 (52.24)	21 (42.86)	56 (48.28)	1.00 (0.318)
Female	32 (47.76)	28 (57.14)	60 (51.72)	
Ethnicity				
Akan	8 (12.12)	8 (16.33)	16 (13.91)	1.83 (0.400)
Ewe	58 (87.88)	40 (81.63)	98 (85.22)	
Ga	0 (0.0)	1 (2.04)	1 (0.87)	
Educational level				
None	1 (1.49)	0 (0.0)	1 (0.86)	10.15 (0.017)
JHS	8 (11.94)	4 (8.16)	12 (10.34)	
Secondary	39 (58.21)	17 (34.69)	56 (48.28)	
Tertiary	19 (28.36)	28 (57.14)	47 (40.52)	
Religion				
Christian	65 (97.01)	48 (97.96)	113 (97.41)	0.10 (0.752)
Islam	2(2.99)	1 (2.04)	1 (2.59)	
Marital status				
Single	29 (43.28)	18 (36.73)	47 (40.52)	2.21 (0.530)
Married	36 (53.73)	31 (63.27)	67 (57.76)	
Divorced	1 (1.49)	0 (0.00)	1 (0.86)	
Separated	1(1.49)	0(0.00)	1(0.86)	
Type of shop				
OTCM	61 (91.04)	33 (67.35)	94 (81.03)	10.34 (0.001)
Pharmacy	6 (8.96)	16 (32.65)	22 (18.97)	
Years of experience				
≤5 years	37(55.22)	22 (44.90)	59 (50.86)	1.21 (0.272)
>5 years	30 (44.78)	27 (55.10)	57 (49.14)	
Ever disposed products				
Never disposed	15 (22.39)	20 (40.82)	35 (30.17)	4.56 (0.033)
Ever disposed	52 (77.61)	29 (59.18)	81 (69.83)	
Knowledge level				
Low	30 (44.78)	12 (24.49)	42 (36.21)	5.04 (0.025)
High	37 (55.22)	37 (75.51)	74 (63.79)	

Table 4.5a and 4.5b presents predictors of disposal practice of respondents. In the bivariate logistic regression model, respondents who had tertiary level of education were 3.38 times more likely to have good disposal practice of unsafe and unused medicines compared to respondents who had secondary education and was statistically significant, [COR=3.38, (95% CI: 1.49, 7.63), P=0.003]. Similarly, respondents at pharmacies were 4.93 times more likely to have good disposal practice of unsafe and unused medicines compared to sellers from OTCM and was statistically significant [COR=4.93, (95% CI: 1.76, 13.80), P=0.002]. Despite not being statistically significant, respondents with more than 5 years' experience in selling were 51% more likely to have good disposal practice of unsafe and unused medicines compared to respondents with 5 or less years' experience, [COR=1.51, (95% CI: 0.72, 3.17), P=0.273]. Again, respondents who had ever disposed unsafe and unused medicines were 58% times less likely to have good disposal practice and is statistically significant, [COR=0.42, (95% CI: 0.19, 0.94), P=0.035]. Respondents with good knowledge level on disposal of unsafe and unused medicines were 2.50 times more likely to have good disposal practice and was statistically significant, [COR=2.50, (95% CI: 1.11, 5.62), P=0.027].

In the multiple logistic regression model, respondents who had tertiary level of education were 2.95 times more likely to have good disposal practice on unsafe and unused medicines compared to respondents who had secondary education and was statistically significant, [AOR=2.95, (95% CI: 1.21, 7.16), P=0.017]. Also, respondents at pharmacies were 3.24 times more likely to have good disposal practice on unsafe and unused medicines compared to sellers from OTCM and was statistically significant [AOR=3.24, (95% CI: 1.07, 9.81), P=0.038].

Respondents who ever disposed unsafe and unused medicines were 65% times less likely to have good disposal practice and was statistically significant, [AOR=0.35, (95% CI: 0.14, 0.88), P=0.025]. Again, respondents who had good level of knowledge on disposal of unsafe and unused medicines were 2.66 times more likely to have good disposal practice on unsafe and unused medicines compared to respondents with poor level of knowledge and was statistically significant, [AOR=2.66, (95% CI: 1.08, 6.59), P=0.034].

