

**SCHOOL OF PUBLIC HEALTH  
COLLEGE OF HEALTH SCIENCES  
UNIVERSITY OF GHANA**

**ADVERSE DRUG REACTION REPORTING AMONG  
COMMUNITY PHARMACISTS IN THE GREATER ACCRA  
REGION OF GHANA**

**BY**

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LEGON IN PARTIAL FULFILMENT OF THE REQUIREMENT FOR THE  
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## DECLARATION

I, **Johnson Yaw Osei**, declare that except for other people's investigation which have been duly acknowledged, this work is the result of my own original research and this dissertation in part or in whole has not been presented elsewhere for another degree

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Date:.....



## **DEDICATION**

This dissertation is dedicated to my wonderful bestfriend, Ama Sarpomaa Acheampong and to my family; George, Augustina, Enoch and Juliet Osei.



## ACKNOWLEDGEMENT

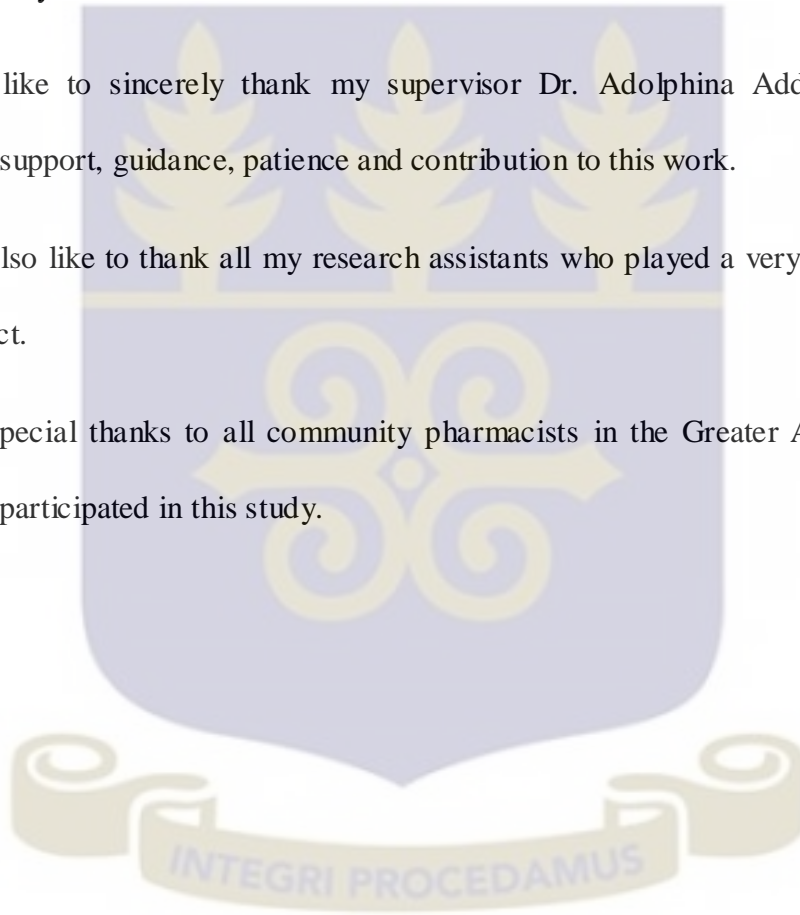
I would like to express my sincere gratitude to the Almighty God, who has made it possible for me to complete this Master of Public Health Programme.

This dissertation would not have been possible without the help of some special people, of which only few can be mentioned here.

I would like to sincerely thank my supervisor Dr. Adolphina Addo-Lartey for her immense support, guidance, patience and contribution to this work.

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Finally, special thanks to all community pharmacists in the Greater Accra region who willingly participated in this study.



## ABSTRACT

**Background:** Adverse drug reactions (ADRs) are a significant cause of mortality and morbidity across the globe. Spontaneous reporting systems are the commonest means of reporting adverse drug reactions with the overall aim of protecting patients from the harmful effects of medications. ADR reporting is however low among healthcare professionals due to several factors. A large number of Ghanaians often visit community pharmacies as the first point of call to access healthcare; however, there is limited knowledge about the factors that influence adverse drug reaction reporting among community pharmacists in Ghana.

**Objective:** This study had the overall objective of assessing ADR reporting among community pharmacists in the Greater Accra Region of Ghana. It also investigated factors affecting reporting and how to improve adverse drug reaction reporting among community pharmacists.

**Methods:** The study was a cross-sectional survey of 210 community pharmacists in the Greater Accra Region. The pharmacists were randomly sampled from community pharmacies across the region. Data collection was by a self-administered questionnaire and all analysis carried out using STATA Version 13.

**Findings:** Two hundred and ten filled questionnaires were returned out of the two hundred and fifty administered, giving a response rate of 84%. Among the 210 pharmacists who took part in the study, 93 had seen a patient with a suspected adverse drug reaction in the past one year. However, only 16% of them reported by filling an

ADR form.

Ninety-six percent of the pharmacists who participated in the study had heard of ADR reporting in Ghana. Eighteen percent of pharmacists had never seen the ADR reporting form. Twenty-four percent did not know where to obtain the reporting form and thirty-seven percent did not know where to submit the form on completion.

The main reason given by the pharmacists who failed to report suspected ADRs was the unavailability of reporting forms (77%). Uncertainty about causality of the ADR (20.5%) and the fact that some of the pharmacists considered the reaction as “normal” with the medication in question (21.8%) were other reasons given. About 56% of pharmacists had excellent knowledge about the reporting system in Ghana. Age, gender and training were all found not to be significantly associated with ADR reporting (p-values, 0.24, 0.49 & 0.40).

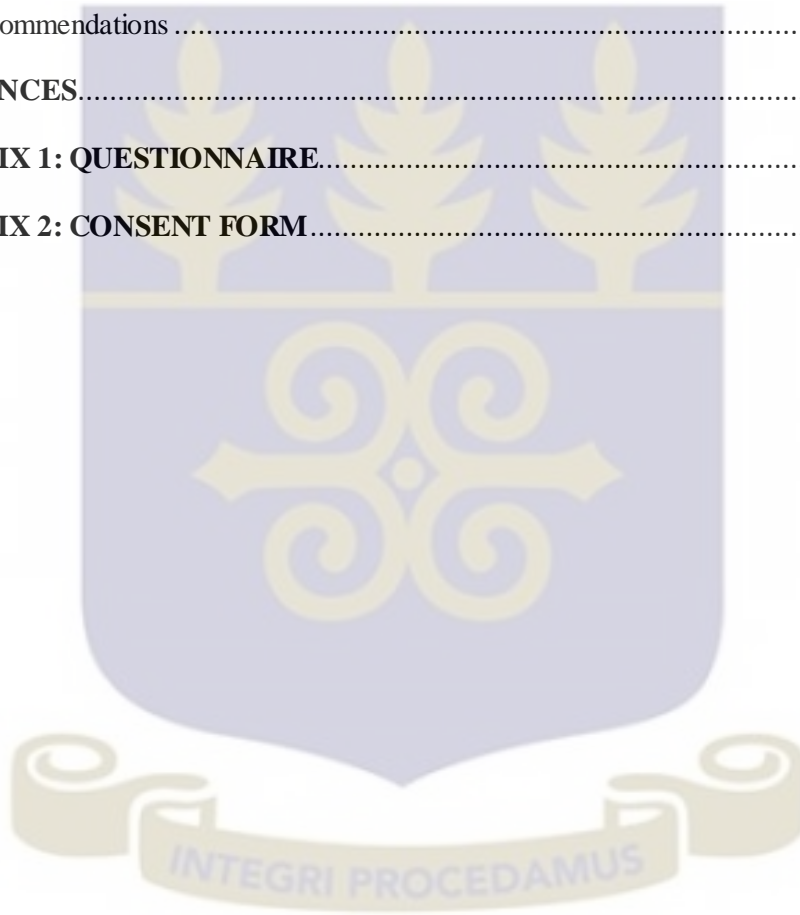
**Conclusion and Recommendation:** ADR reporting by community pharmacists remains low despite the efforts of the Food and Drugs Authority to sensitize pharmacists about its importance. To improve the proportion of reporting, the reporting forms should be made widely available in all pharmacies with continuous professional development in the area of Pharmacovigilance.

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## LIST OF ABBREVIATIONS

ACTs – Artemisinin based combination therapies

ADE – Adverse Drug Event

ADR – Adverse Drug Reaction

FDA – Food and Drugs Authority

ICSR – Individual Case Safety Report

IPAT – Indicator-based Pharmaceutical

NHP – Natural Health Product

NSAIDS – Non-Steroidal Anti-inflammatory Drugs

OTC – Over the Counter

POM – Prescription Only Medicine

PV – Pharmacovigilance

RDT – Rapid Diagnostic Test

SRS – Spontaneous Reporting System

UMC – Upsala Monitoring Centre

WHO – World Health Organization

## DEFINITION OF TERMS

**Adverse Drug Reaction** - A response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function (WHO, 2002)

**Individual Case Safety Report** - an adverse effect report for an individual patient.

**Noise** – this refers to the presence of background phenomenon that interferes with the process of signal detection and confirmation.

**Pharmaceutical Care** – A philosophy of practice in which the patient is the primary beneficiary of the pharmacist's actions (WHO, 2016).

**Pharmacovigilance** - The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems (WHO, 2002).

**Spontaneous Reporting System** – A system whereby case reports of adverse events are voluntarily submitted from health professionals and pharmaceutical manufacturers to the national regulatory authority (WHO, 2002).



## CHAPTER ONE

### INTRODUCTION

#### 1.1 Background

One goal in pharmacotherapy is to optimize patient care by increasing drug efficacy and reducing drug toxicity. However this goal is not always achieved particularly in instances where a patient suffers an adverse drug reaction (ADR). An ADR is defined as ‘a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function’(WHO, 2002) . ADRs are a leading cause of mortality and morbidity globally (Goyal, et al 2013). It is reported that in Europe 20% of ambulatory patients on drug therapy experience ADRs while drug-related problems also account for 10 – 20% of geriatric hospital admissions (Khan, Goyal, & Tonpay, 2015). It is therefore of utmost importance that strong medication monitoring systems are put in place to protect patients from the harmful effects of medications.

Pharmacovigilance is, “The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems” (WHO, 2002). Reporting of ADRs constitutes an integral part of the pharmacovigilance process. Spontaneous Reporting Systems (SRSs) are the commonest means of reporting suspected ADRs in majority of developed countries and some developing countries (Hazell & Shakir, 2006). Spontaneous reporting helps to detect serious and unusual adverse effects previously undetected during clinical trials (Khan et al., 2015).

However, underreporting remains a challenge even in developed countries. The international database on adverse drug reaction reports is kept by the Uppsala Monitoring Centre (UMC, WHO), Sweden. Only an estimated 6-10% of all ADRs are reported to this global database (Gupta et al, 2011). There have been instances where drugs with potential harmful effects have been withdrawn from the market due to spontaneous reporting. This has great financial implications for the Pharmaceutical industry (Khan et al., 2015). In most countries, healthcare professionals like doctors, nurses and pharmacists are responsible for reporting ADRs to their national pharmacovigilance centres. Patients are however able to directly report ADRs to the SRS in some countries like the United States (Vilhelmsson, 2015).