Table 4.5a: Predictors of good disposal practice among respondents (Bivariate and Multiple logistic regression

Variable	COR (95% CI) p-value	AOR (95% CI) p-value
Age (years)		
<20	Ref	
20-29	0.98 (0.20, 4.81) 0.985	
30-39	1.23 (0.26, 5.88) 0.794	
40-49	0.83 (0.14, 4.99) 0.842	
50-59	1.66 (0.27, 10.33) 0.583	
60+	8.33 (0.63, 110.02) 0.107	
Sex		
Female	Ref	
Male	0.69 (0.33, 1.44) 0.319	
Ethnicity		
Akan	Ref	
Ewe	0.69 (0.24, 1.99) 0.492	
Ga	-	
Educational level		
None	-	
JHS	1.15 (0.30, 4.33) 0.840	1.40 (0.35, 5.57) 0.640
Secondary	Ref	Ref
Tertiary	3.38 (1.49, 7.63) 0.003 **	2.95 (1.21, 7.16) 0.017 **

Table 4.5b: Predictors of good disposal practice among respondents (Bivariate and Multiple logistic regression

Variable	COR (95% CI) p-value	AOR (95% CI) p-value
Marital status		
Single	Ref	
Married	1.39 (0.65, 2.96) 0.398	
Divorced	-	
Separated	-	
Type of shop		
OTCM	Ref	Ref
Pharmacy	4.93 (1.76, 13.80) 0.002 **	3.24 (1.07, 9.81) 0.038 **
Years of experience		
≤5 years	Ref	
>5 years	1.51 (0.72, 3.17) 0.273	
Ever disposed products		
Never disposed	Ref	Ref
Ever disposed	0.42 (0.19, 0.94) 0.035	0.35 (0.14, 0.88) 0.025 **
Knowledge level		
Low	Ref	Ref
High	2.50 (1.11, 5.62) 0.027 **	2.66 (1.08, 6.59) 0.034 **

Note: ** Indicates statistical significance at 95% Confidence Interval and Ref means base level of reference

CHAPTER FIVE

5.0 DISCUSSION

5.1 Level of Knowledge of retail pharmacies and OTCM sellers

The objective of the study was to assess the level of compliance with FDA and international guidelines for the disposal of expired and unused medicines and associated factors among retail pharmacies and OTCM sellers in the Ho Municipality.

The findings from this study indicated an overall high level (63.79%) of knowledge amongst respondents on disposal of expired and unused medicines. This is however contrary to the findings of the study carried out in Karbala by Albaroodi (2019), who reported poor knowledge among pharmacists. The WHO recommendation for the disposal of semi-solid waste is by encapsulation, where waste materials are packed into non-reactive materials prior to disposal (WHO, 2012). This recommendation was common knowledge among respondents of this study. However, Albaroodi (2019) reported that pharmacists in Karbala, Iraq, said disposal of semi-solid waste was by dumping in the trash, a direct contradiction to the WHO recommendations. Most over the counter medicine sellers and retail pharmacists involved in this study indicated their knowledge on FDA guidelines for disposal of unwholesome pharmaceuticals. This is likely because such guidelines may be available to them. Inconsistent with this finding, however, a study conducted in Nigeria reported that medical facilities had no guidelines or documentation on disposal of expired or unused medications (Michael et al., 2019). High level of knowledge exhibited by respondents of this study was exhibited in their acknowledgement of the need for FDA approval and supervision in disposing off unwholesome medications, among others.