According to Isah et al (2012), in Africa including Ghana self-medication is rampant with easy access to both Over the Counter (OTC) medications and Prescription-only medicines (POMs) in most community pharmacies. Irrational medicine use is rife among both healthcare providers and consumers further increasing the risk of drug-related harm. There is also wide patronage of herbal medications; with estimates of about 80% of the African population resorting to herbal therapies. Polypharmacy, inappropriate pharmaceutical promotional activities and irrational prescribing are common in many African countries (Isah, et al 2012). Community pharmacists could play an important role in the detection, documentation and prevention of ADRs because of the large numbers of patients they see (Smith, 2004). However no studies have been carried out in Ghana among this group of healthcare providers to assess reporting rates. This study therefore investigates the contribution of

and factors influencing the reporting of ADRs by community pharmacists in the Greater Accra region of Ghana.

## **1.2 Problem Statement**

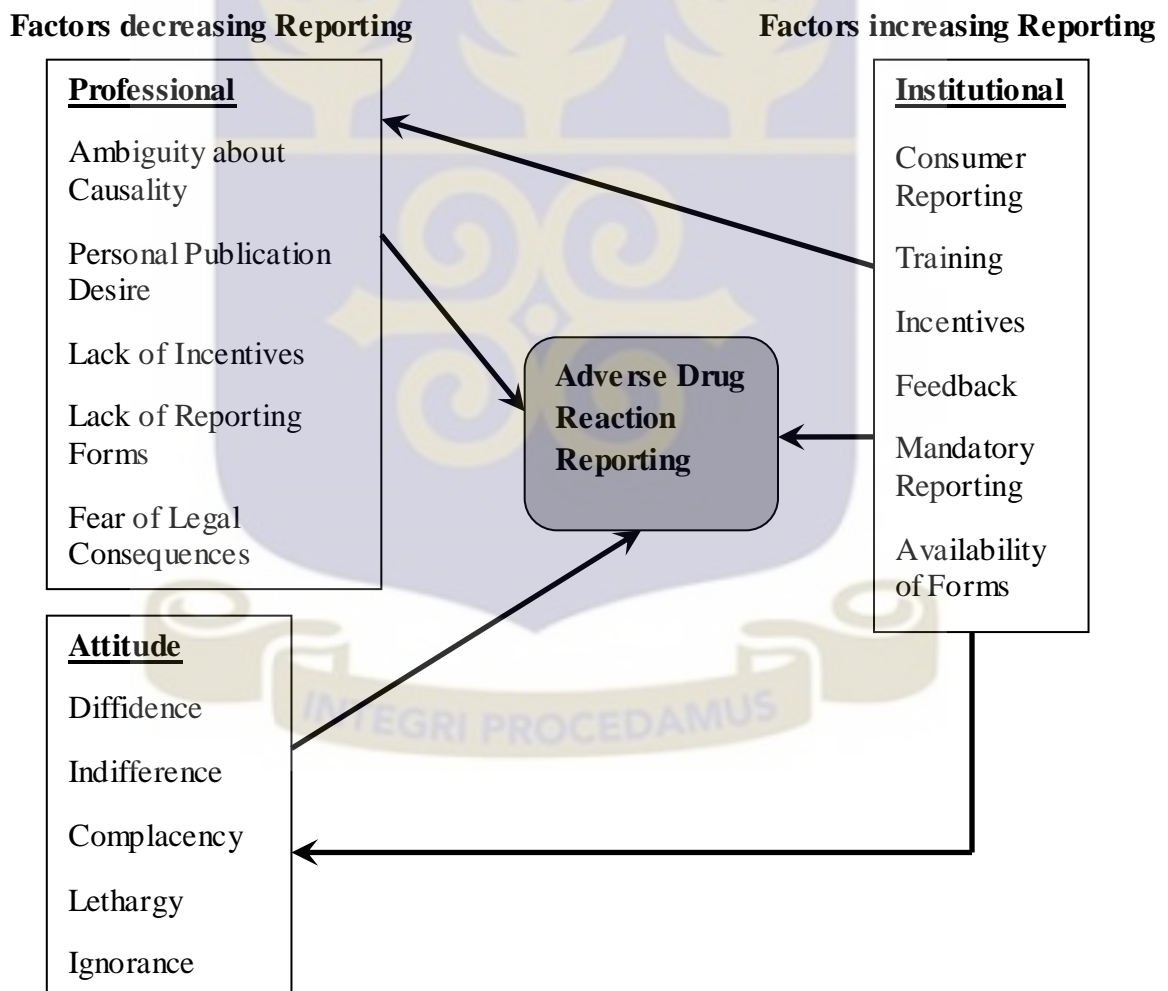
Medications are administered to prevent, cure or manage various diseases ultimately improving health and wellbeing. However they do have the potential to result in undesirable pharmacological effects commonly referred to as Adverse Drug Reactions (ADRs). ADRs may also cause death and were estimated to be among the top ten leading causes of death in the United State (Pirmohamed, 2005). Reporting of these adverse effects forms the basis of pharmacovigilance (Gupta et al, 2011). In Africa, setting up of pharmacovigilance systems has lagged behind that of the developed world with ADR reports from our part of the globe constituting only a small portion of the global database (Isah et al., 2012).

Reporting rates as low as 20% was recorded among doctors in the Greater Accra region in hospital settings (Sabblah, et al 2014). However, little work has been done to assess reporting rates among other healthcare practitioners like nurses and pharmacists. In Ghana most people go to community pharmacies as the first point of call whenever they are feeling unwell either to purchase medication over the counter or to consult a pharmacist (Smith, 2004). Many pharmacies in Ghana, for instance sell a wide range of over the counter pain relievers which contain multiple analgesics. Misuse of these analgesic medications poses a safety risk to the general populace due to their side-effect

profile, potentially compromising patient care. Although the Food & Drugs Authority (FDA) has circulated ADR forms to various community pharmacies, it isn't clear if these forms are being used at all. It is therefore imperative that ADR reporting is assessed among community pharmacists.

### 1.3 Conceptual Framework

Fig 1: Factors affecting ADR Reporting



The conceptual framework is based on the factors that increase ADR reporting and those that decrease it. Inman (1996) as cited by (Gupta et al, 2011), described factors that decrease ADR reporting as the ‘seven deadly sins’ namely; indifference, diffidence, complacency, ignorance, lack of monetary incentives, fear of legal consequences and personal desire to publish cases. Zolezzi & Parsotam, (2005)’s summary of factors decreasing ADR reporting also included lack of reporting forms and ambiguity about causality among others. According to Zolezzi and Parsotam (2005) these factors can be grouped into those related to professional activities and those related to attitude. These factors will be assessed among community pharmacists in our setting to determine if they apply here as well.

Factors that could increase ADR reporting include widespread availability of ADR forms, mandatory reporting, direct patient reporting (consumer reporting), training on pharmacovigilance, incentivizing community pharmacists to report ADRs, prompt feedback on all submitted reports by the national pharmacovigilance centre and mandatory reporting. Most of these factors tend to be institutional and impact directly on the professional and attitudinal factors that negatively affect ADR reporting.

#### **1.4 Research Questions**

- What proportion of community pharmacists in the Greater Accra Region report ADRs?

- What factors influence ADR reporting by community pharmacists in the Greater Accra region?
- How can reporting be increased among community pharmacists?

### **1.5 Justification**

Patient safety is paramount whenever medication is administered. Detection, management, documentation and reporting of ADRs are essential in ensuring patient safety. However, under reporting of ADRs by healthcare providers has been observed globally and in Ghana as one of the challenges to pharmacovigilance systems (Sabblah et al., 2014).

In some developing countries such as Ghana accessibility of pharmacies within the community means most people go to pharmacies to access healthcare. There is the added incentive that they don't have to pay medical consultation fees (Smith, 2004). Community pharmacists are therefore strategically placed to play a leading role in furtherance of ADR reporting and pharmacovigilance. With no studies to date assessing ADR reporting by community pharmacists this study will serve this purpose, describing factors affecting ADR reporting and potential policy interventions to improve ADR reporting among community pharmacists, ultimately enhancing patient care and safety.

## 1.6 Objectives

### 1.6.1 General Objectives

- To assess ADR reporting among community pharmacists.

### 1.6.2 Specific Objectives

- To determine the proportion of ADR reporting by community pharmacists in Accra.
- To identify factors affecting ADR reporting by community pharmacists.



## CHAPTER TWO

### LITERATURE REVIEW

#### 2.1 Adverse Drug Reactions

The World Health Organization (WHO) defines adverse drug reactions (ADR) as 'a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function' (WHO, 2002). An adverse drug event (ADE) is by comparison a medical occurrence temporally associated with the use of a medicinal product, but not necessarily causally related (WHO, 2002). ADEs therefore include ADRs and other events associated with prescribing, dispensing or administration of medications including medication errors (Zolezzi & Parsotam, 2005). These drug-related problems cause significant mortality and morbidity globally (Howard et al, 2006).

A prospective analysis of hospital admissions in the United Kingdom conducted on 18820 patients by Pirmohammed et al (2004) found that hospital admissions related to ADRs had a prevalence of 6.5%. This study also reported a fatality rate of 0.15% from ADRs. ADRs also accounted for 4% of hospital bed capacity. Another prospective analysis was carried out on 3695 in-patients by (Davies et al, 2009). Their findings revealed that approximately one in seven hospital in-patients experience ADRs. They also reported that ADRs increase the length of stay of patients by 0.25 days/patient admission episode.

ADRs have been linked to 4.2-30% of hospital admissions in the United States and Canada as reported by (Khan et al, 2015).

A systematic review was conducted by Howard et al., (2006) to estimate the percentage of preventable drug-related hospital admissions in the United Kingdom. The median percentage of preventable drug-related hospital admissions from their review was 3.7%. The economic burden posed by ADRs on healthcare resources is also immense (Goyal et al., 2013). Data on the prevalence and economic burden of ADRs in Africa generally and Ghana specifically is however limited.

## **2.2 Adverse Drug Reactions: Types**

ADRs may be classified mainly as Type A and Type B reactions. Type A reactions tend to be dose related, resulting from the known pharmacological effect of the medication. They are therefore predictable and potentially preventable. They are more common accounting for about 80% of all ADRs and also tend to be reversible upon dose reduction or withdrawal, affecting elderly patients in particular (Rohilla & Yadav, 2013). Type A reactions are further divided into two; those caused by the primary pharmacology of the drug (amplification of the drug's main therapeutic effect) and those caused by the secondary pharmacology of the drug (a response different from the drug's main therapeutic effect but still rationalisable from the pharmacology of the drug (Pirmohammed et al, 1998).

Type B ADRs are bizarre or idiosyncratic reactions. They tend to be less common than type A reactions and also unpredictable (Routledge, et al 2003). They however tend to be more serious and account for many deaths (Pirmohammed et al, 1998).

Less common types C, D and E have also been identified. Type C ADRs develop upon long term exposure to the drug as a result of drug accumulation. Type D reactions are also termed delayed reactions and manifest after the drug has been used for a prolonged period of time. Type E reactions occur after termination of drug therapy (Rohilla & Yadav, 2013).

### **2.3 Adverse Drug Reactions: Predisposing Factors**

Some of the factors that could increase susceptibility to ADRs include age, multiple drug therapy (polypharmacy) and disease severity (Lobo et al, 2013). Several studies have shown a link between age and ADRs with the elderly being more susceptible. Elderly patients are also more likely to be on multiple medications simultaneously according to Routledge, et al (2003) who reported ADR rates of more than 20% percent among geriatric patients in the United States and Europe. They also assert that most ADRs in the elderly are potentially avoidable due to their predictability.

Polypharmacy is an important risk factor for ADRs. A prospective study conducted in a tertiary hospital in Brazil found polypharmacy was present in almost 80% of ADR reports (Lobo et al, 2013). A retrospective cohort study of ADR reports in emergency departments of Lombardy, Italy was carried out by (Perrone et al., 2014). They found the organ systems most affected by ADRs were skin and subcutaneous tissue, gastrointestinal, respiratory thoracic and mediastinal, and nervous system disorders with polypharmacy being an identified risk factor.

Genetic susceptibility to ADRs has also been investigated by (Pirmohamed, Park, & Park, 2001). Polymorphism in enzyme genes, membrane transporters, drug receptors and mutations in ion channels are some of the genetic factors that could influence the occurrence of ADRs according to their review.

Males and females are physiologically different in certain respects. They are also anatomically different. These differences affect how they react to medications. Gender therefore plays a role in the development of ADRs. Females have been reported to be more susceptible to the development of ADRs compared to males. In females, serious ADRs that have been frequently recorded include neuropsychiatric and cardiovascular effects (Ayub, 2015). According to Ayub (2015), genito-urinary, sex hormones, antineoplastic, anti-parasitic and respiratory drugs are the commonest classes of drugs reported for gender based ADRs.

Social factors have also been implicated in the development of ADRs. Alcohol and tobacco smoke both interfere with the metabolism and effect of certain medications. For instance both alcohol and smoking are risk factors for the development of peptic ulcer. NSAIDs induced ulcer could therefore be a common occurrence in alcoholics and smokers who are prescribed NSAIDs (Ayub, 2015).

## 2.4 Adverse Drug Reactions: Commonly Implicated Medications

All medications have the potential to cause harm and ADRs could occur even with appropriate usage of a medication (Adedeji, Ibraheem, & Fehintola, 2013). Drugs mostly responsible for causing ADR related admissions include diuretics, warfarin, low dose aspirin and other non-steroidal anti-inflammatory drugs (NSAIDs) according to a prospective study in the United Kingdom (Pirmohammed et al, 2004). This finding was consistent with those of Davies et al, (2009) who found opioid analgesics, diuretics, systemic corticosteroids, anti-coagulants (like warfarin) and antibiotics as the most commonly implicated drugs among patients admitted at the Royal Liverpool University Hospital in the United Kingdom. Perrone et al, (2014) found antibiotics were the leading class of medications implicated in ADRs in their retrospective cohort study. Two thousand three hundred and thirty-three representing 21% of all ADRs in this study were associated with anti-biotics. Forty-two percent of all ADR reports submitted by community pharmacists in Nepal were caused by anti-biotics (Palaian, Ibrahim, & Mishra, 2011). NSAIDs followed accounting for 25% of the ADRs. They also found the commonest type of ADR was itching, followed by generalized edema.

ADRs are not limited to orthodox medications alone but could also occur in complementary and alternative medicine. A study conducted in Germany by Susskind, et al (2012) sought to estimate ADR rates caused by anthroposophic medicine, a branch of alternate medicine. This study reported that 4.6% of patients experienced ADRs but symptoms were mild. Ekor, (2014) in his review of herbal medicines reported a growing

trend of adverse reactions associated with their usage. Vohra et al., (2012) conducted an active surveillance of adverse events following concurrent natural health product (NHP) and prescription drug use in community pharmacies in Ontario, Canada. 7.4% of patients on concurrent NHP and prescription drugs reported a possible adverse event.

## 2.5 Pharmacovigilance

Pharmacovigilance is a science that plays an essential role in the reduction of ADRs and is therefore critical for safe and effective clinical practice (Suyagh, Farah, & Farha, 2015). The Thalidomide disaster of the late 1950's and early 1960's led to the setting up of pharmacovigilance systems in the developed world to protect patients from medication related harm (Isah et al., 2012). Signal detection, signal evaluation and risk management are key processes of pharmacovigilance. Signal detection is the first step and is usually achieved by reporting suspected ADRs to the relevant national institutions (Nwokike & Eghan, 2010). The Uppsala Monitoring Centre (UMC) is the WHO Collaborating Centre for International Drug Monitoring. The centre collates ADRs through the pharmacovigilance centres of its member nations. The UMC had 104 member countries and 32 associate members as at 2010. (See fig 2). (Kuemmele et al, 2011). Today, there are one hundred and twenty-five full member countries and twenty-eight associate members (WHO, 2016).

Pharmacovigilance systems in Africa have lagged behind that of the developed world with Africa's first ADR reporting centres being set up in 1992 in Morocco and South Africa (Isah et al., 2012). However, according to Issah et al (2012) there is evidence to

suggest the growth of pharmacovigilance in Africa, with the number of ADR reports rising from 2695 in 2000 to over 25,000 in 2010. An important boost for pharmacovigilance in Africa has been the establishment of a WHO Collaborating Centre for Advocacy and Training in Accra, Ghana (Issah et al, 2012).

In Ghana, the drug regulatory body Food and Drugs Authority (FDA) has responsibility for coordinating pharmacovigilance activities together with the national pharmacovigilance centre. Ghana joined the WHO International program for drug monitoring in 2001 as its 65<sup>th</sup> member. An analysis of pharmacovigilance in Ghana was carried out by Nwokike and Eghan (2010) using an Indicator-based Pharmaceutical Assessment Tool (IPAT). Their study revealed that Ghana generated 155 ADR reports in 2009. This was a long way off the expected number of 2300 reports per year, using a threshold of 100 reports per million population per year. In spite of this, adverse event reporting in Ghana has recorded gradual improvement over time between 2005 and 2009 as shown in fig 3. More effort is therefore needed in this regard to consolidate the gains made (Nwokike & Eghan, 2010).



Fig 2: African WHO members of the program for International Drug monitoring as at 2010

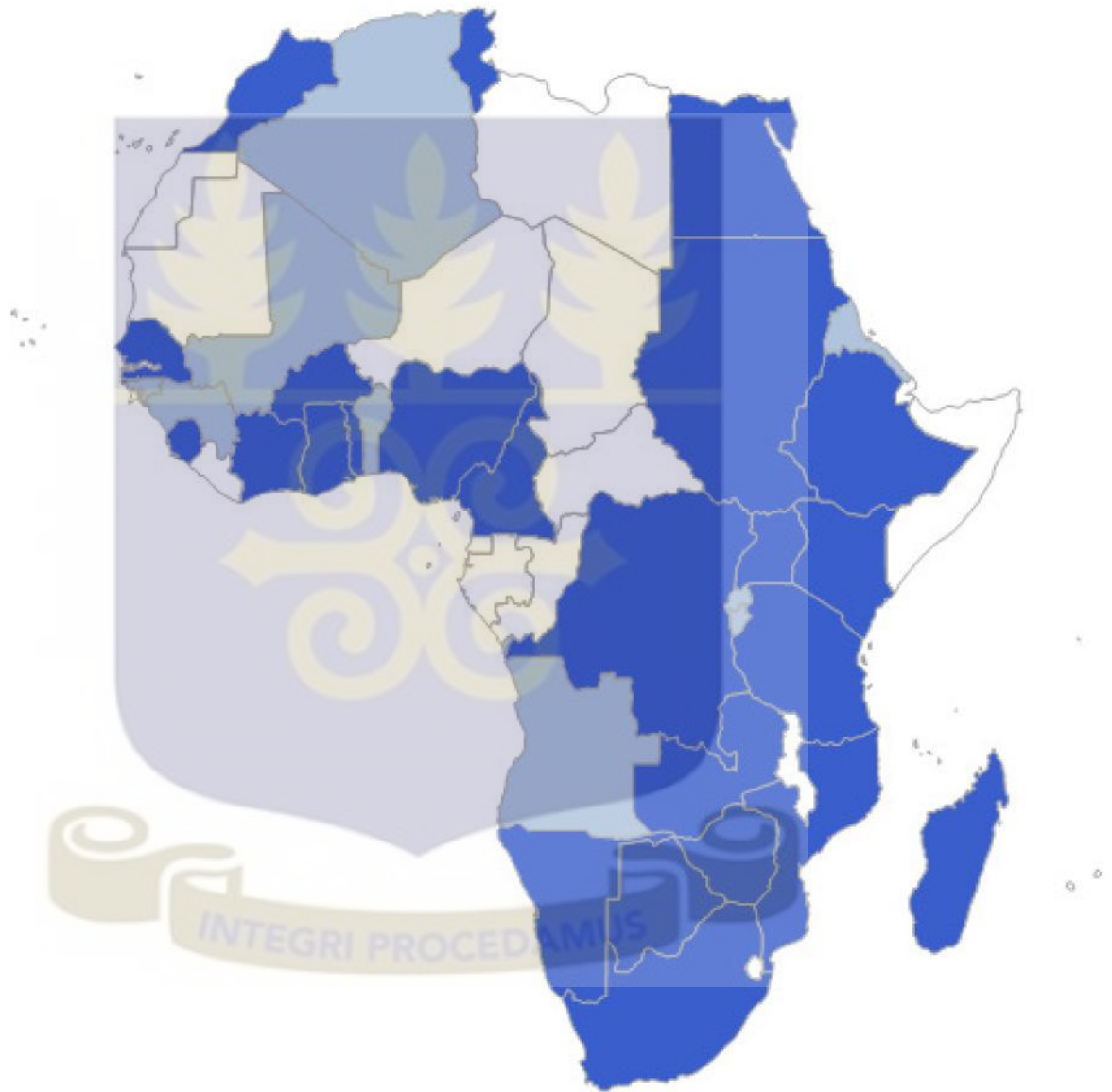
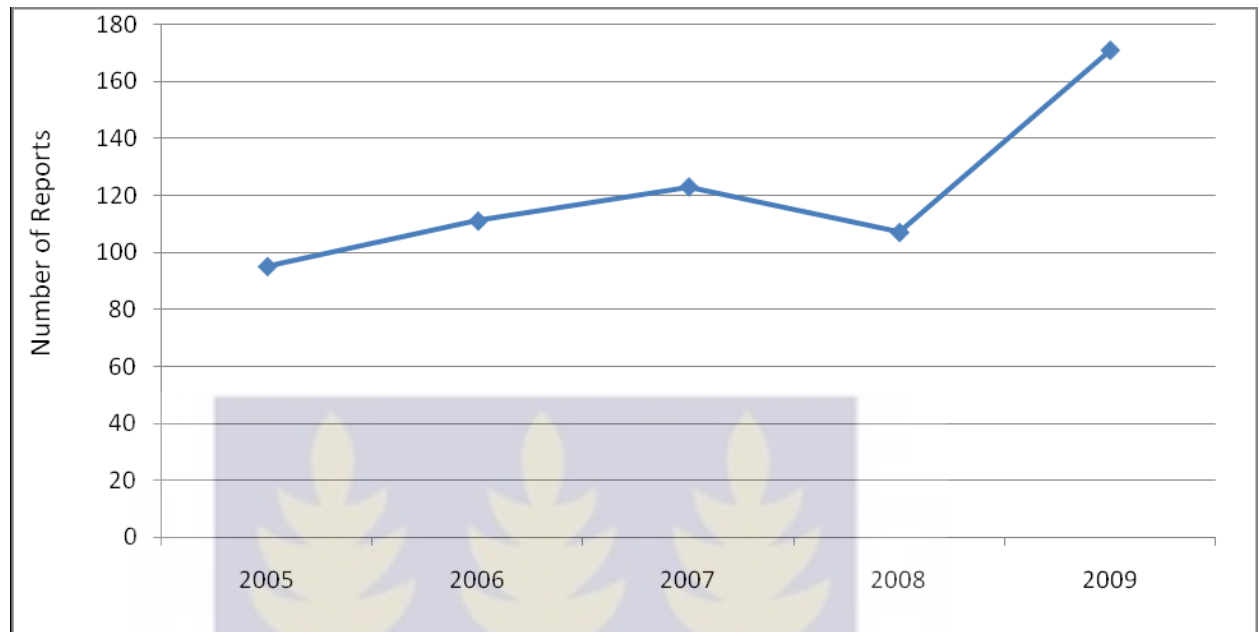