Consequently, the services of waste management agencies can be sought for this purpose. In Nigeria, the National Agency for Food and Drug Administration and Control (NAFDAC) is one such agency, which has provided guidelines on the disposal of unused and expired medications (Michael et al., 2019). The results from this study showed that less than half 50 (43.10%) of the respondents knew how waste management agency dispose expired and unused solid medicines, all (100.0%) did not know how waste management agency dispose expired and unused liquid medicines and majority 67 (57.76%) knew how waste management agency dispose expired and unused semi-solid medicines. This is different from what was found in the study carried out in New Zealand where over 60% of community pharmacist revealed that they believed the contractors burned the pharmaceutical waste obtained from them (Tong et al., 2011). In addition, some pharmacists in Nigeria stated that NAFDAC disposes off outdated pharmaceuticals using incineration or other forms of heat, while 24.7 percent stated that they have no idea how NAFDAC disposes of their expired drugs (Michael et al., 2019). The differences observed in the knowledge level of pharmacist and OTCM sellers on the disposal of expired and unused medicines with other studies could be attributed to differences in the roles and programs played by these governing agencies across various countries in ensuring proper disposal of expired and unused medicines.

5.2 Level of Compliance to the disposal of expired and unused medicines

The findings of this study indicated poor compliance (57.76%) to FDA and international guidelines for the disposal of expired and unused medicines. This finding is consistent with findings from Michael et al. (2019), who reported poor compliance (54.5%) among pharmacists to national guidelines for disposing off unused and expired medications in

Nigeria. Unused and expired medications are classified as “unwanted”, and therefore need to be disposed safely, to avoid harm to the ecosystem (Gidey et al., 2020). In Ghana, the FDA guidelines of disposal of unused and expired medications require that retail pharmacies and OTCM sellers involve their outfit in the disposal process, including seeking for formal approval which is typically accompanied with a prescribed fee, as well as involving a waste management agency to assist in the destruction of the unwanted pharmaceutical product (FDA, 2020). In this study, although all the pharmacies and OTCM sellers involved were registered with the pharmacy council and had involved the FDA at one point or the other, very few contacted them prior to disposal of unused or expired medications. It is imperative to appreciate that because waste products come in varying forms, including liquids, solids, and semi-solids, their disposal must be done appropriately (Gidey et al., 2020). Typically, although international guidelines provided by the WHO require for semi-solids to be disposed by encapsulation, respondents in this study disposed most of their waste through dustbins and dumping sites, similar to findings in Nigeria (Michael et al., 2019) and Iraq (Albaroodi, 2019). Other disposal methods identified in this study include burning and burying. Michael et al. (2019) found similar results, reporting disposal methods such as burning and flushing down the sink or toilet. Further, in Ethiopia, unused or expired medications have been reported to be disposed primarily in household garbage and flushing down the sink or toilet (Ayele & Mamu, 2018). It is worthy of note, that both national and international guidelines do not recommend waste disposal of unused or expired medications in household garbage bins (WHO, 2012). The indiscriminate disposal of expired and unused medicines endangers the environment as these pharmaceutical waste and chemicals flow through sewerages into water bodies and

absorbed into the soil (Peake et al., 2015). Compliance to safe disposal guidelines is essential to protect the environment from pharmaceutical waste which poses many health threats in the future.

5.3 Factors associated with the disposal practices of expired and unused medicines

The study also determined the factors associated with the disposal practices among retail pharmacist and OTCM sellers. The multiple logistic regression model showed that respondents who had tertiary level of education were 2.95 times more likely to have good disposal practice on unsafe and unused medicines compared to respondents who had secondary education. In the study carried out by Zajacova and Lawrence (2018), they reported the influence of education on health practices, indicating that individuals with higher levels of education tend to be more cautious of their health decisions. Thus, knowledge of harmful effects of poor disposal of pharmaceutical waste positions individuals with a higher level of education to be more compliant. Further, higher educational levels can be argued to influence appreciation and understanding of guidelines and rules, which consequently influences compliance. Also, respondents at pharmacies were 3.24 times more likely to have good disposal practice on unsafe and unused medicines compared to sellers from OTCM shops. The role of pharmacists in providing information to the general public on proper disposal of unused and expired pharmaceuticals in the home has been reported by Gidey et al. (2019). Thus, retail pharmacists are generally considered more educated in pharmaceutical knowledge, compared to over-the-counter medicine sellers. This could explain why retail pharmacists were more likely to be compliant to waste disposal guidelines. Also, the *Take Back Of Unwanted Medicine (TBUM) Project* launch by FDA in 2020 where in the Greater Accra region, certain community pharmacy shops

were assigned with receiving unused and expired medicines from the public for proper disposal may have raised pharmacists' perceived responsibility for the disposal of expired and unused pharmaceuticals. (FDA, 2020).