Fig 3: Trend in adverse event reporting in Ghana from 2005 to 2009



## 2.6 Spontaneous Reporting System

Spontaneous Reporting System (SRS) is a system whereby case reports of adverse events are voluntarily submitted from health professionals and pharmaceutical manufacturers to the national regulatory authority (WHO, 2002). It is the most widely used means of reporting ADRs across the globe (Kc, Tragulpiankit, Gorsanan, & Edwards, 2013). It continues to play a vital role in pharmacovigilance, helping to detect ADRs that were missed during clinical trials (Khan, Goyal & Tonpay, 2015). Spontaneous reporting systems have led to the withdrawal of potentially harmful medications from the market (Goyal et al., 2013). The advantages offered by spontaneous reporting system include low cost and relative ease of operation, coverage of all drugs and patient populations, and

non-interference with prescribing habits (Issah et al, 2012; Goyal et al, 2013). In spite of its inherent advantages, the system is beset with widespread under-reporting among healthcare professionals. Only an estimated 6-10% of all ADRs worldwide are reported (Hazell & Shakir, 2006). This has been blamed on a lack of reporting culture among healthcare practitioners (Gupta et al, 2011). In a study to assess global ADR reporting for anti-malarials, Kuemmerle et al, (2011) analysed reports submitted to the WHO global database, Vigibase covering the period of 1968 to 2008. They found only 1.2% of Individual Case Safety Reports (ICSR) had come from low income countries and observed a general trend of underreporting of ADRs associated with anti-malarials including Artemisinin based combination therapies (ACTs).

Underreporting delays the detection of ADRs thereby posing a threat to patient safety (Khan, Goyal & Tonpay, 2015). An estimated 7 million patients had been exposed to fenfluramine prior to the detection of its association with vulvular heart disease and subsequent withdrawal from the market (Goyal et al, 2013).

## **2.7 Factors affecting ADR reporting**

Zolezzi and Parsotan, (2005) summarised factors affecting ADR reporting as; fear of personal and organizational liability, lack of resources for surveillance and reporting, labor-intensive, complex, and time-consuming reporting processes, ambiguity in establishing causality between the medication the reaction, minimal feedback provided to

reporters, no incentives, rewards, or motivation to report, inability to distinguish between significant ADRs and minor ones, surveillance and reporting functions without a leader.

They further reported that factors affecting ADR reporting in hospitals have been classified broadly as predisposing and disabling factors. Knowledge, attitudes and beliefs tend to be predisposing factors while some disabling factors include unavailability of ADR forms and time constraints.

According to Gupta et al, (2011), Inman (1996) described factors inhibiting ADR reporting as the “seven deadly sins”. These are attitudes relating to professional activities and problems related to knowledge and attitudes to ADRs. Those attitudes related to professional activities are **monetary incentives**; reward for reporting, **legal aspects**; fear of legal repercussions and **desire to publish personal case series**. The problems related to knowledge and attitudes to ADRs also include **complacency**; belief that all serious ADRs are documented prior to marketing of the medication, **diffidence**; belief that an ADR would only be reported if there was certainty that it was related to a certain drug, **indifference**; belief that a single case of ADR might not contribute significantly to medical knowledge and **ignorance**; belief that only serious ADRs should be reported and excuses made by professionals (lethargy; procrastination, lack of interest in reporting, lack of time or other excuses).

Jose et al (2013) carried out a cross-sectional survey of community pharmacists in Oman to assess their knowledge, attitude and behavior to ADR reporting. Their result showed that lack of awareness about the reporting protocol and concern that their report might be wrong were the main factors discouraging community pharmacists from reporting.

A similar study conducted in Jordan by Suyagh, Farah, & Farha, (2015) also found that most pharmacists had inadequate knowledge about the concept of pharmacovigilance and spontaneous ADR reporting hence low reporting rates.

A study was conducted in seven hospitals in the holy city of Makkah by Al-hazmi & Naylor II, (2013) among all healthcare professionals. They found that more than half of the respondents didn't know how to report an ADR and lacked access to reporting forms.

A reported 50.4% of those who had access to the forms felt in was too complicated, while 58.1% found it time consuming. Khan, Goyal and Tonpay, (2013) also reported that lack of awareness about ADR monitoring centres and the national pharmacovigilance program were the driving factors behind low reporting rates by Indian dentists. This was consistent with the findings of Al-arifi, Mayet, Wajid, & D, (2015), who reported that over 80% of physicians in a Saudi Arabian hospital did not know about the National Pharmacovigilance Centre.

Gavaza et al., (2011) investigated the influence of pharmacists' attitudes on adverse drug events reporting. Their study included both hospital and community pharmacists practicing in Texas, United States. Majority of the pharmacists found the reporting procedure time consuming and opined that it disrupted their normal workflow. Years of practice, practice setting and number of hours worked were also associated with pharmacists' attitudes towards reporting.

A prospective Indian study among community pharmacists conducted by Prakasam, Nidamanuri, & Kumar, (2012) found that majority of the pharmacists believed most of the adverse events they encountered were very simple and non-serious hence they didn't

report. Adedeji, Ibraheem and Fehintola, (2013) conducted a study in Nigeria among physicians and found that the reason most of them gave for low reporting rates was that they did not consider ADR reporting as a useful tool in preventing mortality or morbidity arising from medication use.

In Ghana, Sabblah et al, (2014) assessed reporting rates among doctors in the Greater Accra Region. The doctors were sampled from both private and government hospitals. Reporting rate recorded among these doctors was 20% with most of them citing unavailability of reporting forms as the main barrier to reporting. It was also observed that doctors in the government sector were 5 times more likely to report an ADR than their counterparts in the private hospitals. Factors affecting ADR reporting among community pharmacists in Africa and Ghana have not been extensively studied.

### **2.8 Improving ADR reporting**

A number of strategies have been introduced over the years to improve ADR reporting rates. These include electronic and online reporting, and introduction of nurse and pharmacist reporting i.e. multi-disciplinary approach (Hazel and Shakir, 2006). Direct patient reporting also termed consumer reporting has also been proposed as an alternate way to increase ADR reporting (Vilhemsson, 2015). According to Vilhemsson, (2015) some concerns have been raised about Consumer reporting. One of such is the potential lack of medical confirmation which makes it difficult to establish a causal link between medication and adverse effect. Another concern is the potential for the media to

influence consumer reports. A third and final concern mostly from health professionals is that consumer reporting would create “noise” and end up being a drain on surveillance systems.

The WHO however advocates for consumer reporting as key to safeguard public health with an estimated 46 countries having consumer reporting systems in place.

Pharmacovigilance training and education of healthcare professionals is one of the strategies proposed to increase ADR reporting rates. Elkalmi, Hassali, & Ibrahim, (2011) assessed the impact of educational intervention for improving pharmacist knowledge in adverse drug reaction reporting in Malaysia. A comparison of community pharmacist’ knowledge before and after the intervention showed significant improvement. Only 7% of participants said they couldn’t successfully report an ADR to the Malaysian authorities post intervention compared to 50% prior to the intervention.

## **2.9 The Role of Community Pharmacists**

Sources of ADR reports by healthcare professionals differ from one country to the next. In Canada and the United States majority of reports originate from pharmacists but in countries like France, Ireland and the United Kingdom physicians are largely responsible for the reports (Zolezzi and Parsotan, 2005). Pharmacy as a profession is primarily concerned with the promotion of safe and rational use of medication. In Ghana, most community pharmacies are concentrated in urban areas particularly in the Greater Accra and Ashanti Region (Smith, 2004). In most

communities, pharmacies are very accessible and stock a wide array of medications ranging from over the counter drugs (OTCs) to prescription drugs (POMs) as well as medical devices. In order to avoid the cost of medical consultation many people visit community pharmacies as the first point of call to access their healthcare needs (Smith, 2004). Community pharmacists are therefore well placed to influence health outcomes among members of the community.

The role of the community pharmacist has changed somewhat over recent years from the traditional dispensing to a more patient-centred approach. This concept of pharmaceutical care as propounded by Hepler and Strand, (1990) is at the core of pharmacy practice in many countries. The term pharmaceutical care encompasses an extended professional role in which pharmacists assume responsibility for pharmaceutical and health outcomes that affect a patient's quality of life; for instance identification and management of potential and actual drug-related problems of the patient (Smith, 2004). Most community pharmacies in Ghana now offer more services that impact directly on patient's health including blood pressure monitoring and Rapid diagnostic tests (RDT) for malaria and other common ailments.

The FDA having recognized the potential of community pharmacists to play an active role in pharmacovigilance has circulated ADR forms to community pharmacies across the country. However, no studies have been conducted in Ghana to assess ADR reporting among community pharmacists or the extent of their participation in pharmacovigilance activities. This study will seek to do this as well as examine factors that influence ADR reporting among community pharmacists.

## CHAPTER THREE

### METHODOLOGY

#### 3.1 Study Design and Location

This study was a cross-sectional survey of 210 community pharmacists within the Greater Accra Region selected randomly. The Greater Accra region was chosen because it has the largest number of registered community pharmacists in Ghana, approximately 1200 according to the Pharmaceutical Society of Ghana. The study population was community pharmacists who had been actively practicing within the past one year. The one year limit was placed on respondents to reduce recall bias.

Data was collected by self-administered questionnaires at the various pharmacies where participating pharmacists worked. Data analysis was by STATA 13 and histograms constructed with Microsoft Excel. The study was carefully explained to all participating pharmacists and assurance given them about the anonymity and confidentiality of the information they submitted.

The population of the Greater Accra region is 4,010,054 (GSS, 2012) with most community pharmacies being privately owned. It is divided into sixteen metropolis, municipals and districts (AMA, 2014).

### 3.2 Study Variables

The dependent variable for the study was adverse drug reaction reporting. Important independent variables that were considered include; knowledge about ADR reporting procedure, availability of ADR forms, training on pharmacovigilance and ADR reporting among others. The table below shows a list of independent variables and indicators for their assessment.



Table 1: Independent Variables and their Indicators

Independent Variables	Indicator
Knowledge about ADR reporting procedure	<ul style="list-style-type: none"> <li>• Awareness of ADR reporting system in Ghana</li> <li>• Where to obtain ADR form</li> <li>• Where to submit form upon completion</li> </ul>
Availability of ADR forms	<ul style="list-style-type: none"> <li>• Presence or absence of ADR forms in the facility</li> </ul>
Training in pharmacovigilance and ADR reporting	<ul style="list-style-type: none"> <li>• Previous participation in any training program of the National Pharmacovigilance Centre on ADR reporting</li> </ul>
Years of Practice	<ul style="list-style-type: none"> <li>• Years of active community pharmacy practice</li> </ul>
Workload	<ul style="list-style-type: none"> <li>• Average number of patients seen per day.</li> </ul>
Age	<ul style="list-style-type: none"> <li>• Years</li> </ul>
Sex	<ul style="list-style-type: none"> <li>• Male or Female</li> </ul>

### 3.3 Sample Size Estimation

The sample size was calculated using the formula;

$$n = Z^2PQ/d^2$$

where, n = sample size;

Z = Z statistic for a level of confidence (at 95% Confidence Interval)

P = expected prevalence

Q = complement of P and

d = precision (fixed at 5%)

The prevalence of ADR reporting among physicians in the Greater Accra Region of Ghana as reported by Sabblah et al (2014) was 20%. Hence assuming expected prevalence among pharmacists will be the same as in physicians i.e. P of 20% (i.e. 0.2) of ADR reporting in the region among community pharmacists, with precision, d of 0.05 at 95% confidence interval (Z- value being 1.96), the calculated sample size was 246. Q is 0.8.

i.e.  $\frac{(1.96^2) \times (0.2) \times (0.80)}{0.05^2}$ , giving us the figure of approximately 246.

This sample size exceeds 5% of the population of community pharmacists in the Greater Accra Region (i.e. approx 1200); hence Cochran's (1977) correction formula will be used to calculate the final sample size;

$$n_1 = \frac{n_0}{(1+n_0/\text{population size})}, \quad \frac{246}{(1+246/1200)}, \text{ giving us } 204.$$

Where population size is 1200 and  $n_0$  = required sample size is 246  
 $n_1$  = corrected sample size because sample > 5% of population.  
 The minimum sample required for this study was therefore 204.

### 3.4 Sampling

The number of community pharmacists required was 204; however a sample size of 250 was used to cater for non-response. The pharmacists were therefore sampled from 250 community pharmacies located in the Greater Accra Region of Ghana. The community pharmacies were selected by simple random sampling. A list of 1048 pharmacies representing all registered community pharmacies in the Greater Accra was obtained from the Pharmacy Council of Ghana. These pharmacies were arranged in alphabetical order and duly numbered in the Pharmacy Council database. A set of 250 random numbers between 1 and 1048 was generated using computer software. Pharmacies whose numbers were generated by the software out of the total 1048 were included in the study.

For a community pharmacist to participate in this study, the inclusion criteria was that he/she must have practiced community pharmacy within the past one year at least.

Pharmacists who hadn't been involved in community pharmacy practice in the past one year were excluded from the study.

### **3.5 Data Collection Techniques and Tools**

Data collection was carried out in June, 2016 after ethical clearance had been granted by the Ethical Review Board of the Ghana Health Service. A semi-structured questionnaire was administered to participating community pharmacists at the different pharmacies in which they practiced.

The questionnaire was four pages long and comprised of four sets of questions, under four sections i.e. sections A, B, C and D. Section A consisted of demographic information of the community pharmacists. Knowledge about the ADR reporting process was under section B. Factors affecting ADR reporting and ways of improving ADR reporting were under sections C and D respectively. (see Appendix 1)

The questionnaires were delivered to the pharmacists at their working posts. All participating pharmacists were given a short overview of the study, taken through how to fill the questionnaire and given assurance of confidentiality. They were encouraged to fill the questionnaires right away for collection. Those who could not fill the questionnaire immediately were however afforded a maximum of three days within which to complete it.

### **3.6 Quality Control**

The study questionnaire was pretested in the Ashanti Region to determine its suitability for this study. Pretesting resulted in a few corrections, rewording of various sections of the questionnaire. Research assistants were trained on how to administer the

questionnaire and solicit information from respondents in order to ensure uniformity throughout the conduct of the study.

### **3.7 Data Processing and Analysis**

Data analysis was done using STATA Version 13. Demographic information obtained about the participating pharmacists was described using descriptive statistics (frequency tables, histograms etc)

The association between the dependent variable ADR reporting and the independent variables was tested using Chi square test and simple logistic regression. Multiple regression was then be used to test the strength of association between variables that proved significant under the Chi square test. The results were expressed as p-values, odds ratios and confidence intervals. A p value  $<0.05$  was considered statistically significant.

Four questions were used to assess the knowledge of community pharmacists on ADR reporting in Ghana. These were if they had ever heard of the reporting system, ever seen the reporting form, knew where to obtain ADR forms and whether they knew where to submit the form after being able to complete it. A grade of 1 was assigned to each of these four questions. The responses obtained were coded on a scale of 0 to 4. Pharmacists answering all four questions in the affirmative hence a score of 4 were deemed as having excellent knowledge of the reporting system. A score of 3, 2, 1 and 0 were rated good, average, poor and no knowledge of the reporting system respectively.

The proportion of community pharmacists reporting ADRs was obtained by dividing the number of community pharmacists who had seen an ADR within the past year and reported by the number of community pharmacists who had seen an ADR within the past year.

The factors affecting ADR reporting among community pharmacists were assessed based on multiple responses to questions like availability of reporting forms, time constraints etc. Measures that could improve reporting rates were also assessed in the same manner through multiple responses to questions like need for incentives, simplification of reporting forms and procedure etc.

### **3.8 Ethical Considerations**

Ethical approval was sought from the Ghana Health Service Ethical Review Board of the Ghana Health Service for the conduct of the study. Informed consent was obtained from all community pharmacists prior to their participation in the study. Permission was also sought from the managers of the various pharmacies prior to delivery of the questionnaires to the community pharmacists.

#### **3.8.1 Potential Risks and Benefits**

The procedures involved in this study were non-invasive and caused no physical discomfort to participants. There was no compensation paid to consenting pharmacists, either monetary or in kind. This study could result in greater protection and safety of all

persons who patronize community pharmacies to access medication, ultimately enhancing the quality of pharmaceutical care delivered by the participating pharmacists.

### **3.8.2 Consenting Process**

Informed consent was sought from all participating community pharmacists and their names kept confidential. The purpose of the study and all implications of participating were explained to them before signing of the consent form.

### **3.8.3 Confidentiality and Voluntary Withdrawal**

Participation in this study was voluntary and all participating pharmacists were free to refuse to answer any individual question or all the questions. They could withdraw from the study at anytime if they so wished. All information provided on the questionnaire was held in strict confidence and not shared with anyone who wasn't part of the study team.

### **3.8.4. Data Storage and Usage**

All study materials were stored by the principle investigator, Mr. Johnson Yaw Osei of the School of Public Health, University of Ghana, Legon. The materials were locked in a secure cabinet at the School of Public Health. All electronic files were stored on the laptop of the principle investigator and pass word protected. Only members of the research team had access to the data.

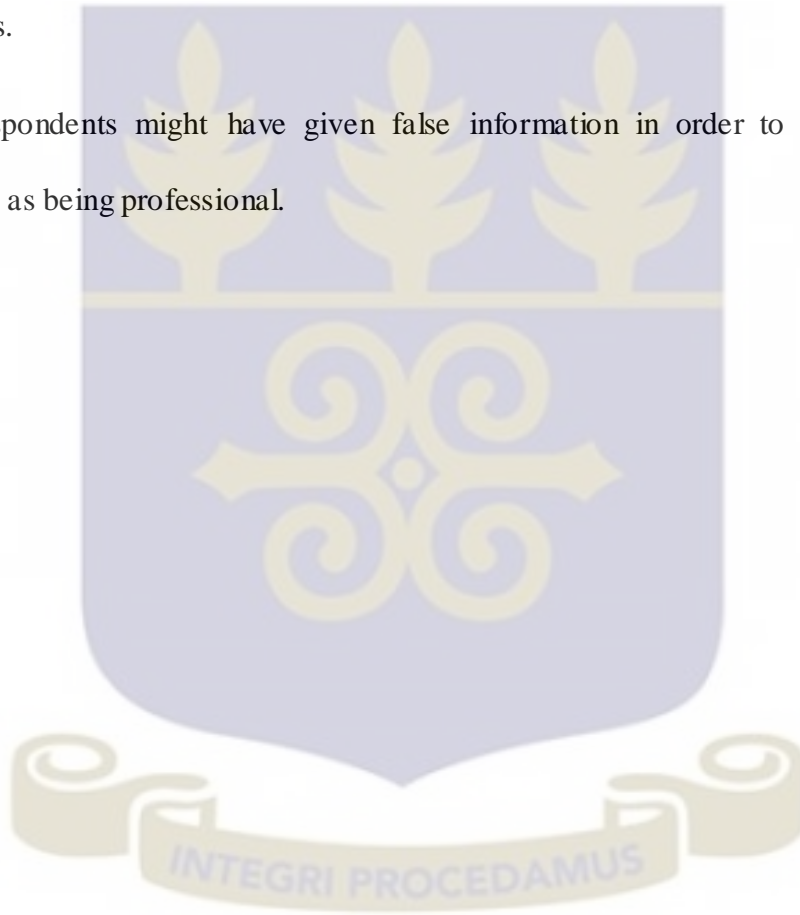
Results obtained from this study would be made available to the Food and Drugs Authority (FDA) so that issues relating to ADR reporting will be addressed to improve reporting rates among community pharmacists. Results would also be sent by mail to all participating pharmacists.

There was no conflict of interest on the author's part.

### **3.9 Limitations of the Study**

This study might have been affected by recall bias as some of the community pharmacists were not able to accurately remember if they had encountered any ADRs. However they were asked about ADRs they had encountered in the past year only in order to reduce recall bias.

Some respondents might have given false information in order to look good or be perceived as being professional.



## CHAPTER FOUR

### RESULTS

Two hundred and ten community pharmacists spread out throughout the Greater Accra region completed the questionnaire. They were sampled from pharmacies within the various districts of the region. About 75 of the pharmacists were sampled from the Accra Metropolis, with about half that number from the Tema Metropolis. About 50 were located in the Ga East, Ga Central and Adenta Municipal Districts. The rest were from Ga South, Ledzokuku-Krowor and Ashaiman Municipal Districts. The pharmacists were made up of fifty-four percent male pharmacists and forty-six percent female pharmacists. The mean age of participating pharmacists was 32 years (SD10.3). The youngest reported age was 23 years while the oldest was 71 years (Table 2).

The average number of years practiced was 6 years (SD8.9), ranging from 1 year to 40 years. Ninety-six percent of respondents were Christians while four percent (8) were Moslems. Seventy eight (37%) of the respondents were married while one hundred and thirty-one (62%) were single.

The average number of patients seen per day by each pharmacist was approximately 60 patients. The respondents had practiced for an average of six years. The study showed that age was not a significant determinant of adverse drug reaction reporting ( $X^2= 5.46$ ,  $p\text{-value}=0.243$ ). Sex ( $X^2= 0.48$ ,  $p\text{-value}=0.490$ ) and religion ( $X^2= 0.39$ ,  $p\text{-value}=0.531$ ) were also not significantly associated with ADR reporting. Community pharmacists who saw more than fifty patients per day were just as likely to report an ADR as their colleagues who saw fewer than fifty patients ( $X^2= 0.01$ ,  $p$ -

value=0.991). Marital status however was significantly associated with ADR reporting, with singles being three times more likely to report an ADR compared to married pharmacists ( $X^2= 4.23$ , p-value=0.04). (Table 3).