Respondents who ever disposed unsafe and unused medicines were 65% times less likely to have good disposal practice. This is of concern to public health because improper discarding of expired and unutilized medicines has resulted in medication poisoning in adults and children. Similar evidence from a study that explored selected hospitals in Ghana also indicated that there was no separate collection and disposal of pharmaceutical waste at the various hospitals studied as the waste were indiscriminately disposed (Sasu et al., 2012). There is the need for the FDA, Pharmacy Council, the Environmental Protection Agencies, non-Governmental Organizations (NGOs) and other relevant stakeholders to develop cost-effective pharmaceutical waste management system to support retail pharmacies and over the counter medicines (OTCMs) sellers in the Ho Municipality. Respondents who had good level of knowledge on disposal of unsafe and unused medicines were 2.66 times more likely to have good disposal practice on unsafe and unused medicines compared to respondents with poor level of knowledge. This means knowledge acquired has been translated into good practice. There is therefore the need to intensify knowledge on the disposal of expired and unused medicines among retail pharmacies and OTCM sellers. Further, although not statistically significant, respondents who had more than 5 years of working experience were more likely to be compliant on waste disposal practices, compared to those with 5 or less years of experience. According to Isa et al. (2021) adequate adaptation to workplace culture occurs with increasing work hours. Thus, as individuals spend more time at a workplace, the easier they become acquainted with the

workplace culture. Consequently, pharmacists and over the counter medicine sellers gain more experience on disposal of used or expired medicines with increasing work years.

5.4 Limitations of the study

This study is not without limitations. A major limitation is to this study is that it was conducted only in the Ho municipality, thus its generalization for other parts of the country is limited. Also predictors associated with the knowledge and disposal practices of expired and unused medicines were not identified.

CHAPTER SIX

6.0 CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

The overall knowledge of retail pharmacies and over the counter medicines sellers on FDA and international guidelines for the disposal of expired and unused medicines was found to be high (63.3), although compliance to these guidelines was poor (55.0%).

Those with tertiary level of education were more likely to have good disposal practice on unsafe and unused medicines compared to respondents who had secondary education.

Respondents who operated pharmacy shops were more likely to have good disposal practice on unsafe and unused medicines compared to sellers from OTCM shops. Those who have ever disposed unsafe and unused medicines were less likely to have good disposal practice.

Those with good knowledge on disposal of unsafe and unused medicines were more likely to have good disposal practice on unsafe and unused medicines compared to respondents with poor level of knowledge.

6.2 Implications of the Study

The study findings call upon the strategies to strengthen and widen the Take back of Unwanted Medicine (TBUM) project as well as foster the appropriate disposal practice.

6.3 Recommendations

Based on the findings from the study, the following are recommended;

1. The FDA, Pharmacy Council, the Environmental Protection Agencies, non-Governmental Organisations (NGOs) and other relevant stakeholders should

organise frequent refresher training programmes on the disposal of unsafe and unused medicines for retail pharmacies and OTCMs sellers in the Ho Municipality.

2. The FDA and Pharmacy Council should intensify public education on the disposal of unsafe and unused medicines
3. Future studies to investigate the reasons why retail pharmacies and OTCMs sellers do not comply to the FDA and international guidelines on the disposal of unsafe and unused medicines.

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INFORMATION SHEET AND CONSENT FORM

SECTION A: BACKGROUND INFORMATION

Title of Study: Compliance with Food and Drugs Authority and International Guidelines for the Disposal of Expired and Unused Medicines by Retail Pharmacies and OTCM Sellers in the Ho Municipality, Ghana

Introduction: My name is Adjei Mensah Charles, Principal Investigator and I am a Master of Public Health Student at the University of Ghana. The name of the lead supervisor for this study is Professor Francis Anto. He is also a lecturer at the University of Ghana.