Table 2: Background Characteristics of Pharmacists in the Study (N=210)

Background Characteristics		Frequency	Percentage
<b>Sex</b>	Male	114	54
	Female	96	46
<b>Age</b>	<30	127	60.48
	30 – 39	43	20.48
	40 – 49	21	10.00
	50 – 59	12	5.71
	60+	7	3.33
<b>Religion</b>	Christian	202	96.2
	Moslem	8	3.8
<b>Marital Status</b>	Married	78	37.1
	Single	131	62.4
	Divorced	1	0.5
<b>Years of Practice</b>	>2years	98	46.7
	≤2years	112	53.3
<b>Training on ADR reporting</b>	Trained	139	66.2
	Untrained	71	33.8
<b>Number of patients Seen per day</b>	≤50	133	63.3
	>50	77	36.7

Table 3: Association between Background Characteristics and ADR Reporting (N=210)

Background Characteristics		X <sup>2</sup> (df), p-value	Crude OR, CI95%	
<b>Sex</b>	Male		1.00	
	Female	0.48(1), 0.490	0.68	0.22 – 2.06
<b>Age</b>	<30		1.00	
	30 – 39		4.35	0.52 – 36.28
	40 – 49	5.46(4), 0.243	0.36	0.74 – 1.77
	50 – 59		0.87	0.88 – 8.63
	60+		1.00	
<b>Marital Status</b>	Married		1.00	
	Single	4.23(1), 0.04	3.18	1.02 – 9.12
<b>Years of Practice</b>	>2years		1.00	
	≤2years	0.64(1), 0.423	1.58	0.51 – 4.86
<b>Training on ADR reporting</b>	Trained	4.16(1), 0.041	0.22	0.41 – 1.04
	Untrained		1.00	
<b>Number of patients seen per day</b>	>50		1.00	
	≤50	0.01(1), 0.911	0.93	0.03 – 2.90
<b>Knowledge</b>	None		1.00	
	Poor		1.00	
	Average	8.27(4), 0.082	2.93	0.34 – 25.21
	Good		1.00	
	Excellent		1.00	

In the multivariate logistic regression, factors such as marital status, training and knowledge in ADR reporting turned out not to be statistically significant determinants of ADR reporting. (Table 4)

Table 4: Determinants of Adverse Drug Reaction Reporting

<b>Variables</b>	<b>Adjusted OR</b>	<b>p-value</b>	<b>95% CI</b>
Marital Status	2.28	0.193	0.66 – 7.89
Training	2.18	0.378	0.39 – 12.28
Knowledge	2.00	0.551	0.20 – 19.67

#### **4.1 Adverse drug reaction reporting by Community Pharmacists in Accra**

Among the two hundred and ten responding community pharmacists, one hundred and thirty-nine (66.2%) had ever been trained on Pharmacovigilance and ADR reporting. Ninety-three (44%) of the pharmacists had seen a patient with an ADR within the past one year. However, only fifteen of them had reported it by filling an ADR form. The ADR reporting prevalence among community pharmacists in the Greater Accra region was therefore sixteen percent (16%). Of the fifteen pharmacists who had reported the suspected ADR in the past one year, 13 (86%) had received training and education on Pharmacovigilance and ADR reporting.

The main reason given by the pharmacists who failed to report suspected ADRs was the lack of reporting forms (77%). Only thirty-four percent of all respondents in the study had the reporting forms available in their facilities. Uncertainty about causality (20.5%) and the fact that the pharmacists considered the reaction as “normal” with the medication in question (21.8%) were the other leading reasons given. (Figure 4)

Among the ninety-three pharmacists who had reported an adverse drug reaction, antibiotics were the leading group of medications associated with the ADRs (50%). This was followed by analgesics (31.52%). One pharmacist had reported an ADR associated with an anti-coagulant. Other groups of medications mentioned in connection with reported ADRs included anti-malarials and anti-helminthics constituting 17.39%. (See Fig 5)

Fig 4: Reasons for failure to report Adverse Drug Reactions by community pharmacists.

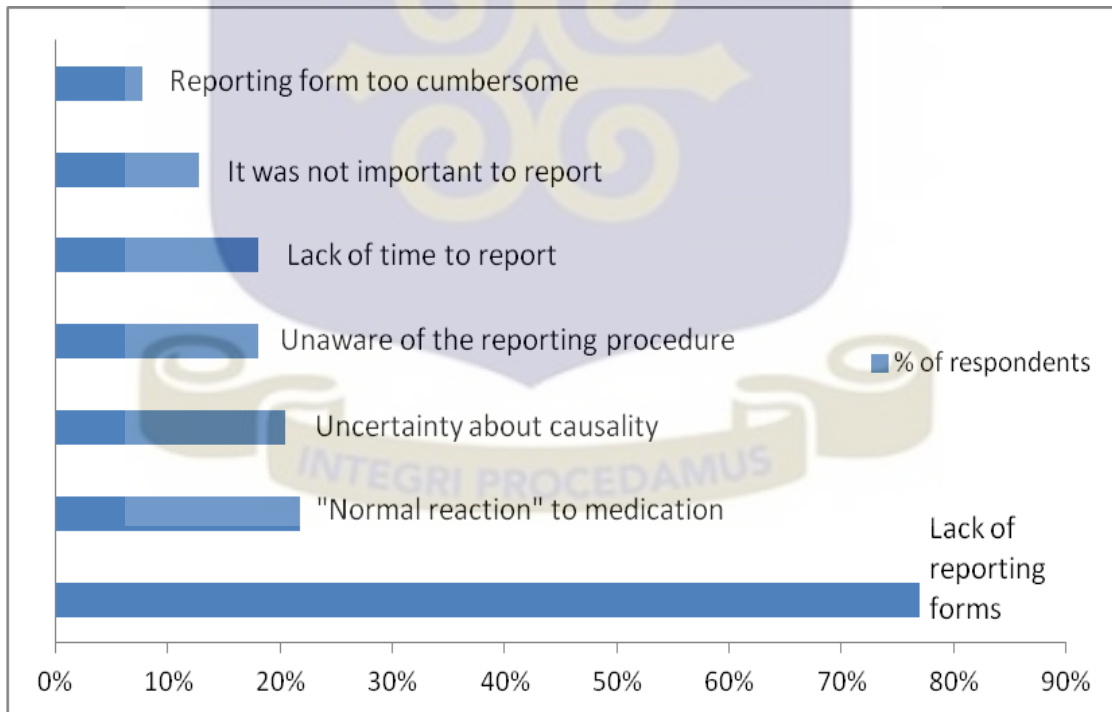
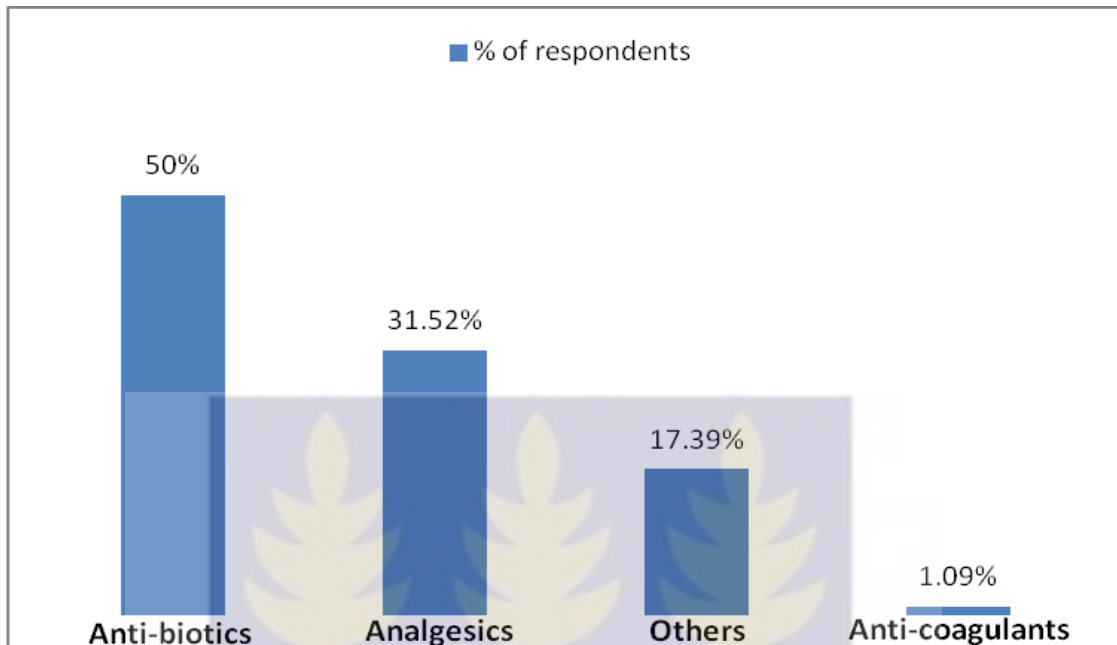


Fig 5: Medications commonly associated with ADRs



#### 4.2 Perceived Factors Contributing to Underreporting of ADRs

One hundred and thirty-seven (66%) of the pharmacists were of the view that unavailability of the reporting forms was a reason why ADRs were underreported. Other major reasons were ignorance about the reporting procedure and how to obtain ADR forms (49.5%) and heavy workload and lack of time (42.9%).

Lack of confidence in the reporting system was another view that came to the fore front. Sixty-six pharmacists representing 31% of respondents expressed this view. They disclosed that they were not certain ADR reports they submitted would be thoroughly investigated by the National Pharmacovigilance authority to develop necessary regulatory actions.

Some pharmacists provided additional reasons for not reporting ADRs, including insufficient patient awareness about ADRs. This consequently prevented patients from reporting ADRs to their pharmacist for onward submission to the FDA. (Table 5)

#### **4.3 Knowledge about the Reporting System**

Two hundred and one (96%) of the pharmacists who participated in the study had heard of ADR reporting in Ghana. Thirty-eight (18%) of pharmacists had never seen the ADR reporting form. Fifty (24%) pharmacists did not know where to obtain the reporting form and seventy-eight (37%) did not know where to submit the form on completion.

There were four questions intended to measure the knowledge of pharmacists about ADR reporting, namely; awareness of the reporting system, having seen the reporting form, how to obtain the form and where to submit it upon completion. One hundred and nineteen pharmacists, representing 57% answered all four questions correctly which meant they had excellent knowledge of the reporting system. Twenty eight (13%) of the pharmacists had average knowledge while eight (4%) of pharmacists had no knowledge whatsoever about the ADR reporting system in Ghana. (Table 6)

Table 5: Factors Perceived Contributes to Underreporting of Adverse Drug Reactions

<b>Factors</b>	<b>Frequency</b>	<b>Percent</b>
Heavy workload and lack of time	90	42.9
Unavailability of reporting forms	138	65.7
Ignorance of reporting procedure and how to obtain forms	104	49.5
Ignorance about the need to report ADRs	76	36.2
All ADRs are documented before allowed onto market	13	6.2
Uncertainty about causality	54	25.7
Fear of legal consequences	52	24.8
Lack of confidence in the reporting system	66	31.4
Fear of negative impact on drug manufacturer	18	8.6
Fear of negative publicity for my pharmacy	51	24.3
Consumers who suffer an ADR should be responsible for reporting	28	13.3
Lack of reward for reporting ADRs	43	20.5
It is not part of my professional responsibility to report ADRs	2	1.0
Others	9	4.3

Table 6: Knowledge of Pharmacists about the Reporting System in Ghana (N=209)

Knowledge	Value	Frequency	Percentage
None	0	8	3.83
Poor	1	16	7.66
Average	2	28	13.4
Good	3	38	18.18
Excellent	4	119	56.94

Eighty-six (93%) of the pharmacists who had reported an ADR in the past one year had excellent knowledge about the reporting system. This suggests that knowledge of the reporting system was a strong predictor for ADR reporting. However, the Chi-square test showed no significant association between pharmacist knowledge of the reporting system and their reporting of ADRs ( $X^2=8.27$ , p-value 0.082). There was also no significant association between knowledge and age of respondent ( $X^2=11.87$ , p-value 0.753).

#### 4.4 Strategies to Improve ADR reporting

One hundred and twenty-two (58%) of the pharmacists were in favor of the institution of a reward or incentive package to improve ADR reporting. Of this number, fifty-seven (47%) of them considered a letter of acknowledgement per report submitted as adequate

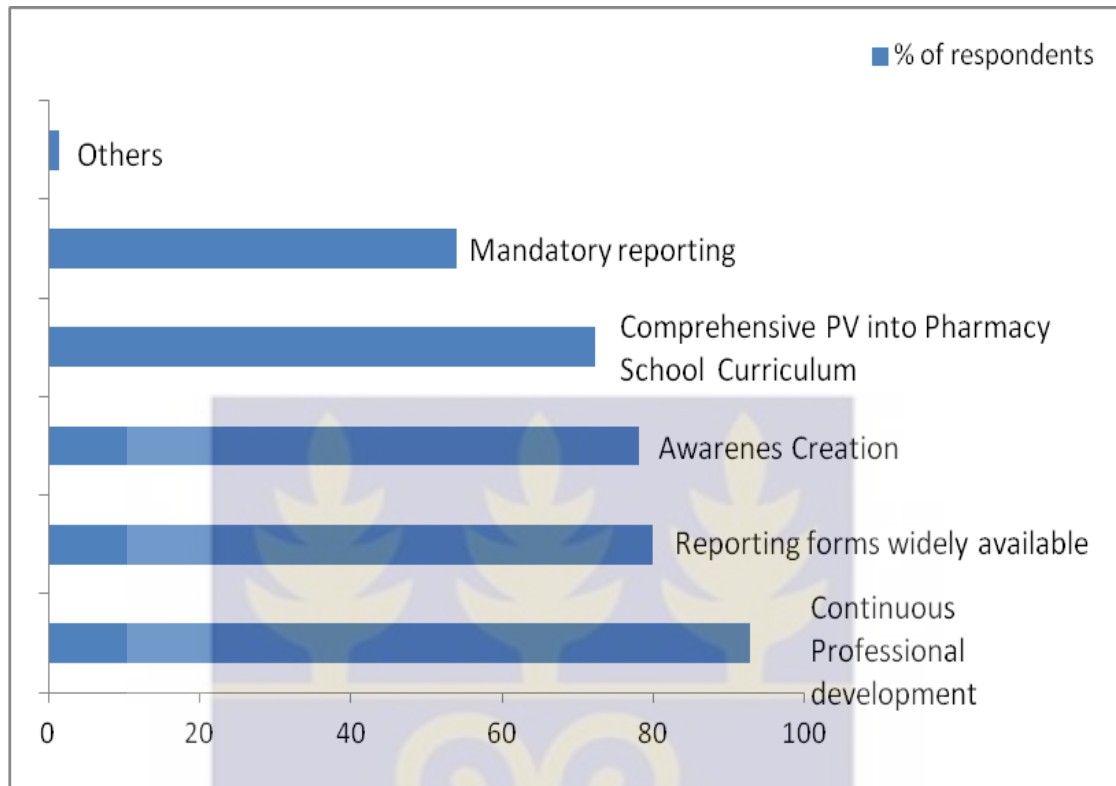
motivation for ADR reporting. Also, thirty-two (26%) agreed that the award of credits for Continuous Professional Development (CPD) as well as publishing of the names of pharmacists in a scientific journal (24%) would encourage more ADR reporting by pharmacists.

Eighty-eight (42%) of pharmacists did not believe a reward was necessary to improve ADR reporting. Two of the pharmacists subscribed to monetary rewards. Additionally, pharmacists wanted feedback from the National Pharmacovigilance Centre on specific actions taken on the reports submitted.

One hundred and ninety-five (93%) of the pharmacists agreed that continuous education and training on pharmacovigilance could improve ADR reporting. (Figure 6). One hundred and sixty-eight (80%) of the pharmacists opined that making the reporting forms readily available in all community pharmacies would improve ADR reporting. Other suggestions that came up were awareness creation among patients (78%) and making ADR reporting mandatory (52%).

Almost all the participating pharmacists, two hundred and eight (99%) thought it was part of their professional responsibility to report ADRs. Many pharmacists felt doctors, nurses and medical assistants also ought to report ADRs with about one hundred and sixty-eight (80%) of pharmacists agreeing that doctors ought to report suspected ADRs; one hundred and thirty-four (64%) felt nurses should report and one hundred and twenty-eight (61%) thought medical assistants should also report ADRs.

Fig 6: Suggested Methods of Improving ADR reporting (N=210)



## CHAPTER 5

### DISCUSSION

Two hundred and ten questionnaires were retrieved from the two hundred and fifty administered, giving a response rate of 84%. This study showed that reporting prevalence of ADRs among community pharmacists in the Greater Accra Region was 16%. This figure was slightly lower than the 20% among doctors in the region as reported by Sabblah, et al (2014). This was however much higher than the reported 2.9% among doctors in Nigeria (Adedeji, Ibraheem and Fehintola, 2013). Other studies have reported similarly low reporting figures (Prakasam, 2012; Qassim et al 2014; Carandang et al, 2015; Toklu et al, 2016). Patient ignorance about their role in reporting adverse drug reactions they suffer to their community pharmacist may have played a role in the low reporting of ADRs found among pharmacists in the Greater Accra region. This is backed by the fact that less than half of the pharmacists (44%) who took part in the study had patients reporting an ADR to them as reported in the Results section 4.1. The recent campaign by the Food and Drugs Authority to increase public awareness about ADR reporting is therefore a step in the right direction.

In this study there was no significant difference in age and years of practice between pharmacists who reported ADRs and non-reporters. This was consistent with other studies conducted elsewhere. Duarte et al, (2015) in their study among Portuguese pharmacists also found no statistically significant association between age as well as

years of practice and ADR reporting. This was also true for pharmacists in Qatar as reported by (Wilbur, 2013).

Community pharmacists who failed to report ADRs they had encountered mostly blamed it on a lack of reporting forms, considering the reaction as “normal” and uncertainty about the causal relationship between the drug and the suspected ADR. It is important that pharmacists are made aware that they don’t necessarily have to establish a causal linkage between a suspected ADR and a drug before going ahead to report it (Duarte et al., 2015). Prakasam et al., (2012) also reported that majority of community pharmacists in India felt that the reaction they had encountered was simple and non-serious, hence their failure to report. Yu, et al (2016) reported similar findings among community pharmacists in Korea with the main barriers to ADR reporting being perception of ADR being “unserious” (77.9%) and already “well known” (81.5%), as well as uncertainty about causality (73.3%).

About eighty-seven percent of pharmacists who had reported an ADR within the past year had received previous training on Pharmacovigilance and ADR reporting. This is due to recent efforts by the Food and Drugs Authority of Ghana in organizing various training sessions and workshops for community pharmacists on Pharmacovigilance. However, training was found not to be significantly associated with improving reporting of ADRs when factors like knowledge and marital status were adjusted for (Adjusted OR=2.18, p-value 0.378). Duarte et al, 2015 similarly found no statistically significant association between pharmacists who reported adverse reactions and those who didn’t

with respect to training in Pharmacovigilance ( $X^2=3.5$ , p-value 0.062). This was however in contrast to Sabblah, et al (2014), who reported that training significantly improved ADR reporting rate among medical doctors in the Greater Accra Region ( $X^2=11.6$ , p-value<0.001).

Duarte et al, (2015) proposes new educational measures such as hands-on involvement with real cases, thereby placing ADR reporting closer to the daily routine activities of community pharmacists. Pharmacovigilance, though part of most pharmacy school's curriculum in Ghana is not treated comprehensively enough, possibly contributing to underreporting of adverse drug reactions by community pharmacists.

The leading factors perceived by pharmacists in the study as contributing to underreporting of ADRs were unavailability of the reporting forms and ignorance about the reporting procedure and where to obtain forms. This was consistent with findings by Hazmi et al, (2013), where sixty percent of pharmacists believed the ADR reporting forms were not widely available. Fifty-five percent of the pharmacists felt insufficient clinical knowledge was a factor contributing to underreporting and fifty-four percent stated lack of knowledge about the reporting address. Jose et al, (2013) found lack of awareness on how to report and concerns that the report may be wrong were the two prominent perceived factors leading to underreporting among community pharmacists in Oman.

Antibiotics (50%) were associated with most of the ADRs that community pharmacists encountered. They were followed by analgesics (31.5%), with anti-malarials, antihelminthics and multivitamins being other groups of medications responsible for

ADRs (17%). The indiscriminate use of antibiotics and analgesics in Ghana probably contributes to this trend. This was consistent with the findings of Palaian et al, (2010) who reported anti-biotics (42%) and analgesics (25%) as the leading cause of ADRs among reports submitted by community pharmacists in Nepal. Davies et al, (2009) similarly found that analgesics especially the opioids were among the medications most frequently associated with ADRs.

By way of motivation, nearly half (47%) of all the pharmacists felt a letter of acknowledgement per report submitted was an adequate means of encouraging reporting of adverse drug reactions by community pharmacists. Toklu, (2016) reported that approximately eighty percent of pharmacists in Cyprus strongly agreed that receiving feedback to reports from the National Pharmacovigilance Centre will motivate them to report adverse drug reactions.

More than half of the respondents (52%) held the view that making ADR reporting mandatory will improve reporting rates. Similarly, more than half (67%) of health professionals in Saudi Arabia stated that reporting of adverse drug reactions ought to be compulsory (Al-hazmi & Il, 2013). In Cyprus, an even greater proportion of pharmacists (80%) supported mandatory ADR reporting (Toklu et al., 2016).

Most pharmacists (93%) opined that continuous professional development and training on pharmacovigilance was an effective strategy to improve ADR reporting. This was consistent with results of a Ugandan study by Kiguba, et al (2014), where majority of healthcare professionals advocated for sensitization, training and continuous education on

pharmacovigilance. Moreover, about 90.0% of pharmacists in Cyprus also suggested training in ADR reporting to improve reporting (Toklu, 2016).

Training in Pharmacovigilance among community pharmacists in the Greater Accra region is still in its nascent stages and it should help to improve ADR reporting overtime.



## CHAPTER SIX

### CONCLUSION AND RECOMMENDATIONS

#### 6.1 Conclusion

The reporting prevalence of adverse drug reactions among community pharmacists in the Greater Accra was only 16%. This means a lot of ground still needs to be covered by the National Pharmacovigilance centre to improve reporting of ADRs and ensure patient safety.