General information about the study

We are conducting this study to assess the compliance with Food and Drugs Authority and International Guidelines for the disposal of expired and unused medicines by retail pharmacies and OTCM Sellers in the Ho Municipality. Indiscriminate disposal of unused and expired medicines can cause environmental contamination which leads to health hazards and medication poisoning in adults and children. The information obtained from this study will provide more insight on the knowledge level and disposal practices among retail pharmacies and OTCM sellers and help address factors that influence inappropriate disposal of unused and expired medicines.

Nature of the study: This study involves a face to face interview with you. You have been selected to participate in this study because, you are a retail pharmacies or OTCM seller in Ho Municipality and registered with the Pharmacy Council in Ho Municipality.

Duration/What is involved: For participation in this study, you will be required to spend about 30 minutes. If you decide to participate in the study, this what we would do;

1. The PI or Research assistant will first explain the purpose of the study to you. After that, you will be required to give written consent to participate in the study. In doing so, the PI or Research assistant will give you 2 copies of the approved informed consent form by the ethic committee to sign. You will be given one copy for keep and the PI or Research assistant will take the other copy.
2. After consenting, you will then proceed to answer the research questions. You are required to give your responses without any force.
3. To prevent the spread of COVID-19, we will do this when we visit your facility;

i. The PI or research assistant visiting your facility will wear a clean face mask. The face mask will be worn throughout the interview.

ii. The study respondent will be asked to use a clean pair of nose mask throughout the interview. He/she will be provided with a clean nose mask if they do not have one at the time of visit. The purpose for using the mask will be explained and will be adviced to start use before any interactions. In cases where the study respondents declines to use the mask, we will keep a distance of 2 m (one arm length) before the start of interview. We will explain that it is because of COVID-19 that we want to sit at a distance.

iii. The interview will be done in a well-ventilated area (that is open widow to allow fresh air to freely circulate or under an open shade). Confined air conditioned rooms will be discouraged.

iv. We will not shake hands with you or hug you, as well as spit anywhere within the premises

v. We will use hand sanitizer when we visit, we will also give you some to use periodically preferably 2 to 3 times during the interview

vi. We will use a clean tissue or elbow to cover our faces (nose and mouth) when we sneeze or cough. We will also encourage you to use a clean tissue or elbow to cover our faces (nose and mouth) when you want to sneeze or cough.

vii. We will avoid touching faces our faces (nose, mouth, eyes) with our hands

viii. We will wash our hands with soap under running water immediately we get to our destination from the field. We will ask you to also wash your hands with soap under running water after the interview.

Potential Risk: If you take part in this study, you may feel some discomfort because of some of the questions. Also, in this COVID-19 era, it is possible you can be exposed to an interviewer who unknowingly has the virus. In other to mitigate this occurrence or exposing the participant or interviewer, we will strictly comply to all the COVID-19 prevention protocols instituted by the Government of Ghana as well as the Ghana Health Service guidelines instructions such as social distancing, the use of face mask etc. We will follow this recommendations to ensure that the study is carried out in a safe environment to protect the study participant and interviewer **(Detailed in Point 3)**

Confidentiality

All information obtained from you will be kept confidential and will not be revealed to anyone except where required by law and regulations. Special codes will be assigned to you, as your name(s) will not be captured in any form. The Principal Investigator (PI) will be the only one who will have access to the entered database, which will be encrypted with a special password. This is to ensure that the data is secured and properly managed.

Potential benefits: You will not benefit directly from participating in this study. The information given would be beneficial to the PI for the completion of his Master's degree. In addition, stakeholders and other researchers will use the information to make appropriate decisions to strengthen the compliance to disposal of expired and unused medicines.

Compensation

You will not receive any compensation for participating in the study. You will not be given any cash for participation. Because this work solely for academic purpose.

Freedom to participate and withdraw from the study by the participant

Your participation in this study is completely voluntary. If you do not want to take part in this study, you may withdraw from the study at any time and for any reason. You will not be physically or verbally abused if you decide not to participate in this study. However, your participation is greatly appreciated

Withdrawal from the study by the investigator

The investigator (**Adjei Mensah Charles**) may decide that you discontinues with this study if any of the following happens:

- You develop any illness during the time of the data collection process
- If you are not able to communicate clearly with the PI or research assistant during the interview

The reason why you should not continue participating in this study will be explained to you.

How to get information about the study

If you want any more information at any time during the study please contact:

- The principal investigator Adjei Mensah Charles, University of Ghana

  Contact number: 055 229 9757

For questions or problems about your rights as a research participant please call Nana Abena Apatu, GHS ERC Administrator on **0503539896** or write to The Ethics Review Committee, Ghana Health Service at ethics.research@ghsmail.org

CONSENT FORM

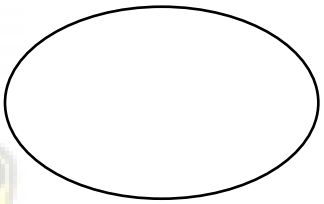
Section C- PARTICIPANT AGREEMENT

" I have read or have had someone read all the above , asked questions , received satisfactory answers regarding participation in this study and am willing to give consent to participate in this study. I will not have waived any of my rights by signing this consent form. Upon signing this consent form, I will receive a copy for my personal records".

_____

Name of Participant

Signature of Participant _____ or



Date _____

INVESTIGATOR STATEMENT AND SIGNATURE

I certify that the participant has been given ample time to read and learn about the study.

All questions and clarifications raised by the participant have been addressed.

Researcher's Name……..

Signature …….

Date: …….

QUESTIONNAIRE FOR THE STUDY

COMPLIANCE WITH FOOD AND DRUGS AUTHORITY AND INTERNATIONAL GUIDELINES FOR THE DISPOSAL OF EXPIRED AND UNUSED MEDICINES BY RETAIL PHARMACIES AND OTCM SELLERS IN THE HO MUNICIPALITY, GHANA

Form Number: ……

Community Name: …….

Date of data collection: ……. /……/……

SECTION A: DEMOGRAPHIC CHARACTERISTICS OF RESPONDENTS

S/N	Questions	Responses	Code
1	How old are you?	…….	Years
2	Sex	1. Male [ ] 2. Female [ ]	
3	What is your religious affiliation?	1. Christian [ ] 2. Islam [ ] 3. Traditional [ ] Others …….	
4	What tribe do you belong to?	1. Ewe [ ] 2. Akan [ ] 3. Guan [ ] Others ……	
5	What is your highest educational attainment?	1. None [ ] 2. Primary [ ] 3. JHS [ ] 4. Secondary [ ] 5. Tertiary [ ]	
6	What is your marital status?	1. Single [ ]	

		2. Married [ ] 3. Divorced [ ] 4. Separated [ ] 5. Widowed	
7	Type of medication shop	1. Pharmacy [ ] 2. OTCM shop [ ]	
8	How long have you been operating as a pharmacist or OTCM seller?	……..	Year(s)
9	Is your pharmacy/OTCM registered with any pharmacy council?	1. Yes [ ] 2. No [ ]	
SECTION B KNOWLEDGE ON THE DISPOSAL OF UNUSED AND UNSAFE MEDICINES			
10	Food and Drugs Authority has guidelines available for safe disposal of unwholesome products	1. Yes [ ] 2. No [ ] 3. Don't know [ ]	
11	Expired and unsafe medicines can be disposed off without the permission and supervision from FDA?	1. Yes [ ] 2. No [ ] 3. Don't know [ ]	
12	Approval for disposing off expired and unsafe medicines should not be sought from FDA?	1. Yes [ ] 2. No [ ] 3. Don't know [ ]	
13	Applicants pay a fee for the destruction of their expired and unsafe medicines with the help of FDA?	1. Yes [ ] 2. No [ ] 3. Don't know [ ]	
14	The applicant does not need to work with any waste management agency for the safe destruction of expired and unsafe medicines?	1. Yes [ ] 2. No [ ] 3. Don't know [ ]	