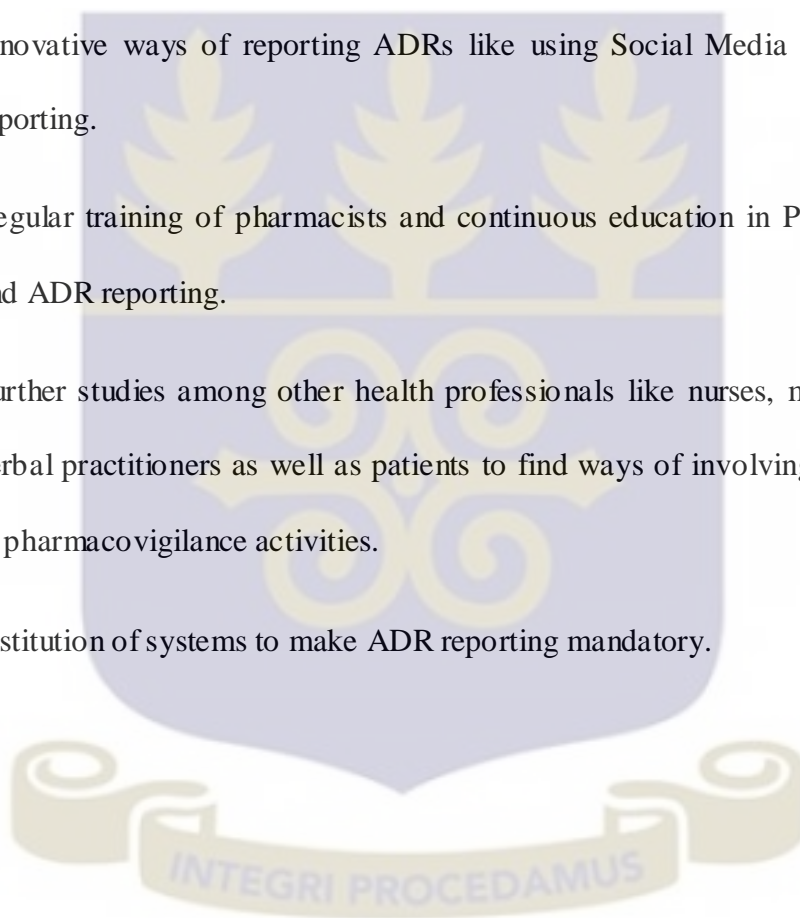
Community pharmacists by virtue of their training and background as experts of medications are very well placed to contribute significantly to national pharmacovigilance efforts and ADR reporting. There however remains widespread unavailability of the reporting forms in most community pharmacies contributing to underreporting.

Most community pharmacists feel reporting of ADRs forms part of their professional responsibility but require special training in pharmacovigilance and ADR reporting to effectively carry out this responsibility. Acknowledgement of their efforts in this regard and regular feedback from the National Pharmacovigilance authorities counts as adequate motivation for most pharmacists.

It is clear therefore that in spite of considerable strides that Ghana has made in the area of Pharmacovigilance, all stakeholders including the National Pharmacovigilance authorities and pharmacists cannot relent in their effort to safeguard public health through ADR reporting.

## 6.2 Recommendations

1. The reporting forms should be made readily available in all community pharmacies across the nation.
2. There should be prompt acknowledgement of all submitted reports and feedback on actions and results implemented by the National Pharmacovigilance Centre.
3. Innovative ways of reporting ADRs like using Social Media and direct online reporting.
4. Regular training of pharmacists and continuous education in Pharmacovigilance and ADR reporting.
5. Further studies among other health professionals like nurses, medical assistants, herbal practitioners as well as patients to find ways of involving all these groups in pharmacovigilance activities.
6. Institution of systems to make ADR reporting mandatory.



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**APPENDIX 1: QUESTIONNAIRE**

**QUESTIONNAIRE ON ADVERSE DRUG REACTION (ADR) REPORTING BY  
COMMUNITY PHARMACISTS IN THE GREATER ACCRA REGION OF  
GHANA**

**SECTION A: Demographic Characteristics**

1. **Gender:** Male  Female
2. **Age:** ..... (years)
3. **Years of Practice:** .....
4. **Marital Status:** Married  Single  Divorced
5. **Children:** Yes  No
6. **Religion:** Christian  Moslem  Other
7. **Average number of patients seen per day:** ..... (in the past 1 year)

**SECTION B: Knowledge of adverse drug reaction (ADR) reporting**

1. **Have you ever heard of ADR reporting in Ghana?** Yes  No
2. **Have you ever seen the form for reporting ADRs?** Yes  No
3. **Where can the form be obtained?** (please select all that apply)  
Pharmacy Council  FDA  Online Download  No idea   
Other (specify).....
4. **Do you have the reporting form in your pharmacy?** Yes  No
5. **Do you know where to submit the form upon completion?** Yes  No
6. **If Yes to Q5 above, please state where** .....

7. **Have you ever been trained on Pharmacovigilance and ADR reporting?** Yes

No

8. **Has a patient reported an ADR to your pharmacy in the past one year?** Yes

No

**If NO to Q8, proceed to Section C**

9. **If YES to Q8, did you report the ADR by filling the form?** Yes  No

10. **If YES to Q9, did you receive feedback from the Pharmacovigilance centre?** Yes

No

11. **Select one class of medication which commonly causes the most ADRs among the reports you got**

A. Antibiotics

B. Analgesics

C. Anti-coagulants

D. Others (please specify) .....

12. **If NO to Q9 why didn't you report?** (please select all that apply)

A. Reporting form not available

B. I did not know I was supposed to report

C. I did not know the reporting procedure

D. I did not have time to report

E. The reporting form is too cumbersome

F. I did not think it was important to report

G. The reaction is often associated with that medication so I considered it “normal”

H. I couldn't tell for certain if the reaction was caused by medication

I. I was afraid of legal consequences

J. Others (pleases specify) .....

**SECTION C: Factors affecting ADR reporting by community pharmacists**

**1. In your view, what are some of the factors that affect ADR reporting by community**

**pharmacists?** (please select all that apply)

A. Heavy workload and lack of time

B. Unavailability of reporting forms

C. Ignorance of reporting procedure and how form can be obtained

D. Ignorance about the need to report ADRs

E. All ADRs are well documented prior to the award of marketing authorization for medications

F. Inability to recognize ADRs

G. Fear of being legally accused of administering the wrong medication

H. Lack of confidence in the reporting system

I. Fear of the negative impact on the drug manufacturing company

J. Fear of negative publicity for my pharmacy

K. Consumers who suffer an ADR should be responsible for reporting it

L. Lack of reward or incentive package for community pharmacists who report ADRs

M. It is not part of my professional responsibility to report ADRs

O. Other (specify) .....

2. **Do you think pharmacists should be rewarded for reporting ADRs?** Yes   
No

3. **If Yes to Q2 above, which one of the following rewards will you consider most appropriate?**

A. Acknowledgement letter per report submitted

B. Publish name in local scientific journal

C. Award credits for CPD

D. Others, please specify

.....

3. **Which group of health professionals should report ADRs?** (please select all that apply)

Doctors  Pharmacists  Medical assistants  Nurses  Other  
(specify).....

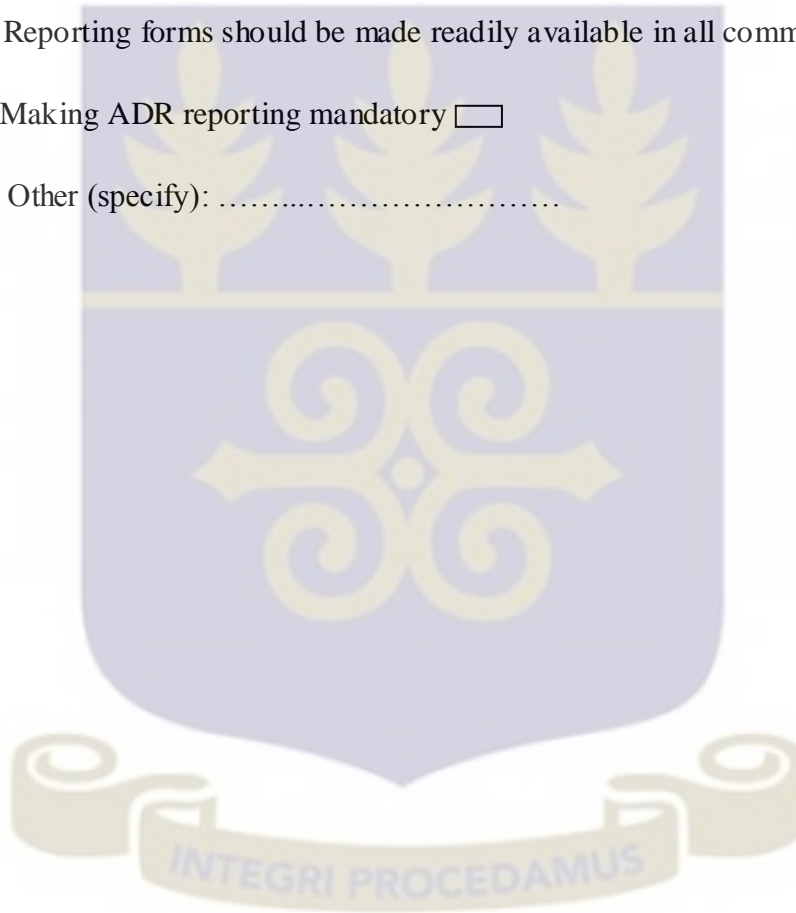


**SECTION D: Improving ADR reporting**

**1. Which of the following would you recommend to improve ADR reporting by community**

**pharmacists?** (please select all that apply)

- A. Continuous professional education and training on Pharmacovigilance
- B. Introduction of Pharmacovigilance and ADR reporting into the pharmacy curriculum
- C. Awareness creation by the National Pharmacovigilance Centre
- D. Reporting forms should be made readily available in all community pharmacies
- E. Making ADR reporting mandatory
- F. Other (specify): .....



## APPENDIX 2: CONSENT FORM

### CONSENT FORM

**Project Title:** Adverse Drug Reaction Reporting Among Community Pharmacists in the Greater Accra Region

**Institution:** University of Ghana School of Public Health, College of Health Sciences

#### Background

I am Johnson Yaw Osei, a student of the School of Public Health, University of Ghana. I am conducting a study titled “Adverse Drug Reaction Reporting among Community Pharmacists in the Greater Accra Region of Ghana”. The objective of this study is to assess ADR reporting rates among community pharmacists and investigate factors that affect ADR reporting with the aim of improving reporting rates among community pharmacists.

#### Procedures

The study will involve answering a four page questionnaire about knowledge on ADR reporting, factors affecting ADR reporting, and ways of improving ADR reporting. The questionnaire will take approximately 10 minutes to complete. It will be much appreciated if you would be willing to participate in this study. This is purely for academic research and forms part of my work for the award of a Masters Degree in Public Health.

#### Risks and Benefits

The procedures involved in this study are non-invasive and will cause no physical discomfort to you. Results obtained from this study will be made available to the Food and Drugs Authority (FDA) so that issues relating to ADR reporting will be addressed to improve reporting rates among community pharmacists.

**Right to Refuse**

Participation in this study is voluntary and you are free to refuse to answer any individual question or all the questions. You can withdraw from this study at anytime. I will however encourage you to participate fully in this study since your input will be very valuable to assess factors affecting ADR reporting and how to improve reporting rates among community pharmacists in the Greater Accra Region.

**Anonymity and Confidentiality**

All information you provide on the questionnaire would be held in strict confidence and would not be shared with anyone who isn't part of the study team.

**Dissemination of Results**

The results of this study will be sent to you by email if you provide your email address below.

**Before taking Consent**

Do you have any questions you wish to ask about the study? Yes  No

(If yes, please indicate the questions below)

.....  
.....

Contact Johnson Yaw Osei on **0209056872** if you have any questions later.

**Consent**

I ..... declare that the purpose, procedures, risks and benefits of the study have been explained to me in English Language and I have understood them.

I hereby agreed to take part in the study.

Signature of participant: .....

**Interviewers Statement**

I, the undersigned, have explained this consent to the subject in English Language that s/he understands the purpose of the study, procedures to be followed, as well as the risks and benefits of the study.

The participant has fully agreed to participate in the study.

Signature of Interviewer: .....

Date: .....

Address: .....