15	According to the FDA regulations, representatives from the Environmental Protection Agency, Custom Exercise and Preventive Services, Audit service and the Ghana Police service shall be present to witness.	1. Yes [ ] 2. No [ ] 3. Don't know [ ]	
16	In the management of unwholesome product such as expired and unsafe medicines, the FDA regulations do not expect that;		
16a.	Maintain a register for the unwholesome product (expired and unsafe medicines)	1. Yes [ ] 2. No [ ] 3. Don't know [ ]	
16b.	Keeping separately unwholesome products especially products that fall under controlled drugs and any other hazardous products	1. Yes [ ] 2. No [ ] 3. Don't know [ ]	
16c.	Keeping unwholesome products into different categories by dosage forms (e.g. solids, liquids etc.)	1. Yes [ ] 2. No [ ] 3. Don't know [ ]	
16d.	Unwholesome products should be clearly labelled to avoid its intended use	1. Yes [ ] 2. No [ ] 3. Don't know [ ]	
SECTION C DISPOSAL PRACTICES OF UNUSED AND UNSAFE MEDICINES			
17	Have you ever disposed off expired and unsafe medicines?	1. Yes [ ] **2.** No [ ]	

18	What are the steps you take in the disposal of expired and unsafe medicines?		
19	How will you dispose off expired and unsafe medicines in the SOLID dosage form? (such as tablets, capsules, suppositories, pessaries, transdermal patches) (excluding controlled drug)	1. In the rubbish bin [ ] 2. In the sink [ ] 3. In the toilet [ ] 4. Contacting FDA for disposal approval [ ] 5. Others ……..	
20	How will you dispose off expired and unsafe medicines in the LIQUID dosage form? (such as suspensions, elixirs, topical lotions, injections) (excluding controlled drug)	1. In the rubbish bin [ ] 2. In the sink [ ] 3. In the toilet [ ] 4. Contacting FDA for disposal approval [ ] 5. Others ……..	
21	How will you dispose off expired and unsafe medicines in the SEMI-SOLID dosage form? (such as creams)	1. In the rubbish bin [ ] 2. In the sink [ ] 3. In the toilet [ ] 4. Contacting FDA for disposal approval [ ] 5. Others ……..	
22	How does the waste management agency dispose		

	off expired and unsafe medicines?		

22a.	Solid waste	1. By placing medicine in garbage before disposal in landfill [ ] 2. By incineration (or other forms of heat destruction) [ ] 3. By flushing the medicines down the toilet [ ] 4. By flushing the medicines down the sink [ ] 5. Don't know, never heard and seen how the medicines are destroyed 6. Others …….	
22b.	Liquid Waste	1. By placing medicine in garbage before disposal in landfill [ ] 2. By incineration (or other forms of heat destruction) [ ] 3. By flushing the medicines down the toilet [ ] 4. By flushing the medicines down the sick [ ] 5. Don't know, never heard and seen how the medicines are destroyed 6. Others …….	
22c.	Semi-Solid waste	1. By placing medicine in garbage before disposal in landfill [ ] 2. By incineration (or other forms of heat destruction) [ ]	

		3. By flushing the medicines down the toilet [ ] 4. By flushing the medicines down the sick [ ] 5. Don't know, never heard and seen how the medicines are destroyed 6. Others …….	

THANK YOU FOR YOUR TIME

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
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Email: ethics.research@ghsmail.org

My Ref. GHS/RDD/ERC/Admin/App | 22/057
Your Ref. No.

28th February, 2022

Charles Adjei Mensah
Food and Drugs Authority,
PMB, Ho Volta Region

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

GHS-ERC Number	**GHS-ERC: 019/02/22**
Study Title	Compliance With Food and Drugs Authority and International Guidelines for the Disposal of Expired and Unused Medicines by Retail Pharmacies and OTCM Sellers in the Ho Municipality, Ghana
Approval Date	28th February, 2022
Expiry Date	27th February, 2023
GHS-ERC Decision	**Approved**

This approval requires the following from the Principal Investigator

- Submission of a 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.

You are kindly advised to adhere to the national guidelines or protocols on the prevention of COVID -19

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